Energy Systems Environmental Restoration Program
ORNL Environmental Restoration Program

**Quality Assurance Plan for Waste Area Grouping 6 at
Oak Ridge National Laboratory, Oak Ridge, Tennessee**

Date Issued—January 1994

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Oak Ridge, Tennessee 37831-6285
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APPROVAL PAGE
Quality Assurance Plan for the Waste Area Grouping 6

By affixing their signatures to this Approval Page, the signatories to this document signify that they have reviewed and are in agreement with its contents and intend to apply these contents to the conduct of the Waste Area Grouping 6 design, construction, characterization, and monitoring activities within their respective areas of responsibility.

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QUALITY ASSURANCE EVALUATION

[QAE]

Date April -16, 1991

Activity No.: ENGR-007

QAP No.: QAP-X-91-ENGR-007

Title: Waste Area Grouping (WAG) 6 Closure

Description:

WAG 6 will be closed according to requirements continued in a revised closure plan to be submitted in June, 1991.

INSTRUCTIONS: Complete checklist and assign a Q-Category. If ANY response is YES, a Category I or II QA Plan must be prepared. If ALL responses are NO, a Category III Plan may be prepared. In all cases a RATIONALE for the choice of category must be given. Minimum required attachments, if the QAE is to be used as part of the QA Plan, are an organization chart, a Functional Responsibilities Matrix, and a Quality Records list.

Quality Category Checklist	Yes	No
1. Does the project/activity involve design, construction, maintenance, or modification of engineered safety systems or structures?		X
2. Are there unique sponsor requirements?	X	
3. Are data or results of analyses to be used for design or construction of engineered safety systems or structures?		X
4. Could failure result in the loss of an ORNL facility?		X
5. Could failure result in significant risk of inadvertent environmental, public, or personal exposure to biological, chemical or radiological hazards that would exceed the current authorized levels?	X	
6. Could failure cause significant adverse publicity that could damage the laboratory's reputation?	X	
7. Could failure cause significant negative impact on an important or critical area of research?		X
8. Is there a significant risk of release of incomplete or inaccurate data?		X

Q-CATEGORY

Select I, II, or III

Rationale for Q-Category:

Due to the nature of the work and potential for inadvertent exposures of personnel, and/or environment, a Q-Category II has been assigned to the project.

A significant activity, item, material, or process is one that would cause a dramatic negative impact on cost, health, safety, environment, or the laboratory's facilities or reputation, or a dramatic violation of state or federal regulations should failure occur. An insignificant impact would not be expected to exceed consequences beyond those expected from minor, normal, day-to-day operational failures. Decisions regarding the significance of an impact due to failure must include consideration of cost, schedule, complexity, and safety.

ACTIVITY PHASE MATRIX

Indicate activity phases such as design, construction, procurement, operations, etc.

Phase	Responsible Manager	Scheduled Completion Date
Feasibility Study/ Design/Construction	S. B. Garland S. D. VanHoesen	FY 1997

QUALITY ASSURANCE PLAN MATRIX

Reference existing QA Plans that will be used to control the activity.

Activity Job Elements	QA Plan Title	QA Plan Number	Responsible Organization

Add attachments or explanations if necessary.

QAE Approval:		
Division Responsible Manager	<u>S. B. Garland</u>	Date <u>4/17/91</u>
Engineering Responsible Manager	<u>S. D. VanHoesen</u>	Date <u>4/16/91</u>
QA Specialist	<u>MA Woody</u>	Date <u>4-17-91</u>

QUALITY ASSURANCE EVALUATION (QAE)

Date: 04/12/93

Activity No.: ENGR-93

QAE No.: QAE-X-93-ENGR-93

Title: WASTE AREA GROUPING (WAG) 6 CLOSURE – MONITORING ACTIVITIES

Description:

Monitoring will be performed to obtain record data on geotechnical conditions and concentrations of key contaminants previously detected in the groundwater and surface water at WAG 6, and on the expected changes to the conditions and concentrations as a result of the Interim Remedial Actions and Remedial Actions.

INSTRUCTIONS: Complete checklist and assign a Q-Category. If *ANY* response is *YES*, a Category I or II QA Plan must be prepared. If *ALL* responses are a *NO*, a Category III is assigned. In all cases a *RATIONALE* for the choice must be given. Minimum required attachments, if the QAE is to be used as a part of a QA Plan, are an organization chart, a Function Responsibilities Matrix, and a Quality Records and Controlled Documents List.

Quality Category Checklist	Yes	No
1. Does the project/activity involve design, construction, maintenance or modification of engineered safety systems or structures?		X
2. Are there unique sponsor requirements?		X
3. Are data or results of analyses to be used for design or construction of engineered safety systems or structures?		X
4. Could failure result in the loss of an ORNL facility?		X
5. Could failure result in significant risk of inadvertent environmental, public, or personal exposure to biological, chemical, or radiological hazards that would exceed the current authorized levels?	X	
6. Could failure cause significant adverse publicity that could damage the laboratory's reputation?	X	
7. Could failure cause significant negative impact on an important critical area of research?		X
8. Is there a significant risk of release of incomplete or inaccurate data?		X

Q-CATEGORY

II

Select I, II, or III

Rationale for Q-Category:

Due to the significant potential for inadvertent exposure of personnel, and/or inadvertent environmental insult, a Q-Category II has been assigned to the project.

A significant activity, item, material, or process is one that would cause a dramatic negative impact on cost, health, safety, environment, or the laboratory's facilities or reputation, or a dramatic violation of state or federal regulations should failure occur. An insignificant impact would not be expected to exceed consequences beyond those expected from minor, normal, day-to-day operational failures. Decisions regarding the significance of an impact due to failure must include consideration of cost, schedule, complexity, and safety.

Date: 04/12/93

Activity No.: ENGR-93

QAE No.: QAE-X-93-ENGR-93

Title: WASTE AREA GROUPING (WAG) 6 CLOSURE - MONITORING ACTIVITIES

ACTIVITY PHASE MATRIX

Indicate activity phases such as design, construction, procurement, operations, etc.

Phase	Responsible Manager	Scheduled Completion Date
Characterization & Monitoring Activities	S. D. VanHoesen, ER Project Manager D. R. Watkins, Responsible Division Manager	FY 1999

QUALITY ASSURANCE PLAN MATRIX

Reference existing QA Plans that will be used to control the activity.

Activity Job Elements	QA Plan Title	QA Plan Number	Responsible Organization

Add attachments or explanations if necessary.

QAE Approval:

Division Responsible Manager

DR Watkins

Date

4/12/93

ER Responsible Manager

S D Van Hoesen

Date

4/16/93

QA Specialist

MA Moody

Date

4/22/93

ABBREVIATIONS

A-E	architect-engineer
ASME	American Society of Mechanical Engineers
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
DOE	U.S. Department of Energy
DOE-OR	U.S. Department of Energy, Oak Ridge Field Office
DQO	data quality objectives
EPA	U.S. Environmental Protection Agency
ER	environmental restoration
ESD	Environmental Sciences Division
NQA	nuclear quality assurance
ORNL	Oak Ridge National Laboratory
PRP	project records plan
QA	quality assurance
QAMS	Quality Assurance Management Staff
QAP	quality assurance plan
QAPjP	quality assurance project plan
QAS	Quality Assurance Specialist
QC	quality control
RA	remedial action
RCRA	Resource Conservation and Recovery Act
SOP	standard operating procedure
SWSA	solid waste storage area
WAG	waste area grouping

EXECUTIVE SUMMARY

This Quality Assurance Plan (QAP) has been developed in compliance with U.S. Department of Energy (DOE) Order 5700.6C, "Quality Assurance Requirements"; DOE Oak Ridge Field Office Order 5700.6B, "Quality Assurance"; and the *Environmental Restoration (ER) Quality Program Plan*, issued as report ES/ER/TM-4/R2. The outline of the plan is based on the outline used in the Martin Marietta Energy Systems, Inc. (Energy Systems), *Policy, Standards and Procedures Manual*, Volume 4, and it specifies that, beyond requirements explicitly identified in the plan itself, applicable Energy Systems standards and policy procedures identified in *Policy, Standards and Procedures Manual*, Volume 4, shall be applied. The QAP follows the best management practices described in the American Society of Mechanical Engineers (ASME) documents *Quality Assurance Program Requirements for Nuclear Facilities* (ASME NQA-1) and *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories* (ASME NQA-3), as well as applicable DOE Orders. In addition to these documents, the ER Division QAP also addresses *Quality Requirements for Nuclear Facility Applications* (ASME NQA-2) as well as the U. S. Environmental Protection Agency (EPA) guidance established in *Interim Guidelines and Specifications for Preparing Quality Assurance Plans* [EPA-600/4-83-004 Quality Assurance Management Staff- (QAMS-) 005/80)]. The plan also provides for compliance with DOE Orders 4700.1, "Project Management System"; 5000.3B, "Occurrence Reporting and Processing of Operations Information"; and 1324.2A, "Records Distribution." The Waste Area Grouping (WAG) 6 Quality Assurance (QA) Program will be supplemented by site-level QA programs and WAG 6 subproject-specific QAPs, tailoring the requirements of the project plan to the needs and requirements of each subproject.

Specifically, the QAP for WAG 6 identifies the chain of command for the execution of WAG 6 QA requirements and the responsibilities of ER Division and Central Engineering personnel identified in that hierarchy. These personnel include the ER Program Manager, the ER WAG 6 Program Manager, Quality Assurance Specialists, central ER Division program directors, site program managers, and other functional managers.

1. QUALITY ASSURANCE PLAN

1.1 SCOPE

This Quality Assurance Plan (QAP) is concerned with design and construction (Sect. 2) and characterization and monitoring (Sect. 3). The basis for Sect. 2 is the *Quality Assurance Plan for the Design and Construction of Waste Area Grouping 6 Closure at Oak Ridge National Laboratory, Oak Ridge, Tennessee* (Energy Systems 1991), and the basis for Sect. 3 is the *Environmental Restoration Quality Program Plan* (Energy Systems 1992). Combining the two areas into one plan gives a single, overall document that explains the requirements and from which the individual QAPs and quality assurance project plans (QAPjPs) can be written.

The Waste Area Grouping (WAG) 6 QAP establishes the procedures and requirements to be implemented for control of quality-related activities for the WAG 6 project. Quality Assurance (QA) activities are subject to requirements detailed in the Martin Marietta Energy Systems, Inc. (Energy Systems), QA Program and the Environment Restoration (ER) QA Program, as well as to other quality requirements. These activities may be performed by Energy Systems organizations, subcontractors to Energy Systems, an architect-engineer (A-E) under prime contract to the U.S. Department of Energy (DOE), or a construction manager under prime contract to DOE. This plan specifies the overall Energy Systems quality requirements for the project. The WAG 6 QAP will be supplemented by subproject QAPs that will identify additional requirements pertaining to each subproject. The flow down of QA requirements is shown in Fig. 1. The organizational chart for design and construction is shown in Fig. 2. The organizational chart for characterization and monitoring is shown in Fig. 3.

1.2 PROJECT DESCRIPTION

WAG 6 is a 68-acre site, southwest of the Bethel Valley facilities at the Oak Ridge National Laboratory (ORNL). Solid Waste Storage Area (SWSA) 6, one of the remediation sites on WAG 6, was opened in 1969 as a shallow land burial site for low-level radioactive waste. It was used for disposal of radioactive waste in open trenches for the low-level-activity waste and in auger holes for the higher activity wastes. In May 1986, operations at SWSA 6 were temporarily stopped because of the finding that hazardous waste, as defined by the Resource Conservation and Recovery Act (RCRA), had also been disposed of in some areas of the SWSA along with the radioactive waste. Operation of SWSA 6 for the disposal of radioactive wastes was resumed in July 1986.

The finding that RCRA hazardous waste had been disposed of in SWSA 6 led to the submission of a closure plan for SWSA 6 in 1988. In 1989, ORNL was placed on the National Priorities List, which required that WAG 6 remediation comply with Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) regulatory requirements. A revised closure plan proposed a source control action to be completed in 1997. The source control measure was intended to hydrologically isolate buried waste from the ground and surface water systems at WAG 6, which would reduce the off-site flux of contaminants from the site. Following public evaluation of the cost benefit vs risk, preferred remedial action for source control was deferred and monitoring activities were selected as the preferred action. A 5-year environmental monitoring program will be implemented.

Fig. 1. Flowdown of quality assurance requirements.

Fig. 2. Waste Area Grouping 6 organization chart for design and construction.

Fig. 3. Waste Area Grouping 6 organization chart for characterization and monitoring.

2. DESIGN AND CONSTRUCTION

2.1 NQA-1 APPLICABILITIES

The Modular Profile (Table 1) gives an overview of the content of the design and construction section of the QAP. It identifies the elements of NQA-1 that are applied to a specific project or activity. The column "Implementing ENG/Energy Systems QA Procedures" is a list of all Energy Systems Engineering and QA Procedures that could be applied to a specific element of NQA-1. However, this does not mean that all of the implementing procedures are used. The column "Project-Specific Procedures" is a list of the procedures to be used to control the quality-related activities of the project. Only the procedures identified in this column are implemented during the project.

The matrix is a way of identifying the procedures to be followed during the course of the project. However, in some cases the QAP will call out additional requirements and/or deletions to specified procedures. These additions and/or deletions will be specified within the body of the QAP.

2.2 DISCUSSION OF NQA-1 REQUIREMENTS

2.2.1 Organization

The management and operating contractor, Energy Systems, shall provide oversight for the purposes of ensuring that the remedial action (RA) operations interface smoothly with plant operations; that all plant systems required to support the RA effort are available when needed; and that plant environmental, safety, and health procedures are followed. Each subproject shall develop a project organization chart that identifies subproject personnel and their position within the subproject.

2.2.2 QA Program

The QA program described herein is responsive to DOE Oak Ridge Field Office (DOE-OR) Order 5700.6C, "Quality Assurance"; Energy System Policy Procedure GP-5, *Quality Assurance Program*; Y/QD-15 Procedure, *Quality Program Plan*; ES-QA-1.0, *Quality*; ESP.2.6, *Quality Assurance Planning*; and the procedures referenced in the modular profile.

Controls to ensure that the QA program is effectively implemented are maintained through use of self-assessments, readiness reviews, audits, and surveillances. These are described later in this section. Stop work authority shall be exercised through line management by anyone who identifies a situation that threatens personnel, public health, or environmental safety.

Work procedures and sites shall be accessible under the coordination of the Engineering Project Manager or the Program Project Manager during normal business hours for purposes of audit, surveillance, inspection, or visit by authorized QA representatives.

Personnel shall be indoctrinated, trained, qualified, and certified as necessary for project-related activities.

Table 1. Procedure modular profile for design and construction

Waste Area Grouping 6 design and construction				
NQA-1 Basic element	To be applied (Y/N)	Implementing Eng/Energy Systems quality assurance procedures(s)	Project-specific procedures	See indicated Quality Assurance Plan section
1. Organization	Y	ESS.1.0 ESP.1.1 EP-A-06 EP-A-11	EP-A-06 EP-A-11	Sect. 2.2.1
2. Quality Assurance Program	Y	ESS.2.0 ESP.2.2 ESP.2.5 ESP.2.6 ESP.2.7 GP-5 EP-A-32 EP-B-31 EP-E-04 EP-E-10	GP-5 EP-E-04 ESP.2.6 Y/QD-15 ES-QA-1.0	Sect. 2.2.2
3. Design control	Y	EP-A-12 EP-B-03 EP-B-16 EP-B-22 EP-B-23 EP-B-35 EP-B-36 EP-C-02 EP-C-04 EP-C-05 EP-C-06 EP-C-07 EP-C-17 EP-C-18 EP-C-20 EP-C-22 EP-C-23 EP-C-25 EP-C-27 EP-C-29 EP-C-35 EP-D-02 EP-D-09 EP-E-05 EP-E-07 EP-E-12 ES-O.1-2 K/D-5364	EP-B-16 EP-C-02 EP-C-07 EP-C-17 EP-C-18 EP-C-27 EP-C-35 EP-D-02 EP-E-07 EP-E-12 QA-L-3-102 QA-L-3-101	Sect. 2.2.3
4. Procurement document control	Y	ESS.4.0 EP-C-22 EP-C-23 EP-C-25 EP-C-27 K/D-5364	EP-C-22 EP-C-23 EP-C-25 K/D-5364	Sect. 2.2.4
5. Instructions, procedures, and drawings	Y	ESS.5.1 EP-A-01 EP-A-13 EP-C-01 EP-C-03 EP-C-13 EP-C-30	EP-C-01 EP-C-03 EP-C-13 EP-C-30	Sect. 2.2.5

Table 1 (continued)

Waste Area Grouping 6 design and construction				
NQA-1 Basic element	To be applied (Y/N)	Implementing Eng/Energy Systems quality assurance procedures(s)	Project-specific procedures	See indicated Quality Assurance Plan section
6. Document control	Y	ESS.6.1 EP-A-12 EP-B-16 EP-C-01 EP-C-13 EP-C-17 EP-C-18 EP-C-28 EP-D-09	EP-A-12 EP-B-16 EP-B-36 EP-C-13 EP-C-18 EP-C-28	Sect. 2.2.6
7. Control of purchased items and services	Y	ESS.7.0 EP-C-22 EP-C-30 EP-D-11 EP-D-13 EP-D-14 EP-D-20	EP-C-22 EP-D-11	Sect. 2.2.7
8. Identification and control of items	Y	ESS.8.1 EP-D-01 EP-D-11	ESS.8.1	Sect. 2.2.8
9. Control of processes	Y	ESS.9.1 EP-D-01	ESS.9.1	Sect. 2.2.9
10. Inspection	Y	ESS.10.0 EP-B-36 EP-D-01 EP-E-12 ES-0.4-1	EP-E-12 ES-0.4-1	Sect. 2.2.10
11. Test control	Y	ESS.11.1 EP-D-01 EP-E-12 ES-0.4-1	EP-E-12 ES-0.4-1	Sect. 2.2.11
12. Control of measuring and test equipment	Y	ESS.12.0 EP-E-12	ESS.12.1	Sect. 2.2.12
13. Handling, storage, and shipping	Y	ESS.13.1 EP-C-22 EP-D-11	ESS.13.1	Sect. 2.2.13
14. Inspection, test, and operating status	Y	GP-24 EP-C-22 EP-D-05 EP-E-09	EP-E-09 ER/C-P1610	Sect. 2.2.14

Table 1 (continued)

Waste Area Grouping 6 design and construction				
NQA-1 Basic element	To be applied (Y/N)	Implementing Eng/Energy Systems quality assurance procedures(s)	Project-specific procedures	See indicated Quality Assurance Plan section
15. Control of nonconforming items	Y	ESS.15.1 ESP.15.2	EP-D-10	Sect. 2.2.15
16. Corrective action	Y	ESS.16.0 ESP.16.1 ESP.16.2 ESP.16.4	ESP-QA-16.1 X-GP-13	Sect. 2.2.16
17. Quality assurance records	Y	ESS.17.0 EP-A-12 EP-B-36 EP-C-25		Sect. 2.2.17
18. Audits	Y	EP-A-29 ESS.18.0 ESP.18.1	EP-A-29	Sect. 2.2.18
19. Software	N	ESS.ADP.1 EP-E-11 Development		Sect. 2.2.19

2.2.3 Design Control

The technical baseline for the project shall be documented via internal correspondence or other written documentation. The technical baseline shall be developed and maintained with the project scope by the ER Program Manager, with the concurrence of the Engineering Project Manager. All changes to the technical baseline shall be documented and approved by the same organizations that approved the original technical baseline.

Technical design decisions used as a basis for equipment selection and specifications shall be supported by calculations, in accordance with EP-C-20, *Design Analysis and Calculations*. These calculations shall be reviewed and approved by the appropriate responsible engineering designer, as a minimum.

Computer programs used for analyses shall be verified to produce a correct solution to the encoded mathematical model, and mathematical models shall be shown to produce a valid solution to the physical problem.

All design drawings, regardless of their origin, shall be controlled in accordance with Engineering Procedure EP-C-18, *Design Document Change Control*. Each drawing shall identify change control system 2 within the document change control block.

A project review plan shall be prepared for the project by the Engineering Project Manager or his designee in accordance with Engineering Procedure EP-C-17, *Design Verification*. The Engineering Project Manager shall identify all key reviewers who are appropriate to the design submittal. As a minimum, the ER Program Manager and the applicable responsible engineering designer shall be identified as key reviewers.

Design reviews shall be conducted at approximately 50% and 90% design completion as a minimum. All design review comments shall be documented using the "Engineering Design Review Record" forms, UCN-12149 and UCN-12149A, in accordance with Appendix A. Comment resolution shall be documented on the form and distributed to the comment originators, the ER Program Manager, the Engineering QAS, and the ER QAS, as a minimum.

Before issuance of certified for construction package, all drawings shall undergo a QA review to verify that they meet QA requirements. If any corrections are necessary, the Engineering QAS shall sign the drawing after all corrections are made. Quality verification records shall be used as specified in the WAG 6 QA subproject QAPs.

During construction, deviations from approved documents (e.g., procedures and plans) shall be approved and documented using the ORNL Deviation Report form, UCN-5458A. The deviation request shall be approved by the ER Program Manager, the Engineering Project Manager, the responsible engineering designer, and the Engineering Quality Assurance Specialist (QAS), as a minimum. Telephone approval from the Engineering Project Manager or ER Program Manager is acceptable to avoid delaying construction. Telephone approval shall be documented by using a deviation request and obtaining approval signatures from all individuals within 10 working days. The Engineering QAS shall assign a unique deviation request number and enter the data into a tracking system.

Requirements and specifications conveyed to other contractors or Energy Systems organizations shall identify the QA records required. The Engineering Project Manager shall indicate the QA requirements to be included in the equipment specification for each item or service procured.

Test plans, procedures, and specifications will be reviewed, approved, and included in the design control systems for this project.

2.2.4 Procurement Document Control

Applicable subcontractor procedures, QAPs, and procurement documentation shall be reviewed and approved by the ER Program Manager and the Engineering Project Manager and reviewed by the Engineering QAS.

2.2.5 Instructions, Procedures, and Drawings

All design drawings, regardless of their origin, shall contain the Energy Systems or DOE title block and document change control blocks.

2.2.6 Document Control

The design and construction documents to be controlled are listed in Appendix A.

The ER Program Manager shall ensure that a records management system is established and maintained throughout the life of the WAG 6 project. The ER Program Manager shall routinely submit record copy materials generated by the project to the ER Document Management Center for retention.

The ER Program Manager shall ensure that documents designated as controlled are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the appropriate locations. When revised, the designated documents shall be reviewed and approved by the same organizations that provided the original review and approval, unless other organizations are specifically designated by the ER Program Manager. A functional responsibility profile is shown in Appendix A.

2.2.7 Control of Purchased Items and Services

The QA requirements contained in the equipment specifications shall be incorporated into the terms and conditions section of the purchase order for each procurement.

2.2.8 Identification and Control of Items

Requirements for identification and traceability of items shall be included in procurement specifications and construction contract documents.

The geotechnical samples shall be entered into a drillers geologic log. Each sample shall have a unique sample number. Traceability between sample location, testing results, and log shall be maintained. All geotechnical test results shall be documented by the technician performing the test. The technician responsible for collection and analysis shall sign and date each entry. A copy of the completed log and all test results shall be transmitted to the Engineering Project Manager and ER Program Manager for record purposes.

2.2.9 Control of Processes

The personnel taking and testing the geotechnical samples shall be trained in approved procedures. Sampling and testing procedures shall be provided to the Engineering Project Manager and ER Program Manager for review and concurrence and for record purposes.

Health Physics and Industrial Hygiene personnel shall be trained in applicable procedures and shall be certified as required.

2.2.10 Inspection

Energy Systems, with the support of the remedial design contractor, Ebasco Services, Inc., shall provide Title III field services. These services will begin with the placement of the first purchase order or construction contract and end with the acceptance of the project. The requirements for conducting inspection activities are detailed in Engineering Procedure EP-D-01, *Title III Engineering Services*. Energy Systems and the remedial design contractor will ensure design compliance with the Record of Decision and RA work plan.

The inspection organization shall provide documented procedures and instructions, trained and qualified personnel, and properly operating and calibrated equipment.

Inspection procedures and instructions and personnel qualifications shall be reviewed and approved by the Engineering Project Manager and the Engineering QAS.

2.2.11 Test Control

The testing organization shall provide documented procedures and instructions, trained and qualified personnel, and properly operating and calibrated inspection equipment.

Test procedures and instructions shall be reviewed and approved by the Engineering Project Manager, ER Program Manager and the Engineering QAS, as a minimum.

2.2.12 Control of Measuring and Test Equipment

The testing organization shall provide documented procedures and instructions for the control and calibration of tools, gages, instruments, and other measuring and test equipment used for performing quality-related activities. To maintain accuracy within specified limits, testing equipment will be periodically calibrated and adjusted, in accordance with procedures and instructions.

2.2.13 Handling, Storage, and Shipping

Requirements for handling, storage, and shipping of procured items shall be included in the procurement and construction specifications.

The handling, storage, and shipping of sample materials and equipment shall be performed in accordance with established instructions and procedures to prevent loss or damage and to minimize deterioration.

2.2.14 Inspection, Test, and Operating Status

The Title III Engineer (Construction Engineer) shall verify and document that materials, components, and equipment specified in the construction specifications have successfully passed all required tests and inspections before installation.

An operational readiness review shall be conducted after completion of the design, as a minimum. A review will be conducted at the completion of construction, if deemed necessary by the Engineering Project Manager, ER Program Manager, and Engineering QAS. As a minimum, the operational readiness team shall consist of the Engineering Project Manager, ER Program Manager, Engineering QAS, and Facility Manager. U.S. Department of Energy Oak Ridge Field Office (DOE-OR) shall be informed of all readiness reviews. Reviews shall be conducted according to ER/C-P1610, *Conducting Project Readiness Reviews*.

2.2.15 Control of Nonconforming Items

No additions to the control of nonconforming items is planned for the design and construction activities.

2.2.16 Corrective Actions

All corrective actions, regardless of their origin, shall be documented on the ORNL Corrective Action Report and Status form. All corrective actions shall be handled and resolved in accordance with ESP-QA-16.1, *Corrective Action Program*.

Issues that fall under the occurrence criteria shall be reported in accordance with Energy Systems General Policy Procedure GP-13, *Occurrence Reporting System*. Nonconformances shall be handled and documented in accordance with procedures identified in Element 15 of the "Procedure Modular Profile."

2.2.17 QA Records

The following additional requirements are applied to record copy documents:

- Test and inspection records and results to be maintained as record copy material shall be designated in the construction project test summary. The originator of documents generated within Energy Systems Engineering shall identify record copy material in accordance with the project records plan (PRP). The Energy Systems Engineering recipient of documents generated outside Engineering shall identify record copy material in accordance with the PRP.
- Duplicate records, as identified in Appendix A, that provide evidence of quality, shall be maintained by the personnel or organization identified as the point file. The records sets shall be stored at locations sufficiently distant from one another to prevent damage to both sets in the event of unforeseen circumstances. The records shall be reviewed for legibility and completeness; protection against deterioration, damage, or loss; efficient retrieval; and controlled access.
- Project working files shall be turned over to the appropriate storage facilities by the ER Program Manager and Engineering Project Manager at completion of the project. The ER Program Manager shall turn over the final design documents to the ER Document Management Center.

The ER Program Manager shall receive a copy of all record copy materials generated by the project. The ER Program Manager shall be responsible for transmitting all applicable documents to the DOE-OR ER Administrative Record.

2.2.18 Audits

Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality program and to determine its effectiveness. Personnel who do not have direct responsibility for performance of the activities being audited shall perform the audits using written procedures or checklists. Audit results shall be documented and reported to the responsible management for their review. Corrective and follow-up action shall be taken when necessary.

Audit requirements shall be implemented through adherence to Energy Systems QA Standard ESS.18.0, *Audits*. The audit schedule shall be a part of the subproject-specific QAP.

Surveillance activities are governed by Energy Systems QA Procedure ESP.2.7, *Quality Assurance Surveillance*. Program, technical, and QA personnel shall be required to adhere to the requirements and methods contained in this procedure during the conduct of surveillance activities for WAG 6 work. An example document surveillance schedule is given in Appendix A.

2.2.19 Software

No software development is planned for the design and construction activities.

3. CHARACTERIZATION AND MONITORING ACTIVITIES

3.1 QUALITY ASSURANCE PROGRAM

The purpose of this section is to ensure that

- WAG 6 management provides planning, organization, direction, control, and support for characterization and monitoring activities;
- the line organization achieves quality; and
- overall performance is reviewed and evaluated using a rigorous assessment process.

This section identifies requirements; assigns responsibilities for ensuring that program objectives are achieved as planned; and describes or references the controls, quality procedures, and guidelines to be followed during characterization and monitoring activities. This quality program is based on the American Society of Mechanical Engineers (ASME) *Quality Assurance Program Requirements for Nuclear Facilities* (NQA-1) (ASME 1989a). The plan incorporates requirements from the U.S. Environmental Protection Agency (EPA) *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988) and EPA Office of Solid Waste and Emergency Response Directive 9502.00-6D, *RCRA Facility Investigation (RFI) Guidance* (EPA 1989), which both require that environmental QA and quality control (QC) plans and procedures be based on EPA-600/4-83-004 [Quality Assurance Management Staff- (QAMS-) 005/80], *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (Stanley 1983) and EPA/540/G-89/004 *Data Quality Objectives for Remedial Response Activities* (EPA 1987).

3.1.1 Scope

This section merges the requirements of NQA-1 with those of QAMS-005/80 and provides for their implementation. Table 2 shows the relationship between this QAP, DOE Order 5700.6C, NQA-1, and QAMS-005/80. The numbers in the first column of Table 2 designate the sections of this document where applicable NQA-1 or QAMS-005/80 element requirements are delineated. For example, Sect. 3.1.4.4 describes the requirements of element 3, Project Description, of QAMS-005/80. All elements of QAMS 005/80 and NQA-1 are addressed within this QAP, and each element of QAMS-005/80 is associated with the corresponding element of NQA-1.

3.1.2 Source and Application of Quality Assurance Requirements

The elements identified in this section were derived from the requirements identified in QAMS-005/80 and in the *Policy, Standards, and Procedures Manual*, Volume 4, (Energy Systems 1991b) that addresses the requirements of NQA-1 and the software requirements of NQA-2. This plan also addresses applicable DOE and EPA QA requirements.

The format of the characterization and monitoring activities is based on DOE Order 5700.6C and complies with the requirements of NQA-1 and QAMS-005/80. The format and requirements of QAPjPs will be based on the elements of QAMS-005/80.

Table 2. Relationships between the characterization and monitoring activities, DOE Order 5700.6c, NQA-1, and QAMS 005/80

Characterization and monitoring Activities Section	DOE Order 5700.6c	NQA-1 element	QAMS-005/80 element
3.1 3.1.3 3.1.4 3.1.4.4 3.1.4.5	1. Program	1. Organization 2. Program	5.4 Project organization and responsibility 5.3 Project description 5.16 Quality reports to management
3.2	2. Personnel training and qualification	2. Program	
3.3 3.3.1 3.3.2	3. Quality improvement	15. Control of nonconforming items 16. Corrective action	
3.4 3.4.1 3.4.2	4. Documents and records	6. Document control 17. Quality assurance records	5.1 Title page 5.2 Contents 5.3 Project description 5.6 Sampling procedures 5.7 Sample custody 5.9 Analytical procedures

Table 2 (continued)

Characterization and monitoring Activities Section	DOE Order 5700.6c	NQA-1 element	QAMS-005/80 element
3.5 3.5.1 3.5.2 3.5.3 3.5.3.1 3.5.3.2 3.5.3.3 3.5.4 3.5.5	5. Work processes	5. Instructions, procedures, and drawings 8. Identification and control of items 9. Control of processes 12. Control of measuring and test equipment 13. Handling, storage, and shipping	5.6 Sampling procedures 5.7 Sample custody 5.9 Analytical procedures 5.8 Calibration procedures and frequency 5.13 Preventive maintenance, procedures and schedules
3.6 3.6.1 3.6.1.1 3.6.1.2 3.6.1.3 3.6.1.4 3.6.1.5 3.6.1.6	6. Design	3. Design control	5.5 Quality assurance objectives for measurement data 5.6 Sampling procedures 5.9 Analytical procedures 5.10 Data reduction, validation, & reporting 5.11 Internal C checks and frequency 5.14 Specific routine Procedures

Table 2 (continued)

Characterization and monitoring Activities Section	DOE Order 5700.6c	NQA-1 element	QAMS-005/80 element
3.7 3.7.1 3.7.2	7. Procurement	4. Procurement document control 7. Control of purchased items and services	Not addressed Not addressed
3.8 3.8.1 3.8.2	8. Inspection and acceptance testing	10. Inspection 11. Test control 14. Inspection, testing, and operating status	5.11 Internal C checks and frequency
3.9 3.9.3 3.94	9. Management assessment	2. Quality Assurance Program	5.12 Performance and systems audits and frequency
3.10 3.10.1 3.10.1.3	10. Independent assessment	18. Audits	5.12 Performance and systems audits and frequency

3.1.3 Organization and Program Responsibilities

Figure 3 is the organizational chart for the characterization and monitoring activities. For increased efficiency, support elements, including quality support, are matrixed from Energy Systems organizations. The ER Program Quality Manager is matrixed from the Energy Systems Central Support Quality Organization. The Quality Manager reports administratively to the Energy Systems Quality Director through the Central Support Quality Manager. The Environmental Science Division (ESD) QAS assigned to provide support to the characterization and monitoring activities reports functionally to the ER Site Program Manager and administratively to his Quality Manager for policy and guidance.

3.1.3.1 WAG 6 Manager

The site RA Program Managers are responsible for

- ensuring that applicable quality requirements are met;
- ensuring the quality of assigned work;
- ensuring that any necessary detailed operating procedures are developed to establish and maintain consistency of program activities;
- ensuring that operating procedures are effectively implemented;
- ensuring that appropriate QA/QC requirements are included in subcontracts and that subcontract technical commitments are met;
- ensuring that quality-related issues and problems are promptly identified and corrected;
- ensuring that applicable state and federal codes, standards, and regulations are appropriately specified and effectively implemented;
- interfacing with the ER QAS on all quality-related matters;
- implementing training plans by assessing training needs, scheduling necessary training, and ensuring that training is completed and documented;
- implementing continual quality improvements as appropriate in assigned work areas; and
- stopping work when the severity of conditions adverse to quality warrants such action.

3.1.3.2 QAS

The ER Program QAS reports functionally to the ER Site Program Manager and is responsible for

- helping the assigned ER Site Program Manager prepare procedures and documents to establish and implement the quality program in accordance with this document;
- evaluating the effectiveness of QA activities in the ER Program through scheduled audits and surveillance and reporting results to the ER Quality Manager and the responsible ER Site Program Manager;
- promoting ER Program quality and awareness programs and attending training sessions to enhance skills;
- providing guidance to resolve quality problems and ensuring that corrective action is taken and appropriately documented in response to occurrence reports, nonconformance reports, and so forth;
- helping ER Program management track corrective actions and analyze data pertaining to quality;
- participating in ER Program readiness reviews;
- participating as a member of the project team;

- providing advice and recommendations to the ER Program Quality Manager on quality program anomalies;
- identifying areas where improvement could benefit the ER Program; and
- initiating stop-work actions when the severity of conditions adverse to quality warrants immediate action.

3.1.3.3 Performance Evaluation Manager

The Performance Evaluation Manager reports to the WAG 6 Manager and is responsible for

- including the appropriate QA requirements of this document in all planning, investigative, analytical, and reporting activities of ER projects;
- including the QAS on the project teams;
- consulting with the QAS on all quality-related matters;
- investigating quality problems, determining their root causes, proposing solutions, implementing corrective actions, and obtaining the concurrence of the QAS on the appropriateness of the corrective action;
- initiating stop-work actions when the severity of conditions adverse to quality warrants immediate action;
- submitting the appropriate documents (such as QAPjPs, health and safety plans, work plans, and investigation reports) to the QAS for comment and approval;
- conducting operational readiness reviews according to ER/C-P1610, *Conducting Project Readiness Reviews*;
- specifying the appropriate QA/QC requirements in subcontracts and service orders;
- implementing cost-effective quality improvements; and
- prescribing work processes affecting quality that are performed according to instructions, procedures, or drawings that are documented, controlled, reviewed, and approved (e.g., work plans, health and safety plans).

3.1.3.4 Project organization

A table or chart showing the organization and lines of authority of key projects will be included in QAPjPs. As a minimum, the following personnel shall be included:

- WAG 6 Program Manager,
- Manager of WAG 6 Performance Evaluation,
- Site Health and Safety Officer,
- Site Project Manager,
- Environmental Laboratory Manager,
- QAS,
- ER Waste Disposal Coordinator,
- Health Physics personnel,
- Industrial Hygiene personnel, and
- Statistical Services personnel.

Project personnel QA responsibilities are as follows:

- ensuring that applicable quality requirements are met;
- ensuring the quality of assigned work;
- ensuring that operating procedures are identified, required, and effectively implemented;

- ensuring that appropriate QA/QC requirements are included in subcontracts and internal work authorizations and that subcontract technical commitments are met;
- ensuring that quality-related issues and problems are promptly identified, reported and corrected;
- ensuring that applicable state and federal codes, standards, and regulations are appropriately specified and effectively implemented;
- interfacing with the assigned QAS on all quality-related matters;
- implementing continual, cost-effective quality improvements; and
- performing surveillance of assigned project activities.

3.1.4 QA Project Requirements

3.1.4.1 Project QAP requirements

QAPjPs will be developed for measuring and monitoring activities to implement the requirements of QAMS-005/80 and to evaluate the applicability of other quality requirements for the activity to be performed. When other Energy Systems organizations, contractors, and subcontractors perform work for the WAG 6 Program, the QAPjP may be prepared by that organization and reviewed or approved by the WAG 6 Program as defined in the statement of work or contract.

The QAPjPs will be based on the applicable requirements of this QAP and will include any additional project-specific information needed to effectively manage and control the project. Project plans meeting the requirements of QAMS-005/80 are required for each measuring and monitoring operation. Major projects that do not include measuring and monitoring operations would not require a QAMS-005/80 QAPjP but will require development of a QAP in accordance with ES/ER/TM-4/R2.

3.1.4.2 QAMS-005/80 QAPjP

A QAPjP for measuring and monitoring activities is a written document that presents in specific terms the policies, organization (where applicable), objectives, functional activities, and specific QA/QC activities designed to achieve the data quality goals of a specific project or continuing operation. The elements that must be included in a QAPjP are described in QAMS-005/80 and they are listed in Table 3.

Table 3 also identifies implementation procedures for the characterization and monitoring section and QAMS-005/80 elements. Some of the procedures required to implement other elements of the QAPjP were developed at the Energy Systems level. Procedures for other elements must be identified by the project team. (In cases where the project team is required to identify the procedure, Table 3 shows the procedure as to be determined in the "Implementing Procedures" column.) The requirements of those elements are further described within this document. The requirements also must be addressed by WAG 6 personnel in planning, implementing, and reporting environmental investigation, environmental restoration, and closure activities.

All QAMS-005/80 QA/QC requirements must be addressed in the QAPjP. In cases where specific QA/QC requirements are addressed as an integral part of a technical work plan, it is only necessary to cite the page number where the requirements are located in the

Table 3. Quality Assurance Management Staff- (QAMS-) 005/80 crosswalk

U.S. Environmental Protection Agency (EPA) QAMS-005/80 requirements	Characterization and monitoring section	Implementing procedures
5.1 Title page	3.4.2	Not applicable
5.2 Table of contents	3.4.2	Not applicable
5.3 Project description	3.1.4.3	Not applicable
5.4 Project organization and responsibility	3.1.3	Not applicable
5.5 Quality assurance objectives for measurement data in terms of precision, accuracy, completeness and representativeness	3.6.1.1	Environmental Surveillance Procedure 700
5.6 Sampling procedures	3.5.3.1, 3.6.1.2	Environmental Surveillance Procedures: 300 series, 400, 701, 800
5.7 Sample custody	3.5.3.2	Environmental Surveillance Procedures 500
5.8 Calibration procedures and frequency	3.5.4	TBD*
5.9 Analytical procedures	3.5.3.3, 3.6.1.3, 3.6.1.6	ES/ER/TM-16, Environmental Surveillance Procedure 700
5.10 Data reduction, validation, and reporting		TBD*
5.11 Internal quality control checks	3.6.1.4	TBD*
5.12 Performance and system audits	3.6.1.5	TBD*
	3.9.2, 3.9.3, 3.9.4	Audits: Energy Systems ESP.18.1
5.13 Preventive maintenance procedures and schedules	3.10.1	Surveillance: ER Procedure
5.14 Specific routine procedures		ER/C-P1600
5.15 Corrective action	3.5.4	TBD*
5.16 Quality assurance reports to management	3.6.1.6, 3.8.2	TBD*
	3.3.2	TBD*
	3.1.4.4	TBD*

*To be determined. The procedure for implementation of these QAMS-005/80 elements must be incorporated or referenced in the Quality Assurance Project Plan and are to be based on U.S. Environmental Protection Agency guidance and/or requirements.

work plan on the QAPjP locator page. The QAPjP locator page must identify each of the elements required for the QAPjP and the section and pages that address the requirement. The locator page must be inserted immediately following the work plan table of contents. If a QAPjP element is not applicable to the work plan in question, the words "Not Applicable" should appear on the locator page in the appropriate section. Justification must be provided for identifying elements as "Not Applicable," and the justification must be approved by the WAG 6 Manager and the QAS.

3.1.4.3 Project description

The purpose of the project description is to define the objectives or goals of the project and to describe the project design for obtaining the information needed to accomplish the goals. The project description shall include the following:

- identification of the phase of the work and the specific objectives of the investigation;
- description (including a map) of the site location and size and important physical features of the site such as streams, ponds, roads, and buildings;
- chronological history of the uses of the site, including the types of chemical, radioactive, or hazardous materials known or suspected to have been used;
- brief summary of any previous sampling efforts and results;
- description of how the data will be used to address each project objective; and
- anticipated beginning and completion dates.

3.1.4.4 QA reports to management

Reports will be prepared for the WAG 6 Program Manager to provide evidence of project quality, cost, and schedule. Individuals responsible for preparing reports to management will be identified in the QAPjP. The reports to be prepared follow.

- **Formal, written reports.** These reports will assess the performance of measurement systems and the quality of data.
 - Audit and surveillance reports will be prepared and submitted by the person who conducts the audit or surveillance.
 - Field observation reports will be prepared by the field sampling team.
 - Site investigation reports will be prepared by the appropriate project team personnel.
 - Reports on significant quality problems, recommended solutions, and corrective actions will be prepared by the ESD QAS.
- **Informal reports.** These reports will be prepared by project personnel designated by the Program Manager, and the content will vary. Examples include identifying the status of
 - permit approvals;
 - document preparation and approvals;
 - scheduled vs actual completions of field sampling and laboratory analyses;
 - accuracy and precision of field and laboratory analyses;
 - amount, type, and location of field-generated wastes; and
 - actual vs anticipated costs and schedules.

Informal communication between line management and work level employees will be effected whenever deemed necessary or whenever health, safety, or environmental deficiencies are identified.

3.1.5 Data Quality Objectives

Data quality objectives (DQOs) are qualitative and quantitative specifications used to design a study that will limit uncertainty to an acceptable level. The DQO process is a systematic planning process for ensuring that environmental data will be adequate for their intended use. To develop DQOs, environmental variability and analytical quantitation requirements must be considered along with measures to evaluate the precision, accuracy, representativeness, comparability, and completeness of both sample collection and analysis and the level of documentation required to support the intended use of the data.

This process has a logical structure that focuses planning on the intended use of the data. There are seven steps to the DQO process. The steps are listed here.

- State the problem.
- Identify the decision.
- Identify the inputs to the decision.
- Define the study boundaries.
- Develop a decision rule.
- Specify acceptable limits on uncertainty.
- Optimize the design.

The aforementioned process is a systematic, iterative method whereby one ensures that the sampling and analysis program provides data that, with a known level of certainty, will permit the data user to make desired decisions. DQOs themselves are the full set of constraints necessary to design a study, encompassing historical and analytical data as well as a specified acceptable level of uncertainty. These steps will be used for the WAG 6 characterization and monitoring activities, and the DQOs will be developed in the QAPjP and other lower tier documents associated with this project. The QAPjP will address the form, approvals, and process details for establishing the DQOs.

3.2 TRAINING AND QUALIFICATION

Personnel managing or performing activities affecting quality shall receive necessary indoctrination and performance-based training to ensure that suitable proficiency is achieved and maintained.

3.2.1 Implementation

Training shall be provided to achieve and maintain proficiency and to adapt to changes in technology, methods, or job responsibilities. Task leaders and the QA/QC Coordinator have the primary responsibility for training in the field and laboratory procedures area. QA training is the responsibility of the applicable Quality Manager and QAS.

3.2.2 Records

Records of the indoctrination and training will be maintained as quality records by the ER Training Manager. The form of the records and retraining schedules shall be specified. The records shall include evidence of performance of the trainee.

3.3 QUALITY IMPROVEMENT

The Energy Systems quality policy endorses a no-fault environment where personnel have the freedom and responsibility to identify nonconforming activities, items, and procedures without fear of reprisal. Quality improvement results from applying lessons learned when quality problems are solved.

Trending of nonconformances shall be carried out to help determine root causes of discrepancies. Surveillances and audits shall be used as a guide to quality improvement. Interaction of ideas between project personnel will generate quality improvements that shall be reported to the QAS and Performance Evaluation Manager.

3.3.1 Control of Nonconforming Items

Controls will be provided and maintained to identify, document, evaluate, segregate, and dispose of nonconforming items or samples. All nonconformances will be reviewed by the ER Program whether the nonconformances were generated by the ER Program or by its subcontractors.

Additional quality requirements for control of nonconforming items are identified in ESS-QA-15.0; ESP-QA-15.2; and ESS.ENV.1, Sect. 4.15, in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.3.2 Corrective Actions

Corrective actions are required for those situations or items that exceed predetermined acceptability limits, deviate from prescribed methods, fail to meet performance requirements or DQOs. Corrective actions shall be developed and reported together with root cause and contributing causes. The status of corrective actions shall be periodically evaluated.

Additional requirements for corrective actions and occurrence reporting are found in ESS.16.0 and ESP-QA-16.1.

3.4 DOCUMENTS AND RECORDS

3.4.1 Document Control

Characterization and monitoring activities result in many documents that require review, approval, and distribution. Document control is essential to ensure the precision and integrity of the sampling activities and laboratory analyses. Procedures, plans, forms, log books, manuals, and reports are some of the documents to be controlled. The document control system shall be documented and provide for

- identification of documents to be controlled and their distribution and
- assignment of responsibility for preparation, review, approval, issuance, and filing points.

Document control shall meet the requirements of ESS.6.1. Controlled documents and organizational interfaces are listed in Appendix B.

3.4.2 QAPjP Document Control

In addition to the general requirements previously discussed, the QAPjP shall include a document matrix specifying the project-specific documents to be controlled and maintained. Responsibilities for review and approval shall be stated. Lower tier procedure documents [e.g., standard operating procedures (SOPs)] shall be included or referenced. An approval page will be included in the QAPjP following the title page. As a minimum, approval is required by the Activity Project Manager, Site Program Manager, and the QAS.

3.4.3 QA Records

Documents specified as QA records will be distinguished from project records by stamping or identification in the records index. Records may include physical samples or materials that retain or support data. The requirements for identifying, controlling, validating, storing, and retrieving QA records are given in ESS.17.0.

Records that require special processing and control, such as computer codes and software, and information stored on high density media or optical disks shall be maintained and controlled to ensure they are readily retrievable and useable. Requirements are found in ESS.ADP.1.

3.5 WORK PROCESSES

3.5.1 Instructions, Procedures, and Drawings

Work processes affecting quality will be prescribed by and performed according to instructions, procedures, or drawings that are documented, controlled, reviewed, and approved (e.g., work plans, health and safety plans). Instructions, procedures, and drawings will contain quantitative or qualitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished. Activities affecting quality that are performed for WAG 6 by other divisions, plant organizations, contractors, or subcontractors may be performed in accordance with instructions, procedures, or drawings prepared by the organization doing the work. Responsibility for the adequacy of the procedures used to perform WAG 6 activities remains with the WAG 6 Project Manager, regardless of which organization prepares and issues the procedures. Therefore, as a minimum, the project team will review the procedures listed in the following paragraph before work is done. Specific requirements imposed by DOE and/or regulatory agencies will be adhered to, and all requirements will be clearly identified.

Procedures prescribing the following work processes will be included in each QAPjP:

- sampling processes;
- sample custody;
- calibration of equipment used in obtaining samples or data;
- analytical processes;

- data reduction, validation, and reporting;
- internal QC checks;
- audits and surveillances;
- preventive maintenance of sampling and data collecting equipment;
- data monitoring and installation of data monitoring equipment;
- specific, routine functions required to assess data precision and completeness; and
- corrective action processes.

Procedures prescribing work processes to be incorporated in QAPs not involving measuring and monitoring activities will be identified according to requirements specified in Sect. 2.

3.5.2 Identification and Control of Items

This section addresses the control of quality-related items. Identification of an item will be maintained either on the item itself or in documentation traceable to the item (e.g., chain-of-custody forms). Identification requirements apply to instrumentation, equipment, materials, and WAG-6-generated wastes and samples (all items except paperwork). Item identification, whether on the item itself or in documentation, will be clear and legible. All equipment and instruments used in the program will be correctly identified and logged in the field logbook or the laboratory record book. Requirements for identifying, handling, storing, shipping, maintaining, inspecting, and documenting samples are described in the *Environmental Surveillance Procedures Quality Program Manual* (Kimbrough 1990).

3.5.3 Control of Processes

Processes affecting the quality of items or services will be identified in a QAPjP and controlled by instructions, procedures, drawings, checklists, permits, or other appropriate means. Qualifications of personnel, procedures, and equipment will follow approved criteria and processes.

Each special process will be performed according to appropriate instructions. The conditions necessary to accomplish a process, including requirements, will be specified. For special processes not covered by existing codes and standards, or for situations where the quality requirements specified for an item exceed those of existing codes or standards, the instructions for that process will specify or reference the necessary procedures, equipment, and/or personnel levels and qualifications. Instructions for such special processes will become QA documents.

The requirements for procedures and equipment used in the field and in the laboratory are discussed in the *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990). All personnel using the procedures or equipment will adhere to those requirements. Additional quality requirements for control of processes are identified in ESS-QA-9 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

As a minimum, the field sampling and analytical processes will be controlled as indicated in the following paragraphs.

3.5.3.1 Sampling procedures

Sampling procedures to be used on WAG 6 activity-specific projects will be selected from the *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990)

or another Energy Systems procedures based on EPA standard sampling protocols. The WAG 6 sampling and analysis QAPjP will be developed from the data specified in a preliminary assessment/site investigation or in other remedial investigation/feasibility study work plans or sampling plans. The sampling and analysis procedures to be selected, including sample preservation and holding times for the relevant chemical analyses and matrixes, will comply with applicable techniques selected from the following documents:

- *Code of Federal Regulations*,
- federal and state regulations and criteria for chemicals,
- EPA manuals and guidance documents,
- EPA handbooks,
- American Society for Testing and Materials standards,
- American Public Health Association standards, and
- *Federal Register*.

Sampling operations will be performed to provide reliable information that meets the DQOs of the project. Procedures describing the performance of field sampling activities will be described or referenced in the QAPjP. As a minimum, procedures will address the following:

- ventilation, protection from extreme weather and temperatures, access to stable power, and provision for water and gases of required purity;
- equipment and equipment calibration and maintenance procedures;
- personnel training requirements;
- sequence of operations;
- holding times;
- solvents, reagents, and standards;
- storage of solvents, reagents, and standards;
- decontamination and cleanliness control;
- personnel protection equipment;
- storage and disposal of wastes;
- documentation requirements;
- sample numbering and labeling requirements;
- reagent and standard preparation methods;
- field measurement methods for chemical, radiological, and physical parameters;
- corrective actions;
- data review, reduction, and validation;
- reporting requirements;
- records management;
- control samples and sampling analysis;
- acceptance criteria for field activities;
- sampling equipment, techniques, containers, volumes, types, preservation methods, custody, and shipment;
- frequency; and
- special conditions.

Personnel performing sampling activities will be trained and qualified according to a documented program. The QAPjP will identify training program requirements or reference the appropriate procedure.

3.5.3.2 Sample custody

Sample custody will be documented on chain-of-custody forms to trace sample possession from the time of collection to final disposition according to the *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990). The QAPjP will also use the sample chain-of-custody procedure described therein. Sample custody will be documented throughout sample collection, shipping, analysis, and disposal. After collection and identification, samples requiring chemical analysis will be maintained under chain-of-custody procedures.

Each sample will be identified so that the location where it was obtained, the method used to obtain it, the date it was obtained, and the person(s) who obtained it can be traced. All wastes generated and handled at the WAG 6 site will be appropriately defined, physically identified, and appropriately segregated. To ensure that the sample can be traced after it is received by the analytical laboratory, the following information shall be part of the sample custody documentation: all tests and analyses to be performed on the sample will be identified, plus the sample and methods used to obtain the data, the date the tests are performed, and the person(s) performing the test(s) will be documented and traceable.

A sample is considered to be under custody if one or more of the following conditions is met.

- It is actually in the possession of the person responsible for sample collection and chain of custody.
- It is visible to the person who has taken possession.
- It is secured by the person responsible for possession so that tampering can be detected.
- It is in a secure area.

3.5.3.3 Analytical procedures

Procedures for test methods that describe how analyses are performed in the laboratory will be described or referenced in the QAPjP. Procedures approved by EPA will be used for preparing and analyzing samples, provided that such procedures are available and appropriate to meet the specific DQOs of the project. Company or contractor SOPs may be used if they describe the analysis exactly as it is described in published, EPA-approved procedures.

The selection of procedure(s) for each analysis will be based on the Energy Systems *Environmental Surveillance Procedure*, ESP-700. Subcontractor procedures will be reviewed for approval by the project team to ensure that their analytical methodologies comply with ESP-700. Some of the EPA-approved methods and procedures referenced in ESP-700 are as follows:

- *Methods for Chemical Analysis of Water and Wastes*, EPA-600/4-79-20 (EPA 1984);
- *Test Methods for Evaluating Solid Waste: physical and chemical methods*, SW-846 (EPA 1986); and
- *Prescribed Procedures for Measuring Radioactivity in Drinking Water*, EPA 600/4-80-32 (EPA 1980).

If no EPA-approved procedure exists for analyzing a specific parameter, then the procedure to be used will be reviewed and approved by the WAG 6 project team and by appropriate technical personnel who are independent of the procedure preparer. Procedures will adhere to EPA technical and documentation requirements. The project team will confer with the appropriate

regulatory agencies about the need for their review and approval of procedures that are not in accordance with existing EPA procedures. In addition to the aforementioned review and approval requirements, all analytical methods and procedures will conform to ES/ER/TM-16.

Laboratories that use limited-shelf-life solutions and reagents will be required to establish procedures to control those items to prevent use of a chemical for which the shelf life has expired.

If analytical laboratories are to provide reliable information, procedures and policies that address requirements beyond sample preparation and analysis must be implemented. Chapters 4.0–4.6 of SW-846 identify requirements for facilities, equipment and instrumentation, operating procedures, QA and QC procedures, QA reviews (audits and surveillances), and records. The QAPjP will describe or reference the procedures that implement the requirements of these chapters in SW-846. Changes to such procedures will be controlled by the laboratory quality program; those changes are subject to project team review.

For each parameter analyzed, the sample preparation and analysis procedure(s), the revision used, and the detection limits will be listed in the QAPjP. Once the QAPjP is approved, these requirements will not be changed without the review and approval of the same organizations that approved the original plan.

The QAPjP will specify a method of ensuring that the required sample preparation and analysis methods are properly conveyed to the laboratory.

Personnel performing analyses will be trained and qualified according to a documented program. The QAPjP will identify the training program requirements or reference the appropriate procedure. A list of currently qualified personnel shall be maintained.

3.5.4 Control of Measuring and Testing Equipment

The selection of measuring and testing equipment used for activities affecting quality will be controlled to ensure that the equipment is of the type, range, accuracy, and tolerance required and to determine whether the equipment conforms to specified requirements. Equipment selection will be based on the sampling and analysis methods described in the specific work activity and the *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990). When an organization other than the ER Division selects equipment, responsibility for the proper selection remains with the WAG 6 program management. However, the owner of the equipment is responsible for seeing that it is properly calibrated and that documentation of calibration to nationally recognized standards or methods or to manufacturers instructions is available to WAG 6 program management.

The work plan will list the calibration standards to be used and the sources for each major measurement parameter, including all pollutant measurement systems. Equipment will be calibrated initially and recalibrated at established intervals against instruments certified as traceable to nationally recognized standards or methods. Calibration will be documented by either entering calibration activities into a daily log or by tagging the individual instrument.

The QAPjP will include a table listing the calibration procedure, schedule, and frequency for each type of equipment used for field sampling and analytical measurements. Preventive maintenance of measuring and testing equipment will be scheduled and a list of critical spare parts

will be developed for each specific work activity. To avoid lost time, the availability of spare parts will be determined before equipment is used.

3.5.5 Handling, Storage, and Shipping

Samples collected and waste produced by characterization and monitoring activities will be controlled during handling, storage, and shipping to prevent damage and loss and to prevent deterioration of perishable materials and other environmental or safety insults. Handling, storage, and shipping of hazardous wastes will be coordinated with the applicable ER Waste Management Program manager and the applicable site Waste Management Division.

The shipping of all hazardous and nonhazardous wastes must comply with appropriate federal, state, and local regulatory standards and requirements. For materials such as hazardous chemicals and radioactive mixed wastes, special procedures may need to be developed to define requirements for generating, handling, storing, packaging, shipping, preserving, transferring, and receiving the wastes at the specific site involved.

3.6 DESIGN CONTROL

Design control, as applied to characterization and monitoring activities, is intended to define, control, and verify technical investigations, feasibility studies, remedial designs, and subsequent related activities. Design control measures are used to identify variables affecting the quality of those investigations and feasibility studies and to identify and control variables affecting the quality of interrelated activities to ensure comparability.

Procedures for conducting technical investigations and other associated characterization and monitoring activities and the implementation of those procedures will be reviewed and approved for technical adequacy by qualified individuals other than those who wrote the procedures. Changes to procedures for conducting characterization and monitoring activities will be reviewed and approved by qualified individuals familiar with both the original procedure and the purpose of the activity. This is to ensure that the original purpose of the characterization and monitoring activity is fulfilled. Documentation and records providing evidence that characterization and monitoring activities were performed in accordance with this QAP will be collected, stored, and maintained as prescribed in documented and approved procedures or instructions.

Additional QA requirements for design control are identified in ESS-QA-3.0 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.6.1 QA Objectives for Measurement Data

Overall QA objectives for characterization and monitoring scientific investigations (e.g., field sampling activities and analyses of laboratory and other data) will be identified to ensure that sufficient data of known quality are gathered to legally defend and support the study of environmental remedial alternatives. The DQOs described in the QAPjP should match the DQOs identified in the WAG 6 work plan if sampling is involved. These quality objectives will be summarized in a table with a defined measurement objective for precision, accuracy, and completeness at the appropriate analysis level in accordance with EPA/540/G-87/003A (EPA 1987). Each associated DQO will be related to a method for determining the specific objective.

Appropriate procedures will be identified, prepared, and used to ensure that all data will be gathered or developed for the intended use.

3.6.2 Sampling Procedures

The sampling procedures to be specified in WAG 6 QAPjPs will be selected to ensure that the work plan or sampling plan requirements are satisfied. This section of the QAPjP will present a table giving all sampling points, the sampling frequency, and the total number of each sampling activities. For additional information, see Sects. 3.5.3.1 and 3.5.3.2.

3.6.3 Analytical Procedures

All analytical procedures will follow appropriate EPA standard methodology as contained in the Energy Systems *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990). All samples and their associated analytical procedures should be identified in a summary table. Any analytical procedure that differs from a standard EPA method will be identified along with the reasons for the specific deviation.

3.6.4 Data Reduction, Validation, and Reporting

The data reduction, validation, and reporting procedure to be specified in the WAG 6 QAPjP will be selected to ensure that the work plan or sampling plan data reduction, validation, and reporting requirements are satisfied. Data reduction, validation, and reporting will be done according to the approved laboratory SOP referenced in the work plan. The principal criteria used to validate data integrity during collection, required calculations, and reporting will be specified and described by a flow chart. Reporting units will be specified for all parameters, and a unique system to be used for flagging data will be specified. The appropriate WAG 6 person responsible for data reduction, validation, and reporting will be identified. As a minimum, the procedure will describe

- data reduction scheme planned for collected data, including all equations used to calculate the concentration or value of the measured parameter and reporting units;
- principal criteria that will be used to validate data integrity during collection and reporting of data;
- methods used to identify and treat outliers;
- data flow or reporting scheme, from collection of raw data through storage of a validated concentration (a flow chart usually will be needed); and
- key individuals who will handle the data in this reporting scheme (if these have already been described under project organization and responsibilities, it need not be repeated here).

3.6.5 Internal QC Checks and Frequency

The internal QC checks and frequency will be identified in the WAG 6 QAPjP. These checks usually consist of control samples, which may include blanks, duplicates, spikes, split samples, analytical standards, and reference materials. These different types of control samples can be used in different phases of the data collection process, beginning with sampling and continuing through transportation, storage, and analysis. The quantity of QC samples should be consistent with the level of quality indicated in Sect. 3.6.1.1 for each DQO. All data, calculations, and analyses will be checked by technically qualified individuals who were not responsible for managing or

performing the work. These checks will be made and documented to ensure that both technical and quality requirements have been satisfied.

3.6.6 Specific Routine Procedures

The specific routine procedures for assessing precision, accuracy, and completeness of each major measurement, as specified in the DQO table mentioned in Sect. 3.6.1.1, will be identified in the QAPjP. The procedures will include a detailed description of the equations to be used to calculate precision, accuracy, and completeness, along with a description of the methods that were used to accumulate the data. These equations shall be equivalent to those described in EPA/540/G-87/003A (EPA 1987).

3.6.7 Automated Data Processing Software

Automated data processing software (including modifications) used to produce or manipulate data for characterization and monitoring activities will be documented, verified and validated, approved, and controlled. The application of specific requirements will be prescribed in plans for software quality, which will describe the planned and systematic actions to be taken to ensure quality achievement. Software verification and validation activities shall ensure that (1) the software adequately and correctly performs all intended functions and (2) the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

Software verification and validation activities will be planned and performed for each system configuration that may affect the software. The results of the software verification will be documented, and validation activities will be performed by individuals other than those who designed the software.

Additional quality requirements for automated data processing software are identified in ESS-QA-19 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.7 PROCUREMENT

3.7.1 Procurement-Document Control

Procurement-document control, as applied to the characterization and monitoring activities, is intended to ensure that applicable design bases, technical and quality requirements, and administrative controls are prepared, reviewed, and included or referenced in the procurement requisition packages prepared for quality-related activities.

Procurement-document control applies to documents supplied by organizations inside and outside Energy Systems. Documents such as statements of work and program service orders that are used to identify specific internal service requirements will be reviewed to ensure that necessary technical and quality requirements are included where applicable.

Procurement requisition packages for quality-related activities (to be prepared by WAG 6 personnel) will

- define technical and quality requirements for items or services through documented statements of work, specifications, or references to national codes or standards;
- include drawings, inspection and test plans, acceptance criteria, and nonconformance reporting criteria;
- specify supplier technical and quality documentation to be submitted to ER or retained by the supplier;
- identify special inspection requirements for receiving, code inspecting, and supplier surveillance; and
- designate individuals or groups responsible for performing special inspection activities.

Completed procurement requisition packages that identify quality requirements must be reviewed and approved by designated ER Program technical and quality staff before the packages are submitted to Energy Systems Procurement.

Energy Systems Procurement administrative requirements for procurement requisition packages will include terms and conditions for

- access to supplier facilities for performance monitoring
- warranty protection,
- company acceptance criteria, and
- payment processes.

Energy Systems Procurement also will review procurement requisition packages for clarity, completeness, and conformance with the legal obligations imposed on the supplier by administrative, technical, and quality requirements that are specified.

Any changes or revisions to purchase orders or to procurement requisition packages that identify quality requirements are subject to further review and approval by ER Program technical and quality personnel and by Energy Systems Procurement. This requirement includes changes that may result from ER Program technical or quality reviews or from the Energy Systems Procurement administrative review.

When review and revision of procurement requisition packages are completed, Energy Systems Procurement administrative, technical, and quality requirements will be incorporated in requests for proposals. Requests for proposals will be issued for bids; they will become purchase orders when a subcontract is awarded.

3.7.2 Control of Purchased Items and Services

Purchased items and services that have the potential to affect health, safety, the environment, production, or schedules are controlled to ensure conformity with ER Program procurement requirements. Such control is provided through procurement planning, supplier evaluation and selection, and supplier performance evaluation and verification.

Control of purchased items and services applies to items and services supplied by organizations inside and outside Energy Systems. Purchase documents such as requests for proposals, specifications, drawings, statements of work, and program service orders will be reviewed to ensure that deliverables meet necessary technical and quality requirements.

Procurement activities that are controlled will be planned. The plans will include documentation of the activities to be performed, the sequence of actions to be taken, milestones for completion, and the assignment of responsibilities.

Supplier selection is based on a documented evaluation of the supplier's capability to conform to ER procurement requirements. The basis for selection may include a review of the supplier's past history, existing documentation, or an evaluation performed at the supplier's facility.

Techniques for evaluating and verifying supplier performance are included in ER procurement documents. Techniques used to ensure that suppliers understand procurement-document requirements include, as applicable, bid proposal reviews, pre-award and post-award meetings, and reviews of alternatives and exceptions identified by suppliers. These techniques may include

- supplier document reviews (including nonconformance reports),
- waivers,
- source surveillances,
- inspections or tests done in receiving, and
- certificates of conformance that must be submitted by suppliers.

In addition to the aforementioned requirements for control of purchased items and services, the WAG 6 Program Management will provide overall oversight of DOE prime contract ER activities according to DOE and Energy Systems contract DE-AC01-849R21400, modification M066, paragraph H.17.

Additional quality requirements for the control of processes are identified in ESS-QA-9.0 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.8 INSPECTION AND ACCEPTANCE TESTING

Field and laboratory work (e.g., sampling, drilling, and laboratory analysis) conducted in association with WAG 6 will be inspected periodically. Inspections will be based on requirements for the given activity outlined in EPA guidance documents, the *Environmental Surveillance Procedures Quality Control Program Manual* (Kimbrough 1990), site-specific investigation plans, and other available references. The Site Program Manager will ensure that inspections are performed by qualified persons other than those who performed or directly supervised the work being inspected. Inspection results will be recorded in a field logbook, a daily logbook, or other relevant documents; they will verify that the characteristics of an activity are within specified limits. Corrective actions performed in response to inspection activities will be reported as outlined in Sect. 3.3.2, "Corrective Actions."

Additional quality requirements for inspection are identified in ESS-QA-10.0 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.8.1 Test Control

Tests required to verify that an item conforms to specific quality requirements or to demonstrate the satisfactory performance of an item will be planned, executed, and controlled.

Site-specific work plans will identify the tests, requirements, acceptance criteria, and organizational responsibilities for performing tests. Tests will be performed by qualified persons using approved procedures that reference or include provisions to ensure that

- prerequisites, such as instrument calibration, special equipment maintenance and condition, and data acquisition needs, are identified and completed before testing begins;
- proper instruments are available and used to perform the test;
- schedules are developed to provide time for monitoring test equipment and to ensure the availability of test personnel;
- suitable environmental conditions exist for conducting tests; and
- any special tests to be required for the laboratory chemical analysis of samples will be identified in the QAPjP.

Test requirements will be provided by the Site Program or Project Manager or by the subcontractor responsible for planning and conducting site activities (excluding requirements for tests performed to verify that an item conforms to specific standards or requirements for qualification tests to verify design adequacy). These requirements may also be part of existing design documentation. Additional quality requirements for test control are identified in ESS-QA-11.1 and ESS.ENV.1, Sect. 4.11 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.8.2 Inspection, Testing, and Operating Status

This section covers the inspection, testing, and operating status of items used and wastes generated by characterization and monitoring activities. To ensure that required inspections are performed and that items that have failed in tests are not inadvertently installed, used, or operated, the inspection and testing status of items will be identified either on the items themselves or in documents traceable to the items. Status will be tracked through indicators such as physical location and tags, markings, stamps, inspection records, or other suitable means.

Field and laboratory QC procedures will be prepared that describe the methods used to establish and control the status of samples (e.g., soil, water, wastes). As a minimum,

- samples will be identified with a unique serial number;
- nonconforming samples will be identified with a unique nonconforming item tag, bag, or other marking (only designated Quality personnel will be permitted to remove nonconforming sample identifications);
- nonconforming samples will be segregated from acceptable samples;
- untested samples will be segregated from tested samples; and
- sample custody procedural requirements of Sect. 3.5.3.2 will be an integral part of establishing and controlling the inspection, testing, and operating status of samples.

3.9 MANAGEMENT ASSESSMENT

3.9.1 Self-Assessment

Self-assessment is an integral part of the overall management assessment process. An ER and Waste Management self-assessment management plan is being developed to implement the DOE self-assessment guidance document. This self-assessment program requires definition of assessable

units, development of measurable performance criteria, assessment of program activities against performance criteria, and routine reporting of assessment results. The key to the self-assessment program is continual, open ended assessment by the line management responsible for organization performance. This process is supplemented by assessments performed by individuals from the line organization who are independent from the activities being performed. The process also includes assessment results from organizations with oversight responsibilities.

The current Energy Systems self-assessment program states that the principal self-assessment activities of line management are related to establishment of proper operations for implementing requirements of DOE orders and the law, establishment of how to implement such standards, and surveillance of organizational performance as compared with the requirements and standards.

Additional information regarding Energy Systems self assessment may be found in *Description of Self-Assessment Program*, Y/EX-43, Rev. 1 (Energy Systems 1992a).

3.9.2 Surveillance

In support of the self-assessment program, surveillances will be conducted by WAG 6 personnel and subcontractors performing activities in support of WAG 6 goals and objectives. Surveillance is defined as monitoring or observing to verify that requirements have been specified and that items or activities conform to the specified requirements. Surveillances are internal evaluations conducted and performed by line management personnel or their representatives to regularly assess the adequacy and effectiveness of the part of the quality program for which they are responsible.

Surveillances will be performed according to ER Division procedure ER/C-P1600, *Surveillance*, which assigns responsibilities for identifying, scheduling, planning, and performing surveillance activities. The reporting of findings, observations, management responses, implementation and verification of corrective actions, and final closure of findings and negative observations will be tracked and documented.

Additional quality requirements for surveillance are identified in ESP-QA-2.7 in *Policy, Standards and Procedures Manual*, Volume 4 (Energy Systems 1991b).

3.9.3 Field Audits and Surveillances

Audits and surveillances of field activities shall consider the following:

- permits and document approvals;
- availability and use of procedures;
- personnel training and qualifications;
- equipment calibrations;
- site control and identification;
- pre-entry briefings;
- personnel protective equipment;
- health and hazardous material monitoring;
- adequacy of work implementation by observation of techniques and assessment of end results;
- sampling equipment cleanliness and decontamination;
- sample collection, preparation, and controls;

- waste controls and disposal; and
- corrective actions.

3.9.4 Analytical Laboratory Audits and Surveillances

Audits and surveillances of analytical laboratory activities shall consider the following:

- permits and document approvals;
- availability and use of procedures and analytical methods;
- personnel training and qualifications;
- equipment calibrations;
- laboratory QC;
- accuracy and precision;
- statistical control limits;
- laboratory method control samples;
- method blanks;
- matrix-specific bias;
- detection limits;
- personnel protective equipment;
- sample receipt, chain-of-custody practices, handling, scheduling, and storage;
- sample preparation;
- data reduction and validation;
- reporting;
- adequacy of work implementation by observation of techniques and assessment of end results;
- corrective actions; and
- waste controls and disposal.

3.9.5 Operational Readiness Process

An operational readiness process will be conducted to ensure that a given activity is ready for the next increment of work to proceed. This is done by identifying and minimizing the risks associated with mission success. The operational readiness process establishes and verifies the status of an activity and the degree of readiness for the next phase of work to begin or proceed. The ER Division Site Program Manager is responsible for identifying the activities that require application of the readiness process and for requesting a readiness review board. The readiness process must result in an auditable record of the measures taken to determine and ensure that the activity is ready for the next increment of work to proceed.

Additional quality requirements for the operational readiness process are identified in *Conducting Project Readiness Reviews* (Energy Systems 1993).

3.9.6 Risk Assessment

Risk assessment will be conducted as required to gather the risk information necessary to aid in decision making during each phase of environmental restoration. The risk assessment

- provides an analysis of baseline risks and determines the need for site action,
- determines the levels of contaminants that can remain on-site without presenting possible risks to public health,

- compares potential health impacts of various remedial alternatives, and
- evaluates and documents public health threats at sites.

The Site Program Manager will ensure that risk assessments are effectively integrated with ER activities.

3.10 INDEPENDENT ASSESSMENT

Independent audits and surveillances will be scheduled, planned, performed, and documented. The requirements set forth in this document are delineated in Energy Systems Quality Procedures ESP-QA-2.7, *Surveillance* and ESP-QA-18.1, *Audits*.

These audits are planned and documented activities that determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation.

Surveillance will be used to verify that requirements have been specified and that items or activities conform to the specified requirements.

A performance audit or surveillance is one that evaluates the effectiveness of the project in fulfilling its objectives. A system audit or surveillance is one that examines project activities to determine whether they comply with procedures and other applicable documents.

3.10.1 Audits

Audits of organizations performing work for WAG 6 will be performed early in a project to determine whether there is objective evidence that activities comply with procedures, instructions, drawings, and other documented requirements and that DQOs are clearly defined and implemented in plans, procedures, and other documentation. The requirement for conducting an audit of a laboratory may be waived by the WAG 6 Quality Manager if the laboratory has been audited recently, and no major unresolved quality problems have been found.

Audits will be performed by personnel who are independent of the organization being evaluated. Audits will be performed according to Energy Systems Quality Procedure ESP-QA-18.1, *Audits*. The reporting of findings, observations, and management responses; implementation and verification of corrective action; and final closure of findings and negative observations will be tracked and documented.

3.10.2 Surveillances

Independent surveillances will be conducted in support of WAG 6 goals and objectives. They will meet the intent of ER Division Procedure ER/C-P1600, *Surveillance*, which assigns responsibilities for identifying, scheduling, planning, and performing surveillance activities. The reporting of findings, observations, and management responses; implementation and verification of corrective action; and final closure of findings and negative observations will be tracked and documented.

3.10.3 Field and Laboratory Audits and Surveillance

Independent audit and surveillance of field and laboratory activities associated with WAG 6 will be conducted. These independent evaluations will consider the same activities that are identified in Sects. 3.9.3 and 3.9.4. The analytical laboratories used for this project will be audited and approved by the Analytical Projects Office in accordance with ES/ER/TM¹-16.

4. REFERENCES

The WAG 6 Quality Program will conform to the current revisions of orders and standards referenced in the preceding sections and fully identified here.

ASME (American Society of Mechanical Engineers) 1989a. *Quality Assurance Program Requirements for Nuclear Facilities*, ASME NQA-1, N.Y.

ASME (American Society of Mechanical Engineers) 1989b. *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*, ASME NQA-3, New York.

ASME (American Society of Mechanical Engineers) 1989c. *Quality Assurance Requirements for Nuclear Facility Applications*, ASME NQA-2, N.Y.

Energy Systems (Martin Marietta Energy Systems, Inc) 1991 *Quality Assurance Plan for the Design and Construction of Waste Area Grouping 6 Closure at Oak Ridge National Laboratory, Oak Ridge, Tennessee*. ORNL/ER/Sub/92-UB147/5 QAP-X-91-ENGR-007, Oak Ridge, Tenn.

Energy Systems (Martin Marietta Energy Systems, Inc) 1991a. *Management Plan for the Oak Ridge Operations Environmental Program*, DOE/ORO-931, Oak Ridge, Tenn.

Energy Systems (Martin Marietta Energy Systems, Inc.) 1991b. *Policy, Standards and Procedures Manual, Martin Marietta Energy Systems, Inc.*, Volume 4, Oak Ridge, Tenn.

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Energy Systems (Martin Marietta Energy Systems, Inc.) 1992b. *Quality Program Plan*, Y/D-15 Rev. 0, Oak Ridge, Tenn.

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Energy Systems Central Engineering Procedures and Guidelines, Martin Marietta Energy Systems, Inc, current version.

- EPA (U.S. Environmental Protection Agency) 1980. *Prescribed Procedures for Measuring Radioactivity in Drinking Water*, EPA-600/4-80-032, Washington, D.C.
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- EPA (U.S. Environmental Protection Agency) 1987. *Data Quality Objectives for Remedial Response Activities*, EPA/540/G-87/003A, OSWER Directive 9355.0-7B, Office of Emergency and Remedial Response, Washington, D.C.
- EPA (U.S. Environmental Protection Agency) 1988. *Guidance for Conducting Remedial Investigations and Feasibly Studies Under CERCLA*, Interim Final, EPA/540/G-89/004, Office of Solid Waste and Emergency Response (OSWER) Directive 9355.3-01, Washington, D.C.
- EPA (U.S. Environmental Protection Agency) 1989. *RCRA Facility Investigation (RFI) Guidance*, EPA 530/SW-89-031, Office of Solid Waste and Emergency Response (OSWER) Directive 9502.00-6D, Washington, D.C.
- Kimbrough, C. W. L. W. Long, and L. W. McMahon. 1990. *Environmental Surveillance Procedures Quality Control Program Manual*, Revision 1, ESH/Sub/87/21706/1, Martin Marietta Energy Systems, Inc., Oak Ridge National Laboratory, Oak Ridge, Tenn.
- Stanley, T. W. and S. S. Verner. 1983. *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans*, EPA-600/4-83-004, QAMS-005/80, Office of Exploratory Research, U.S. Environmental Protection Agency, Washington, D.C.

Appendix A

DESIGN AND CONSTRUCTION

FUNCTIONAL RESPONSIBILITY PROFILE DESIGN AND CONSTRUCTION

Title: Waste Area Grouping 6 Design & Construction										
P = Prepare/Perform A = Approve I = Input R = Review S = Surveillance C = Concurrence Blank - Not Required	W M A A G N 6 G E R	E M N G A G P R O J	P E R N I N C I E P E R A L	R E D S	C O N S T E N G	V . E N D O R / S E L	O R N L Q A M G R	Q E & I	E N G R Q A S	E R Q A S
Documents/Actions										
QAP	I/R/A	R/A	R	R	R				P/A	R/A
Design Drawings, Specifications, and Calculations	I/A	I/A	I/R	R	R				R/C	R/A
Design Change Requests	A	A	P						A	R/A
Deviation Requests	I/A	I/A	I/A	I	P/A				R/A	
Purchase Requisitions ¹		R	P	I					R ²	
Vendor/Seller QAPs	R/A	R/A	R			P			R	
Nonconformance Reports	I/A	I/A	I/R				S		R/A	
Functional/Pre-Oper. Tests	R/A	P/A	A	I	S				R	
Operational Readiness Review Plan	I/P	I							I	
Surveillance Reports	P/A	P			P		S		R/A	
Receiving Inspection								P/A		
Technical Baseline	P/A	R/A	R							C

²If necessary¹If procured by MMES

A-E DESIGN REVIEW RECORD INSTRUCTIONS
UCN-12149 and 12149A

UCN-12149 INSTRUCTIONS

1. **PROJECT TITLE:** Obtained from the Engineering Transmittal. Will be the same as indicated on the "Project Title" line.
2. **JOB TITLE:** Obtained from the Engineering Transmittal. Will be the same title as on the "Job Title" line.

A-E TRANSMITTAL:

3. **No.:** The transmittal number initiated by the A-E. If this is not provided on the form, it may be found on the A-E's letter accompanying the design review package. If this letter is not available, place "N/A" in the space provided.
4. **Date:** The date the transmittal was initiated by the A-E. If this information is not available, place "N/A" in the space provided.
5. **Log No.:** The Engineering transmittal number which has been assigned to the package. This information may be found on the Engineering transmittal in the right hand corner.
6. **Received:** The date the material was received by the reviewer.
7. **Due Out:** The date the review comments are due to the indicated person. The date and person to return comments to may be found on the Engineering transmittal in the right hand column.

DESIGN REVIEW RECORD:

8. **PLANT:** The plant related to the project (i.e., ORNL, K-25, Y-12).
9. **A-E:** The A-E responsible for the design package (i.e., G/C). If package is an internal design, MMES is identified.
10. **DEPT:** Organization which the reviewer represents.
11. **STATUS REVIEW** The status of the review. Status information can be found in the job title of the Engineering transmittal.
12. **ITEM NO.:** The numerical value given to the comments by the reviewer.

13. **DRAWING OR
SPEC. NO. &
PARAGRAPH:** The appropriate drawing number and/or specification number which relate to your comments. If comment concerns a specification, the paragraph number is also needed. If more than one drawing has the same comment, the drawings may be listed together.

14. **COMMENTS:** Reviewer's comments in relation to the drawings and/or specifications identified in the column to the left.

15. **A-E ACTIONS:** Indicates the action proposed by the A-E or designer to resolve the indicated comments. This section is filled in by the A-E.

16. **REVIEWED BY:** Handwritten signature and date indicating the reviewer and the date the review occurred.

17. **APPROVED for
COMPANY:** Handwritten signature and date of the Engineering Project Manager. The reviewer signs and dates the form after the reviewer has made his comments and prior to submission of the review comments package to DOE-OR for transmission to the A-E.

18. **APPROVED
DOE-
ENGINEERING:** Handwritten signature and date of the DOE-OR Project Manager or Representative. DOE-OR signs and dates after receipt from Energy Systems and prior to submission of package to the A-E.

19. **A-E:** Handwritten signature and date of the A-E Project Manager. The A-E signs and dates after "A-E Action" is indicated and prior to the re-submission to DOE-OR Project Manager.

20. **PAGE-- OF --:** Indication of the current page number and the total number of comment pages.

UCN-12149A INSTRUCTIONS

1. PROJECT TITLE: Obtained from the Engineering Transmittal. Will be the same as indicated on the "Project Title" line.
2. JOB TITLE: Obtained from the Engineering Transmittal. Will be the same title as on the "Job Title" line.
3. DATE: The date the comments were made.
4. TRANSMITTAL NO.: The Engineering transmittal number which has been assigned to the package. This information may be found on the Engineering transmittal in the right hand corner.
5. ITEM NO.: The numerical value given to the comments by the reviewer.
6. DRAWING OR SPEC. NO. & PARAGRAPH: The appropriate drawing number and/or specification number which relate to your comments. If comment concerns a specification, the paragraph number is also needed. If more than one drawing has the same comment, the drawings may be listed together.
7. COMMENTS: Reviewer's comments in relation to the drawings and/or specifications identified in the column to the left.
8. A-E ACTIONS: Indicates the action proposed by the A-E or designer to resolve the indicated comments. This section is filled in by the A-E.
9. PAGE -- OF --: Indication of the current page number and the total number of comment pages.

U.S. DEPARTMENT OF ENERGY OAK RIDGE OPERATIONS		DESIGN REVIEW RECORD	
		Plant _____	
Project Title _____		A-E _____	
Job Title _____		Dept. _____	
A-E Transmittal _____ No. _____ Date _____ Log No. _____ Received _____ Due Out _____		Status Review _____	
ITEM NO.	DRAWING OR SPEC. NO. & PARAGRAPH	COMMENTS	
Reviewed By _____ Date _____		Approved for Company _____ Date _____ Operating Contractor	Approved _____ Date _____ DOE-Engineering
		A-E	

[illegible]

QA RECORDS AND CONTROLLED DOCUMENTS LIST

QAP No.:	Title: WASTE AREA GROUPING 6
-----------------	-------------------------------------

Instructions: List records name/title, Master and Duplicate File Points (building and room number) and name of person responsible. List the Retention Period (RP): L for lifetime records, or if non-permanent indicate the number of years it is to be maintained. Indicate status as QA Record and/or Controlled document. Controlled indicates controlled distribution.

RECORD NAME/TITLE OR DOCUMENT NUMBER	RP	MASTER FILE POINT	DUPLICATE FILE POINT	QA RECORD		CONTROLLED	
				YES	NO	YES	NO
QAP	L	Engineering Project Files/Bldg. 1000, Rm 207	Engineering Project Files Y-12, Bldg. 9739, Rm 175	X		X	
Nonconformance Reports	05	"	"	X			X
Readiness Review Reports	L	"	"	X			X
Occurrence Reports	05	"	"	X			X
Surveillance Reports	05	"	"	X			X
Audit Reports	05	"	"	X			X
Corrective Action Reports ¹	05	"	"	X			X
Test/Inspection Reports	L	"	"	X		X	
As-Built Drawings	L	"	"	X		X	
Deviation Requests	05	"	"	X		X	
Design Changes ²	L	"	"	X		X	
Equipment Specs/Data Sheets	L	"	"	X		X	
Construction Project/Test Summary	L	"	"	X		X	
Log Book/Sample Document	L	"	"	X			X

NOTES: 1 = After Completion
2 = Until Incorporated

EXAMPLE SURVEILLANCE PLAN

QAP No.:	Activity No.: ENGR-007
Title: WASTE AREA GROUPING 6 DESIGN AND CONSTRUCTION	

Area/Subject to be Surveilled	*Frequency	Responsible Person
<ul style="list-style-type: none"> • Design Review Records 	Once during Project Life	Engineering QAS M. A. Woody
<ul style="list-style-type: none"> • Project Records in Engineering Services 	Twice during Project Life	Engineering QAS M. A. Woody
<ul style="list-style-type: none"> • Project Records in Environmental Restoration Document Management Center 	Twice during Project Life	ER QAS P. A. Schrandt
<p>* Minimum frequencies for each WAG-6 subproject. Each subproject shall identify additional surveillance areas as applicable to specific subproject activities.</p>		

Appendix B

CHARACTERIZATION AND MONITORING ACTIVITIES

FUNCTIONAL RESPONSIBILITY CHARACTERIZATION AND MONITORING

Characterization and monitoring document summary

Document title	Controlled document	Prepare	Review				Approve			
Quality Assurance Project Plan	YES	QAC	PM		ERP-QAS	HSC	PM	ERP-QAS		
Personnel training records	NO	QAC	PM				PM			
Standard operating procedures and instructions	YES	PS	QAC	PM			PM			
Chain-of-custody forms	NO	FSC	DBM	QAC						
QA audit and surveillance reports	NO	AO	PM	QAC	ERP-QAS	ESD-QAS	DD	PRM		
Standards traceability documents	NO		TL	QAC						
Lab/field forms	NO	PS	FSC	QAC						
Lab/field notebooks	NO	PS	FSC	QAC	TL					
Data: electronic/hard copy	NO	DBM	QAC	TL						
Variance logbook	NO	FSC	QAC	ESD-QAS	PM		PM	ERP-QAS	ESD-QAS	
Deviation request forms	NO	PS	QAC	ESD-QAS	PM		PM	ERP-QAS	ESD-QAS	
Controlled software	YES	DBM, TL								
QA summary reports	NO	QAC					PM	ERP-QAS	ESD-QAS	PRM
Inspection reports	NO	EI	LS							
Corrective action reports	NO	QAC	PM	ESD-QAS	ERP-QAS		AO	PRM	DD	

Table Key

AO auditing organization
 DBM data base manager
 DD division director
 EDS external data source
 EI equipment inspector
 EPC extra project coordinator
 ERP-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
 PRM ER program manager
 PS project staff
 QAC quality assurance coordinator
 TL team leader
 TSK task leader

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