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Hanford Analytical Services Quality Assurance Requirements Documents

Volume 1: Administrative Requirements

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LIST OF TERMS

ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
ASQ	American Society for Quality
ASTM	American Society for Testing and Materials
BS	blank spike
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CCV	continuing calibration verification
CFR	Code of Federal Regulations
DLR	decision level count rate
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
DQO	data quality objective
DQR	Data Quality Requirements
EM	Environmental Restoration and Waste Management
EPA	U.S. Environmental Protection Agency
EQL	estimated quantitation limit
FWHM	Full Width Half Maximum
GC/MS	gas chromatograph/mass spectrometer
HASQARD	*Hanford Analytical Services Quality Assurance Requirements Document*
HEIS	Hanford Environmental Information System
HQ	DOE Headquarters
HSQMP	*Hanford Sampling Quality Management Plan*
HSRCM	Hanford Site Radiological Control Manual
ICP	inductively coupled plasma
ICP/MS	inductively coupled plasma specrometry/ mass spectrometry
ICV	initial calibration verification
IDL	instrument detection limit
LCS	laboratory control sample
MDA	minimum detectable activity
MDC	minimum detectable concentration
MSDS	material safety data sheets
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Sample Tracking System
OSHA	Occupational Safety and Health Act
%D	percent difference
%R	percent recovery

LIST OF TERMS (Continued)

%Y	yield percent recovery
PDS	post digestion spike
QA	quality assurance
QAPjP	Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan
QC	quality control
R&D	research and development
RCRA	Resource Conservation and Recovery Act
RF	response factor
RL	U.S. Department of Energy, Richland Operations Office
RPD	relative percent difference
RSD	relative standard deviation
SAP	Sampling and Analysis Plan
TPA	*Tri-Party Agreement Hanford Federal Facility Agreement and Consent .....Order*
VOA	volatile organic analysis
VOC	volatile organic compound
V/DUA	Validation/Data Useability Assessment
WAP	Waste Analysis Plan

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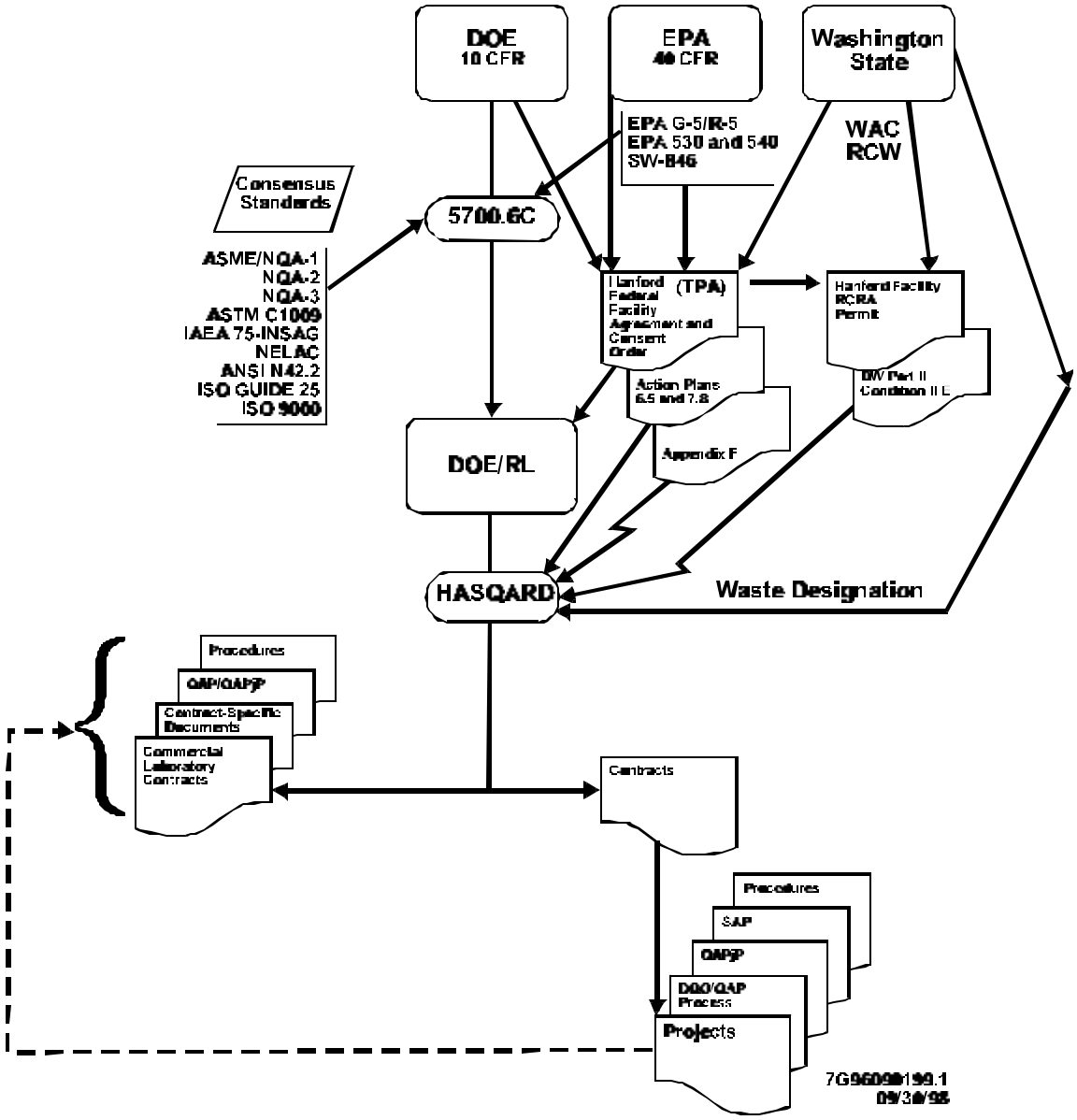
1.0 INTRODUCTION

The *Hanford Analytical Services Quality Assurance Requirements Document* (HASQARD) is issued by the Analytical Services Program of the Waste Management Division, U.S. Department of Energy (DOE), Richland Operations Office (RL). The HASQARD establishes quality requirements in response to DOE Order 5700.6C. The HASQARD is designed to meet the needs of the RL for maintaining a consistent level of quality for sampling as well as 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 RL in support of Hanford Site environmental clean up mission. This includes work performed by contractor and commercial laboratories and covers both radiological and nonradiological analyses. The HASQARD applies to field sampling, field analytical and research and development activities that support work conducted under the *Hanford Federal Facility Agreement and Consent Order* (Tri-Party Agreement) (Washington Department of Ecology, et al.) and regulatory permit applications, and applicable permit requirements described in subsection 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 research and development (R&D) projects related to 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 (Semi-quantitative analysis); and Volume 4, Laboratory Technical Requirements (Quantitative Analysis). 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 semi-quantitative analysis, and Volumes 1 and 4 describe the requirements for quantitative analysis).

Document Hierarchy Flow Diagram



1.1 SCOPE

HASQARD is based on professional and regulatory quality assurance (QA) principles and practices that cover environmental sampling as well as field/laboratory analytical chemistry activities. The American National Standards Institute (ANSI) N42.2, *Measurement Quality Assurance for Radioassay Laboratories*, is the primary driver for the radiochemical quality assurance/quality control (QA/QC). The U.S. Environmental Protection Agency (EPA) SW-846, *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 model for organic and inorganic analytical QA/QC.

The HASQARD specifies the quality principles, practices, and procedures for contractor and commercial laboratory (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 as well as field and laboratory analytical services to meet professional standards of QA/QC as well as the regulatory requirements of the Tri-Party Agreement and site permits (see Section 1.1.1 and 1.1.2 of Volume 1).

A flexible framework for meeting the client's special quality 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 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 the 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 beginning with initial R&D investigations, permitting, waste characterization, and treatment and proceeding to 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 data base 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 quality control (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.

Research and development 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 Volume 1, Section 4.0 specifically). 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-RL Analytical Services Program.

Additionally, sampling and analytical services can be performed under regulatory requirements other than 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 of 1997

Clean Water Act of 1997

Safe Drinking Water Act of 1994

Occupational Safety and Health Act of 1970 (OSHA) including clinical analyses.

State Waste Discharge Permit Program (WAC 173-216)

Where a Site activity requires using a specific regulatory method (e.g., permits, NPDES), and the regulatory method is in conflict with HASQARD, the calibration and QC requirements in the regulatory method shall take precedence over those sections of HASQARD (Volume 4, Sections 4.0 and 6.0). All other sections of HASQARD would be applicable.

1.1.2 Activities Outside the Scope of HASQARD

The HASQARD does not cover sample analysis in support of Department of Defense Samples. In addition; sample analysis performed as part of the Hanford Radiation Control Program (Rad Con) and the Industrial Hygiene Program (IH) are not controlled by HASQARD.

1.2 HASQARD QUALITY CONTROL MODEL

The HASQARD QA/QC model supports the site cleanup mission. It recognizes a graded approach which bases the level of quality control in procedures and practices for data collection based upon the intended use of the data and the degree of confidence needed in their quality. It accommodates the project's selection of analysis of environmental samples in the field or in a fixed laboratory located at some distance from where the samples originate. While there are differences in the quality procedures and practices based on methods, instruments and intended data use there is no difference in the quality principles that apply to analyses conducted at field laboratory organizations.

The HASQARD uses QC criteria adapted from ANSI N42.2, EPA SW-846, and EPA's Contract Laboratory Program protocols, and prevailing industry standards. Selection of specific requirements was based on the following:

Technical merit

Consensus standards

Manufacturer specifications

Current analytical methodologies and instrumentation technologies

Appropriateness for Hanford Site specific matrices.

The HASQARD will be used for all analytical/field work except as modified by client/project-specific DQOs/DQRs. In that case, clear written instructions must be received from the client and, field/laboratory concurrence must be obtained prior to submission of samples. The client is advised to use the DQO planning process to determine the QA objectives that will influence field/laboratory performance criteria (e.g. number and type of QC samples, precision, and accuracy). In lieu of a formal DQO planning process, the recommendation is that the client work 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 should then agree on the analytical approach to implement the unique quality requirements.

1.3 HASQARD REVISIONS

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

A cc:Mail mailbox has been established to facilitate the commenting process. Commentors are requested to submit their comments and rationale to the ^HANFORD ANALYTICAL SERVICES QA cc:Mail address. Comments submitted on comment resolution forms (e.g., Review Comment Record or Document Review Record forms) are appreciated, however, comments will be accepted in any format.

When a comment on the document or a request is made to the cc:Mail mailbox, the commentor will receive an acknowledgement from the mailbox. The comment will be reviewed and determined 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 commentor 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 commentor. The HASQARD focus group will then decide if the comment should be incorporated into the document by general consensus.

Commentors are encouraged to support their request for HASQARD modification with 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 commentors. 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.

1.4 HASQARD APPLICABILITY MATRIX

This section provides a cross-reference of the applicability of each of the major sections of HASQARD to areas important to project planning and execution. It is provided as a user's aid so that individuals who are interested in one or more specific areas can go directly to those sections of most interest to them. The areas identified are those which are commonly considered during the development of a project. Users are cautioned that this cross-reference or applicability matrix must not be used as the sole guide to the relevant requirements in each area. It is provided only for the purpose of providing a general overview or ready reference of where to find material pertaining to a subject.

The nine subject areas are:

- Determining Applicability,
- DQO and Other Project Planning Activities,
- Quality Assurance/Administrative Requirements,
- Procedures
- Sample Custody and Handling ,
- Calibration- Semi-Quantitative Considerations,
- Calibration- Quantitative Considerations,
- Sampling QC Considerations,
- Semi-quantitative QC Considerations,
- Quantitative QC Considerations,
- Data Reduction, Reporting and Validation,
- Audits and Assessments, and
- Quality Assurance Reporting.

The following sections provide a brief explanation of the material found in each of these areas. The tables provide a ready reference tool.

1.4.1 Determining Applicability

The referenced sections of HASQARD provide information about the scope and intended applications of the document. This material will guide Hanford project managers and analytical service providers in understanding when to apply HASQARD to site projects and/or analytical support services. The material in Volume 1 covers the overall QA program and the information in Volume 2 provides information specific to sampling activities. Volumes 3 and 4 provide QA/QC requirements specific to semi-quantitative and quantitative analysis respectively.

1.4.2 DQO and Other Project Planning Activities

The referenced sections of HASQARD provide information about integrating the project-specific quality requirements into project plans using the DQO process. The importance of incorporating the project data quality needs into initial project planning is pointed out. Specific recommendations for the sampling and analytical processes are provided. Early involvement of sampling and analytical staff in the planning activity will aid in selecting technically defensible and cost effective strategies for designing and implementing sampling and analytical efforts. The referenced material will assist project staff, and sampling and analytical organizations in obtaining only the data they need, with the quality necessary, to support their project decisions.

1.4.3 Quality Assurance/Administrative Requirements

The referenced sections describe the overall quality systems that need to be addressed in order to ensure adequate program control. These requirements ensure appropriate control over the work processes exist and that the information that results from the sampling and analysis activity has the appropriate checks and balances to permit collecting, reporting, and documenting the quality of all work performed. These processes are designed to ensure the technical defensibility of data and allows for current and future use of the data for important Hanford applications/decisions.

The majority of the administrative systems are found in Volume 1. Volume 2 references provide additional information related to sampling activities. References to Volume 3 and 4 address semi-quantitative and quantitative analysis respectively.

1.4.4 Procedures

The referenced sections provide details on procedure content, control and distribution. Information is also provided to allow the user to understand what latitude exists in following procedures. Situations requiring DOE-RL involvement are also addressed.

1.4.5 Sample Custody and Handling

The referenced sections provide information on what constitutes custody and how custody is documented. Information is also provided on holding time considerations as well as general sampling handling practices.

1.4.6 Requirements for Calibration: Semi-Quantitative and Quantitative

The referenced sections of HASQARD discuss the specific requirements for the calibration of all systems and equipment used in the sampling and analytical processes that support Hanford projects. The material also discusses the application of the graded quality approach and how it applies to the calibration process. Most techniques that are in use at Hanford are discussed.

1.4.7 QC Requirements: Sampling, Semi-Quantitative, Quantitative

The referenced HASQARD sections provide the QC requirements pertaining to the technical activities associated with sampling and analysis. The use of the graded approach to quality is included in these requirements to permit the work to be adapted to project-specific requirements as laid out in DQOs, SAPS, QAPjPs, and other appropriate planning documents. Adherence to these requirements assures that all work performed will be technically defensible.

The material found in Volume 2 is specific to sampling activities while the references to Volumes 3 and 4 cover semi-quantitative and quantitative analysis respectively.

1.4.8 Quality Control Requirements for Data Deliverables and Reports

The QC requirements that cover the collection, processing, review, and issue of project reports and other project documentation is covered in the referenced sections. Sections that are applicable to common data quality calculations used to support project decisions are provided. Additionally, data validation strategies and considerations are identified. The material in Volume 2 is directly related to sampling while the material in Volumes 3 and 4 covers the analytical process.

1.4.9 Audits and Assessments

The requirements for audits, and assessments are provided in the referenced sections.

1.4.10 Quality Assurance Reporting

The requirements for providing periodic reports to management (program or organizational) are referenced.

Table 1-1. Applicability Matrix for HASQARD Volume I, Administrative Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
I.1.0 INTRODUCTION	X									
I.1.1 SCOPE	X									
I.1.2 HASQARD QUALITY CONTROL MODEL	X									
I.1.3 HASQARD REVISIONS										X
I.2.0 ORGANIZATION AND RESP0NSIBILITY			X							
I.2.1 MANAGEMENT POLICY			X							X
I.2.2 STRUCTURE, RESPONSIBILITY			X						X	
I.3.0 PERSONNEL QUALIFICATION AND TRAINING			X							
I.3.1 QUALIFICATION			X						X	
I.3.2 TRAINING			X							
I.3.3 TRAINING RECORDS			X							
I.4.0 PROCEDURES			X	X			ALL			
I.4.1 GENERAL LABORATORY/FIELD OPERATIONS			X	X			ALL			
I.4.2 TECHNICAL AND TEST PROCEDURE REQUIREMENTS			X	X			ALL			
I.4.3 NEW PROCEDURES			X	X			ALL			
I.4.4 CATEGORIES OF CHANGES			X	X			ALL			
I.4.5 CHANGE CONTROL			X	X			ALL			

Table 1-1. Applicability Matrix for HASQARD Volume I, Administrative Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
I.4.6 QUALIFICATION OF METHODS				X			ALL			
I.4.7 MODIFICATION OF REQUIRED REGULATORY METHODS			X				ALL		X	X
I.5.0 CORRECTIVE ACTION AND QUALITY IMPROVEMENT			X						X	X
I.5.1 INITIATION OF CORRECTIVE ACTION			X						X	X
I.5.2 EVALUATING IMPACT			X						X	X
I.5.3 ROOT CAUSE ANALYSIS			X						X	X
I.5.4 RECURRING CONDITIONS ADVERSE TO QUALITY			X				ALL		X	X
I.5.5 TREND ANALYSIS			X				ALL		X	X
I.5.6 CONTINUOUS QUALITY IMPROVEMENT			X				ALL		X	X
I.5.7 CONTROL OF NONCONFORMANCES			X						X	X
I.6.0 DOCUMENT AND QUALITY RECORDS			X							
I.6.1 DOCUMENT CONTROL			X							
I.6.2 INSTRUCTIONS, PROCEDURES AND DRAWINGS			X							
I.6.3 QUALITY RECORDS			X							
I.7.0 SOFTWARE SYSTEMS QUALITY ASSURANCE			X							
I.8.0 PROCUREMENT CONTROLS			X							
I.9.0 PREVENTIVE MAINTENANCE			X							

Table 1-1. Applicability Matrix for HASQARD Volume I, Administrative Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
I.10.0 ASSESSMENTS			X						X	X
I.10.1 MANAGEMENT SYSTEM ASSESSMENTS			X						X	X
I.10.2 TECHNICAL SYSTEM ASSESSMENTS (SURVEILLANCES)			X						X	X
I.10.3 PERFORMANCE EVALUAITON ASSESSMENTS			X				ALL		X	X
I.10.4 DATA QUALITY ASSESSMENTS			X						X	X
I.10.5 EXTERNAL ASSESSMENTS			X						X	X
I.11.0 QUALITY ASSURANCE REPORTING			X							X
I.B DATA QUALITY OBJECTIVE PROCESS USER'S GUIDE		X								
I.C PREVENTIVE MAINTENANCE			X							

<DEFINITIONS HERE>

ALL = Applies to Sampling, Quantitative, Semi-Quantitative
S = Sampling
Q = Quantitative
SQ = Semi-Quantitative

Table 1-2. Applicability Matrix for HASQARD Volume II, Sampling Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reports
II.1.0 SAMPLING AND ANALYSIS PROCESS	X	X								
II.T1-1 SAMPLING AND ANALYSIS PROCESS FLOW	X									
II.2.0 DATA QUALITY OBJECTIVES		X								
II.T2-1 THE SEVEN STEPS OF THE DQO PROCESS		X								
II.3.0 SAMPLING SYSTEMS			X							
II.3.1 FACILITY MANAGEMENT			X							
II.3.2 SAMPLING METHODS			X	X			S	X		
II.4.0 SAMPLING OPERATIONS			X		X		S	X		
II.4.1 SITE/FIELD DOCUMENTATION			X	X	X		S			
II.4.2 MANAGEMENT OF SAMPLES					X		S			
II.4.3 WASTE DISPOSITION			X		X		S			
II.4.4 CHAIN-OF-CUSTODY			X		X		S			
II.4.5 SUBSAMPLING AND COMPOSITING					X		S			
II.4.6 HOLDING TIMES			X		X		S			
II.4.7 SAMPLE CONTAINERS					X		S			
II.5.0 QUALITY CONTROL FOR THE SAMPLING PROCESS							S			
II.5.1 TRIP BLANKS							ALL			

Table 1-2. Applicability Matrix for HASQARD Volume II, Sampling Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reports
II.5.2 EQUIPMENT RINSATES (BLANKS)							ALL			
II.5.3 FIELD SOURCE WATER BLANKS							ALL			
II.5.4 FIELD DUPLICATES (REPLICATES)							ALL			
II.5.5 FIELD SPLIT SAMPLES							ALL			
II.5.6 COLLOCATED SAMPLES							ALL			
II.5.7 FIELD BLANKS							ALL			
II.6.0 SAMPLING DATA								X		
II.A DESCRIPTION OF THE SAMPLING AND ANALYSIS PROCESS FLOW CHART		X								
II.B CHECKLIST FOR THE PURPOSE OF SELF-ASSESSMENT									X	X

<PUT DEFINITIONS HERE>

ALL = Applies to Sampling, Quantitative, Semi-Quantitative
S = Sampling
Q = Quantitative
SQ = Semi-Quantitative

Table 1-3. Applicability Matrix for HASQARD Volume III, Field Analytical Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Assurance Reports
III.1.0 INTRODUCTION	X	X								
III.2.0 QUALITY ASSURANCE OBJECTIVES	X	X								
III.2.1 DATA QUALITY OBJECTIVES	X	X								X
III.2.2 CLIENT DATA QUALITY REQUIREMENTS		X								X
III.3.0 FIELD ANALYTICAL PLANNING AND DESIGN		X	X							
III.3.1 ANALYTICAL OBJECTIVES OF FIELD ACTIVITIES		X								
III.3.2 EXAMPLES OF ANALYTICAL AND QUALITY CONTROL DESIGNS		X								
III.3.3 INFORMATION FROM THE PLANNING AND DESIGN ACTIVITY		X								
III.3.4 GENERAL OBJECTIVES OF FIELD PROJECTS		X								
III.4.0 SYSTEMS QUALITY ASSURANCE			X							X
III.4.1 ADMINISTRATIVE SYSTEMS			X							
III.4.2 SOFTWARE SYSTEMS			X							
III.4.3 TECHNICAL SYSTEMS			X	X			X		X	
III.4.4 PHYSICAL FACILITY SYSTEMS			X							
III.5.0 METHOD REQUIREMENTS			X	X			S, Q			
III.6.0 CALIBRATION						S, Q				

Table 1-3. Applicability Matrix for HASQARD Volume III, Field Analytical Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Assurance Reports
III.6.1 CALIBRATION OF FIELD ANALYTICAL MEASUREMENT SYSTEMS						S, Q				
III.6.2 GENERAL REQUIREMENTS FOR CALIBRATION STANDARDS						S, Q				
III.6.3 CALIBRATION REQUIREMENTS FOR SEMI-QUANTITATIVE ANALYSIS						S, Q				
III.6.4 CALIBRATION REQUIREMENTS FOR QUANTIATIVE ANALYSIS						S, Q				
III.6.5 CALIBRATION RECORDS			X			S, Q				
III.6.6 BALANCES, THERMOMETERS, AND PIPETTES						S, Q				
III.6.7 GENERAL REUIREMENTS FOR CALIBRATION STANDARDS			X			S, Q				
III.7.0 QUALITY CONTROL							S, Q			
III.7.1 INTRODUCTION		X					S, Q			
III.7.2 OVERVIEW OF QUALITY CONTROL PROCEDURES		X					S, Q			
III.7.3 FREQUENCY OF QUALITY CONTROL SAMPLES ANALYSIS							S, Q			
III.7.4 GENERAL FIELD ANALYTICAL QUALITY CONTROL							S, Q			
III.T7-1 INSTRUMENT QUALITY CONTROL PROCEDURES							S, Q			
III.T7-2 METHOD QUALITY CONTROL PROCEDURES							S, Q			
III.T7-3 SAMPLE MATRIX QUALITY CONTROL PROCEDURES							S, Q			

Table 1-3. Applicability Matrix for HASQARD Volume III, Field Analytical Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA/ Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Assurance Reports
III.T7-4 POTENTIAL VALUE-ADDED FOR GAS CHROMATOGRAPH IN SEMI-QUANTITATIVE ANALYSIS							S, Q			
III.8.0 DATA COLLECTION, REDUCTION, REVIEW, AND REPORTING			X	X			S, Q	X		
III.8.1 DATA COLLETION			X	X			S, Q	X		
III.8.2 DATA REDUCTION			X	X			S, Q	X		
III.8.3 DATA REPORTING			X	X			S, Q	X		
III.8.4 COMMON DATA QUALITY CALCULATIONS		X	X	X			S, Q	X	X	X
III.9.0 DATA VERIFICATION, VALIDATION, AND ASSESSMENT								X	X	X

<PUT DEFINITIONS HERE>

ALL = Applies to Sampling, Quantitative, Semi-Quantitative
S = Sampling
Q = Quantitative
SQ = Semi-Quantitative

Table 1-4. Applicability Matrix for HASQARD Volume IV, Laboratory Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
IV.1.0 QUALITY ASSURANCE OBJECTIVES	X	X								
IV.1.1 DATA QUALITY OBJECTIVES		X								
IV.1.2 CLIENT DATA QUALITY REQUIREMENTS		X								
IV.2.0 SYSTEMS QUALITY ASSURANCE			X							X
IV.2.1 TECHNICAL SYSTEMS			X				X			X
IV.2.2 PHYSICAL FACILITIES SYSTEMS			X		X					X
IV.3.0 SAMPLE CUSTODY AND HANDLING			X		X		X			
IV.3.1 CHAIN-OF-CUSTODY DEFINITION			X		X		X			
IV.3.2 HOLDING TIMES			X		X		X			
IV.3.3 SAMPLE RECEIVING PROCEDURE			X	X	X		X			
IV.3.4 SAMPLE LOG-IN AND TRACKING PROCEDURE			X	X	X		X			
IV.3.5 LABORATORY INTERNAL CHAIN-OF-CUSTODY			X		X		X			
IV.3.6 SAMPLE DISPOSITION			X		X		X			
IV.4.0 CALIBRATION						Q				
IV.4.1 CALIBRATION RECORDS			X			Q				
IV.4.2 BALANCES, THERMOMETERS, AND PIPETTES						Q				

Table 1-4. Applicability Matrix for HASQARD Volume IV, Laboratory Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
IV.4.3 GENERAL REQUIREMENTS FOR STANDARDS						Q				
IV.4.4 CALIBRATION OF LABORATORY MEASUREMENT SYSTEMS						Q				
IV.T4-1 MINIMUM REQUIREMENTS FOR CALIBRATION, BACKGROUND, AND COUNTER CONTROL FOR ALPHA AND BETA COUNTING						Q				
IV.T4-2 MINIMUM REQUIREMENTS FOR CALIBRATION, BACKGROUND, AND COUNTER CONTROL FOR GAMMA SPECTROMETRY						Q				
IV.T4-3 MINIMUM REQUIREMENTS FOR CALIBRATION, BACKGROUND, AND COUNTER CONTROL FOR ALPHA SPECTROMETRY						Q				
IV.T4-4 MINIMUM REQUIREMENTS FOR CALIBRATION, BACKGROUND, AND COUNTER CONTROL FOR BETA SPECTROMETRY						Q				
IV.T4-5 MINIMUM CALIBRATION REQUIREMENTS FOR INORGANIC ANALYSES						Q				
IV.T4-6 MINIMUM REQUIREMENTS FOR GAS CHROMATOGRAPH/MASS SPECTROMETER SYSTEMS						Q				
IV.T4-7 MINIMUM REQUIREMENTS FOR CALIBRATION AND CALIBRATION VERIFICATION FOR GAS CHROMATOGRAPH SYSTEMS						Q				
IV.T4-8 MINIMUM CALIBRATION REQUIREMENTS FOR TOTAL ORGANIC CARBON, TOTAL INORGANIC CARBON, AND TOTAL CARBON ANALYSIS USING DIFFERENT INSTRUMENTS						Q				

Table 1-4. Applicability Matrix for HASQARD Volume IV, Laboratory Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
IV.T4-9 MINIMUM CALIBRATION REQUIREMENTS FOR THERMOGRAVIMETRIC ANALYSIS, DIFFERENTIAL THERMAL ANALYSIS/THERMAL GRAVIMETRY, AND DIFFERENTIAL SCANNING CALORIMETRY						Q				
IV.5.0 DATA COLLECTION, REDUCTION, AND REPORTING			X				Q	X		
IV.5.1 DATA COLLETION			X				Q	X		
IV.5.2 DATA REDUCTION			X				Q	X		
IV.5.3 DATA REPORTING			X				Q	X	X	
IV.6.0 QUALITY CONTROL							Q			X
IV.6.1 GENERAL LABORATORY QUALITY CONTROL							Q			
IV.6.2 PREPARATIVE TECHNIQUES FOR RADIOCHEMISTRY							Q			
IV.6.3 RADIOANALYTICAL TECHNIQUES						X	Q			
IV.6.4 INORGANIC PREPARATIVE TECHNIQUES							Q			
IV.6.5 INORGANIC ANALYTICAL TECHNIQUES						X	Q			
IV.6.6 ORGANIC PREPARATIVE TECHNIQUES							Q			
IV.6.7 ORGANIC ANALYTICAL TECHNIQUES						X	Q			
IV.6.8 PHYSICAL TESTING							Q			
IV.T6-1 PREPARATIVE REQUIREMENTS FOR RADIOCHEMISTRY QUALITY CONTROL							Q			

Table 1-4. Applicability Matrix for HASQARD Volume IV, Laboratory Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
IV.T6-2 PREPARATIVE REQUIREMENTS FOR INORGANIC QUALITY CONTROL							Q			
IV.T6-3 ANALYTICAL REQUIREMENTS FOR INORGANIC QUALITY CONTROL							Q			
IV.T6-4 PREPARATIVE REQUIREMENTS FOR VOLATILE, SEMIVOLATILE, AND GAS CHROMATOGRAPHY QUALITY CONTROL							Q			
IV.T6-5 ANALYTICAL REQUIREMENTS FOR VOLATILE QUALITY CONTROL (GAS CHROMATOGRAPHY/MASS SPECTROMETRY)							Q			
IV.T6-6 ANALYTICAL REQUIREMENTS FOR SEMIVOLATILE QUALITY CONTROL (GAS CHROMATOGRAPHY/MASS SPECTROMETRY)							X			
IV.T6-7 ANALYTICAL REQUIREMENTS FOR GAS CHROMATOGRAPHY							X			
IV.T6-8 ANALYTICAL REQUIREMENTS FOR TOTAL CARBON, TOTAL INORGANIC CARBON, AND TOTAL ORGANIC COMPOUND QUALITY CONTROL							X			
IV.T6-9 PHYSICAL TESTING QUALITY CONTROL (DIFFERENTIAL SCANNING CALORIMETRY, THERMOGRAVIMETRIC ANALYSIS, AND DIFFERENTIAL THERMAL ANALYSIS/THERMOGRAVIMETRIC ANALYSIS)							X			
IV.7.0 COMMON DATA QUALITY CALCULATIONS		X	X	X			Q	X		X
IV.7.1 PRECISION		X					Q			
IV.7.2 ACCURACY		X					Q	X		
IV.7.3 YIELD RECOVERY		X					Q	X		

Table 1-4. Applicability Matrix for HASQARD Volume IV, Laboratory Technical Requirements.

Volume Number, Section Number, and Title	Scope and Application	DQO and Planning Activities	QA Administrative	Procedures	Sample Custody & Handling	Calibration	Quality Control	Data Reduction, Reporting & Validation	Audits and Assessments	Quality Assurance Reporting
IV.7.4 MEASURES OF AGREEMENT		X					Q	X		
IV.7.5 DETECTION LIMIT CONSIDERATION		X				Q	Q	X		
IV.7.6 UNCERTAINTY			X			Q	Q	X		
IV.7.7 CONTROL CHARTS										
IV.8.0 DATA ASSESSMENT AND VALIDATION		X						X	X	
IV.8.1 DATA ASSESSMENT PROCESS		X						X	X	
IV.8.2 PLANNING CONSIDERATION		X						X	X	
IV.8.3 ASSESSMENT AND VALIDATION		X						X	X	
IV.8.4 DATA USABILITY		X						X	X	

<PUT DEFINITIONS HERE>

ALL = Applies to Sampling, Quantitative, Semi-Quantitative
S = Sampling
Q = Quantitative
SQ = Semi-Quantitative

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2.0 ORGANIZATION AND RESPONSIBILITY

The organizational structure shall be documented, and the lines of management authority shall be identified and areas of individual responsibilities 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 such responsibilities as stop work authority and 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, including 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. The integration shall ensure that the quality elements are an integral part of day-to-day operations.

Regulatory actions toward the organization or its parent corporation should 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 report to the highest level of management (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 laboratory results from a measurement system that is out of control

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 corrective actions

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3.0 PERSONNEL QUALIFICATION AND TRAINING

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

The organization shall have a documented training program which details the processes for identifying statutory, regulatory, or professional certifications which 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, 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 which 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 which 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.

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 upon 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/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 quality control shall be included to ensure that the precision, accuracy, sensitivity, and associated limitations of the methodology are well understood upon completion of the work.

4.1 GENERAL LABORATORY/FIELD OPERATIONS

Laboratory/field 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.

4.1.1 Sampling Procedures

Sampling activities may be conducted at the sites using a variety of equipment and procedures, (e.g., well drilling procedure for ground water sampling, soil sampling procedures, sampling from wells, pipes, pits, and lagoons, sampling containerized wastes [tanks, trucks, drums etc.]). Each sampling method performed in the field shall have an procedure associated with the particular activity. The equipment and procedures shall be selected on site-specific basis, depending on the media and nature of the contaminant to be sampled.
The procedure shall describe in detail the equipment needed, and how to use and maintain the equipment properly. The procedure shall address typical difficulties associated with the

sampling activity, limitations, and any precautions required to complete the task successfully. 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.

Sampling/Field operations covered by procedures shall include but not be limited to the following: (as appropriate):

Sample identification

Chain-of-custody

Sample preservation

Sample packaging and shipping

Sample tracking

Field notebooks

Data (records) Management activities

Environmental Health & Safety activities

Quality activities

Waste minimization and disposition

4.1.2 Field Analysis Procedures

Field Analytical operations covered by procedures shall include but not be limited to the following: (as appropriate)

Environmental, health, and safety activities

Quality activities
Sample shipping and receipt

Laboratory sample chain-of-custody

Sample storage

Sample preparation

Sample analysis

Standard preparation and handling

Post-analysis sample handling

Data security and confidentiality

Control of reagents and water quality

Cleaning of glassware

Waste minimization and disposition.

4.1.3 General Laboratory Procedures

Laboratory operations covered by procedures shall include but not be limited to the following: (as appropriate)

Environmental, health, and safety activities

Quality activities

Sample shipping and receipt

Laboratory sample chain-of-custody

Sample storage

Sample preparation

Sample analysis
Standard preparation and handling

Post-analysis sample handling

Data security and confidentiality

Control of reagents and water quality

Cleaning of glassware

Waste minimization and disposition

4.2 TECHNICAL AND TEST PROCEDURE REQUIREMENTS

Each technical or test procedure, at a minimum, shall have a unique code, title, revision number traceable to the date issued, and referenced documents: title, author(s), year published, publisher, document code. Each page shall carry the code and revision, at a minimum. The following information is recommended for technical and test procedures as appropriate to the scope and complexity of the procedure or work requested:

Scope: parameters measured, range, matrix, expected precision, and accuracy

Terminology used

Summary of method

Interferences/approaches to address background corrections

Apparatus and instrumentation

Reagents and materials, hazards, and precautions (Material Safety Data Sheet [MSDS] references)

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 testing organization shall document all approvals required on procedures.

4.3 NEW PROCEDURES

New technical procedures shall be qualified before use (see Section 5.6). New technical procedures are defined as technical procedures used for the first time whether based on published, well-understood methods or developed in the laboratory.

4.4 CATEGORIES OF CHANGES

Laboratories make changes to procedures (both regulatory and internally developed procedures) for a variety of reasons. The nature of the change can vary from minor to significant. Therefore, this document defines three categories of changes made in the laboratory. Laboratory conformance to the documentation requirements for each of these changes 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. Refer to Section 5.7 and specifically Section 5.7.2 for direction on how to proceed prior to implementing substitution, deviation and modification in these limited cases.

4.4.1 Substitution

4.4.1.1 Definition. Substitution is an adjustment in a procedure which 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 SW-846 (EPA 1986a). For documentation requirements, see Section 4.5.1.

4.4.1.2 Examples. Examples include substitution of equivalent columns yielding equivalent performance characteristics (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.

4.4.2 Deviation

4.4.2.1 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. For documentation requirements, see Section 4.5.2.

4.4.2.2 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.

4.4.2.3 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. Clearly, 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.

4.4.3 Modification

4.4.3.1 Definition. Modification changes the character of a procedure, and thereby, 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. For documentation requirements, see Section 4.5.3.

4.4.3.2 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.

4.5 CHANGE CONTROL

4.5.1 Substitution

Because substitution does not impact the procedure performed, no documentation of change is required (see Section 4.4.1.1). Only the documentation necessary to allow reproducibility of results is required.

4.5.2 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 used routinely, it shall be incorporated into the procedure.

4.5.3 Modification

Modification requires the procedure to be qualified (see Sections 4.6 and 4.7), 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 quality control is addressed to permit an understanding of the precision, accuracy, sensitivity, and associated limitations of the results.

4.6 QUALIFICATION OF METHODS

Qualification is the process of determining the suitability of a method (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 (laboratory approved or regulator recognized, see Volume 4, Appendix B) method; 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 method detection level determination and/or minimum detectable activity (according to Volume 4, Section 7.0), method blank evaluation, precision and accuracy determination, counter performance, uncertainty, and determination of method interferences as appropriate to the method (i.e., preparative versus determinative).

All method 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 should the need arise.

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.

4.7 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 4.4.3 and 4.5.3. Method qualification requirements are in Section 4.6. Guidance in understanding when a particular method qualifies as a required regulatory method can be found in *Selection of Analytical Methods for Mixed Waste Analysis at the Hanford Site*, DOE/RL-94-97 (RL 1994).

4.7.1 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 upon whether the procedure has short-term or long-term application (i.e., use 1 or 2, respectively).

4.7.2 Regulatory Notification

The notification mechanism available to the laboratory requires RL to coordinate with the regulator. The laboratory must obtain documented approval from RL to use the new procedure before starting work. The time frame for acceptance shall be documented and agreed upon. Information regarding regulatory acceptance considerations can be found in references such as WAC 173-303-910(2) and 40 CFR 136.4.

4.7.3 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). See Section 4.6 for the approach required for method qualification.

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 should the need arise.

4.7.4 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.

4.7.5 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, and this system shall be subject to ongoing documented review by management to assess it's 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. Correction shall include identifying the causes of problems and working to prevent recurrence for significant problems. 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 some level of corrective action is required are as follows:

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 in performance evaluation sample analysis audits, surveillances, and assessments

Validation and/or verification issues negatively impacting reported results

Recurring adverse problems, 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. The credibility of the investigative process is highly dependent on the knowledge and experience of the individuals who are performing the investigation. Additionally, investigators should be trained in techniques for conducting an investigation.

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 corrective action shall be verified. Corrective action shall be complete when the affected systems meet specifications. Measures to eliminate or minimize recurrence of quality problems shall be established.

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

Recommending 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.

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

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 them 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 the problems; and

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 in order 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 work place.

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 whether activities are satisfactorily accomplished.

Instructions, procedures, and drawings shall be reviewed and approved by appropriate qualified individuals. Revisions to instructions, procedures, and drawings which 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, the identification of the inspector or data recorder, the type of observation, the results, the acceptability, and the 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 1324.5B, *Records Management Program*.

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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 the protection of 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 the test 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 checks manually against another software product that has been previously tested or by analysis of standards.

Documentation of the testing should include the test cases, print-outs 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 in place.

Personnel should be trained on license requirements and proper control of 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; this process shall be subject to ongoing review by management to assess its effectiveness.

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:

Identify 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

Accepting purchased items and/or services

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.

NOTE: When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action (e.g., subsequent reporting to the DOE Office of the Inspector General).

9.0 EQUIPMENT/PREVENTIVE MAINTENANCE

9.1 EQUIPMENT

Equipment and/or systems requiring periodic maintenance shall be identified and the records of major equipment shall include: 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, 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 PREVENTIVE 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 should be considered for inclusion:

Routine inspections (e.g., daily, weekly, or as needed) should be based on the manufacturers' recommendations, performed by the responsible analyst, and followed by corrective action(s) if required. Anomalies should be noted individually in a logbook, record sheet, or electronic record system, which will be kept next to the instrument.

Significant corrective action(s) for the M&TE or instrument should be documented in a logbook, record sheet, or electronic record system. The notation should include a description of the corrective action, the date performed, and the initials of the person who performed the corrective action.

Instrument maintenance should be performed by appropriate personnel. This could include services provided through an external maintenance contract.

Equipment and instrument maintenance and repairs should be documented, including the date and signatures of personnel who performed the maintenance. This documentation may be in a logbook, record sheet, or electronic record system, and should be reviewed annually.

Critical spare parts lists and inventory should be maintained. If applicable, a written contingency plan specifying backup equipment should be established.

A recommended laboratory instrument preventive maintenance plan is provided in Volume 1, Appendix C.

10.0 ASSESSMENTS

Assessments are evaluations intended to provide an increased understanding of the program or system being evaluated, and to provide a basis for improving such programs or systems. A QA program can only be effective if meaningful assessment systems are in place to continuously monitor, assess, and respond to issues associated with program or organizational performance.

Assessment tools may consist of management system assessments, technical system assessments (surveillances), performance evaluation assessments, data quality assessments, peer and technical assessments (reviews), readiness reviews, and/or external audits and assessments.

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

Management system assessments

Technical system assessments

Performance evaluation assessments

Data quality assessments, and

External assessments

The QA program shall identify each assessment element as well as the frequency of each assessment, the position or individual responsible for each assessment, the qualifications, responsibilities, authority, and accountabilities of assessor(s), the format of the assessment, distribution, action owner(s), expectation for timely corrective action, expectation for timely closure of 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 and 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 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, and
applicability of data quality requirements.
client complaints

Management assessments determine both noteworthy accomplishments, significant QA problems, and identify 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 systems assessments consist of a review of laboratory or field operations, specific procedures, and related documentation. For example, areas of interest might include:

M&TE calibration or control procedures,

document control procedures,

technical procedure compliance,

adherence to data quality requirements,

identification, control, storage and preservation of samples or standards, or

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 upon 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, and how identified corrective actions will be resolved, as well as the timeframe required for corrective action. This information shall be made available to regulators and clients upon request.

10.4 DATA QUALITY ASSESSMENTS

Data quality assessments are independent evaluations of the data reported to a client, and are used specifically to assess the degree of compliance to client data quality requirements. These assessments may be organizationally or programmatically driven. They should be performed by the responsible organization's QA representative whenever practical. Each organization or program shall establish a frequency for such evaluations based upon the complexity or significance of the work being performed.

10.5 EXTERNAL ASSESSMENTS

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

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

11.0 QUALITY ASSURANCE REPORTING

A formal mechanism for reporting to management the status of the QA program 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
- Corrective actions and status

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13.0 CLARIFICATIONS AND INTERPRETATIONS

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APPENDIX A

GLOSSARY

Accuracy	The degree of agreement of a measurement (or an average of measurements of the same thing), X, with an accepted reference or true value, T, usually expressed as the difference between the two values, X - T, or the difference as a percentage of the reference or true value, 100 (X - T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system.
Analyst	A person performing a measurement.
Analyte	The element, isotope, specie, or characteristic of a measurement.
Anomalie	Something different, abnormal, or peculiar, not easily classified.
Assessment	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. 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.
Audit	A systematic and independent examination to determine whether 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 which behave similarly with respect to the sampling or testing procedures being employed and which are processed as a unit. For QC purposes, if the number of samples in a group is greater than 20, then each group of 20 samples or less will all be handled as a separate batch.

Bias	The systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).
Blank	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 process: Laboratory or Preparation Blank - An analytical control prepared by the laboratory that contains distilled, deionized water and reagents, which is carried through the entire analytical procedure (digested and analyzed) concurrently with samples per each sample deliverable group. An aqueous method blank is treated with the same reagents as a sample with a water matrix. A solid method blank is treated with the same reagents as a soil sample. It is a test for contamination in sample preparation and analyses. Holding Blank - is stored and analyzed with VOA samples at the laboratory It is a test for contamination in sample storage as well as sample preparation and analyses. Trip Blank - A blank sample which 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 typically only analyzed for volatile organic compounds. Field Blank - A blank sample prepared in the field at the sample collection site and returned to the laboratory with the samples to be analyzed. Tests for contamination from the atmosphere as well as those activities listed under trip blank. Equipment Blank/Equipment Rinsate - An artificial sample usually consisting of deionized/carbon free water designed to monitor sampling device cleanliness. Equipment blanks are opened in the field and poured over or through the sample collection device as appropriate, collected in a sample container, and returned to the laboratory as a sample. Equipment blanks may also be comprised of sand of known cleanliness. Equipment blank results may indicate that decontamination procedures were

	inadequate or that contamination was inherent to the equipment used.
Blind Sample	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. 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.
Calibration	Comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustment.
Carrier	Carriers are stable counterparts of the radioactive isotope(s) to be measured. Carriers are added to all samples in an analytical batch such that each sample has a specific measurable QC 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 (such as inductively coupled plasma atomic emission spectrometry) to determine radiochemical yield. The mass effects of a carrier on the final sample counting configuration must be taken into account. The carrier yield is used in the data calculations to correct for any and all sources of analytical losses.
Certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
Chain of Custody	An unbroken trail of accountability that ensures the physical security of samples, data, and records.
Client	The person or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Collecting	[In the context of this document,] 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 and are intended to be identical. Used where homogenizing samples for split or duplicates is not allowed; such as, for VOA 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) which indicates the degree of dependence between two variables (concentration vs absorbance). The more dependent they are, the closer the value to one. Determined on the basis of the least squares function.

Data Quality Assessment (DQA)	Process is the scientific and statistical evaluation of data to determine whether the data are of the right type, quality, and Quantity to support their intended use. The DQA Process completes the Data Life Cycle (planning, implementation, and assessment) that was begun by the Data Quality Objectives (DQO) Process.
Data Quality Objectives (DQO)	A strategic, systematic process for planning scientific data collection efforts. The DQO process helps investigators answer the following basic questions: Why do we need data? What must the data represent? How will we use the data? and How much uncertainty is tolerable? By using the DQO Process, investigators ensure that the data collected for decision making are the right type, quantity, and quality.
Data Usability	The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.
Data Validation	Process where the data package provided by the analytical provider is subjected to a rigerous review to assure 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 assuring 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 in which physical and chemical reactions and other phenomena occur: air, water, soil, debris, bottom sediment, waste. See Medium.
Equipment Rinsate	See Equipment Blank
Estimated Quantitation Limit (EQL)	The lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The EQL is generally 5 to 10 times the MDL. However, it may be normally chosen within these guidelines to simplify data reporting. For many analytes the EQL 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 utilizing 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 (IDL)	The smallest signal above background noise that an instrument can detect reliably.
Laboratory Duplicate	An initial subsample of a sample which 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. 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 (MS)	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 (MSD)	A second aliquot of the same sample as the Matrix Spike, with the same known quantities of compounds added as the MS and subjected to the entire analytical procedure with the MS.
May	Denotes permission but not a requirement.
Method Detection Limit	The minimum concentration of a compound that can be (MDL) 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 upon the reviewers evaluation of factual evidence.
Organic-free	For volatiles, all reference to water in the methods refer to reagent water to water in which an interferant 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.

	For semivolatiles and nonvolatiles, all reference to water in the methods refer to water in which an interferant 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.
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 (PE)from a measurement system are 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 upon 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, such as standards or tests, that 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 is to provide evidence of meeting a performance standard for fitness by training skill or ability for a designated purpose. To qualify analytical procedures or computer programs is to provide evidence 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 (QAPjP)	A formal document describing in comprehensive detail the necessary QA, QC, 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. Such management programs generally entail 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 agree upon 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	Water that has been generated by a method which would achieve the performance specifications for ASTM Type II water. 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 represent 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 QC 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 so 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 sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

Specification	A document stating requirements and which 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, which 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 which is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but which 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 QC parameter (yield). From the time of spiking, tracers undergo all 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, 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.

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APPENDIX B

DATA QUALITY OBJECTIVE

PROCESS USER'S GUIDE

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APPENDIX B

DATA QUALITY OBJECTIVE

PROCESS USER'S GUIDE

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APPENDIX B

Data Quality Objective Process User Guide

Overview

The result of the DQO process is a set of specific and detailed DQOs that are incorporated into program supporting documents. Often a DQO document is issued, and Quality Assurance Project Plans are built from the specifications outlined in the DQO document.

The implementation of DQOs at Hanford is oriented toward enabling programs to meet site requirements in a cost-effective and technically sound manner. This can be accomplished using the disciplined rigor of program decision identification and preplanning in the application of the DQO process.

The use of the DQO process is one part of the QA planning and the Data Life Cycle. The Data Life Cycle is composed of three distinct areas: Planning, Implementation, and Assessment. The Planning stage is comprised of the DQO process and the development of the quality assurance project plan. The Implementation stage consists of field data collection and associated quality assurance/quality control activities. The final stage, Assessment, focuses on the data validation/verification and data quality assessment activities.

These three areas are further broken down into areas of organizational responsibilities in Table B-1. The program has specific leadership roles in the process for initiation and utilization of the data generated. Analytical Services Program of DOE-RL is the primary point-of-contact with the program to identify areas where DQO application is appropriate. A graded approach in the application of DQOs should be considered as depending on the size and complexity of the program.

Table B-1. Data Quality Objective Implementation Process.

	Process Steps	Product	Who is Responsible
PLANNING PHASE	Advanced Data Quality Objective (DQO) planning	Identify Master strategy Questions Risk/uncertainty	Senior technical experts Decision makers
	DQO Preparation	Identify detailed data needs; Quantify risk/uncertainty; Accept and approve DQO documentation.	Personnel Program Regulator AS DOE
	Logistics Personnel	Prepare Characterization documents; Sampling/analytical procedures; Integrated schedules/budgets; Personnel training.	Program lead AS personnel
DATA COLLECTION PHASE	Sampling and Transportation	Determine sampling operations.	Program lead Support from others
	Historical and Process Data Collection	Compile available data.	Program lead Support from others
	Engineering and Technical Studies	Develop new data through studies and	Program lead

	Process Steps	Product	Who is Responsible
PLANNING PHASE	Advanced Data Quality Objective (DQO) planning	Identify Master strategy Questions Risk/uncertainty	Senior technical experts Decision makers
		analysis.	Support from others
	Sampling and Analysis/ Reporting Data	Verify/validate Laboratory Operations data reporting.	Analytical Laboratory
	Data compilation into characterization report	Report preparation Data analysis/Interpretation Data validation.	Program lead Support from others
DECISION MAKING PHASE	Decision making	Implement decisions based on DQOs.	Regulators Program decision makers Support from others

NOTE: Feedback loops exist throughout this process but are not shown. Process steps will be complete so that handoffs from step to step are transparent.

Data Quality Objective Process Outline

I. State the Problem To Be Resolved

Purpose

Summarize the contamination problem that will require new data, and identify the resources available to resolve the problem.

Activities

Identify members of the scoping team.
Develop/refine the conceptual site model.
Define the exposure scenarios.
Specify available resources.
Write a brief summary of the contamination problem.

II. Identify the Decision That Addresses the Problem

Purpose

Identify the decision that requires new data to address the contamination problem.

Activities

Identify the key decision for the current phase or stage of the project.

Identify alternative actions that may be taken based on the findings of the field investigation.

Identify relationships between this decision and any other current or subsequent decisions.

III. Identify Inputs Affecting Decision

Purpose

Identify the information needed to support the decision and specify which inputs require new measurements and/or data.

Activities

Identify the informational inputs needed to resolve the decision.

Identify sources for each informational input, and list those inputs that are obtained through measurements and/or data.

Define the basis for establishing contaminant-specific action levels.

Identify potential sampling approaches and appropriate analytical methods.

IV. Define Boundaries of the Study

Purpose

Specify the spatial and temporal aspects of the media that the data must represent to support the decision.

Activities

Define the geographic areas of the field investigation.

Define each medium of concern.

Divide each medium into strata having relatively homogeneous characteristics.

Define the scale of decision making.

Determine when to take samples.

Determine the time frame to which the decision applies.

Identify practical constraints that may hinder sample collection (reconsider previous steps as necessary).

V. Develop a Decision Rule

Purpose

Develop a logical "if….then...." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

Activities

Specify the parameter of interest (such as mean, median, or proportion).

Specify the action level for the decision.

Combine the outputs of the previous DQO steps into an "if....then...." decision rule that includes the parameter of interest, the action level, and the alternative actions.

VI. Specify Limits on Uncertainty

Purpose

Specify the decision maker's acceptable limits on decision errors, which are used to establish appropriate performance goals for limiting uncertainty in the data.

Activities

Determine the range of contaminant levels that may be encountered at the site.

Define both types of decision errors and identify the potential consequences of each.

Specify a range of contaminant levels over which the consequences of decision errors are relatively minor (the gray region).

Assign acceptable limits on decision errors above and below the gray region.

Check for consistency.

VII. Optimize the Design

Purpose

Identify the most resource-effective sampling and analysis design for generating data that are expected to satisfy the DQOs.

Activities

Review the DQO outputs and existing data.

Develop general sampling and analysis design alternatives.

For each design alternative, verify that the DQOs are satisfied.

Select the most resource-effective design that satisfies all of the DQOs.

Document the operational details and theoretical assumptions of the selected design in the SAP or Characterization Plan.

Data Quality Objective Process Template

Step 1: State the Problem

Purpose:

To clearly define the problem so that the study will be unambiguous

Expected Outputs:

A list of the planning team members and identification of the decision maker

A concise description of the problem

A summary of available resources and relevant deadlines for the study

Activities:

Identify members of the planning team
- Size related to size and complexity of the problem
- Include representatives from all groups associated in the project

Identify the primary decision maker(s) and define each member's role

- Enable ultimate authority for making decisions based on team recommendations
- Assign roles and responsibilities
- Develop a concise description of the problem
- Describe the conditions or circumstances that are causing the problem and the reason for understanding the study
- Describe the problem as it is currently understood by briefly summarizing existing information
  - Study objectives/regulatory context
  - Persons or organizations involved in the study
  - Persons or organizations that have an interest in the study
  - Political issues surrounding the study
  - Sources and amount of funding
  - Previous study results
  - Existing sampling design constraints
- Conduct literature searches and examine past or ongoing studies to ensure that the problem is correctly defined and has not been solved previously
- If the problem is complex, consider breaking it into more manageable pieces

Specify the available resources and relevant deadlines for the study
- Stipulate anticipated budget, available personnel and contractual vehicles
- Enumerate deadlines for completion and any intermediate deadlines

Step 2: Identify the Decision

Purpose:

To define the decision statement that the study will attempt to resolve

Expected Outputs:

A decision statement that links the principal study question to possible actions that will solve the problem

Activities:

Identify the principal study question
- Identifies key unknown conditions or unresolved issues that reveal the solution. Common examples:
- "Is the permittee out of compliance with discharge levels?"
- "Is the contaminant concentration significantly above background levels?"

Define the alternative actions that could result from resolution of the principal study question

- Identify possible actions, including the alternative

Combine the principal study question and the alternative actions into a decision statement

- Following standard form helpful in drafting decision statements:
  "Determine whether or not [unknown environmental conditions/ issues/criteria from the principal study question] require (or support) [taking alternative actions]."

Organize multiple decisions (refer to Flowchart)

- List decision statements and sequence of resolution

Step 3: Identify Inputs

Purpose:

To identify the informational inputs that will be required to resolve the decision statement and determine which inputs require environmental measurements

Expected Outputs:

A list of informational inputs needed to resolve the decision statement

A list of environmental variables or characteristics that will be measured

Activities:

Identify the information needed to resolve the decision statement

- Determine environmental variables and information needed
- Consider whether monitoring or modeling approaches will be used

Determine information sources for each item

- Identify and list sources for information needed to resolve problem
- Evaluate whether existing data is appropriate

Identify the information needed to establish action level

- Define basis for setting action level
- Determine criteria used to set numerical value

Confirm that appropriate measurement methods exist

- Develop a list of potential measurement methods
- Note method detection limit and limit of quantitation for each potential method

Step 4: Define Boundaries

Purpose:

To define the spatial and temporal boundaries that are covered in the decision statement

Expected Outputs:

A detailed description of the spatial and temporal boundaries of the problem

Any practical constraints that may interfere with the study.

Activities:

Specify the characteristics that define the population of interest

- Define attributes of population and state them so focus of study is unambiguous

Define the spatial boundary of the decision statement

- Define the geographic area to which the decision statement applies

Region marked by physical features (i.e., volume, length, width, boundary)

- When appropriate, divide population into strata that have relatively homogenous characteristics

Stratify or segregate elements of population into subsets or categories that exhibit homogeneous properties or characteristics that may influence outcome

Define the temporal boundary of the problem

- Determine the timeframe to which the decision applies

  Determine timeframe data should reflect

- Determine when to collect data

  Determine when conditions are favorable for data collection and most appropriate time period

Define the scale of decision making

- Define smallest, most appropriate subsets of population based on spatial or temporal boundaries

Identify any practical constraints on data collection
- Identify constraints that could interfere with implementation of data collection design such as inability to gain site access or unavailability of personnel, time or equipment

Step 5: Decision Rule

Purpose:

To define the parameters of interest, specify the action level and integrate previous DQO decision outputs into a statement that describes a logical basis for choosing among alternative actions

Expected Outputs:

The statistical parameter (the parameter of interest) that characterizes the population

The action level

An "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions

Activities:

Specify the statistical parameters that characterize the population
- Specify parameter of interest

Specify the action level for the study
- Specify numerical value to be used in choosing alternative actions
- Confirm that action level is greater than detection and quantitation limits for identified measurement methods

Develop a decision rule
- MEAN

  Positive Attributes
  - Useful when action level is based on long-term, average health effects
  - Useful when the population is uniform with relatively small spread
  - Generally requires fewer samples than other parameters

  Negative Attributes

- Not a very representative measure of central tendency for highly skewed populations
- Not useful when the population contains a large proportion of values that are less than measurement detection limits

- MEDIAN

  Positive Attributes
  - Useful when action level is based on long-term, average health effects
  - Provides a more representative measure of central tendency than the mean for skewed populations
  - Useful when the population contains a large number of values that are less then measurement detection limits
  - Relies on few statistical assumptions

  Negative Attributes
  - Will not protect against the effect of extreme values
  - Not a very representative measure of central tendency for highly skewed populations

- UPPER PROPORTION/PERCENTILE

  Positive Attributes
  - Useful for protection against extreme health effects
  - For highly variable populations, provides best control of the extreme values
  - Useful for skewed distributions
  - May be appropriate when the population contains a large number of values less than the measurement detection limit, as long as the limit is less than the action level
  - Relies on few statistical assumptions

  Negative Attributes
  - Requires larger sample sizes than mean

Step 6: Decision Errors

Purpose:

To specify the decision maker's tolerable limits on decision errors, which are used to establish performance goals for the data collection design

Expected Outputs:

The decision maker’s tolerable decision error rates based on a consideration of the consequences of making an incorrect decision

Activities:

Determine the possible range of parameters of interest
- Estimate upper and lower bounds of parameter of interest

Identify the decision errors and null hypothesis
- Define both types of decision errors and establish the true state of nature of each decision error
- Specify and evaluate the potential consequences of each decision error
- Establish which decision error has more severe consequences near the action level
- Define the null hypothesis (baseline condition) and the alternative hypothesis and assign the terms "false positive" and "false negative" to the appropriate decision error

Specify parameter values where the consequences of decision errors are relatively minor (gray region)
- Establish boundary by evaluating consequences of not rejecting the null hypothesis when it is false

Assign probability limits to points above and below the action level that reflect the tolerable probability for the occurrence of decision errors
- Select value of parameter and choose a probability limit

Step 7: Optimize the Design

Purpose:

To identify a resource-effective data collection design for generating data that are expected to satisfy the DQOs

Expected Outputs:

The most resource-effective design for the study that is expected to achieve the DQOs

Activities:

Review the DQO outputs and existing environmental data
- Review DQO outputs to ensure they are internally consistent

Develop general data collection design alternatives

- Find cost-effective alternatives that balance sample size and measurement performance such as:
  - Factorial design
  - Simple random sampling
  - Stratified random sampling
  - Sequential random sampling
  - Systematic sampling
  - Composite sampling

Formulate the mathematical expressions needed to solve the design problems for each design alternative

- Define a suggested method for testing the statistical hypothesis and define a sample size formula that corresponds to the method, if one exists
- Develop a statistical model that describes the relationship of the measured value to the "true" value
- Develop a cost function that relates the number of samples to the total cost of sampling and analysis

Select the optimal sample size that satisfies the DQOs for each design alternative

- Increase the budget for sampling and analysis
- Increase the width of the gray region
- Increase the tolerable decision error rates
- Relax other project constraints, such as the schedule
- Change the boundaries

Select the most resource effective data collection design that satisfies all the DQOs

- Evaluate the design options based on cost and ability to meet DQO constraints

Document the operational details and theoretical assumptions of the selected design in the sampling and analysis plan

Document statistical assumptions that could be violated through errors in or practical constraints on field sample collection procedures or analytical methods.

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APPENDIX C

PREVENTIVE MAINTENANCE

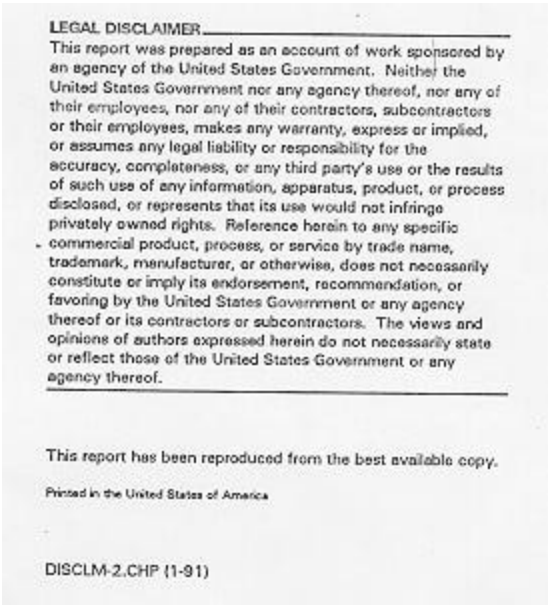
The following table contains recommendations on the frequency for instrument preventive maintenance.

Table C-1. Recommended Preventive Maintenance Frequency for Specific Instruments

Instruments	Frequency
Atomic Absorption (AA) Spectrophotometer	
Inspect nebulizer	Daily
Inspect spectrophotometer quartz windows	Daily
Check burner head; check tubing, pump, and lamps	Daily
Check O rings	Daily
Fine tune wavelength; check optics	Semiannually
Check electronics	Semiannually
Furnace AA Spectrophotometer	
Check graphite tubes	Daily
Flush autosampler tubing	Daily
Replace graphite electrodes	Annually
Clean furnace housing and injector tip	Daily
Check electronics	Annually
Cold Vapor and Hydride AA Spectrophotometer	Daily
Check flushing tubing (automated systems)	Daily
Check absorption cell for vitrification	As needed
Replace or clean quartz cell	Semiannually or as needed
Check electronics	
Inductively Coupled Plasma Spectrometer (ICP)	
Inspect torch	Semiannually
Clean nebulizer and spray chamber	Weekly
Clean fan filters	Semiannually
Check peristaltic pump tubing and vacuum pump oil	Semiannually
Check optical system	Semiannually
Check water lines, torch compartment, and gases	Semiannually
Check electronics (e.g., voltages, waveforms)	Semiannually
Check wavelength calibration and adjust as needed	Semiannually

Run interference (interelement) standard	Daily
Gas Chromatograph (GC) General	
Check septa, cylinder gas pressure, oxygen/moisture traps	Daily
Bake out injector body	
Check electronics (e.g., voltages, waveforms)	Daily
Check GC temperature calibrations (injector, oven, detector)	Annually
Columns (change glass sleeve inserts, shorten ends of columns, change glass wool plugs, check for leaks or replace)	Semiannually
Electron capture detector, wipe tests	As needed
Electron Capture Detector	Semiannually
Hydrogen cleaning	
Returned to factory for cleaning and refoil	As needed
GC/Mass Spectrometer	
Replace vacuum pump oil and change desiccant,	Semiannually
Check ion source and analyzer (dismantle, clean, and replace parts as needed)	As needed,
Check mechanic (vacuum pumps, relays, gas pressures and flows)	Daily
Check mass calibration with FC-43 (perfluorotributylamine)	Daily
Purge and trap	
Clean sparger	Daily
Change trap	As needed
Bake trap	As needed
Check purge flow	Daily
Check for leaks	As needed As needed
High Pressure Liquid Chromatography	
Gas lines checked for leaks	Daily
Clean mobile phase flow system and detector flow cells with nitric acid	Semiannually
Check pump seals and valve assemblies	Daily
Check solvent filters	Monthly
Auto Samplers	
Auto-injector or autovial	Daily

Check needles and tubing Clean	As needed As needed
Total Organic Carbon Analyzer	Annually
Uranium Fluorometry Laser source	 As needed from quality control check
Gas Proportional Counters Clean autosample chamber	 Monthly
Alpha Energy Analysis Clean and inspect Check microamps and verify voltage settings Check peak channel Check Detector resolution	 Monthly Monthly Monthly Monthly
Gamma Energy Analyzer Check and inspect Pole zero Lower level discriminator Time constant Amplifier's fine gain for energy/channel setting Check Detector resolution	 Monthly Monthly Monthly Monthly Monthly
Liquid Scintillation Counter Internal standard source Clean and check autosampler and sampler well Clean and inspect	 As needed Semiannually Monthly
Differential Scanning Calorimetry	Annually
Thermogravimetric Analyzer	Annually
pH Meter	Annually
Thermometers	Annually
Analytical Balance cleaning and calibration	 Annually
Density Meter	Annually
Ultraviolet/Visible Spectrophotometer	Annually



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