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Quality Assurance Plan for the Remedial Investigation of Waste Area Grouping 2 at Oak Ridge National Laboratory, Oak Ridge, Tennessee

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EXECUTIVE SUMMARY

The Oak Ridge National Laboratory (ORNL) Waste Area Grouping (WAG) 2 Site Investigation (SI) includes the lower portion of the White Oak Creek (WOC) drainage and its tributaries, embayment, and associated floodplain and subsurface environment. The ORNL main plant and the major waste storage and disposal facilities at ORNL are located in the WOC watershed and are drained by the WOC system to the Clinch River, located off-site. Environmental media are contaminated and continue to receive contaminants from hydrologically upgradient WAGs. WAG 2 is important as a conduit from upgradient areas to the Clinch River.

The White Oak Creek (WOC) system, consisting of WOC, its tributaries, White Oak Lake, and the WOC Embayment on the Clinch River, is the primary surface drainage for ORNL on the Department of Energy's Oak Ridge Reservation in East Tennessee.

WAGs are defined by hydrologic units that contain contiguous remedial action sites. ORNL WAG 2 consists of the WOC drainage downstream of ORNL discharge points and includes the associated floodplain and subsurface environment.

The WAG 2 SI Project is supported by the Environmental Restoration (ER) Program but is located within the Environmental Sciences Division.

The general objectives of the WAG 2 SI Project are to conduct a multimedia environmental monitoring and characterization program to

1. define and monitor the input of contaminants from adjacent WAGs,
2. monitor and gather sufficient information for processes controlling or driving contaminant fluxes to construct an appropriate conceptual model for WAG 2, and
3. prepare for the eventual remediation of WAG 2.

Long term objectives of the WAG 2 SI include

1. definition of the nature and extent of contamination in WAG 2,
2. quantification of any risk to human-health and the environment resulting from the contamination, and
3. preliminary evaluations of potential corrective measures and remedial action alternatives for the operable units in WAG 2.

Results of human-health and environmental risk assessments will be used to focus monitoring, sampling, and analytical efforts, and ultimately to determine the need for corrective measures to reduce risks. The risk-driven monitoring, sampling, and analysis will proceed while adjacent WAGs are undergoing remediation.

Monitoring activities at ORNL provide an important source of information as well as opportunities for collaboration on data collection. Activities related to environmental restoration under way in the WOC watershed and Clinch River Program by necessity are linked to the WAG 2 project. Data from all activities are being evaluated for utility and

acceptability under WAG 2 SI data quality objectives. These projects and monitoring programs are being integrated with the WAG 2 SI efforts.

All organizations performing tasks for the WAG 2 SI must have a quality assurance (QA) plan that meets WAG 2 data quality objectives. If there is no approved QA plan for the task, then the organization will be required to develop an acceptable plan.

The WAG 2 QA plan is designed to comply with corporate and governmental requirements.

1. PROJECT DESCRIPTION

1.1 DESCRIPTION

The Oak Ridge National Laboratory (ORNL) Waste Area Grouping (WAG) 2 includes of the lower portion of the White Oak Creek (WOC) drainage, tributaries, embayment, and associated floodplain and subsurface environment. The ORNL main plant and the major waste storage and disposal facilities at ORNL are located in the WOC watershed and are drained by the WOC system to the Clinch River, located off site. Environmental media are contaminated and continue to receive contaminants from hydrologically upgradient WAGs. WAG 2 is important as a conduit from upgradient areas to the Clinch River.

1.2 OBJECTIVES

The general objective of the WAG 2 Site Investigation (SI) Project is to conduct a multimedia environmental monitoring and characterization program to (1) define and monitor the influx of contaminants from adjacent WAGs; (2) monitor and gather sufficient information about processes controlling or driving contaminant fluxes to construct an appropriate conceptual model for WAG 2; and (3) prepare for the eventual remediation of WAG 2.

2. QUALITY ASSURANCE OVERVIEW

2.1 REGULATING AGENCIES

The WAG 2 Quality Assurance (QA) Plan is designed to comply with the Environmental Restoration Program's QA Program, and with ES/ER/TM-4R2 (Energy Systems 1992), Department of Energy (DOE) Order 5700.6C, U.S. Environmental Protection Agency (EPA) QAMS-005/80 and American National Standards Institute/American Society of Mechanical Engineers (ANSI/ASME) NQA-1 guidelines. EPA QAMS-005-80 (EPA 1980) contains EPA's guidance for project QA/Quality Control (QC) plans. ANSI/ASME NQA-1 (ANSI/ASME 1989) has been adopted as the main QA/QC standard. Because this plan falls under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) regulation, the WAG 2 QA plan is subject to Office of Solid Waste and Environmental Response (OSWER) Directive 9502.00-6C (EPA 1987a), OSWER Directive 9355.0-76 (EPA 1987b), and OSWER Directive 9355.3-01 (EPA 1988a).

2.2 MODULAR PROFILE

The modular profile for the WAG 2 Project (Table 1) shows the relationship between DOE 5700.6C, QAMS-005/80, NQA-1, and ORNL QA elements and the elements of this plan. Some of the regulating agencies' elements identified in the modular profile are not applicable to the WAG 2 SI Project. These elements, excluded from this plan, are identified in Sect. 2.3. Many of the ORNL elements adequately describe WAG 2 project-specific procedures and have been adopted for WAG 2 use with referenced additions and/or clarifications. Where minor additions and/or clarifications to the ORNL QA plan are sufficient, no project-specific procedures have been developed. However, some of the ORNL elements required extensive elaboration to describe WAG 2 SI project-specific procedures. In these cases, project-specific standard operating procedures (SOPs) are referenced in the modular profile. SOPs are compiled in a WAG 2 procedures and instructions manual and are maintained and distributed by the project QA Coordinator.

2.3 EXCLUSION RATIONALE

ORNL QA Element 3, "Design Control," is intended to control project interfaces with design organizations. The WAG 2 SI Project has no current need to interface with the Engineering Division or other Martin Marietta Energy Systems, Inc., design organizations. If this need arises, the design control element will be addressed in this plan.

2.4 WAG 2 DOCUMENT INTERFACE

This QA Plan is a controlled document, and the information contained in this plan is to be used in conjunction with the responsibilities and procedures described in the WAG 2 RI Plan (ORNL 1990) and the WAG 2 Sampling and Analysis Plan (ORNL 1991a). If conflicts occur, the QA Plan takes precedence.

Table 1. Modular Profile for the WAG 2 SI Project

NQA-1 Basic Element	QAMS 005/80	DOE ORDER 5700.6C Criteria	ORNL QA Manual Reference	Implementing Procedures	Location in WAG 2 QAP	Additions/ Clarifications
1. Organization	5.4 Project Organization and Responsibility	1. Program	QA-L-1-100	QA-L-1-100	Section 3.1 page 5	YES
2. Quality Assurance Program	5.3 Project Description 5.16 QA Reports	2. Personnel Training and Qualification	QA-L-2-100 QA-L-2-101 QA-L-2-103	ES-ADM-91-002 SOP Training[a]	Section 3.2 page 10	YES
3. Design Control	5.5 QA Objectives for Measuring Data 5.6 Sampling Procedures 5.10 Data Reduction, Validation and Reporting 5.11 Internal QC Checks 5.14 Specific Routine Procedures 5.9 Analytical Procedures	6. Design	QA-L-3-100	N/A	Section 3.3 page 16	N/A
4. Procurement Document Control		7. Procurement	QA-L-4-100	QA-L-4-100	Section 3.4 page 16	NO
5. Instructions, Procedures, and Drawings	5.9 Analytical Procedures 5.6 Sampling Procedures	5. Work Processes	QA-L-5-100	SOP Procedure development & control[a]	Section 3.5 page 16	YES
6. Document Control	5.1 Title Page 5.2 Table of Contents 5.3 Project Description 5.6 Sampling Procedures 5.7 Sample Custody 5.9 Analytical Procedures	4. Documents and Records	QA-L-6-100	SOP Tech notebooks[a] SOP Document mgmt. center[a] SOP Forms development and control[a]	Section 3.6 page 20	YES
7. Control of Purchased Items and Services		7. Procurement	QA-L-7-100	SOP-Development of statements of work[a] SOP-Data verification and validation[a]	Section 3.7 page 21	YES
8. Identification and Control of Items	5.7 Sample Custody	5. Work Processes	QA-L-8-100	SOP Sample identification and labeling SOP Chain-of-custody[a]	Section 3.8 page 22	YES
9. Control of Processes	5.9 Analytical Procedures	5. Work Processes	QA-L-9-100	N/A	Section 3.9 page 23	YES

Table 1 (continued)

10. Inspection		8. Inspection and Acceptance Testing	QA-L-10-100	SOP Surveillance of project activities[a]	Section 3.10 page 24	YES
11. Test Control		8. Inspection and Acceptance Testing	QA-L-11-100	SOP Data verification and validation[a]	Section 3.11 page 24	YES
12. Control of Measuring and Test Equipment	5.8 Calibration Controls and Frequency 5.13 Preventative Maintenance Procedures and Schedules	5. Work Processes	QA-L-12-100	SOP Calibration failures[a]	Section 3.12 page 26	YES
13. Handling, Storage, and Shipping	5.6 Sampling Procedures 5.7 Sample Custody	5. Work Processes	QA-L-13-100	QA-L-13-100	Section 3.13 page 27	YES
14. Inspection, Test, and Operating Status		8. Inspection and Acceptance Testing	QA-L-14-100 QA-L-14-101	QA-L-14-100 QA-L-14-101	Section 3.14 page 27	YES
15. Non-conformances		3. Quality Improvement	QA-L-15-100	SOP Variance, nonconformance, occurrences and corrective action[a]	Section 3.15 page 28	YES
16. Corrective Action	5.15 Corrective Actions 5.16 QA Reports	3. Quality Improvement	QA-L-16-102	SOP in above SOP[a]	Section 3.16 page 28	YES
17. Quality Assurance Records			QA-L-17-100	[illegible]/P-OS/ERP-DMC SOP Document mgmt. center[a]	Section 3.17 page 28	YES
18. Audits	5.12 Performance and System Audits and Frequency	9. Management Assessments 10. Independent Assessments	QA-L-18-100 QA-L-18-101 QA-L-18-102	QA-L-18-100 QA-L-18-101 QA-L-18-102	Section 3.18 page 29	YES
19. Software			QA-L-19-100	QA-L-19-100	Section 3.19 page 31	YES
20. Program Specific Procedures			QA-L-20-102	SOP Document review[a]	Section 3.20 page 31	YES

[a]Standard operating procedures to be developed or in development.

3. PROJECT REQUIREMENTS

3.1 ORGANIZATION

The project organizational structure and project participants are shown in Fig. 1. The responsibilities defined below are those specific to the development, implementation, and assessment of the WAG 2 SI Project QA Plan. Additional QA-related responsibilities are delineated in Table 2, Project Document Summary.

All organizations performing tasks for the WAG 2 SI must have a QA plan that meets WAG 2 data quality objectives. Review of the QA plans of other organizations is the responsibility of the Extra-Project Coordinator, the WAG 2 QA/QC Coordinator, and the Project Manager. If there is no approved QA plan for the task, then the organization will be required to develop an acceptable plan. It may be necessary to add project-specific attachments, such as organization charts, functional responsibility matrixes, and surveillance plans, to otherwise adequate plans.

Interface agreements will be developed with all organizations performing tasks for WAG 2. These interface agreements will provide configuration and change control statements between organizations.

3.1.1 Responsibilities

3.1.1.1 Project manager

The project manager

- ensures that the appropriate QA requirements of this document are included in planning, investigating, analyzing, and reporting activities of the WAG 2 SI Project;
- ensures that the ER Program and Environmental Sciences Division (ESD) QA Specialists are included on the project activities;
- consults with the QA Specialists on all quality-related matters;
- approves resolutions for quality problems and concurs with root-cause analysis, proposed solutions, and corrective actions as determined by the project QA Coordinator;
- submits the appropriate documents to the QA Specialist for comment and approval; and
- ensures that the project personnel are qualified and trained to perform the assigned project activities.

3.1.1.2 Environmental Restoration Program and Environmental Sciences Division quality assurance specialist

The QA specialist

- provides assistance and approval of the project QA Plan, procedures, and instructions;
- evaluates the effectiveness of project QA activities through scheduled audits and surveillances in cooperation with the WAG 2 QA Coordinator; and

H. L. Boston, Project Manager
S. J. Lavender

RISK ASSESSMENT
G. Blaylock**
V. Chidambariah
G. Sutter
M. Frank
L. Etnier

PROJECT SAFETY

• HEALTH & SAFETY
R. McConathy
L. Baron, HSC
Lab Stewards

• QA/QC
P. Schrandt
L. Roberson

STATISTICAL SUPPORT
R. Gardner**
J. Beauchamp
D. Downing
T. Wright

BASELINE MONITORING AND CHARACTERIZATION
D. Miller**

• SURFACE WATER HYDROLOGY
D. Borders*
R. Clapp
J. Watts

• SURFACE WATER CHEMISTRY
M. Tardiff*
D. Hicks

• SEEPS AND TRIBUTARIES
D. Hicks*
G. Moore

• GROUNDWATER
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• BIOTA
T. Ashwood*
H. Boston

• FIELD SAMPLING COORDINATOR
D. Jones

• TECHNICAL SUPPORT TEAM
S. Short
J. Morris
S. Gregory, LS
L. Baron, LS

DATA MANAGEMENT QA/QC AND INTEGRATION
L.Hook**

• DATA BASE MGMT/GIS
J. Watts*
M. Faulkner
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• QUALITY ASSURANCE COORDINATOR
G. Atwood*

• ANALYTICAL SERVICES COORDINATOR
D. Jones

• EXTRA-PROJECT COORDINATOR
R. Clapp*
D. Miller

SEDIMENT TRANSPORT MODELING
T. Fontaine**
A. Brenkert
S-Y Lee

REMEDIAL ALT. ASSESSMENT
T. Ashwood*
W. Barton
C. Kendrick

** Task leaders
* Team leaders
LS = lab steward
HSC = health and safety coordinator

Fig. 1. WAG 2 RI Project Organization—June 1992.

Table 2. WAG 2 RI document summary

Document title	QA record?	Controlled document?	Prepare	Review				Approve			
Quality assurance plan	YES	YES	QAC	PM	ESD-QAS	ERD-QAS	HSC	PM	ERD-QAS	ESD-QAS	
Personnel training records	YES	NO	QAC	PM				PM			
Standard operating procedures and instructions	YES	YES	PS	QAC	PM	ESD-QAS		PM			
Sampling and analysis plan	NO	YES	PM, PS	PR							
Remedial investigations plan	NO	YES	PM, PS	PR							
Chain-of-custody forms	YES	NO	FSC	DBM	QAC						
QA audit/surveillance reports	YES	NO	AO	PM	QAC	ERD-QAS	ESD-QAS	DD	PRM		
External data source QAPs	NO	NO	EDS	EPC	QAC			TSK	QAC		
Statements of work	YES	NO	ASC, APO	PM	QAC			PM			
Standards traceability documents	YES	NO		TL	QAC						
Lab/field forms	YES	NO	PS	FSC	QAC						
Lab/field notebooks	YES	NO	PS	FSC	QAC	TL					
Data: electronic/hard copy	YES	NO	DBM	QAC	TL						
Memoranda of agreement	YES	NO	PM	QAC	DD	PRM		DD	PRM		
Interface agreements	YES	NO	PM	QAC	PS			PM	AD		
Variance logbook	YES	NO	FSC	QAC	ESD-QAS	PM		PM	ERD-QAS	ESD-QAS	
Deviation request forms	YES	NO	PS	QAC	ESD-QAS	PM		PM	ERD-QAS	ESD-QAS	
Controlled software	NO	YES	DBM, TL								
QA summary reports	YES	NO	QAC					PM	ERD-QAS	ESD-QAS	PRM
Inspection reports	YES	NO	EI	LS							
Lab operations manual	NO	NO	LS	QAC				PM			
Corrective action reports	YES	NO	QAC	PM	ESD-QAS	ERD-QAS		AO	PRM	DD	
Health and safety plan	YES	YES	HSC	ASC		QAC		PM			

Table Key

AD agency/organization director/manager
AL Analytical Laboratory
AO auditing organization
APO Analytical Projects Office
ASC analytical services coordinator
DBM data base manager
DD division director
EDS external data source
EI equipment inspector
EPC extraproject coordinator
ERD-QAS ORNL Environmental Restoration Program quality assurance specialist
ESD-QAS Environmental Sciences Division quality assurance specialist
FSC field sampling coordinator
HSC health and safety coordinator
LS laboratory steward
PM project manager
PR peer reviewers
PRM ER program manager
PS project staff
QAC quality assurance coordinator
RM ER remediation manager
SH section head
TL team leader
TSK task leader

- provides guidance to resolve quality problems and ensures that corrective action is taken and is appropriately documented.

3.1.1.3 Quality assurance/quality control coordinator

The QA/QC coordinator

- provides QA coordination between the Project Manager, QA Specialists, and project participants to ensure implementation and assessment of this plan;
- conducts field and laboratory evaluations of sampling methods and analytical procedures to ensure adherence to this QA Plan, SOPs, and instructions;
- oversees project-specific procedures and training development, implementation, and tracking;
- assures that SOP's are in place and that appropriate personnel have been trained in the procedures; and
- conducts QA Plan orientations to all WAG 2 staff.

3.1.1.4 Task leaders

Task leaders are responsible for integrating available information and collected data to meet the objectives and requirements of their specific tasks. The task leader

- assists the Project Manager in achieving the goals and objectives of the WAG 2 SI project;
- assists in project management and provides the Project Manager with project progress reports;
- supervises and reviews subcontractor activities;
- maintains records in accordance with the WAG 2 SI project QA Plan;
- provides final validation of field and analytical laboratory data and review of data for completeness, documentation, procedures, and consistency with known physical-chemical principles;
- resolves any technical questions concerning the data; and
- implements appropriate staff training and ensures that all project staff have been adequately trained and are in compliance with project QA/QC, health and safety, waste management, and data management requirements.

3.1.1.5 Sampling team leader

Sampling team leader is responsible for the management and coordination of specific field sampling teams. The sampling team leader

- coordinates and supervises field sampling activities and ensures that all sampling activities have been approved by the QA Coordinator;
- coordinates activities with project management;
- provides orientation, hazard information, and training to technical staff, based on the requirements of the support plans;
- ensures that field-related activities are performed correctly and documented as required by the WAG 2 SI project QA Plan;
- reviews and signs field logbooks and transfer copies of field logs to the ER Document Management Center (DMC) and the WAG 2 SI DMC;

- performs initial validation of analytical data provided by internal WAG 2 laboratories prior to data transfer to the ER DMC and the WAG 2 SI DMC;
- provides field implementation of the health and safety (H&S) plan, including communication of requirements to all personnel and field supervision, and ensures that site personnel have received required Occupational Safety and Health Administration (OSHA) and WAG 2 SI training and that they adhere to the site safety requirements;
- informs the project H&S coordinator of any changes in sampling plans so that they may be appropriately addressed; and
- ensures that Corrective Actions and Nonconformance Reports are initiated if necessary.

3.1.1.6 Analytical services coordinator

The WAG 2 SI analytical services coordinator (ASC) is responsible for the custody and transfer of samples and results among the sampling teams and analytical laboratories. The ASC is the main contact for the laboratories concerning chain of custody (COC) and requests for services. The ASC

- establishes and maintains a COC and request-for-services forms control system, in conjunction with the project QA Coordinator;
- receives COC samples from the field crews and transfers them to analytical laboratories;
- ensures that COC and request-for-services forms are properly completed prior to transfer of sample custody;
- ensures that corrective actions and nonconformance reports are initiated if necessary;
- oversees final disposal of samples to ensure that proper procedures are followed.

3.1.1.7 Health and safety coordinator

The H&S coordinator is responsible for ensuring that site personnel adhere to the site H&S requirements. The H&S coordinator

- reviews the QA Plan;
- develops, coordinates, and implements the H&S plan;
- revises the H&S plan as warranted by changed site conditions; and
- ensures that all WAG 2 SI personnel adhere to H&S requirements.

The project manager, with the assistance of the H&S coordinator, handles the agency liaison matters relating to health and safety. During field work, the sampling team leader will normally assume the responsibilities of the H&S coordinator.

3.1.1.8 Extraproject coordination team leader

The extraproject coordination team leader is responsible for establishing linkages, exchanging information, and generally cooperating with other research activities in and around the WAG 2 area.

3.1.1.9 Technical support staff

The technical support staff

- complies with all aspects of the WAG 2 SI QA Plan;
- performs project activities in accordance with approved SOPs; and
- identifies and document variations to SOPs as described under element 15.

3.1.2 Procedures

The WAG 2 SI Project is supported by the ER Program but is located within ESD. A Memorandum of Agreement (MOA) between the ER Program and ESD documents the interfaces and responsibilities of each division as they pertain to the operation of the WAG 2 SI Project. The ESD Division Director and the ER Program Manager are responsible for the approval, implementation, and revision of MOAs. See Table 2 for project-level responsibilities for the development of MOAs.

3.2 QUALITY ASSURANCE PROGRAM

3.2.1 Quality Assurance Program

The Project Document Summary (Table 2) identifies responsibilities for the development, review, approval, and control of the QA Plan.

3.2.2 Quality Assurance Planning

The development, review, approval, revision, and distribution of this QA Plan will follow guidelines set forth in *Preparation, Development, Approval, and Clearance of Environmental Restoration Documents*, ER/C-P1103.

3.2.3 Data Quality Objectives

Data quality objectives (DQOs) are derived from the intended uses of the data. To develop DQOs, environmental variability and analytical quantitation requirements must be considered along with measures to evaluate the precision, accuracy, representativeness, comparability, and completeness (PARCC) of both sample collection and analysis, and the level of documentation required to support the intended use of the data. Because initial WAG 2 sampling efforts emphasize scoping and screening activities, the sampling locations, number of samples, and methods of data collection are intended to

1. provide information for locations, media, and/or analytes for which few data exist, and
2. estimate environmental variability.

Therefore, consideration of environmental variability has not been included in the development of DQOs for this stage of the WAG 2 RI activities.

To allow for flexibility in the WAG 2 Program, the DQO process will incorporate three phases:

1. Qualified individuals designated by the Project Manager will perform an evaluation to determine the logical use of the data and the definition of the parameters that must support the sampling and analysis process.

2. This group will then determine the enhancement of specific requirements such as sampling and analytical methodology resulting in detection limits and determine the QC documentation to support this process.

3. Finally, this group will make a determination of the most effective way to maximize the efficiency of the collection design. This involves, when applicable, the identification of acceptable levels of uncertainty and the inherent variability of environmental samples, while taking into consideration those factors which could account for variability of the data.

The analytical methods selected are based on quantitation limits (levels of concern) required to identify contaminants of potential concern (e.g., the evaluation of applicable or relevant and appropriate requirements, the conducting of risk-based contaminant screening, the establishment of background conditions, etc.). Data meeting historic method quality control criteria therefore meet the analytical requirement of the DQO for this project.

Meeting project data-use requirements will require the use of a decision-making process by which measurement tasks are assigned the appropriate level of QC documentation to support the stated environmental problem. These levels will be designated I through IV, and are intended to be equivalent to the levels defined in *Data Quality Objectives for Remedial Response Activities* (EPA 1987b). The WAG 2 SI risk assessment team, in consultation with the Project Manager, the Site Characterization Coordinator, and the ER Analytical Projects Officer (APO), will determine the QA level required for all measurements and activities.

In general, if data are to be used directly for risk assessment, feasibility studies, or remedial design, QA Level III or higher will be required. Data of two different quality levels will be generated during field investigations. Field data such as the results of radiation monitoring will meet the requirements of Level I or II data quality. Analytical laboratory data collected for surface water, ground water, sediment, and biota sampling will meet the requirements of Level III or Level IV data quality. For example, Level I and II data quality is obtained from field screening exercises using portable instruments. Results may not be quantitative or compound specific but are inexpensive and can be made available quickly. Level I and II data can be used for such scoping and screening activities as (1) initial delineation of contaminated zones, (2) crude presence or absence of contamination, and (3) gross determination of analytes in samples. Level III and Level IV data quality requirements provide laboratory analyses using standard EPA methods such as those in SW-846 (EPA 1986a), EPA 600/4-79-020 (EPA 1983), and the Contract Laboratory Program (CLP). Levels III and IV provide quantitative analytical results that require a level of QA/QC resulting in legally defensible data. Data at both of these levels are produced under equally rigorous conditions. Level IV, however, has a deliverable that is provided in a legally defensible "package." Level III and IV data are suitable for site characterizations and risk assessments. The QA requirements for Level III and IV are (1) detection limits for each

procedure will be consistent with EPA-approved methods; (2) laboratory QA/QC procedures will follow method-specific requirements; and (3) field QA/QC procedures will be assessed by reviewing data generated from the analysis of trip blanks, equipment rinsates, field blanks, and duplicate samples. Level III packages should also include analytical results for the QA/QC samples run, which aids in the extent of validation or verification for WAG 2 SI as the end user. The determination of the appropriate QA level for data collection (field measurements or analytical methods) will depend on the intended use of the data.

Because contaminant inputs into WAG 2 are changing (as upgradient WAGs are remediated), the nature and extent of contamination is also changing. Therefore, in 10 to 20 years a baseline risk assessment will follow the remediation of upgradient WAGs. Data collected in the interim period by the multimedia environmental monitoring program will be used to track contaminant influxes, releases, and inventories, and will form the basis for an abbreviated and very specific sampling and analysis program for the baseline risk assessment. Thus, the majority of data collected by the multimedia environmental monitoring program will require no more than Level III QA. However, because the WAG 2 SI Project involves a long-term monitoring effort and analytical methods that will likely change over the duration of the monitoring effort, approximately 10 to 25% of the data collected will meet the requirements of Level IV QA. The Level IV, full CLP-like data packages will compare to current and future analytical methods and will ensure the ongoing usability of data for the duration of the WAG 2 SI Project.

DQOs may lead to the use of analytical Level V (special methods) for some contaminants. For example, the risk-based contaminant screening found potentially significant risks associated with certain organic contaminants that were not detected but were screened at a concentration equal to the detection limits (Blaylock et al. 1991). For these organic compounds, either (1) analytical methods with lower limits of detection will be used, or (2) compounds will be eliminated from further consideration based on evidence such as a lack of reported detection in any media and no known sources in the watershed. This rationale will be presented in the next iteration of the sampling and analysis (S&A) plan prior to the next and more intensive round of field sampling. Rationale is being developed for dealing with contaminants for which Level III or IV analytical methods may not provide acceptable detection limits in conjunction with Energy Systems' Central Risk Assessment Committee.

3.2.4 QA Program Status Reporting

The active participation of management in the WAG 2 SI is fundamental to the success of this QA/QC Plan. Management will be aware of project activities and will participate in development, review, and operation of the project. Management will be informed of QA status and activities through the receipt, review, and approval of

- laboratory and project-specific QA/QC plans and procedures,
- postaudit reports and audit closures,
- surveillance reports,
- deviation request forms,
- corrective-action overdue notices, and
- nonconformance reports.

The individuals responsible for providing management with the above documentation are defined in Table 2. Copies of these reports will be distributed to appropriate Energy Systems and Oak Ridge Field Office management and regulatory agencies. In addition, biannual assessment of QA/QC activities and data PARCC will be conducted by the QA/QC Coordinator and reported to the WAG 2 Project Manager.

Project management will inform the ER Program and ESD QA Specialists, as appropriate, of the QA status of the project, especially any significant quality accomplishments. WAG 2 SI personnel are required to inform the Project Manager or project support staff of all nonconformances or quality failures. The Project Manager will document and immediately report any nonconformance or quality failure to the QA Specialist. It is the responsibility of the ESD QA Specialist to report all quality-associated activities to the ORNL QA Manager.

3.2.5 QA Training and Awareness

All ORNL and subcontractor personnel working on the WAG 2 SI will be properly trained, qualified individuals. QA awareness will be addressed at information sessions and through distribution of the project QA Plan. The QA Coordinator will be responsible for conducting the sessions and distributing the plans. Receipt of information shall be documented by attendance and document sign-out sheets. Prior to the commencement of work, all sampling team personnel will be given instructions specific to the remedial investigation covering the following areas:

- training needs assessment;
- organization and lines of communication and authority;
- description of the WAG 2 system;
- overview of the S&A, QA/QC, H&S, and Data Management Plans;
- documentation requirements;
- personnel protection procedures;
- waste management procedures;
- decontamination procedures; and
- emergency procedures.

QA information sessions shall be conducted annually or more frequently as needed. Training information is included in each applicable SOP or Instruction.

3.2.6 Quality Control Samples

3.2.6.1 Field QC samples

Field QC sampling will be established to check sampling and will constitute 5 to 10% of the total number of samples. All QC samples will be shipped according to the COC procedures specified in Sect. 3.8 of this Plan. Field QC samples will include blanks and replicates as follows:

Field rinsate. A field rinsate consists of final rinse water from the decontamination of field sampling equipment. Analysis of the field rinsate determines whether the

decontamination procedure is adequate to prevent carryover of contamination from one sampling location to another. A field rinsate will be collected at a minimum of 1 in 10 cleanings of any given piece of equipment.

Laboratory rinsate. A laboratory rinsate consists of final rinse water from the decontamination of laboratory equipment. Analysis of the laboratory rinsate determines whether decontamination procedures are adequate. Laboratory rinsates will be collected prior to each day of activities or at a minimum of 1 in 10 cleanings of any given piece of equipment.

Field blank. One field blank, consisting of source water (distilled or deionized water) used for decontamination, will be collected for every 20 samples or once per sampling event, whichever is greater. Field blanks will also be used to detect airborne metal or organic contaminants present at the time of sample collection. One field blank container consisting of distilled or deionized water will be opened during the collection of one in twenty metal or organic samples.

Field duplicate. Field duplicates, which consist of a duplicate sample from one sampling location, indicate whether the field sampling technique is reproducible. Duplicate samples will be obtained at a collection frequency of 5 to 10% for all sample matrices.

Field QC samples will have discrete sample numbers and be submitted as "blind" to the laboratories. Results of these samples will be included in the analytical data report. Results for QC samples will not be used to adjust the results obtained for original samples. If contaminants are found in the blanks, attempts will be made to identify the source of contamination, and corrective action will be initiated.

3.2.6.2 Laboratory Quality Control samples

Laboratory QC samples will be used to check sample preparation and analysis and to monitor laboratory performance. ER Program guidelines for laboratory QC samples and documentation have been established in ER Program, ORNL 1991a. Specific data deliverables will be approved by the ER Program APO. Specific requirements for groups of samples will be specified in statements of work (SOWs) for those samples. Analysis-specific control samples may be required as indicated by EPA-accepted procedures. QC samples will consist of blanks, duplicates and spikes. Laboratory standards will also function as QC components. QA procedures for laboratory processing include laboratory duplicates of all field samples to determine the precision of laboratory results. The laboratory QC documentation requested for delivery will be specified in the SOW and will be dependent upon the intended use of the data, as determined by DQOs, for a given sampling event. Laboratory QC samples will include the following:

Method blank. A method blank is a blank sample made up of a pure, noncontaminated substance (usually distilled or deionized water or silica sand) that is subjected to all of the sample preparation (e.g., digestion, distillation, and extraction) and analytical methodology applied to the samples. The method blank is used to check for contamination from within the laboratory that might be introduced during sample analysis.

Calibration/continuing calibration blank. A calibration blank is the substance that is used to zero the instrument. The calibration blank comprises the solvent used for the preparation of the calibration standards and samples. The calibration blank accounts for any interferences from the solvent matrix.

Sample container cleaning blanks. If sample containers are cleaned in the laboratory, sample container cleaning blanks are taken for each batch of containers that goes through the cleaning process. If contamination is detected, the containers associated with the contaminated blank will be recleaned, and another blank will be taken and analyzed.

Laboratory duplicates. The laboratory analyst prepares laboratory duplicates for each sample by homogenizing a sample as thoroughly as possible and taking two separate aliquots of that sample for analysis. The duplicate sample, however, should never be a method blank, trip blank, or field blank. The purpose of laboratory duplicates is to check the precision of the analyst, the sample preparation methodology, and the analytical methodology.

Matrix spikes. A matrix spike is an aliquot of a sample to which a known concentration of the compounds of interest has been added. The matrix spike is subjected to the same sample preparation and analytical methodology applied to the samples. The sample to be spiked is selected prior to sample submittal by the ASC; however, the spiked sample cannot be a method blank, trip blank, or field blank. The purpose of the matrix spike is to check for interferences or false readings caused by the sample matrix.

Blank spike or laboratory control sample. The blank spike, or laboratory control sample (LCS), is a blank sample (usually distilled or deionized water or silica sand) to which a known concentration of the compounds of interest has been added. The blank spike is subjected to the same sample preparation and analytical methodology applied to the samples. The purpose of the blank spike is to check the accuracy of the analyst, the sample preparation methodology, and the analytical methodology. The level of accuracy is measured by calculating the percent recovery (%R).

The laboratory QA/QC Coordinator is responsible for preparing QC standards and sending QC samples into the laboratory for analysis. Statistical analyses will then be performed utilizing the results of QC sample analyses. Each laboratory will apply precision and accuracy criteria to each parameter that is analyzed. When analysis of a sample set is completed, the QC data are reviewed and evaluated through the use of control charts to validate the data set. Laboratory QC standards will include the following:

Calibration standards. Calibration standards comprise the compounds of interest at known concentrations. Calibration standards are prepared from EPA reference material or commercially available, certified reference materials traceable to the National Institute of Standards and Technology (NIST), using the same solvent used for sample preparation at the same concentration. Semivolatile and volatile organic analyses by Gas Spectrometry/Mass Spectrometry require one point calibration by current CLP criteria. Calibration standards for other methods require at least three concentration levels plus a blank standard throughout the calibration range required for the analysis. Calibration standards are not subjected to all of the preparation (e.g., extraction, distillation, and digestion) that is applied to the sample; rather they are used (1) to initially calibrate the

instrument by providing reference points throughout the calibration range and (2) to establish linearity throughout the calibration and working ranges of the instrument. The instrument is checked continually throughout the analysis with the calibration standards to check for instrument drift.

Performance evaluation samples. Performance evaluation samples consist of known concentrations of the analytes submitted to the laboratory being audited. These samples are obtained through various EPA-sponsored programs and private vendors to provide an objective evaluation of laboratory performance and comparison with other participating laboratories.

Control charts are statistical representations of the laboratory's performance and are used to monitor laboratory performance and to establish control limits or the acceptance criteria for all compounds of interest. For each analyte, a separate control chart is required for each type of control sample that measures precision or accuracy (blank spike, matrix spike, and duplicate) and for each matrix type and concentration level (high, medium, and low). A minimum of ten measurements of precision and accuracy are required before control limits can be established. Control limits of three standard deviations shall be utilized for all samples.

Once established, control limits are updated as additional precision and accuracy data become available to the laboratory QC Coordinator. Any control sample data point that falls beyond the control limits or any data trend (indicated by seven or more consecutive points on either side of the mean) will require an internal investigation. For all identified contaminants of concern, control limits and corrective actions will be in accordance with EPA protocol. Additional statistics for organics work will be done in accordance with SW-846 (EPA 1986a) or CLP-SOW (EPA 1986b), as applicable.

3.3 DESIGN CONTROL

See exclusion rationale, Sect. 2.3.

3.4 PROCUREMENT DOCUMENT CONTROL

WAG 2 SI Project procurement document control will follow ORNL procedure QA-L-4-100 (ORNL 1988).

3.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

3.5.1 Responsibilities

3.5.1.1 ER procedures coordinator

The ER procedures coordinator reviews the purpose and scope of WAG 2 procedures and task instructions for applicability to other ER activities.

3.5.1.2 WAG 2 procedures coordinator

The WAG 2 procedures coordinator

- assigns numbers to WAG 2 procedural documents and interfaces with the ER procedures coordinator;
- inputs into a data base tracking information on the documents created;
- ensures that the data base remains current;
- coordinates the development and issuance of WAG 2 procedures and instructions;
- facilitates the review of new and revised WAG 2 procedures and instructions with appropriate review staff and makes certain that required approvals are obtained for these documents;
- facilitates the revision of procedures and instructions;
- arranges for a classification review of procedural documents;
- develops appropriate distribution lists, along with the assistance of the author, for review copies and final copies of WAG 2 procedural documents;
- arranges the distribution of these documents with the WAG 2 DMC;
- issues binders for storing procedural documents to individuals on a controlled distribution list;
- prepares and arranges the distribution of revised tables of contents and acknowledgment forms for the receipt of procedural documents;
- conducts routine yearly reviews of procedural documents (in conjunction with the principal author, and/or peer reviewers of the procedural documents) to determine any necessary revisions to these documents; and
- indicates approval of all procedures and instructions on a WAG 2 approval form before they are routed to the principal author and Project Manager for their approvals.

(The WAG 2 procedures coordinator's approval indicates that procedural documents have gone through all necessary reviews and that appropriate required changes have been incorporated in the documents. Procedures coordinator approval is not approval of the technical or administrative content of a document, and it is not approval from a quality assurance perspective).

3.5.1.3 Principal author

The author of a WAG 2 procedure or instruction is responsible for ensuring that the document

- adequately addresses its intended audience;
- communicates complete and accurate information on the process being described;
- complies with federal, state, and local laws and regulatory guidelines and Martin Marietta corporate, Energy Systems, division, and site policies, procedures, and instructions; and
- shows an appropriate effective date on the last page of the document.

The author is also responsible for

- making certain these tasks are accomplished;
- soliciting two peer reviews of the document (see definitions);
- working with the WAG 2 procedures coordinator, other authors who may need to be

assigned to assist with the writing task, the peer reviewers, and the editor to follow the procedure or instruction from conception through management approval; and
- indicating his/her approval of a procedure or instruction before it is routed to the Project Manager for approval.

3.5.1.4 Editor

The editor of a WAG 2-generated procedure or instruction is responsible for

- ensuring that the document's style, format, and organization are consistent with the *Document Preparation Guide* (Energy Systems 1989) and that the document meets the quality guidelines specified in this document;
- editing the document to the level of edit specified by the author, which may include a substantive in-depth review of the document's content;
- ensures that any changes required by the author and other reviewers of the document are made;
- providing a copy of the final document to the author for verbal approval; and
- sending the original document to the WAG 2 procedures coordinator for routing and project approval.

The editor of a WAG 2 procedural document does not indicate approval of the document on the form developed for project approval unless he/she is also the principal author of the document.

3.5.1.5 Quality assurance/quality control coordinator

The quality assurance/quality control coordinator is responsible for

- reviewing technical and administrative procedural documents to ensure that appropriate quality assurance program requirements have been addressed,
- providing written comments on all procedural documents reviewed and indicating approval of final documents, and
- updating the WAG 2 modular profile when procedures or instructions have been approved.

3.5.1.6 Peer reviewer

A peer reviewer of a WAG 2 procedure or instruction is responsible for verifying that the procedural document

- addresses its intended audience,
- accurately describes the process being documented, and
- has an appropriate scope and execution.

The peer reviewer also

- provides written comments on all documents reviewed but is not required to indicate approval of a procedural document,
- requests to see a copy of an approved procedure or instruction prior to its distribution

to verify that all of the peer reviewers' concerns have been addressed.

Two peer reviewers are required for every administrative and technical procedure and instruction generated by the WAG 2 Division. One peer reviewer is required for every PCN issued by WAG 2.

3.5.1.7 Project manager

The WAG 2 SI project manager has ultimate responsibility for

- ensuring the appropriateness of the scope and execution of technical and administrative procedural documents;
- ensuring that procedures and instructions conform to federal, state, and local laws and regulatory guidelines and to Martin Marietta corporate, Energy Systems, division, and site policies, procedures, and instructions;
- verifying that reviews appropriate for the type of procedural document (administrative or technical procedure or instruction) have taken place (as evidenced by the signatures on the approval form for procedures and instructions);
- signing the approval form for all procedures and instructions and signing and dating the last page of procedural documents to indicate division approval; and
- ensuring that procedures and instructions are properly administered and implemented within the project.

3.5.1.8 WAG 2 Document Management Center information assistant

The WAG 2 DMC information assistant works with the WAG 2 procedures coordinator to ensure that WAG 2 procedures and instructions are distributed to all appropriate parties. The information assistant

- prepares approved copies of procedural documents for mailing using distribution lists supplied by the WAG 2 procedures coordinator; and
- maintains the record copy and the original, approved copy of all procedural documents generated by the WAG 2 in accordance with the Energy Systems guidelines outlined in "Retention and Disposition of Records," GP-21, *Policy Procedures.*

3.5.2 Standard Operating Procedures and Instructions

Refer to the Project Document Summary (Table 2) for the identification of individuals involved with project instructions and procedures. All project-specific SOPs and instructions are maintained in the WAG 2 Plan Procedures and Instructions Manual by the WAG 2 QA Coordinator. Refer to Table 3 for a listing of WAG 2 SOPs and instructions.

3.5.3 Laboratory Operations Manual

All WAG 2 laboratories shall develop, control, and maintain a laboratory operations manual (LOM) in accordance with ESD Procedure ES-ADM 91-003 (Energy Systems 1992b). Refer to Table 2 for the identification of individuals responsible for LOMs.

3.6 DOCUMENT CONTROL

This section applies to documents pertaining to the WAG 2 SI project and to the management of those quality-related documents that are in active use during the life of the project. Documents include, but are not limited to,

- QA documents,
- sampling data, and
- technical notebooks.

3.6.1 Responsibilities

Refer to Table 2, Project Document Summary, for a list of project documents and for the identification of record material and controlled documents.

3.6.1.1 Project manager

The project manager

- designates which project documents are to be controlled, and

- informs the QA Coordinator of controlled document designations.

3.6.1.2 QA coordinator

The QA coordinator oversees the control of designated project documents according to the procedures listed in the Modular Profile (Table 1).

3.6.2 Procedures

The QA coordinator ensures adequate document control by

- developing and maintaining a distribution list of individuals requiring controlled project documents,
- distributing revisions to controlled documents, and
- tracking the receipt of revisions by project staff through the use of receipt forms and periodic document checks.

Record copies of all WAG 2 SI documents will be indexed and filed at the WAG 2 DMC and the ER DMC located in ESD.

3.7 CONTROL OF PURCHASED ITEMS AND SERVICES

3.7.1 Responsibilities

Refer to the Project Document Summary (Table 2) for the identification of organizations and WAG 2 staff members responsible for the development, review, and approval of Analytical Laboratory SOWs.

3.7.2 Procedures

Laboratory SOWs will

- be developed in conjunction with the ER APO,
- specify QC requirements and QC sample deliverables, and
- be submitted to the laboratory for approval prior to sample shipment.

The analytical laboratory shall submit the results of requested control sample analyses and other QA/QC documentation to the WAG 2 SI ASC to ensure conformance with established control limits and other QA requirements. The QC requirements will be based on project DQOs. The data validation process will impose sufficient controls over the quality of analytical laboratory data and services. The laboratory will not perform data validation; laboratory data will be validated by an organization independent of the laboratory. The data review process consists of data screening, checking, auditing, verification, certification, and review.

The format and content of hard copy and electronic data reports will adhere to project needs and will be specified in SOWs, which include contract requirements of DOE and regulatory agency reporting formats. The laboratory supervisors are responsible for the preparation of each technical report, including the process of data validation. The required hard copy report format will be specified in the laboratory SOW.

- Final data presentation shall be checked according to data validation requirements and approved by the appropriate sampling team leader and laboratory steward.
- Each page of data will be identified with the project number or project name, sample delivery group number, batch number, and date of issue.
- Electronic copies of the data must match the hard copy reports.

Electronic data contents in the report will include the

- sample identification number used by the laboratory and/or the sample identification provided to the laboratory if it is different from that used in the laboratory;
- sample delivery group number and batch number;
- chemical parameters analyzed, reported values, laboratory data qualifiers, and units of measurement;
- quantification limit of the analytical procedure;
- results of QC sample analysis;
- achieved accuracy, precision, and completeness of data;
- references to specific data if required to explain reported values; and
- analytical methods used.

Analytical methods will be specifically referenced on all laboratory reports. Any method modification will be included in the case narrative provided by the contract laboratory. Data for field QC samples will be reported in the same format as that used for actual samples.

3.8 IDENTIFICATION AND CONTROL OF ITEMS

3.8.1 Responsibilities

3.8.1.1 Field sampling coordinator

The field sampling coordinator

- determines the method of identification of samples in conjunction with the QA Coordinator and the Data Base Manager and ensures that the items are identified in accordance with project SOPs;
- ensures that physical identification of equipment is provided to the maximum extent possible;
- ensures that when identification markings are used the identification materials and methods provide a clear and legible identification; that they do not detrimentally affect the function, integrity, or service life of the item; and that this will last for the time required; and
- ensures that identification markings are transferred to each part of an identified item when the item is subdivided and that the markings shall not be obliterated or hidden by surface treatments or coatings unless other means of identification are substituted.

3.8.1.2 Quality assurance coordinator

The QA coordinator

- determines that sponsor requirements for identification and traceability of samples are met;
- ensures that COC procedures are completely described through the issuance of and training on COC Procedures;
- ensures that procedures for the collection, handling, storage, and identification of samples are included in the WAG 2 SOPs; and
- ensures that procedures for control, identification, and cleaning and maintenance of sampling equipment and instruments are developed and implemented.

3.8.2 Procedures

Each environmental sample collected will have a unique identifier that will be physically associated with the sample and maintained from the time of sample collection to sample disposal.

Sample COC procedures require documented sample possession from the time of

collection to disposal, in accordance with Martin Marietta Energy Systems, Inc. Procedure, ESP-500 (Kimbrough et al. 1990).

Shipping and handling procedures are described in technical SOPs for each sample medium and analysis.

Laboratory Calibration Standards, when commercially available, will be traceable to NIST, EPA, or other certified laboratories. Documents certifying traceability are considered QA records and shall be indexed and filed in the WAG 2 SI DMC and the ER DMC.

3.9 CONTROL OF PROCESSES

For the purpose of this program, control of processes will be used to indicate the use of data/sampling collection through interface agreements. Data from several other projects will be utilized in the WAG 2 SI. The Extra Project Coordinator will be the point of contact for interactions with these various groups (i.e., Clinch River Remedial Investigation, ORNL WAGs Remedial Investigation/Feasibility Study, the Biological Monitoring and Abatement Program, the National Pollutant Discharge Elimination System, the Active Sites Environmental Monitoring Program, and the Environmental Surveillances Program). Data from these groups will be transferred to the Data Management and Integration Group. The QA plans developed for these groups will be reviewed and their status relative to WAG 2 data quality objectives will be documented. WAG 2 QA staff will review the data and data quality objectives to ensure that the data are appropriate for the proposed application in WAG 2. WAG 2 staff will also review or participate in audits and surveillances to ensure that the data are being collected and handled in the manner prescribed in the QA plan of the group providing the data. Interaction between external data sources will be additionally controlled by the implementation of interface agreements.

3.9.1 Responsibilities

Refer to Table 2, Project Document Summary, for the identification of organizations and WAG 2 staff members responsible for the review and approval of QA Plans of external data sources and the development, review, and approval of interface agreements. In addition, the project manager

- identifies organizations and projects for which interface agreements shall be written; and
- implements and revises interface agreements as necessary;

3.9.2 Procedures

Interface agreements for projects or organizations that provide sample collection services, analytical services, and data to the WAG 2 SI but do not receive funds for such services, will be written by the Project Manager and submitted to ER Management for distribution and approval. Because changes in the interface agreement may potentially affect WAG 2 SI data quality, the WAG 2 Project Manager will be notified by the external organization directly if any changes in the interface agreement have occurred. The Project Manager will then notify ER Management of the changes.

Interface agreements shall include, but are not restricted to, the following:

- identification of participating project or organization;
- identification of responsible person(s) within each project or organization;
- effective dates of Interface Agreement;
- responsibilities of each interacting organization;
- definition of and schedule for deliverables; and
- signature approval of both designated responsible persons.

3.10 INSPECTION

3.10.1 Responsibilities of the Project Manager

The project manager

- reviews inspection reports from inspections performed by inspecting and calibrating organizations to verify and track inspections on items important to the success of the project; and
- indicates his/her review and approval by signature on the inspection report.

3.10.2 Responsibilities of the Quality Assurance Coordinator

The QA coordinator

- maintains inspection report copies as QA records, and
- submits reports to the WAG 2 SI DMC and the ER DMC for indexing and filing.

3.10.3 Responsibilities of the Laboratory Steward

The laboratory steward

- monitors and schedules (when necessary) equipment inspections as designated in the LOM for any internal laboratory performing services for the WAG 2 SI Project; and
- provides the Project Manager and the QA Coordinator with inspection reports.

3.11 TEST CONTROL

3.11.1 Data Summarization, Validation, and Reporting

The performance of laboratory equipment will be tested through the analysis of quality control samples and the verification and validation of QC sample data. In addition, the type and frequency of quality control tests shall be specified for different media and analyses in SOPs.

The data validation process compares the objective with the actual through the evaluation of the PARCC parameters. The laboratory will not perform data validation;

laboratory QA/QC data will be validated, independent of the laboratory, by a contract organization or by WAG 2 SI staff as appropriate. An SOW describing data editing, screening, checking, auditing, verification, certification, and review (EPA 1988b) will be implemented prior to the initiation of data validation. All data for this project will be evaluated by QA/QC methods and internal peer review. Data reduction, verification, and reporting will be in accordance with the ongoing ORNL ER Program Data Base Management activities (Voorhees et al. 1988, 1989; Hook et al. 1990). Data will be entered into common, standardized formats. In addition to following field sampling documentation and QA/QC procedures, data are verified using a variety of computerized checks for reasonableness. These procedures will ensure that data are entered, encoded, and manipulated consistently and are available to WAG 2 SI investigators in a usable format.

Data validation for QA/QC Levels I and II will follow the ER Program's requirements for quality control of analytical data. Data validation for Levels III and IV will be performed according to EPA's functional guidelines. Because no raw data is provided with Level III QC documentation, the functional guidelines that require the review of raw data will be omitted for all Level III analyses.

3.11.2 Field Data Reduction and Evaluation

Data collected during field activities will be evaluated by checking the procedures used and comparing the data to previous measurements. The QA/QC Coordinator and sampling team leaders will be responsible for checking field QC sample results to ensure that field measurement and sampling protocols have been observed. These reviews will check

- date and time sampled,
- preservation,
- SOPs utilized,
- calibration method and frequency, and
- COC documentation.

Reviewers are responsible for ensuring that data reduction calculations are documented and checked by qualified personnel. Reviews will be indicated by signature on the sample results. Written reports, including reduced and summarized data, will include the raw data in appendices. Specific calculations used for data reduction will also be included.

3.11.3 Analytical Laboratory Data Reduction and Evaluation

Analytical data generated during the sampling and analysis phase will be evaluated for completeness as an ongoing and concurrent process. This will include, but is not limited to, review of completed custody logs, photocopied pages of laboratory notebooks and data forms completed by the technical staff, including sample weights, dilutions, concentrations, data reduction, instrument logs, and all raw data. Reviewers of materials will include the S&A Team Leader, WAG 2 SI QA/QC Coordinator, and the assigned contract laboratory program manager. In the data review process, the data are compared to information such as the sample history, sample preparation, and QC sample data to evaluate the validity of the results. Data validation includes

- dated and signed entries by technical staff and supervisors on the worksheets and logbooks used for samples;

- sample tracking and numbering systems to track the progress of samples through the laboratory;
- quality control criteria to reject or accept specific data in accordance with EPA CLP protocols and laboratory data validation functional guidelines for evaluating organic and inorganic data (EPA 1988b, EPA 1984), and field QC versus laboratory QC as mandated by this QA document and those requested EPA procedures; and
- examination of all data for a sample and site by checking for consistency among replicate samples, sending split samples to other laboratories for analysis, and using frequency distributions and range checks to evaluate outliers.

Where possible, other checks for internal consistency, such as evaluating ion balances, will be employed.

3.12 CONTROL OF MEASURING AND TEST EQUIPMENT CALIBRATION

3.12.1 Responsibilities

3.12.1.1 Project manager

The project manager reviews and approves LOMs for laboratories conducting analyses for the WAG 2 SI.

3.12.1.2 Laboratory steward

The laboratory steward

- develops and maintains the LOM and calibration logbooks; and
- records calibration failures.

3.12.2 Procedures

A calibration information table for all laboratory and field equipment is located in the LOM of the laboratory where the equipment is stored or operated. The calibration information table defines the calibration schedule, calibration procedure reference, measurement and test equipment (M&TE) category, and the individual responsible for calibration.

Calibration methods, when calibration is performed by the operator, are located in SOPs referenced in the LOM calibration information table.

Registered calibration logbooks shall be maintained for each laboratory. The Laboratory Steward ensures that calibration records are kept current through periodic reviews.

Calibrated equipment shall be uniquely identified by either the manufacturer's serial number or an instrumentation and control number.

All equipment shall be categorized according to M&TE categories described in the WAG 2 SI Plan. The Laboratory Steward shall place calibration category decals on laboratory equipment.

Calibration failures can occur regardless of timely calibration checks. If an individual suspects an equipment malfunction, that person should

1. remove the device from service,
2. tag it so it is not inadvertently used, and
3. notify the laboratory steward or sampling team leader.

If equipment is found to be out of calibration, the sampling team leader or laboratory steward shall evaluate and document (in the calibration logbook) the validity of previous inspection or test results and the acceptability of similar equipment previously inspected or tested. Devices that are out of calibration will be recalibrated prior to reuse. Any equipment found to be consistently out of calibration shall be repaired or replaced. Any such action shall be recorded in the calibration logbook.

3.13 HANDLING, STORAGE, AND SHIPPING

3.13.1 Responsibilities

Refer to Table 2 for the identification of individuals responsible for the development, review, and approval of SOWs.

3.13.2 Procedures

Requirements for controlling the handling, storage, cleaning, packaging, shipping, and preservation of items and samples to prevent damage or loss and to minimize deterioration are described in SOPs for each sample medium and analysis. In addition, SOWs shall be developed in conjunction with the ER APO for each analytical laboratory performing services for WAG 2. These SOWs shall describe specific shipping, handling, and preservation measures for each analysis and sample medium. Refer to the Project Document Summary (Table 2) for additional SOW development, review, and approval responsibilities.

3.14 INSPECTION, TEST, AND OPERATING STATUS

The inspection, test, and operating status determinations of monitoring stations and associated equipment used to collect data used by WAG 2 project management are the responsibility of the monitoring organization. Interface agreements between WAG 2 management and the monitoring organizations, as described under Element 9, ensure that the WAG 2 Project Manager will be notified when test failures or changes affecting data quality occur.

3.15 NONCONFORMANCE

3.15.1 Responsibilities

Refer to Table 2 for the identification of individuals responsible for the review and approval of nonconformance, variance, occurrence, and corrective action documents.

3.15.2 Procedures

All variances from approved WAG 2 standard operating procedures will be documented in a deviation request form. Only WAG 2 SI personnel may initiate a variance. All variances must be reviewed by the WAG 2 SI Project Manager and the QA Specialist and evaluated with its possible impact on reportable data. Upon review, the Project Manager and the QA Specialist may

1. approve the variance and allow field procedures to resume, or
2. proceed with nonconformance, occurrence, and corrective action procedures.

If the issuance of a deviation request form indicates the need for a minor procedural change, the Project Manager, Field Sampling Coordinator, or the Team Leader may initiate a Procedural Change Notice).

3.16 CORRECTIVE ACTIONS

This item is included under Sect. 3.15.

3.17 QUALITY ASSURANCE RECORDS

All project records, including QA records, will be managed by the WAG 2 SI DMC and the ER DMC. The WAG 2 SI DMC is responsible for the processing, maintenance, reporting, and retrieving of all WAG 2 SI record materials and for forwarding copies to the ER DMC.

SOP ER/P-OS/ERP-DMC establishes general responsibilities and guidelines for use of the WAG 2 SI DMC. Duplicate files will be maintained by the ER DMC.

WAG 2 QA records include, but are not limited to, the following:

- data collection information (including electronic and paper forms);
- data verification and validation materials;
- surveillance and audit reports;
- deviation request forms, nonconformance reports, occurrence reports;
- corrective action documentation;
- project-specific training records;
- laboratory notebook, calibration notebook, and field notebook copies;
- COC forms, QA sample forms;
- analytical laboratory SOWs;

- interface agreements;
- variance logbook copies;
- standards traceability documents;
- MOAs;
- SOPs;
- QA summary reports;
- inspection reports;
- calibration reports;
- training needs assessment;
- sampling and analysis plan;
- H&S plan; and
- data management plan.

3.18 AUDITS

This section describes the methods and policies for planning, performing, and reporting audits to verify compliance with all aspects of the QA program and to determine program effectiveness. The requirements of this section apply to internal audits or surveillances.

Audits will be performed in accordance with QA-L-18-100, and personnel performing these audits shall be qualified in accordance with QA-L-18-101.

3.18.1 Responsibilities of the Quality Assurance Coordinator

The QA coordinator

- assigns, tracks, and ensures implementation of all corrective actions identified by formal audits and surveillances;
- together with the Project Manager, ensures that internal surveillances of field and WAG 2 laboratory operations are planned, executed, and documented;
- prepares a brief surveillance summary for review and follow-up determinations by the Project Manager; and
- designates, in conjunction with the Project Manager and QA Specialist, which project activities, if any, require surveillance and develops a plan for implementing surveillances and self-assessments.

3.18.2 Procedures

3.18.2.1 Surveillances

When deemed appropriate by the Project Manager, the QA Coordinator will conduct surveillances of WAG 2 SI field and laboratory operations. The QA adequacy of these operations will be assessed according to the WAG 2 SI sampling and analysis plan and applicable WAG 2 SOPs. Management will be informed of QA status through the receipt of surveillance reports.

Project documents will be regularly surveilled for completion and clarity. Refer to Table 3 for the surveillance frequency of project documents for the WAG 2 Project. A surveillance schedule will be issued upon implementation of this QA plan.

Table 3. Surveillance activities

Item or activity	Responsible person	Frequency	Date
Technical procedures	QAC[a] or QAS[b]	Annually	TBD
Training documentation	QAC or QAS	Annually	TBD
Chain-of-custody records	QAC	Quarterly	TBD
Instrument calibration documentation	QAC or PP[c]	Annually	TBD
Sample identification & storage	QAC or PP	Semi-Annually	TBD
Project QA plans	QAC	Annually	TBD
Laboratory operations manual	PP or QAC	Annually	TBD

[a]Quality assurance coordinator.
[b]Quality assurance specialist.
[c]Project person.

3.18.2.2 Audits

Audits shall be performed utilizing project program documents, highlighting the items to be verified, and/or checklist questions. Audit results shall be documented in a report and issued promptly, providing the status of items reviewed and verified. Copies of audit reports shall be provided to Section Head, Program Director, and QA Specialist for use in management assessment. Audits of WAG 2 field and laboratory activities will be conducted by the ESD QA Specialist and the Central ER audit staff. External analytical laboratories audits shall be conducted by the ER Program's Analytical Program Office. Audits conducted by regulatory agencies shall also be performed at the discretion of the regulatory agencies.

3.18.2.3 Frequency of audits

The ESD QA specialist may perform internal audits according to a schedule that coincides with appropriate activities on the project schedule and sampling plans. These internal audits will be utilized in independent self assessment. Such scheduled audits may be supplemented by additional audits for one or more of the following reasons:

- when significant changes are made in the QA/QC plan,
- when it is necessary to verify that corrective action has been taken on a nonconformance reported in a previous audit, or
- when requested by the Project Manager.

All other audits will be performed according to the discretion of the auditing organization.

3.19 SOFTWARE QUALITY ASSURANCE

3.19.1 Responsibilities of the Project Manager

The project manager, in conjunction with the data base manager and relevant project team leaders, determines the project-related automated data processing (ADP) software (software, computer programs, documentation, etc.) and assigns the ADP software category.

3.19.2 Procedures

ADP software shall be categorized according to the following:

Category 1: ADP software the failure of which can cause the failure of a project or endanger personnel.

Category 2: ADP software the failure of which will not cause the failure of a project or endanger personnel, but the failure of which will have a serious effect on project deliverables, production schedules, and/or cost.

Category 3: ADP software the failure of which will neither endanger personnel nor have a serious effect on project deliverables, production schedules, and/or cost.

Category 4: ADP software subject to NQA-1 or similar standards by sponsor directive. This includes software that will be licensed or used in a licensed facility.

Category 5: ADP software, often with a short shelf-life, developed or modified in the course of continuing research or development activities and that is an integral part of the research or development project.

Category 6: Purchased ADP software that is a standard off-the-shelf item of proven application. If the purchased software is to be modified, the modified software will be categorized as 1, 2, 3, 4, or 5, as described above.

Martin Marietta Energy Systems Policy Standards and Procedures, Quality Vol. 4 will provide QA guidance for the WAG 2 SI regarding ADP software control.

3.20 TECHNICAL AND PEER REVIEWS

3.20.1 Responsibilities

3.20.1.1 Project manager

The project manager

- determines the need for technical or peer reviews of project documents;
- appoints qualified technical or peer reviewers for project procedures and documents; and
- incorporates reviewers comments, as the Project Manager deems necessary, into reviewed document or procedures.

3.20.1.2 Quality assurance coordinator

The QA coordinator

- enters document or procedures tracking information into the database,
- assists the author in developing distribution lists for review and final copies,
- obtains all required approvals,
- confirms that all necessary approvals have been obtained and that all required changes have been made before author and Program Manager final approval, and
- submits copies of reviewers comments to the WAG 2 SI DMC.

3.20.2 Procedures

The ER Program's procedure, *Preparation, Development, Approval, and Clearance of ER Documents* (ORNL 1991b), will be followed.

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