

Vitrification Projects Division High-Level Waste Quality Assurance Program Description

DOE/EM/WO/02

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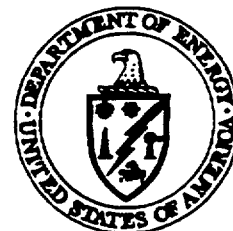
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U.S. Department Of Energy
Office of Environmental Restoration and Waste Management
Office of Waste Management



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Department of Energy
Office of Environmental Restoration and Waste Management
Office of Waste Management
Vitrification Projects Division

QUALITY ASSURANCE
POLICY STATEMENT

It is the policy of the Department of Energy to institute and maintain an effective quality assurance program in all aspects of its work. The Vitrification Projects Division gives quality full consideration over cost and schedule in all Waste Acceptance Process Activities of High-Level Waste Form Production. Therefore, the implementation of the quality assurance program described in this Quality Assurance Program Description (QAPD) is mandatory.



K. A. Chacey, Director
Vitrification Projects Division
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6/4/92

Date

**DOE/EM/WO/02
REVISION LOG**

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DOE/DP-0062	0	Based on Revision 0 of OGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production	11/10/88
DOE/DP-0062	1	Revised to incorporate OGR/B-14, Revision 1	5/89
DOE/EM/WO/02	0	Revised to incorporate Revision 2 of RW-0214, Quality Assurance Requirements Document, which replaced OGR/B-14. Also modified to reflect the current DOE organization and program	10/90
DOE/EM/WO/02	1	Revised to incorporate Revision 3 and 4 and ICN 4.1 of RW-0214 and resolution to comments transmitted from RW-3 to EM-343 on 4/8/91 and 5/1/92. This revision also incorporates the content of and supersedes DOE/EM/WO/01, High-Level Waste Processing QAPD, Revision 0, and DOE/EM/WO/03, Defense High-Level Waste Production QAPD, Revision 0	6/4/92

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ATTACHMENT

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0 INTRODUCTION

0.1 Purpose

This Quality Assurance Program Description (QAPD) describes the plans and actions of the United States Department of Energy (DOE), Office of Environmental Restoration and Waste Management (EM), to ensure that quality is achieved in developing, qualifying, and producing acceptable canistered waste forms for high-level radioactive waste. These canistered waste forms are being developed and qualified, and will be produced at DOE High-Level Waste processing facilities at the Savannah River, Hanford, Idaho, and West Valley sites.

The quality assurance program as described in this QAPD has the following objectives:

- High-level waste processing is achieved with a level of quality that is commensurate with EM's responsibility for protecting the health and safety of government employees, contractors, and the general public; protecting the environment and the government's investment; and efficiently and effectively using national resources.
- Research and development activities; production processes, facilities, equipment, and services; and products by or for the government conform to defined requirements.

0.2 Background

The Nuclear Waste Policy Act (NWPA) of 1982 (as amended in 1987) authorized the acceptance, storage, and disposal of defense and civilian high-level radioactive waste in a geologic repository. The act authorized the Nuclear Regulatory Commission (NRC) to establish regulations under which the repository would be licensed. Pursuant to that authority, the NRC issued regulations in Title 10 Code of Federal Regulations, Part 60, covering the repository, including performance of the waste packages and controlled release of radioactivity.

To implement this law and to carry out the associated programs and projects, the Act provided for the establishment within DOE of the Office of Civilian Radioactive Waste Management (RW), with the Director of that Office reporting to the Secretary of Energy. RW will be the licensee of the geologic repository and the recipient of the canistered waste forms from each waste form producer.

Waste form producer organizations have been established for the purpose of processing high-level waste into canistered waste forms for disposal in a geologic repository. The major participants include DOE/EM Headquarters; the Savannah River, Richland, and Idaho Field Offices; and their management and operating contractors. These major participants are associated through organizational, administrative, or contractual arrangements such that a vertical tier relationship exists.

To illustrate the vertical tier relationship, the waste form producer organization for Defense Waste Processing Facility (DWPF) at the Savannah River Site connects downward from the DOE/EM Headquarters; to the DOE Field Office at Savannah River (SR) and its Defense Waste Processing Division; and to the Westinghouse Savannah River Company (WSRC).

The waste form producer organizations and RW are pursuing an integrated, four-step strategy for ensuring that canistered waste forms are acceptable for disposal in a geologic repository. This strategy is called the Waste Acceptance Process and consists of Waste Acceptance Process Activities of High-Level Waste Form Production, which are:

- Preparing the Waste Acceptance Specifications (WAS) for the waste form, canister, canistered waste form, and quality assurance. These specifications were initially prepared by the RW Waste Acceptance Committee and issued for the Savannah River DWPF and West Valley Demonstration Project as Waste Acceptance Preliminary Specifications. These specifications were agreed upon by all involved DOE organizations. The documents describing the specifications are maintained under the RW configuration management process and are updated from time to time in developing canistered waste forms. The separate documents may eventually be combined and issued as the WAS applicable to all high-level waste processing facilities.
- Preparing and implementing the Waste Form Compliance Plan (WCP), which describes the actions necessary to ensure that the processes, methods, and techniques (developed for waste form production) provide canistered waste forms that meet each requirement of the WAS.
- Collecting the information and data that result from executing the WCP and preparing the Waste Form Qualification Report (WQR), which demonstrates that the canistered waste forms can meet all aspects of the WAS.
- Collecting the information and data that result from producing canistered waste forms, and assembling a Production Records (PR) package for each canistered waste form. The PR will ultimately demonstrate conformance to the WAS.

The quality assurance strategy for controlling the Waste Acceptance Process Activities of High-Level Waste Form Production includes developing a quality assurance program consisting of the constituent quality assurance programs of each major participant in the composite organization. In accordance with the WAS, the participant programs will implement the quality assurance requirements specified for waste form producer organizations in DOE/RW-0214, "Quality Assurance Requirements Document."

0.3 Scope

This QAPD provides: (1) a detailed description of the internal EM-343 quality assurance program requirements for Waste Acceptance Process Activities of High-Level Waste Form Production as they apply to development, qualification, and production of the canistered waste forms, and (2) a general description of the entire three-tier quality assurance program, identifying those program elements that are assigned to the field offices. The field office QAPDs will identify program elements that are assigned to the management and operating contractors. The terms "Quality Assurance Program" or "High-Level Waste Quality Assurance Program" as used in this document apply to both the internal and the three-tier programs.

The Office of Waste Management (EM-30) Quality Assurance Program, as described in the EM-30 QAPD, applies to EM-343 activities that are not associated with the Waste Acceptance Process Activities of High-Level Waste Form Production.

0.4 Responsibility

The Quality Assurance Program described in this document has been developed to implement EM's responsibility for the adequacy and effectiveness for the Waste Acceptance Process Activities of High-Level Waste Form Production. Although activities associated with establishing and executing portions of the High-Level Waste Quality Assurance Program have been assigned to others participating in the program, the Vitrification Projects Division(EM-343) retains ultimate responsibility for the adequacy of program performance.

1 ORGANIZATION

The Secretary of Energy is ultimately responsible for preparing canistered waste forms that result from the national defense programs and other DOE activities for ultimate disposal in the geologic repository. The execution of this responsibility has been delegated to the Assistant Secretary, Office of Environmental Restoration and Waste Management (EM) and other DOE Headquarters and field organizations. Participant waste form producer organizations involved in the processing of high-level waste are shown in Figure 1.1.

The Director, Office of Civilian Radioactive Waste Management (RW), is responsible for executing the Secretary of Energy's responsibilities under the NWPA. In this role, the Director, RW, is responsible for establishing and operating a geologic repository in accordance with NWPA. The Director, RW, interfaces directly with the Assistant Secretary, EM, who is responsible for coordinating requirements and activities for the canistered waste forms and to ensure their acceptability for ultimate disposal in the geologic repository. The Assistant Secretary, EM, is responsible for ensuring that appropriate quality assurance programs, technical and management controls, and systems are in place to provide confidence that activities, structures, systems, and components related to environmental restoration and waste management programs meet program requirements and do not cause undue risk to the environment or to the health and safety of site personnel or to the public.

The Assistant Secretary, EM, and the Director, RW, established a Memorandum of Agreement (MOA) on October 15, 1991, to specify the working relationship for quality assurance activities. This MOA dated October 30, 1991 states that the Director, Office of Quality Assurance RW (RW-3), will interface directly with the Director, Vitrification Projects Division (EM-343), for planning and coordinating the High-Level Waste Quality Assurance Program as described in this QAPD.

1.1 EM Organization

The following EM organizations (reference Figure 1.2) are involved in Waste Acceptance Process Activities of High-Level Waste Form Production:

- Office of Environmental Restoration and Waste Management (EM)
- Office of Waste Management (EM-30)
- Office of Waste Management Projects (EM 34)
- Vitrification Projects Division (EM-343)

In addition to these organizations, the DOE field offices are assigned responsibility for implementing certain portions of the High-Level Waste Quality Assurance Program.

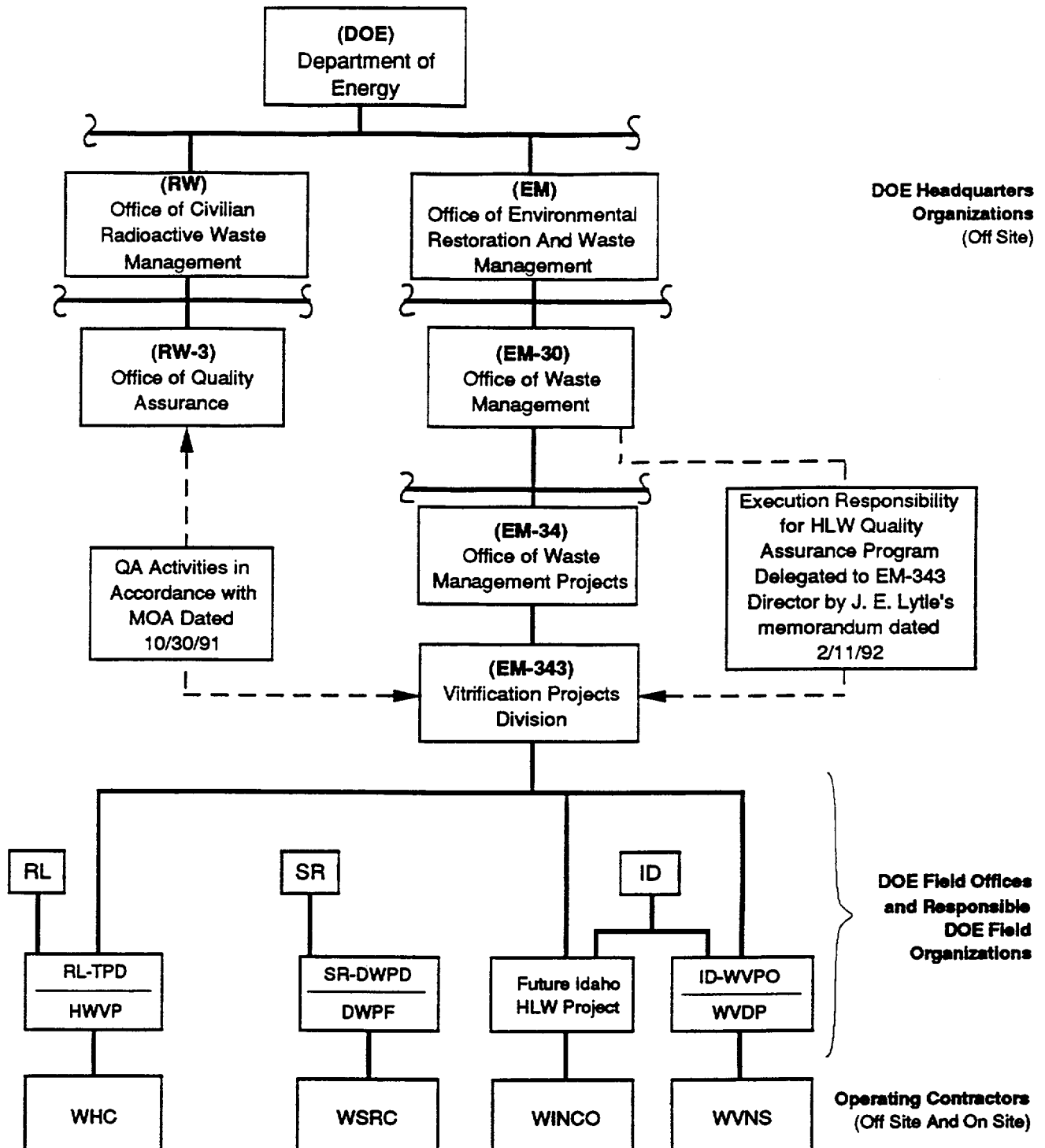


Figure 1.1
WASTE FORM PRODUCTION AND ACCEPTANCE PARTICIPANTS

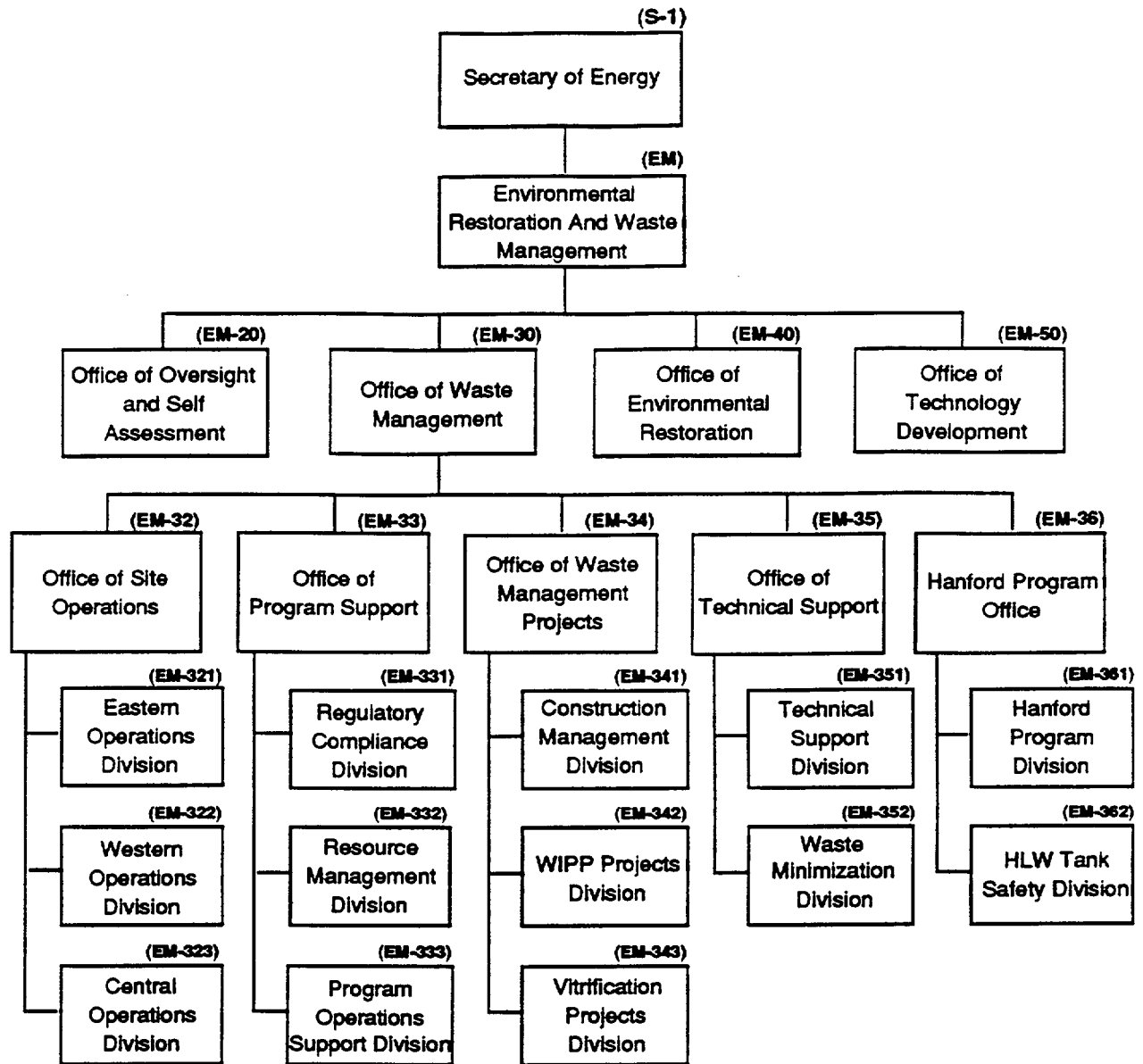


Figure 1.2
DOE/EM HEADQUARTERS ORGANIZATION

1.1.1 Office of Environmental Restoration and Waste Management (EM)

The Assistant Secretary (EM), reports to the Secretary of Energy and has overall responsibility for executive management of EM. The Assistant Secretary, EM, provides program policy guidance and centralized management of operations, environmental restoration, and applied research and development programs and activities, including EM program policy guidance to DOE field offices. The Assistant Secretary, EM, also establishes working policy, interface communications, and memoranda of agreement with RW and other affected organizations.

1.1.2 Office of Waste Management (EM-30)

The Deputy Assistant Secretary for Waste Management, EM-30, reports to the Assistant Secretary, EM, and is responsible for all DOE facilities, operations, or sites or portions thereof that are used for storing, treating, or temporarily disposing of radioactive, hazardous, mixed, and sanitary waste. These wastes are those that have been properly characterized, packaged, and labelled, but are not used for production; or those that are used exclusively for long-term storage of DOE waste material and are not actively used for production. Exceptions to these responsibilities are facilities, operations, or sites under the direction of RW.

A MOA, dated October 30, 1991, was executed between the Deputy Assistant Secretary for Waste Management, EM-30, and the RW Director of Quality Assurance, RW-3. This MOA assigned the Director, EM-343, the responsibility of interfacing directly with RW-3 in planning and coordinating the High-Level Waste Quality Assurance Program.

Execution responsibility for the High-Level Waste Quality Assurance Program was delegated to the EM-343 Director by J. E. Lytle's memorandum dated February 11, 1992. This includes the execution responsibility for development, qualification, implementation, and maintenance of the Program. It also includes the authority for approving the Headquarters High-Level Waste Quality Assurance Program documents, procedures, stop work directives, and the authority to communicate with external organizations in matters involving Waste Acceptance Process Activities for High-Level Waste Form Production.

1.1.3 Office of Waste Management Projects (EM-34)

The Director, EM-34, reports directly to the Deputy Assistant Secretary for Waste Management, EM-30, and is responsible for the planning, design, construction, and initial operation of facilities or facilities improvement projects

for waste treatment, vitrification, canisterization, and storage. The responsibilities for the Waste Acceptance Process Activities of High-Level Waste Form Production including all actions of the High-Level Waste Quality Assurance Program are assigned to the Director, EM-343, by EM-30 in accordance with the MOA discussed in Section 1.1.2.

1.1.4 Vitrification Projects Division (EM-343)

The Director, EM-343, (reference Figure 1.3), reports directly to the Director, EM-34, and is responsible for planning, designing, constructing, and operating all high-level waste vitrification facilities. The responsibilities of the EM-343 Director include the following:

- Developing, qualifying, implementing, and maintaining the High-Level Waste Quality Assurance Program. Approving the Headquarters High-Level Waste Quality Assurance Program documents, procedures, and stop work directives. Communicating with external organizations in matters involving Waste Acceptance Process Activities for High-Level Waste Form Production. These execution responsibilities are assigned to the EM-343 Directors by J. E. Lytle's February 11, 1992 memorandum.
- Serving as the general manager of activities for vitrifying high-level waste; (this includes being responsible for cost, schedule, and technical activities, as well as product quality and quality assurance);
- Providing overall DOE Headquarters coordination and management overview for constructing major, new high-level waste vitrification facilities;
- Providing input to the program guidance for the DOE field offices to define requirements for carrying out the policies, objectives, and milestones associated with planning, designing, constructing, and operating high-level waste vitrification facilities;
- Interfacing directly with RW-3, as delineated in the MOA dated October 30, 1991, for planning and coordinating the High-Level Waste Quality Assurance Program for the Waste Acceptance Process Activities of High-Level Waste Form Production. This interface arrangement provides for the coordination of:
 - Clarification or coordination of RW quality assurance requirements,
 - Information, documentation, and data submittal and review,
 - Plans and schedules for RW overview of EM Waste Acceptance Process Activities,
 - Resolution of nonconformances to RW requirements or resolution of quality problems which may require RW attention for Waste Acceptance purposes;

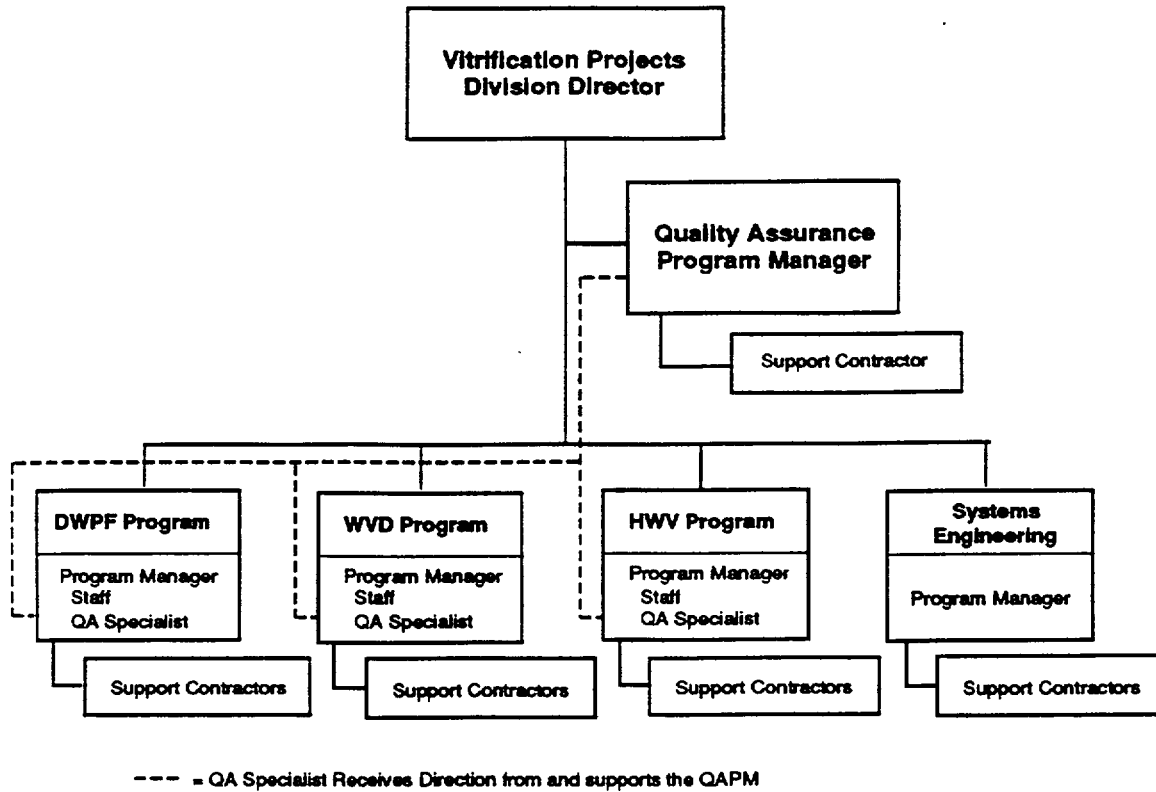


Figure 1.3
VITRIFICATION PROJECTS DIVISION

- Preparing and approving this QAPD and obtaining acceptance from RW;
- Applying and assuring the implementation of the quality assurance requirements identified in this QAPD;
- Ensuring that all major participants involved with the vitrification projects properly implement applicable legislation requirements, regulations, DOE Orders, notices, and other directives;
- Coordinating implementation of the quality assurance requirements with other DOE organizations, as appropriate; and
- Arranging for an annual assessment in determining the adequacy and effectiveness of the High-Level Waste Quality Assurance Program and identifying areas requiring quality improvement;

The EM-343 Quality Assurance Program Manager reports directly to the EM-343 Director, and assists and serves as staff advisor for determining the quality assurance controls to be applied. The Quality Assurance Program Manager ensures that an agreed-upon quality assurance program is established and implemented. The Quality Assurance Program Manager has knowledge and experience in the areas of quality assurance and management, and has no other duties or responsibilities that could compromise the independence required in managing this Quality Assurance Program.

The Quality Assurance Program Manager has sufficient organizational freedom from cost and schedule considerations when they may conflict with quality considerations. The Quality Assurance Program Manager has access to senior management to identify and resolve unresolved quality concerns.

The Quality Assurance Program Manager's responsibilities, at a minimum, include the following:

(1) Program Development and Maintenance

- Ensuring that the quality assurance program requirements and methods of implementation are described in a QAPD;
- Maintaining and reviewing this QAPD every two years;
- Developing and maintaining technical and quality assurance administrative procedures;

- Reviewing and recommending acceptance of DOE field offices' QAPDs; and
- Reporting the status of the quality assurance program quarterly to the Director.

(2) Quality Assurance Program Training

- Developing programs to provide trained, qualified, and certified (where required) personnel to perform quality-related activities; this includes arranging for appropriate quality assurance training and orientation, and establishing files for appropriate records.

(3) Quality Assurance Program Planning

- Developing and maintaining appropriate plans and schedules for use in accomplishing program activities or for monitoring the status of required activities.

(4) Quality Assurance Program Verification

- Managing and updating quarterly the Evaluation and Assessment Plan and Schedule;
- Identifying quality problems; initiating, recommending, or providing solutions; and verifying implementation of solutions;
- Reviewing and recommending approval or disapproval of quality assurance program documentation and revisions to program documentation, and interpreting quality assurance program requirements;
- Verifying through overview activities that, at a minimum, include surveillances, audits, and reviews, that the quality assurance programs of the EM-343 organization, DOE field offices, and their management and operating (M&O) contractor organizations are adequate and effectively implemented; and
- Ensuring that further processing, delivery, installation, or operation is controlled until a nonconformance, deficiency, or unsatisfactory condition is properly dispositioned, or initiating stop work action.

(5) **Quality Assurance Program Improvement**

- Monitoring the completion of audit responses and corrective actions; and
- Identifying areas requiring quality improvement and initiating required actions.

Program Managers are assigned to manage each of the major projects and report directly to the EM-343 Director. The Program Managers are responsible for managing the programs associated with their assigned vitrification projects. This responsibility includes cost, schedule, and technical objectives, as well as implementing the High-Level Waste Quality Assurance Program as defined in this QAPD.

Quality Assurance Specialists are assigned to assist the Program Managers in accomplishing quality assurance duties and receive direction from and support the Quality Assurance Program Manager.

1.2 Delegation of Work

Field offices [Richland (RL), Savannah River (SR), and Idaho (ID)] are assigned responsibilities for implementing certain portions of the High-Level Waste Quality Assurance Program. Figure 1.1 describes the relationship of the field organizations with these field offices and Headquarters. Throughout this document, the term "field office" includes the DOE field organization responsible for a particular high-level waste vitrification project. The responsibilities for each of the field offices include the following:

- Ensuring that design modifications and other engineering developments that affect the Waste Acceptance Specifications are forwarded through EM-343 for approval by RW;
- Ensuring that activities affecting quality are performed under suitably controlled conditions and that prerequisites for each activity have been satisfied;
- Serving as the primary interface with the M&O contractors for passing down quality assurance requirements;
- Reviewing and accepting the M&O contractors QAPD;
- Reviewing and accepting the M&O contractors procedures;
- Developing and maintaining an annual Evaluation and Assessment Plan and Schedule;

- Conducting evaluation and assessment activities;
- Making personnel and resources available when being audited by EM-343 or outside organizations, and ensuring that audit responses and corrective actions are completed within established time frames;
- Initiating and lifting stopwork orders when warranted; and
- Ensuring that personnel performing quality-related activities receive indoctrination and training as necessary to ensure that adequate proficiency is achieved and maintained.

Line management is responsible for planning and meeting product quality requirements, and implementing the High-Level Waste Quality Assurance Program on its work.

1.3 Dispute Resolution

Differences of opinion involving quality assurance matters are brought to the attention of the Director, EM-343, for resolution.

1.4 Resolution of Allegations and Concerns

A system is established that provides individuals a means of registering an allegation of inadequate quality or concern to EM management without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. The individual who registered the concern will be notified of the results of any investigation and disposition of the allegation or concern.

1.5 Stop work Provisions

Stop-work authority at EM-343 for Waste Acceptance Process Activities of High-Level Waste Form Production is assigned to the Director, EM-343 by the Assistant Secretary, EM. The EM-343 Director issues stop work orders on his own or when initiated by the Quality Assurance Program Manager. Stop work is initiated to ensure that further processing or continued work is controlled until proper disposition of a nonconformance or an unsatisfactory condition (including safety considerations) has occurred. The stop work process is delineated in approved procedures, which include requirements for the following:

- (1) Criteria and methodology for stopping work and for lifting stop work orders/requests;
- (2) Exact definition of work being stopped;

- (3) Authorities and responsibilities; and
- (4) Notification.

1.6 Requirements of Field Offices

Field offices are required to describe the organizational structure, functional responsibilities, levels of authority, management controls, and lines of communication for Waste Acceptance Process Activities of High-Level Waste Form Production in accordance with the requirements defined in Section 1 of DOE/RW-0214.

2 QUALITY ASSURANCE PROGRAM

The Vitrification Projects Division High-Level Waste Quality Assurance Program for the Waste Acceptance Process Activities of High-Level Waste Form Production is described in this QAPD. The items and activities that are included in the Waste Acceptance Process Activities of High-Level Waste Form Production are identified in the field offices' and M&O contractors' QAPDs.

2.1 High-Level Waste Quality Assurance Program

The documents that prescribe requirements for quality assurance program activities applicable to high-level waste form development, qualification, and production are shown in Figure 2.1, which identifies requirements that are imposed internally by DOE and externally by other organizations.

The NWPA established RW to research, design, construct, and operate a geologic repository for high-level waste. In addition, it authorized the NRC to license and regulate the geologic repository. RW and NRC were empowered to issue requirements and guidance sufficient to execute their assigned responsibilities.

To that end, NRC has issued Title 10 CFR Part 60 and Title 10 CFR Part 71, which provide requirements for quality assurance activities. NRC guidance documents, such as regulatory guides, nuclear regulations (NUREGs), and generic technical positions, also guide quality assurance policies and requirements. DOE/RW quality assurance requirements pertaining to Waste Acceptance Process Activities of High-Level Waste Form Production are detailed in DOE/RW-0214, "Quality Assurance Requirements Document." DOE/RW-0214 calls for mandatory implementation of ASME NQA-1 1989 requirements, as appropriate.

This QAPD describes (1) EM-343's implementation of applicable requirements of DOE/RW-0214, (2) the EM organizational responsibilities for achieving and verifying quality, and (3) the interfaces with other waste form producer organizations relative to activities affecting quality. The Director, EM-343, prepares, approves, and maintains this QAPD, and submits it for RW's acceptance. Additionally, the EM-343 Quality Assurance Program Manager reviews and accepts field offices' QAPDs.

EM-343 develops and maintains, with controlled distribution, procedures to implement this High-Level Waste Quality Assurance Program. These Standard Practice Procedures (SPPs) are reviewed by the Quality Assurance Program Manager and approved by the Director, EM-343.

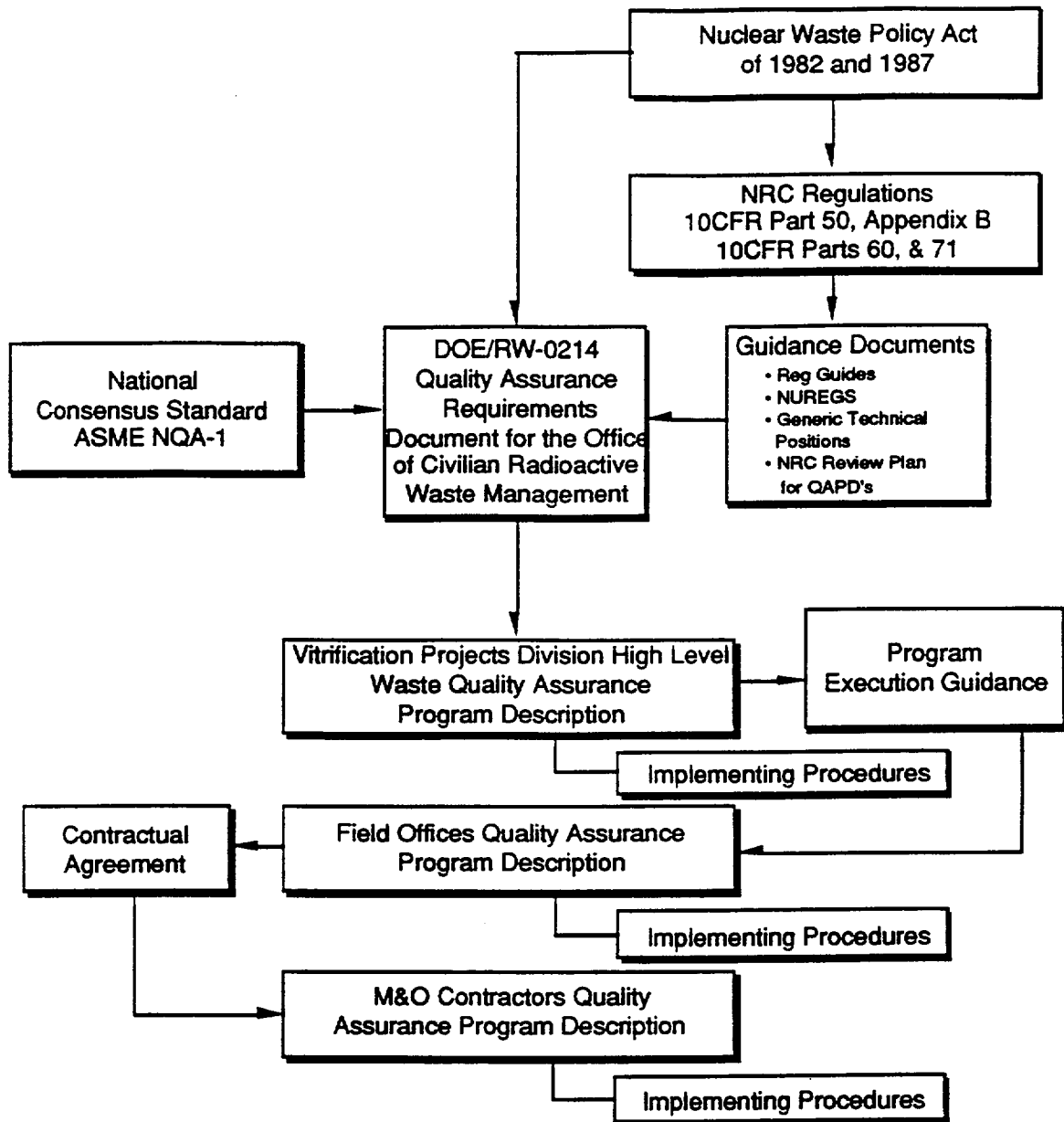


Figure 2.1
HIGH-LEVEL WASTE QUALITY ASSURANCE REQUIREMENTS

2.1.1 Independence of Personnel Performing Verification Activities

EM-343 management, line organization personnel, and the EM-343 Quality Assurance Program Manager implement the quality assurance program. Line organizations evaluate the adequacy of the programmatic systems and technical products through verification activities such as audits, reviews, and surveillances, with participation and overview by the Quality Assurance Program Manager.

Personnel verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational freedom to perform the following:

- Identify quality problems;
- Initiate, recommend, or provide solutions to quality problems through designated channels;
- Verify implementation of solutions; and
- Ensure that further processing, delivery, installation, or use is controlled until a nonconformance, deficiency, or unsatisfactory condition is resolved and properly dispositioned.

When verification personnel are part of the line organization, the Quality Assurance Program Manager overviews the verification activities by conducting independent surveillances, audits, and/or reviews.

2.1.2 Planning

EM-343 directs the planning of those activities required to develop, proceduralize, and implement the High-Level Waste Quality Assurance Program. The following elements are to be considered during planning:

- Defining the activities that affect quality;
- Selectively applying the appropriate quality assurance program activities and procedural controls (i.e., a graded approach) to items and activities;
- Identifying the applicable technical and quality assurance program management control and verification activities;
- Assigning the responsibilities for quality assurance program;
- Identifying the specific scientific or technical information to be collected, analyzed, or used; and

- Identifying required quality assurance records.

EM-343 develops and maintains evaluation and assessment plans and schedules, coordinating appropriate areas of evaluation with the field offices' schedules for reviews, audits, and surveillances. These evaluation and assessment plans and schedules are distributed to RW-3 to permit their participation in the activities as they may choose.

2.1.3 Readiness Reviews

EM-343 conducts readiness reviews of significant transitional events in the waste acceptance process activities of the field offices. Additionally, EM-343 overviews or participates in selected readiness reviews conducted by the field offices. Readiness reviews are used to verify that the following have been accomplished:

- Work activity prerequisites have been satisfied;
- Implementing procedures related to the next phase of work have been developed and reviewed for adequacy and appropriateness;
- Personnel have been suitably trained and qualified; and
- Required equipment, facilities, and instrumentation have been reviewed and judged to be adequate and appropriate.

2.1.4 Graded Quality Assurance Program

Considering all elements of a quality assurance program, EM-343 selectively applies a portion of the quality assurance controls to its own management and overview activities and issues implementation requirements to the field offices. The field offices, in turn, issue quality assurance program requirements to each M&O contractor for execution. The result of this selective application effort is described in the QAPDs for each organizational level.

These QAPDs outline which quality assurance program elements will be implemented internally and which will be assigned to the next lower organizational level for implementation. The resulting controls are applied to the various items and activities that make up a program for the Waste Acceptance Process Activities of High-Level Waste Form Production consistent with the extent of their importance to canistered waste form acceptance. The QAPDs include the strategy and commitment for each program element or requirement, as specified by DOE/RW-0214.

For an M&O contractor's activities, these controls are specified in detail in the technical specifications and prime contract based on the factors outlined in DOE/RW-0214 and are described in the contractor's QAPD. For EM-343, these controls are fully described in this QAPD.

The results of this selective application of requirements and the various controls that are applicable within those requirements are the basis for each section of this QAPD.

2.1.5 Policy Statement

A policy statement (reference page i) has been developed and signed by the EM-343 Director to render mandatory the implementation of this Quality Assurance Program as described herein.

2.1.6 Quality Assurance Requirements Matrix

A matrix is included as Attachment 1 to demonstrate that the requirements of DOE/RW-0214 are properly addressed by this QAPD and its implementing procedures.

2.1.7 Personnel Selection, Indoctrination, Training, and Qualification

Personnel assigned to perform activities that affect quality receive appropriate indoctrination and training in accordance with ASME NQA-1, Supplement 2S-4 prior to performing the work.

(1) Personnel Selection

Personnel assigned to perform quality-affecting activities of the High-Level Waste Programs have the education, experience, and/or training commensurate with the functions and requirements associated with the work. Initial qualifications are verified as a result of DOE-mandated policies, which provide for the inclusion of qualification requirements in position descriptions.

The candidate's qualifications are evaluated against the requirements and are documented. Relevant education and experience are verified accordingly. Records on individuals generated by affected organization's training and qualification program are collected and maintained according to the Privacy Act of 1974, as defined in Section 17 of this QAPD.

(2) Determination of Indoctrination and Training

The EM-343 Director reviews job functions or tasks involved in performing activities associated with the High-Level Waste Quality Assurance Program and determines any additional indoctrination and training required of the supporting staff.

Personnel assigned responsibility for performing High-Level Waste Quality Assurance Program activities are indoctrinated in the purpose, scope, and implementation of the Quality Assurance Program described in this QAPD. This indoctrination includes the following:

- Applicable EM-343 Standard Practice Procedures;
- Applicable quality assurance program elements as described in this QAPD; and
- Job responsibilities and authority.

(3) Training and Qualification

EM-343 classroom training is performed in accordance with documented lesson plans. Records of training are maintained.

EM-343 personnel serving as lead auditors or auditors are qualified in accordance with ASME NQA-1, Supplement 2S-3 and Appendix 2A-3.

(4) Proficiency Evaluations

Supervisors within EM-343 evaluate, at least annually, the proficiency of personnel in performing their assigned duties. These evaluations determine if any additional education and/or training is needed for the individual to maintain the desired level of proficiency.

2.1.8 Surveillance

In addition to audits described in Section 18 of this QAPD, programmatic, implementation, and technical surveillances are planned, scheduled, and performed to provide management timely information on program activities affecting quality. Surveillance activities are performed to provide real-time monitoring or observation of on-going work to ensure that items, activities, or processes conform to specified requirements. Surveillances are performed by knowledgeable personnel on work they have no direct responsibility for supervising or performing.

Surveillances are conducted to accomplish the following objectives:

- Verify the quality of work in progress;
- Identify and document actual and potential deficiencies and deviations;
- Promote prompt corrective action by cognizant management responsible for performing the work; and
- Verify timely implementation of that corrective action.

Surveillances are performed using written procedures, checklists, or plans, and the results are documented and reported to the appropriate level of management. This documentation includes the following:

- The date of the surveillance;
- Description of the activity or item under surveillance;
- Persons conducting the surveillance;
- Persons contacted during the surveillance;
- The requirements governing the activity or item;
- Measuring and test equipment used;
- Any deficiencies identified during the surveillance; and
- A summary of any immediate corrective actions taken.

Deficiencies identified during the surveillance are documented in accordance with the requirements in Section 15 and 16 of this QAPD.

2.1.9 Management Assessment

Independent management assessments of High-Level Waste Quality Assurance Program activities are planned, conducted, and documented annually at the direction of the EM-343 Director. These management assessments evaluate the following program aspects:

- Adequacy of organizational structure and staffing to implement the quality assurance program;
- Effectiveness of quality assurance program implementation;

- Adequacy of the indoctrination and training program;
- Adequacy of planning and procedural controls;
- Effectiveness of the nonconformance and corrective action system;
- Adequacy of the information tracking, evaluation, and reporting system for quality assurance management; and
- Conformance to the Waste Acceptance Specifications.

2.1.10 Quality Assurance Program Management: Information Reporting and Tracking

EM-343 maintains communication and information systems to ensure that quality-related management information is reported, disseminated, and tracked in a timely fashion. This includes the status of quality assurance programs, status of resolution of deficiencies and conditions adverse to quality, and the summary of required management and quality assurance overview results. High-Level Waste Quality Assurance Program information is reported at least quarterly to the Director, EM-343 by the Quality Assurance Program Manager.

2.1.11 Qualification of Data

Field offices are required to implement a practice to ensure that the qualification of data activities are performed in accordance with the requirements of DOE/RW-0214, Section 2.12. This practice is described in the field office QAPDs that are reviewed and accepted by EM-343.

2.1.12 Overview of Field Offices

EM-343 monitors field offices' quality assurance program activities related to Waste Acceptance Process Activities of High-Level Waste Form Production, and performs evaluations and assessments to assist responsible managers in ensuring proper implementation and adequacy of those activities.

2.2 Requirements of Field Offices

Field offices are required to implement and maintain quality assurance programs that fully implement the quality assurance requirements identified in DOE/RW-0214, Section 2 and Appendix B. Their programs are documented in QAPDs that are reviewed and accepted by EM-343.

3 DESIGN CONTROL

3.1 Vitrification Projects Division Implementation

The only technical activities performed by the Vitrification Projects Division (EM-343) are technical reviews and peer reviews. All other design and design control activities are the responsibility of the field offices.

The EM-343 Director selects and determines who performs technical or peer reviews. Technical reviews are performed as follows:

- When the information or document to be reviewed is within the present technology and is based on accepted standards, criteria, principles, and practices;
- When documents, activities, material, or data require technical evaluation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied and/or resulting conclusions are correct; and
- By individuals with sufficient technical knowledge of the area under review.

Procedures are established to ensure that each review is properly performed and documented. The documentation results identify, at a minimum, the reviewers, area or features reviewed, comments by the reviewers, and the resolution of the comments.

Peer reviews are identified, planned, conducted, and controlled for the following:

- (1) Items or data that are essential to waste acceptance process activities;
- (2) Qualifying processes or equipment which go beyond the existing technology; and
- (3) Where conclusions or assumptions have not been clearly validated by conventional means.

These reviews are in-depth critical evaluations of the technology. The reviewers seek to validate the assumptions upon which the task was based, verify calculations, ensure use of validated software, and ensure the credibility of the results by reviewing the methods and controls used to obtain the results.

The cognizant Program Manager, EM-343, arranges for such reviews to be performed by reviewers who have qualifications equivalent to those who performed the work being reviewed. In order to meet the provisions set forth by the NRC's NUREG-1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories", peer reviews are conducted in accordance with a procedure that describes the method of setting up the review and documenting the results.

EM-343 monitors field offices' design control practices related to Waste Acceptance Process Activities for High-Level Waste Form Production and implements a verification program to assess their adequacy and effectiveness.

3.2 Requirements of Field Offices

Field offices are required to exercise appropriate design control practices to ensure that design activities are planned, controlled, and verified; and that they meet the requirements of DOE/RW-0214, Section 3, Section 19, and Appendix B. These practices are described in QAPDs that are reviewed and accepted by EM-343.

4 PROCUREMENT DOCUMENT CONTROL

4.1 Vitrifaction Projects Division Implementation

The Vitrifaction Projects Division (EM-343) conducts the following two types of activities related to procurement:

- (1) Vitrifaction project execution responsibilities for the design, construction and operation of Vitrifaction Plants are assigned to the appropriate four field office(s). This is accomplished through program execution guidance documents and financial plans. EM-343 monitors project execution. EM-343 Standard Practice Procedures ensure that appropriate quality assurance requirements are included in the program execution guidance document.
- (2) EM-343 augments its staff by obtaining support from contractors through competitive procurements. Administrative support contracts are the vehicles through which EM-343 obtains technical support in carrying out its implementation and overview duties. Procurement documents for these services specify the scope of work, technical requirements, quality assurance requirements (which include a statement that personnel supporting the EM-343 Waste Acceptance Process Activities operate in accordance with the High-Level Waste Quality Assurance Program as defined in this Quality Assurance Program Description), as well as administrative and financial considerations.

These procurement documents are reviewed by EM-343 personnel to ensure that both technical and quality assurance requirements are included. The resulting contracts are controlled by DOE administrative procedures and DOE Orders, as well as the Federal Acquisition Regulations (FARs) and Department of Energy Acquisition Regulations (DEARs).

4.2 Requirements of Field Offices

Field offices are required to implement and maintain procurement document control practices that meet the requirements of DOE/RW-0214, Section 4. These practices are described in QAPDs that are reviewed and accepted by EM-343.

5 INSTRUCTIONS, PROCEDURES , AND DRAWINGS

5.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) has established a management procedures system. The procedures prescribe methods for performing quality-related activities, including appropriate quantitative or qualitative acceptance criteria for determining if prescribed activities have been satisfactorily accomplished. These procedures also assign specific responsibilities for performing these activities.

The procedures used by EM-343 are prepared in accordance with a procedure that prescribes the format to be followed and the identification system to be used. The EM-343 Director administers the system and controls the issuance of procedures to ensure necessary coordination and consistency.

Procedures, instructions, plans, and drawings prepared by or issued by EM-343 are subject to an independent, documented review to ensure they are technically adequate, technical requirements are correctly translated, and quality assurance requirements are included.

Documenting the requirements for activities affecting quality is executed in accordance with document control procedures identified in Section 6 of this document. These controlled documents identify the records that are to be designated as quality records.

The EM-343 Director, assisted as needed by the EM-343 Quality Assurance Program Manager, participates in and monitors the execution of these practices. Periodically, the EM-343 Quality Assurance Program Manager, audits or arranges for independent audit of these practices to ensure implementation and adequacy.

EM-343 monitors field offices' documentation practices and implements a verification program to assess their adequacy and effectiveness.

5.2 Requirements of Field Offices

Field offices are required to implement a practice to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, plans, or drawings that meet the requirements of DOE/RW-0214, Section 5. This practice is described in QAPDs that are reviewed and accepted by EM-343.

6 DOCUMENT CONTROL

6.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) has established and implemented a document control system for preparing, issuing, and revising documents prepared by EM-343 that specify quality assurance requirements or prescribe activities affecting quality. These documents are controlled to ensure that they are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

EM-343 procedures standardize the methods of identifying, formatting, and numbering controlled documents. These documents are reviewed for adequacy by the EM-343 Quality Assurance Program Manager. The draft controlled document is routed to the appropriate reviewing personnel/ organizations. Comments are resolved before final approval of the document. The review sequence and comment resolution is documented, and the record of this activity is retained. In every case, the reviewing personnel have access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections or correction of obvious errors, do not receive the same review and approval as the original documents. Changes other than minor changes are considered major changes or revisions and receive the same review and approval as the original document.

The EM-343 Quality Assurance Program Manager establishes an appropriate periodic review schedule for the approved controlled documents. The primary purpose of these reviews is to determine if changes in project or program status have resulted in the need to revise controlled documents.

EM-343 maintains a listing of those documents under its cognizance to be controlled and their required distribution. The responsibility for preparing, reviewing, approving, and issuing these documents is identified. These documents are also reviewed for adequacy, completeness, and correctness prior to their approval and issuance.

These documents are maintained under a receipt control system. A receipt acknowledgement page, attached to the transmitted controlled document, requests the person receiving the document to sign and date the receipt and return it to the Quality Assurance Program Manager. It also provides instructions for disposal of the superseded document or pages in the document.

The Quality Assurance Program Manager reviews the controlled document distribution listing periodically to follow up on any delinquent receipt pages. This distribution listing is a master list that is updated periodically to show current revision, control number of the document distributed, and location or individual assigned.

When controlled documents are released prior to review or approval, they are identified as unapproved documents, released through signature approval, and the basis for release are described. The unverified portions of the document are clearly identified.

The EM-343 Quality Assurance Program Manager participates in and monitors the execution of the document control system. Periodically, the EM-343 Quality Assurance Program Manager audits or otherwise evaluates the document control system for adequacy and effectiveness.

6.2 Requirements of Field Offices

Field offices are required to implement and maintain a document control system that meets the requirements of DOE/RW-0214, Section 6. This system is described in QAPDs that are reviewed and accepted by EM-343.

7 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) utilizes purchased services from administrative support contractors and the field offices. These services are controlled as follows:

- (1) EM-343 reviews and accepts the field office QAPDs in accordance with the requirements of this QAPD. The EM-343 evaluation process includes verifications of field office activities as well as internal verification of EM-343 overview and management activities.

EM-343 evaluates the objective evidence of quality furnished by the M&O contractor and the field offices upon completion of work. In part, these evaluations are accomplished using the Technical Review Groups for the review of selected preliminary and final technical documents.

- (2) EM-343 augments its staff capabilities using support contracts. Procurement documents for these services require that personnel supporting the EM-343 Waste Acceptance Process Activities operate in accordance with the High-Level Waste Quality Assurance Program.

EM-343 verifies the accomplishment of support activities as part of the ongoing management self-evaluation activities in accordance with QAPD and SPP requirements.

7.2 Requirements of Field Offices

Field offices are required to establish and implement a system for controlling procurements that meets the requirements of DOE/RW-0214, Section 7. This system is described in QAPDs that are reviewed and accepted by EM-343.

8 IDENTIFICATION AND CONTROL OF ITEMS

8.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) assigns execution responsibility for identification and control of items (including materials and samples) to the field offices.

EM-343 monitors field offices' identification and control practices for items and periodically verifies those practices to assess their adequacy and effectiveness.

8.2 Requirements of Field Offices

Field offices are required to establish and implement identification and control practices that meet the requirements of DOE/RW-0214, Section 8. These practices are described in QAPDs that are reviewed and accepted by EM-343.

9 CONTROL OF PROCESSES

9.1 Vitrifaction Projects Division Implementation

The Vitrifaction Projects Division (EM-343) assigns to the field offices execution responsibility for control of processes, including special processes in support of waste acceptance process activities.

EM-343 monitors field offices' process control practices and periodically verifies those practices to assess their adequacy and effectiveness.

9.2 Requirements of Field Offices

Field offices are required to establish and implement practices to ensure adequate performance and control of processes, including special processes, that meet the requirements of DOE/RW-0214, Section 9. These practices are described in QAPDs that are reviewed and accepted by EM-343.

10 INSPECTION

10.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) assigns to the field offices the execution responsibility for inspecting items and work practices.

EM-343 monitors field offices inspection practices, including process monitoring, and periodically verifies those practices to assess their adequacy and effectiveness.

10.2 Requirements of Field Offices

Field offices are required to establish and implement inspection and monitoring practices that meet the requirements of DOE/RW-0214, Section 10. These practices are described in QAPDs that are reviewed and accepted by EM-343.

11 TEST CONTROL

11.1 Vitrifaction Projects Division Implementation

The Vitrifaction Projects Division (EM-343) assigns to field offices execution responsibility for testing and test control practices.

EM-343 monitors field offices test control practices and periodically verifies those practices to assess their adequacy and effectiveness.

11.2 Requirements of Field Offices

Field offices are required to establish required tests, including proof tests prior to installation, pre-operational tests, and product certification tests that meet the requirements of DOE/RW-0214, Section 11. These tests are described in QAPDs that are reviewed and accepted by EM-343.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) assigns to field offices execution responsibility for control of measuring and test equipment.

The Vitrification Projects Division, EM-343 monitors field offices measuring and test equipment control practices, and periodically verifies those practices to assess their adequacy and effectiveness.

12.2 Requirements of Field Offices

Field offices are required to overview the establishment and implementation of practices for calibrating and controlling measuring and test equipment for their M&O contractors. The system must meet the requirements of DOE/RW-0214, Section 12. This system is described in QAPDs that are reviewed and accepted by EM-343.

13 HANDLING, STORAGE, AND SHIPPING

13.1 Vitrifaction Projects Division Implementation

The Vitrifaction Projects Division (EM-343) assigns to the field offices execution responsibility for handling, storage, and shipping practices.

EM-343 monitors field offices' handling, storage, and shipping practices and activities, and periodically verifies those practices to assess their adequacy and effectiveness.

13.2 Requirements of Field Offices

Field offices are required to establish and implement practices for handling, storage, and shipping of items that meet the requirements of DOE/RW-0214, Section 13 and Appendix B. These practices are described in QAPDs that are reviewed and accepted by EM-343.

14 INSPECTION, TEST, AND OPERATING STATUS

14.1 Vittrification Projects Division Implementation

The Vittrification Projects Division (EM-343) assigns to the field offices the execution responsibility for inspection, test, and operating status measures.

EM-343 monitors field offices' practices and activities for indicating inspection, test, and operating status, and periodically verifies those practices to assess their adequacy and effectiveness.

14.2 Requirements of Field Offices

Field offices are required to establish and implement practices to indicate the status of inspections and tests. These practices must meet the requirements of DOE/RW-0214, Section 14. These practices are described in QAPDs that are reviewed and accepted by EM-343.

15 CONTROL OF NONCONFORMING ITEMS

15.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) has established and implemented practices for the identification, documentation, evaluation, and disposition of nonconforming items or activities. These practices are designed to ensure that measures are established to control items or activities that do not conform to defined requirements in order to prevent their inadvertent use. These departures from specified requirements are identified as deviations and are documented and tracked on Deviation and Corrective Action Reports (DCARs).

The EM-343 Director dispositions DCARs internal to EM-343. Program Managers are responsible for evaluating and dispositioning DCARs originating from review of their respective field offices.

The EM-343 Quality Assurance Program Manager tracks the status of and initiates closure of DCARs upon documented completion of the required corrective action. These reports, which become quality records when they are closed, are processed in accordance with Section 17 of this QAPD.

Personnel who evaluate deviations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

EM-343 monitors field offices' nonconformance control practices, including occurrence reporting, and periodically verifies nonconformance practices to assess their adequacy and effectiveness.

15.2 Requirements of Field Offices

Field offices are required to establish and implement a practice that meets the requirements of DOE/RW-0214, Section 15 and DOE Order 5000.3A, "Occurrence Reporting and Processing of Operations Information" for the control of nonconforming items or activities. This practice is described in QAPDs that are reviewed and accepted by EM-343.

16 CORRECTIVE ACTION

16.1 Vittrification Projects Division Implementation

The Vittrification Projects Division (EM-343) has established and implemented a system for corrective action. This corrective action system provides that deviations be promptly identified, corrected, and reported using the Deviation and Corrective Action Report (DCAR) procedure.

The corrective action system includes the following elements:

- (1) Nonconformances are evaluated to determine the need for corrective action and if the nonconformance represents a significant condition adverse to quality. Evaluations are performed in accordance with established procedures and criteria.

Deviations identified during an audit require corrective action and action to prevent recurrence.

- (2) Significant conditions adverse to quality require action to prevent recurrence, generic implications evaluation, and root cause analysis.
- (3) The EM-343 Quality Assurance Program Manager or designee performs a review to determine adequacy of the corrective action.
- (4) The EM-343 Quality Assurance Program Manager or designee performs follow-up reviews to verify the proper implementation of the corrective action within prescribed time limits.
- (5) A tracking system is established for all nonconformances to ensure that they are appropriately addressed, prioritized, trended, and closed-out.
- (6) Significant conditions adverse to quality and the root cause(s) are identified, and generic implications are resolved, tracked, and trended for the EM-343 Director. This documented review includes defining corrective action and the action taken to prevent recurrence.
- (7) The EM-343 Quality Assurance Program Manager analyzes information such as audit and surveillance reports, nonconformance reports, corrective action reports, and other deficiency documents in a manner and at a frequency to promptly identify adverse quality trends. These quality trends are evaluated and significant results and plans for quality improvement are reported to the responsible management for review and assessment.

- (8) Any remedial action that can be taken is documented and initiated after a deficiency has been identified. The quality assurance organization evaluates and concurs with the remedial action to ensure that quality assurance requirements are satisfied. Follow-up action is taken by the EM-343 Quality Assurance Program Manager to verify the proper implementation of remedial action and to close out the remedial action in a timely manner.

The EM-343 Director, assisted by the Quality Assurance Program Manager, executes the corrective action system and arranges for periodic, independent audits or other verifications of the system to assess its adequacy and effectiveness.

16.2 Requirements of Field Offices

Field offices are required to establish and implement a corrective action system that meets the requirements of DOE/RW-0214, Section 16. This system is described in QAPDs that are reviewed and accepted by EM-343.

17 QUALITY ASSURANCE RECORDS

17.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) has established and documented a quality assurance records system for collecting, storing, and maintaining EM-343-prepared records.

EM-343 has established and documented the requirements and responsibilities for quality records in transmitting, distributing, retaining, maintaining, and dispositioning in accordance with DOE/RW-0214 requirements.

The EM-343 quality records management system includes the following elements:

- (1) The scope of the quality records program is described to ensure that sufficient records related to quality are identified, maintained, and able to be retrieved. Quality records include reports of audits, surveillances, and monitoring of work performance; procurement documents; qualification of personnel, QAPD and quality assurance program implementing procedures; technical reports; records of management assessments; and nonconformance, corrective action, and trend reports.
- (2) Quality record storage facilities are constructed, located, and secured to prevent destruction of the records by fire, winds, flooding, theft, and deterioration by environmental conditions such as temperature or humidity; or infestation of insects, mold, or rodents. Provisions are made to satisfy the duplicate storage of records requirements of DOE/RW-0214.
- (3) Quality records are legible, accurate, authenticated, identified, and retrievable using an index system that includes record retention times and location of the record within the record system.
- (4) Responsibilities and requirements are detailed for creating, transmitting, retaining, and maintaining quality records consistent with applicable codes and standards.
- (5) Limited access by designated personnel to the files is maintained.
- (6) Records are distributed, processed, and controlled in accordance with written procedures.

- (7) Criteria are established and described for determining when a document becomes a quality record subject to the controls described in this section and the retention periods for such records. These documented retention periods are determined by classifying the records as non-permanent or lifetime records.
- (8) Controls are established and described for controlling, protecting, and maintaining those records before they are entered and stored in the quality record control storage area.
- (9) Methods are described for documenting/recording, reviewing, and confirming the accuracy of quality records.
- (10) Documents are considered to be valid records when they are stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. Quality records may be originals or reproduced copies.
- (11) Corrections to documents that are to become quality records include a line through the part to be corrected, the date, and the initials of the person authorized to make the correction. Once a document is declared a quality record and is entered into the quality records system, no corrections of any kind are made.

Quality assurance training and qualification records meet the requirements of DOE Records System 80. Elements of this program include the following:

- (1) Quality records that contain personnel training and qualification information, including certification records, are collected and maintained according to the Privacy Act of 1974; "Proposed Establishment of a New System of Records," 55 FR 32288, August 8, 1990 (DOE System 80).
- (2) The EM-343 Director is responsible for implementing DOE System 80. The responsibility for managing DOE System 80 is assigned to each of the field offices.
- (3) Access to DOE System 80 records is restricted to authorized personnel and those provided access under a routine use as defined for DOE System 80. Requests for access to DOE System 80 records are directed to the responsible manager.

EM-343 has assigned to the field offices execution responsibility for preparing and collecting, storing, and maintaining quality records prepared by and for them.

EM-343 has identified in the Waste Form Compliance Plan (WCP) and/or the Waste Qualification Report (WQR) those quality records required to be a permanent part of the overall canistered waste form product certification package. These quality records will be identified, packaged, and transferred to RW.

The EM-343 Quality Assurance Program Manager participates in and monitors the implementation of the quality records system. Periodically the EM-343 Quality Assurance Program Manager audits, arranges for independent or otherwise verifies, audit of the quality records system to assess its adequacy and effectiveness.

17.2 Requirements of Field Offices

Field offices are required to maintain a quality records system that meets the requirements of DOE/RW-0214, Section 17 and Appendix B. This system is described in QAPDs that are reviewed and accepted by EM-343.

18 AUDITS

18.1 Vitrification Projects Division Implementation

The Vitrification Projects Division (EM-343) has established and implemented a quality assurance audit program in addition to the surveillance program described in Section 2.1.8 of this QAPD. This audit program provides comprehensive, independent verifications and evaluations, both internal to EM-343 and external, of the status and adequacy of the overall High-Level Waste Quality Assurance Program, including implementation methods, procedures, and quality-affecting activities. The audit program involves all levels of management and includes the EM program as well as the programs of the field offices and their contractors.

The audit program is implemented as early in the life of each activity as practical, and is continued at intervals consistent with the schedule for accomplishing each activity. This audit program is also designed to determine and verify as a method to ensure that program procedures and activities are effectively applied to the quality-related work activities and comply with the overall High-Level Waste Quality Assurance Program requirements. The audit program includes the following elements:

- (1) Planning and Scheduling;
- (2) Conduct;
- (3) Reporting; and
- (4) Follow-Up and Closeout.

The scope and frequency of the High-Level Waste Quality Assurance Program audits scheduled are commensurate with the program needs to support the overall Waste Acceptance Process Activities of High-Level Waste Form Production. An annual audit plan and schedule is developed to evaluate the overall controls applied to quality-affecting activities. This annual audit plan and schedule is reviewed and revised quarterly as necessary, and is implemented using a more detailed quarterly audit plan and schedule.

These audit schedules and the scope of each audit are based on evaluation of the activities to be verified; results of previous reviews, surveillances, and audits; and the impact of significant changes in personnel, organizations, or the quality assurance program.

Internal audits are performed to evaluate the High-Level Waste Quality Assurance Program on a twelve month cycle and include assessments of those portions of the program audited. The regularly scheduled audits are supplemented by additional audits of specific subjects when it is necessary to provide adequate program coverage.

An audit plan is prepared for each audit that identifies the following:

- (1) The scope of the audit;
- (2) The requirements against which the audit will be conducted;
- (3) The audit personnel (by name) who make up the audit team;
- (4) The activities to be audited;
- (5) The organizations to be notified;
- (6) The applicable documents pertaining to the audit itself and the activities to be audited;
- (7) The schedule for the audit; and
- (8) The checklists or procedures that are to be used to conduct the audit (may not be included until the final version of the audit plan is issued).

The development of audit plans includes an evaluation of the results of previous audits and the impact of changes in personnel, organization, or the quality assurance program of the organization to be audited. This audit plan development effort also includes a technical evaluation of the applicable procedures and instructions, as well as plans for technically evaluating the techniques and/or items if appropriate.

Audit team members are selected and assigned based on their auditor qualifications, their professional expertise and experience with respect to the activities to be audited, and their independence from any direct responsibility for performing the activities they will audit. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Personnel having direct responsibility for performing the activities that will be audited are not involved in selecting the audit team (for internal audits).

The audit team is led by a lead auditor who is qualified in accordance with Section 2.1.7. Prior to conducting the audit, the audit team leader concurs that the audit team collectively has experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Each audit team leader is either a member of or represents EM-343, and is responsible for the following:

- Organizing and directing the audit;
- Ensuring that the audit team is prepared prior to initiation of the audit;
- Conducting the pre-audit and post-audit conferences with the audited organization's management and presenting the audit findings; and
- Coordinating the preparation and issuance of the audit report; signing the audit report.

The audit teams consist of qualified personnel normally from the quality assurance organization and technical organizations. Audit team technical representatives have the technical expertise and/or experience in the work, activities, or technology being audited and are indoctrinated in audit techniques, at a minimum.

EM-343 audits are conducted using written checklists as guidance for examining the program activities to be audited against the specified requirements. The audit team examines the objective evidence to the depth necessary to determine if the program activities are being effectively implemented.

Audit results are documented on the checklists. The data obtained from the audit results are evaluated by the audit team to determine the adequacy and effectiveness of the quality assurance program.

Conditions requiring prompt corrective action are reported immediately to the management of the audited organization.

The audit report is signed by the audit team leader, and issued. The audit report includes the following information:

- A description of the audit scope;
- A listing of the audit team members and their parent organizations;
- The identification of persons contacted during the audit activities, including the attendees of the pre- and post-audit conferences;

- A summary of the audit results, including a statement on the effectiveness of the implementation of the quality assurance program elements that were audited; and
- A description of each adverse audit finding is provided in sufficient detail to enable appropriate corrective action to be taken by the audited organization.

The management of the audited organization or activity is required to investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence), and notify EM-343 in writing of the action taken or planned. For significant conditions adverse to quality or recurring conditions adverse to quality, root cause analysis is included in the audit finding response. EM-343 evaluates the responses received from the audited organization, and either accepts or rejects them. Communications continue until acceptable responses are obtained.

Follow-up action is performed by representatives of EM-343 to verify that corrective action has been completed as scheduled and that the corrective action is effective. When this verification is complete, the audit file is closed and is entered into the quality records system. The completed audit record file includes the following:

- The audit plan, including the completed and signed audit checklists;
- The audit report;
- The written responses to the audit findings; and
- The record of the completed, verified, and accepted corrective action.

Audit plans and schedules between EM-343 and participating waste form producer organizations can be combined to accomplish multiple organizational auditing needs whenever the resulting audit scope meets their program needs and the audit report is used by all affected and responsible organizations.

EM-343 monitors field offices' audit activities and audits the field offices' program implementation activities at least annually to assess their adequacy and effectiveness.

18.2 Requirements of Field Offices

Field offices are required to establish and implement an audit program that meets the requirements of DOE/RW-0214, Section 18 and Appendix B. This program is described in QAPDs that are reviewed and accepted by EM-343.

The actions and accomplishments of each field office's overview activities are periodically summarized to EM-343 for review and evaluation.

19 REFERENCES

- ASME NQA-1, (1989) Quality Assurance Program Requirements for Nuclear Facilities
- (DOE/RW-0214) Office of Civilian Radioactive Waste Management (RW) Quality Assurance Requirements Document Revision 4 and ICN 4.1
- 10 Code of Federal Regulations (CFR) Part 60, Disposal of High-Level Radioactive Waste in Geologic Repositories
- Nuclear Waste Policy Act (NWPAA) of 1982 as amended in 1987
- Privacy Act of 1974 and DOE Records System 80, Proposed Establishment of a New System of Records, Federal Register, Vol. 55, No. 153, 8/8/90
- 55 FR 32288, Proposed Establishment of a New System of Records
- DOE Order 5000.3A Occurrence Reporting and Processing of Operations Information, 5/30/90
- 10 Code of Federal Regulations (CFR) Part 71, Packaging and Transportation of Radioactive Material
- NUREG 1297, Peer Reviews for the High-Level Waste Repositories - Generic technical position
- Memorandum of Agreement "Coordination of Waste Acceptance Process Activities Between the Office of Civilian Radwaste Management (RW) and the Office of Environmental Restoration and Waste Management (EM)" dated October 30, 1991.
- NUREG 1298, Qualification of Existing Data for High-Level Waste Repositories - Generic Technical Position.

20 ACRONYMS AND ABBREVIATIONS

ASME	- American Society of Mechanical Engineers
DCAR	- Deviation and Corrective Action Report
DEAR	- DOE Acquisition Regulations
DOE	- Department of Energy
DOE/EM	- DOE Office of Environmental Restoration and Waste Management
DWPD	Defense Waste Processing Division
DWPF	- Defense Waste Processing Facility
EM-30	- Office of Waste Management
EM-34	- Office of Waste Management Projects
EM-343	- Vitrification Projects Division
FAR	- Federal Acquisition Regulation
FARs	- Federal Acquisition Regulations
HWVP	- Hanford Waste Vitrification Plant
ID	- DOE - Idaho Field Office
M&O	- Management and Operating (Contractor)
MOA	- Memorandum of Agreement
NRC	- Nuclear Regulatory Commission
NWPA	- Nuclear Waste Policy Act of 1982 (as amended in 1987)
PR	- Production Records
QAPD	- Quality Assurance Program Description
RL	- DOE - Richland Field Office
RW	- DOE - Office of Civilian Radioactive Waste Management

SR	-	DOE - Savannah River Field Office
TPD	-	Treatment Projects Division
WCP	-	Waste Form Compliance Plan
WHC	-	Westinghouse Hanford Company
WINCO	-	Westinghouse Idaho Nuclear Company
WQR	-	Waste Form Qualification Report
WSRC	-	Westinghouse Savannah River Company
WVDP	-	West Valley Demonstration Project
WVPO	-	West Valley Project Office

ATTACHMENT 1

**QUALITY ASSURANCE
PROGRAM MATRIX**

**Documents That Implement
The Requirements of DOE/RW-0214**

ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
1	ORGANIZATION			
1.0	General			
	• NQA-1, BR-1, Organization	DOE/EM/WO/02 (Section 1.0)	Quality Assurance Program Description	
	• NQA-1, 1S-1, Supplementary Requirements for Organization	DOE/EM/WO/02 (Section 1.0)	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS:			
1.1	Quality Assurance Program Management	DOE/EM/WO/02 (Section 1.1.4)	Quality Assurance Program Description	
1.2	Delegation of Work	DOE/EM/WO/02 (Section 1.2)	Quality Assurance Program Description	
1.3	Dispute Resolution	DOE/EM/WO/02 (Para. 1.3)	Quality Assurance Program Description	
1.4	Resolution of Allegations	DOE/EM/WO/02 (Para. 1.4)	Quality Assurance Program Description	
		and SPP 10.03	Differing Staff Opinions and Allegations	
1.5	Stop Work Provisions	DOE/EM/WO/02 (Para. 1.5)	Quality Assurance Program Description	
		and SPP 5.03	Stop Work Orders	

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ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
2	QUALITY ASSURANCE PROGRAM			
2.0	General			
	<ul style="list-style-type: none"> • NQA-1, BR-2, Quality Assurance Program 	DOE/EM/VO/02 (Section 2.0)	Quality Assurance Program Description	Assigned to Field Office
	<ul style="list-style-type: none"> • NQA-1, 2S-1, Supplementary Requirements for the Qualification of Inspection and Test Personnel 			
	<ul style="list-style-type: none"> • NQA-1, 2S-2, Supplementary Requirements for the Qualification of NDE Personnel 			Assigned to Field Office
	<ul style="list-style-type: none"> • NQA-1, 2S-3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel 	DOE/EM/VO/02 (Para 2.1.7)	Quality Assurance Program Description	
		and SPP 3.03	Qualification of Quality Assurance Audit Personnel	
	<ul style="list-style-type: none"> • NQA-1, 2S-4, Supplementary Requirements for Personnel Indoctrination and Training 	DOE/EM/VO/02 (Para. 2.1.7),	Quality Assurance Program Description	
		SPP 3.01,	Training Needs Assessment	
		SPP 3.02,	Preparation and Conduct of Training	

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ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
2.0 (continued)	General	SPP 3.04	Documentation of Surveillance Personnel Qualification	Assigned to Field Offices
		and SPP 3.05	Administration of Personnel Certification, Qualification, and Training Records	
	<ul style="list-style-type: none"> NQA-1, 2A-1, Nonmandatory Guidance on Qualification of Inspection and Test Personnel NQA-1, 2A-3, Nonmandatory Guidance on the Education and Experience of Lead Auditors 		EM-343 Lead Auditors are Certified by EM-20	
	GENERAL (0214) AMPLIFICATIONS			
2.1	Quality Assurance Program			
	<ul style="list-style-type: none"> Quality Assurance Program Description Technical and Quality Assurance Administrative Procedures 	SPP 2.03	Quality Assurance Program Description	
		SPP 2.01	Standard Practice Procedures	
2.2	Reporting Independence of Personnel	DOE/EM/WO/02 (Para. 2.1.1)	Quality Assurance Program Description	

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ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
2.3	Planning	DOE/EM/WO/02 (Para. 2.1.2) and SPP 2.03	Quality Assurance Program Description Quality Assurance Program Description	
2.4	Readiness Review	DOE/EM/WO/02 (Para. 2.1.3), and SPP 4.14	Quality Assurance Program Description Administration and Conduct of Operational Readiness Reviews	
2.5	Graded Quality Assurance Program	DOE/EM/WO/02 (Para. 2.1.4) and SPP 2.03	Quality Assurance Program Description Quality Assurance Program Description	
2.6	Policy Statement	DOE/EM/WO/02 (Para. 2.1.5 and page i)	Quality Assurance Program Description	
2.7	Quality Assurance Requirements Matrix	DOE/EM/WO/02 (Para. 2.1.6)	Quality Assurance Program Description	
2.8	Personnel Selection, Indoctrination, Training, and Qualification	DOE/EM/WO/02 (Para. 2.1.7), SPP 3.05,	Quality Assurance Program Description Administration of Personnel Certification, Qualification, and Training Records	

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ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
2.8 (continued)	Surveillance	SPP 3.01,	Training Needs Assessment	
		and SPP 3.02	Preparation & Conduct of Training	
2.9		DOE/EM/WO/02 (Para. 2.1.8)	Quality Assurance Program Description	
		SPP 4.01,	Planning & Scheduling of Evaluation & Assessment Activities	
	Management Assessment	and SPP 4.04	Administration & Conduct of Surveillance	
2.10		DOE/EM/WO/02 (Para. 2.1.9),	Quality Assurance Program Description	
		and SPP 8.02	Annual Assessment of the Quality Assurance Program	
2.11	Quality Assurance Program Management- Information Reporting and Tracking	DOE EM/WO/02 (Para. 2.1.10)	Quality Assurance Program Description	
		SPP 8.03,	Quality Assurance Program Progress and Status Reports	
		and SPP 10.01	Analysis of Adverse Quality Trends	
2.12	Qualification of Data of Indeterminate Quality	DOE/EM/WO/02 (Para. 2.1.11)	Quality Assurance Program Description	Assigned to Field Offices

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**DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
APP. B	AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR WASTE ACCEPTANCE PROCESS ACTIVITIES OF HIGH-LEVEL WASTE FORM PRODUCTION:			
2.0 (B)	AMPLIFICATION OF QARD SECTION 2.0-QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WASTE ACCEPTANCE PROCESS			
2.1 (B)	Method Description	DOE/EM/WO/02 (Section 1 and 2)	Quality Assurance Program Description	
2.2 (B)	Readiness Reviews	DOE/EM/WO/02 (Para. 2.1.3)	Quality Assurance Program Description	
2.3 (B)	Graded Quality Assurance Program	DOE/EM/WO/02 (Para. 2.1.4)	Quality Assurance Program Description	
		and SPP 2.03	Quality Assurance Program Description	
2.4 (B)	Personnel Selection, Indoctrination, Training, and Qualification	DOE/EM/WO/02 (Para. 2.1.7),	Quality Assurance Program Description	Inspection & Test Personnel Qualifications assigned to Field Offices
		SPP 3.01,	Training Needs Assessment	

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
2.4 (B) (continued)		SPP 3.02, and SPP 3.05	Preparation and Conduct of Training Administration of Personnel Certification, Qualification, and Training Records	
2.5 (B)	Management Assessments	DOE/EM/WO/02 (Para. 2.1.9) and SPP 8.02	Quality Assurance Program Description Annual Assessment of the Quality Assurance Program	Assigned to Field Offices
3	DESIGN CONTROL			
3.0	General	DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	Design Control Responsibilities are assigned to Field Offices
	• NQA-1, BR-3, Design Control	DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	
	• NQA-1, 3S-1, Supplementary Requirements for Design Control	DOE/EM/WO/02 Section 3.0	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS:			
3.1	Design Deficiency Control			Assigned to Field Offices
3.2	Design Changes			Assigned to Field Offices
3.3	Design Verification			Assigned to Field Offices

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
3.4	Technical Reviews	DOE/EM/WO/02 (Para. 3.1)	Quality Assurance Program Description	Except for selected reviews assigned to Field Offices
		and SPP 4.15	Administration & Performance of Technical Reviews	
3.5	Peer Reviews	DOE/EM/WO/02 (Para. 3.1),	Quality Assurance Program Description	
		SPP 4.08	Administration and Conduct of Peer Reviews	
	APPENDIX B			
3.0	AMPLIFICATION OF QARD SECTION 3-DESIGN CONTROL			
3.1 (B)	Control of Experiments and Development Activities			
3.1.1 (B)	Experimental and Development Activities			Assigned to Field Offices
3.1.2 (B)	Minimum Controls for Developmental Activities			Assigned to Field Offices
3.1.3 (B)	Documentation			Assigned to Field Offices
3.1.4 (B)	Experimental and Developmental Records Control			Assigned to Field Offices
3.1.5 (B)	Modification Control			Assigned to Field Offices

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**DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
3.2 (B)	Computer Software Design Control			Assigned to Field Offices
4	PROCUREMENT DOCUMENT CONTROL			
4.0	General			
	• NQA-1, BR-4, Procurement Document Control	DOE/EM/WO/02 (Section 4.0), and SPP 4.12 and SPP 4.16	Quality Assurance Program Description Quality Assurance Input to the Program Execution Guidance Documents Document Review	
	• NQA-1, 4S-1, Supplementary Requirements for Procurement Document Control	DOE/EM/WO/02 (Section 4.0)	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS			
4.1	Review	DOE/EM/WO/02 (Section 4.0)	Quality Assurance Program Description	
4.2	Applicability of Purchaser's Quality Assurance Program	DOE/EM/WO/02 (Section 4.0)	Quality Assurance Program Description	

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
5	INSTRUCTIONS, PROCEDURES, AND DRAWINGS			
5.0	General <ul style="list-style-type: none"> NQA-1, BR-5, Instructions, Procedures, and Drawings GENERAL (0214) REQUIREMENTS	DOE/EM/WO/02 (Section 5.0) and SPP 2.01	Quality Assurance Program Description Standard Practice Procedures	
5.1	Reviews	SPP 2.01	Standard Practice Procedures	
5.2	Quality Assurance Records	and SPP 7.01	Preparation, Transfer, & Receipt of Quality Records	
6	DOCUMENT CONTROL			
6.0	General <ul style="list-style-type: none"> NQA-1, BR-6, Document Control NQA-1, 6S-1, Supplementary Requirements for Document Control GENERAL (0214) REQUIREMENTS	DOE/EM/WO/02 (Section 6.0) SPP 6.05 SPP 6.05	Quality Assurance Program Description Controlled Documents Controlled Documents	
6.1	Control System	SPP 6.05	Controlled Documents	

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
6.2	Controlled Documents	DOE/EM/WO/02 (Section 6.0)	Quality Assurance Program Description	
6.3	Quality Assurance Organization Review	SPP 6.05	Controlled Documents	
7	CONTROL OF PURCHASED ITEMS AND SERVICES			
7.0	General	DOE/EM/WO/02 (Section 7.0)	Quality Assurance Program Description	
	<ul style="list-style-type: none"> NQA-1, BR-7, Control of Purchased Items and Services 	DOE/EM/WO/02 (Section 7.0)	Quality Assurance Program Description	
	<ul style="list-style-type: none"> NQA-1, 7S-1, Supplementary Requirements for Control of Purchased Items and Services 	DOE/EM/WO/02 (Section 7.0)	Quality Assurance Program Description	
	<ul style="list-style-type: none"> NQA-1, 10S-1, Sections 4, 6.1 through 6.4, and 8, Supplementary Requirements for Inspections 			Assigned to Field Offices
	GENERAL (0214) REQUIREMENTS			
7.1	Supplier Quality Assurance Program			Assigned to Field Offices
7.2	Receipt Inspection Planning			Assigned to Field Offices
7.3	Receipt Inspection Records			Assigned to Field Offices

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**DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
8	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS	DOE/EM/VO/02 (Section 8.0)	Quality Assurance Program Description	Assigned to Field Offices
8.0	General			
	<ul style="list-style-type: none"> - NQA-1, BR-8, Identification and Control of Items - NQA-1, 8S-1, Supplementary Requirements for Identification and Control of Items 			Assigned to Field Offices Assigned to Field Offices
9	CONTROL OF PROCESS	DOE/EM/VO/02 (Section 9.0)	Quality Assurance Program Description	Assigned to Field Offices
9.0	General			
	<ul style="list-style-type: none"> • NQA-1, BR-9, Control of Processes • NQA-1, 9S-1, Supplementary Requirements for Control of Processes 			Assigned to Field Offices Assigned to Field Offices
	GENERAL (0214) AMPLIFICATIONS			
9.1	List of Special Processes			Assigned to Field Offices
9.2	Quality Assurance Organization Involvement in Qualification Activities for Special Processes			Assigned to Field Offices

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**DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214
QUALITY ASSURANCE PROGRAM INDEX**

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
9.3	Evidence of Accomplishment of Special Processes	DOE/EM/WO/02 (Section 10.0)	Quality Assurance Program Description	Assigned to Field Offices
9.0 (B)	APPENDIX B			
	AMPLIFICATION OF QARD SECTION 9.0-CONTROL OF PROCESSES			
9.1 (B)	Process Control			Assigned to Field Offices
10	INSPECTION			Assigned to Field Offices
10.0	General			Assigned to Field Offices
	• NQA-1, BR-10, Inspection			Assigned to Field Offices
	• NQA-1, 10S-1, Supplementary Requirements for Inspection			Assigned to Field Offices
	GENERAL (0214) AMPLIFICATIONS			
10.1	Inspection Planning			Assigned to Field Offices
10.2	Records			Assigned to Field Offices

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
11	TEST CONTROL	DOE/EM/WO/02 (Section 11.0)	Quality Assurance Program Description	Assigned to Field Offices
11.0	General			
	• NQA-1, BR-11, Test Control			Assigned to Field Offices
	• NQA-1, 11S-1, Supplementary Requirements for Test Control			Assigned to Field Offices
	GENERAL (0214) AMPLIFICATIONS			
11.1	Uncertainty and Error			Assigned to Field Offices
11.2	Test Planning	DOE/EM/WO/02 (Section 12.0)	Quality Assurance Program Description	Assigned to Field Offices
12	CONTROL OF MEASURING AND TEST EQUIPMENT			
12.0	General			Assigned to Field Offices
	• NQA-1, BR-12, Control of Measuring and Test Equipment			Assigned to Field Offices
	• NQA-1, 12S-1, Supplementary Requirements for Control of Measuring and Test Equipment			Assigned to Field Offices
	GENERAL (0214) AMPLIFICATIONS			
12.1	Calibration Standards			Assigned to Field Offices

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
13	HANDLING, STORAGE, AND SHIPPING	DOE/EM/WO/02 (Section 13.0)	Quality Assurance Program Description	Assigned to Field Offices
13.0	General			
	<ul style="list-style-type: none"> NQA-1, BR-13, Handling, Storage, and Shipping 			Assigned to Field Offices
	<ul style="list-style-type: none"> NQA-1, 13S-1, Supplementary Requirements for Handling, Storage, and Shipping 			Assigned to Field Offices
13.0 (B)	APPENDIX B			
	AMPLIFICATIONS OF QARD SECTION 13-HANDLING, STORAGE, AND SHIPPING			
13.1 (B)	Archival Samples			Assigned to Field Offices (non-radioactive qualification samples only)
14	INSPECTION, TEST, AND OPERATING STATUS	DOE/EM/WO/02 (Section 14.0)	Quality Assurance Program Description	
14.0	General			Assigned to Field Offices
	<ul style="list-style-type: none"> NQA-1, BR-14, Inspection, Test and Operating Status 			Assigned to Field Offices

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
14.1	GENERAL (0214) AMPLIFICATIONS Sequence of Operations			Assigned to Field Offices
15	CONTROL OF NONCONFORMING ITEMS			
15.0	General	DOE/EM/WO/02 (Section 15.0),	Quality Assurance Program Description	
	• NQA-1, BR-15, Control of Nonconforming Items			
	• NQA-1, 15S-1, Supplementary Requirements for Control of Nonconforming Items	SPP 5.01,	Deviations and Corrective Actions	
		SPP 5.03,	Stop Work Orders	
	GENERAL (0214) AMPLIFICATIONS			
15.1	Closure	SPP 5.01	Deviations and Corrective Actions	
15.2	Nonconformance Disposition	SPP 5.01	Deviations and Corrective Actions	

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
16	CORRECTIVE ACTION			
16.0	General	DOE/EM/WO/02 (Section 16)	Quality Assurance Program Description	
	• NQA-1, BR-16, Corrective Action	DOE/EM/WO/02 (Section 16)	Quality Assurance Program Description	
	GENERAL (0214) AMPLIFICATIONS			
16.1	Trend Analysis	SPP 10.01	Analysis of Adverse Quality Trends	
16.2	Corrective Actions for Significant Conditions Adverse to Quality	DOE/EM/WO/02 (Para. 16.1.1)	Quality Assurance Program Description	
		and SPP 5.01	Deviations and Corrective Actions	
16.3	Deficiencies	SPP 5.01, SPP 5.07	Deviations and Corrective Actions Evaluation and Assessment Commitment Tracking and Reporting System	
16.4	Remedial Action	SPP 5.01	Deviations and Corrective Actions	
17	QUALITY ASSURANCE RECORDS			

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DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
17.0	General <ul style="list-style-type: none"> NQA-1, BR-17, Quality Assurance Records General <ul style="list-style-type: none"> NQA-1, 17S-1, Supplementary Requirements for Quality Assurance Records GENERAL (0214) AMPLIFICATIONS	DOE/EM/VO/02 (Section 17.0),	Quality Assurance Program Description	
		SPP 7.01 and	Preparation, Transfer and Receipt of Quality Records	
		SPP 7.02	Quality Records Management	
17.1	QA Records	SPP 7.01	Preparation, Transfer and Receipt of Quality Records	
		and SPP 7.02	Quality Records Management	
17.2	QA Training and Qualification Records (DOE System 80)	DOE/EM/VO/02 (Section 17)	Quality Assurance Program Description	
17.0	APPENDIX B AMPLIFICATION OF QARD SECTION 17- QUALITY ASSURANCE RECORDS			
17.1 (B)	Product Certification			Assigned to Field Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
17.2 (B)	Determination of Quality Assurance Records	DOE/EM/WO/02 (Para. 17.1.1)	Quality Assurance Program Description	Assigned to Field Offices
17.3 (B)	Production Documentation			

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
18	AUDITS			
18.0	General <ul style="list-style-type: none"> • NQA-1, BR-18, Audits • NQA-1, 18S-1, Supplementary Requirements for Audits GENERAL (0214) AMPLIFICATIONS	DOE/EM/WO/02 (Section 18.0)	Quality Assurance Program Description	
18.1	Technical Considerations	SPP 3.03 and SPP 4.01	Qualification of Quality Assurance Audit Personnel Planning & Scheduling of Evaluation Activities	
18.2	Analysis of Audit			
18.3	Internal Audit Scheduling	SPP 4.01, SPP 4.02,	Planning & Scheduling of Evaluation Activities Administration and Conduct of Quality Assurance Audits	
18.4	External Audit Scheduling	SPP 4.01 SPP 4.02,	Planning & Scheduling of Evaluation Activities Administration and Conduct of Quality Assurance Audits	

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
18.0	APPENDIX B			
	AMPLIFICATION OF QARD SECTION 18.4 - QUALITY ASSURANCE AUDITS			
18.1 (B)	Planning and Certification	SPP 4.02	Administration and Conduct of Quality Assurance Audits	
18.2 (B)	Audit Team Selection	SPP 4.02	Administration and Conduct of Quality Assurance Audits	
19	COMPUTER SOFTWARE			
19.0	Application of Requirements			Assigned to Field Offices
19.1	Computer Software Quality Assurance Plan (SQAP)			Assigned to Field Offices
19.2	Computer Software Verification and Validation			Assigned to Field Offices
19.3	Verification			Assigned to Field Offices
19.4	Validation			Assigned to Field Offices
19.5	Computer Software Configuration Management			Assigned to Field Offices
19.6	Qualification of Existing Software			Assigned to Field Offices
19.7	Documentation			Assigned to Field Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

ATTACHMENT 1

DOCUMENTS THAT IMPLEMENT THE REQUIREMENTS OF DOE/RW-0214 QUALITY ASSURANCE PROGRAM INDEX

REQUIREMENT IN RW-0214		IMPLEMENTING DOCUMENT *		
RW-0214 SECTION	TITLE	DOCUMENT NUMBER	TITLE	REMARKS
19.8	Reviews			Assigned to Field Offices
19.9	Discrepancy Reporting and Corrective Action			Assigned to Field Offices
19.10	Media Control and Physical Security			Assigned to Field Offices
19.11	Acquired Computer Software			Assigned to Field Offices
19.12	Computer Software Application			Assigned to Field Offices
19.13	Exceptions to ASME NQA-1, 1989 Edition			Assigned to Field Offices

* Documents listed as "implementing" do not necessarily indicate a one-to-one relationship with the specific requirements listed in the 0214 "Requirements" column, but are document(s) that either address the listed requirement(s), delegate the requirement(s) to a lower organization, are the implementing procedures; or are a combination thereof.

QA

AUDIT REPORT**HQ-91-003**

memorandum

DATE OCT 25 1991

REPLY TO
ATTN OF RW-3

SUBJECT- Report of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit HQ-9-003 on the Vitrification Projects Branch (EM-343)

TO Chief, Vitrification Projects Branch
Office of Waste Operations, EM-343

Reference: Memorandum from EM-30 to Donald G. Horton dated October 4, 1991, "Stop Work on the Vitrification Projects Technical Review Groups"

Attached is the report for QA Audit HQ-91-003. The audit was conducted by the OCRWM Headquarters QA Division at EM-343 facilities in Germantown, MD on August 26-30, 1991.

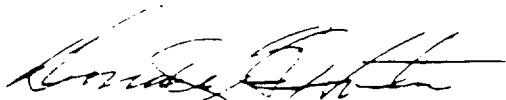
During the course of this audit, the audit team generated nine Corrective Action Requests (CARs) documenting deficient conditions and eight observations of areas where EM-343 might improve their QA program.

Because of the collective severity of the deficiencies found during the audit, EM-30 took the initiative to stop work by the Vitrification Projects Technical Review Groups on October 4, 1991, (see referenced memorandum). RW-3 believes that the actions to be completed prior to lifting the stop work, as given in the referenced memorandum, need to be supplemented to support OCRWM needs. It is requested that EM-343 provide a more detailed list of prerequisite actions necessary to resume work. This list should take into consideration approved responses to open OCRWM CARs, as appropriate, previously issued to EM-343. It is also requested that EM-343 transmit to this office, for the record, documented evidence that this "stop work" is being controlled under the EM QA program (DCAR, etc.). Also, during the period of the stop work, OCRWM OQA representatives shall:

- o participate in all verification activities (e.g., audits, surveillances and assessments) performed by EM-343, and
- o prior to lifting the stop work, verify completion of all agreed to prerequisite actions.

Responses to the CARs (which were transmitted via separate letter) are due by the date indicated in block ten of the CARs. A response to this audit report is not necessary. The subject audit is considered completed as of the date of this letter; however, any open CARs will continue to be tracked until they have been closed to the satisfaction of the audit team leader and the Director, OQA.

If you have any questions, please contact Bob Clark or myself at (202) 586-8858.


Donald G. Horton, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management

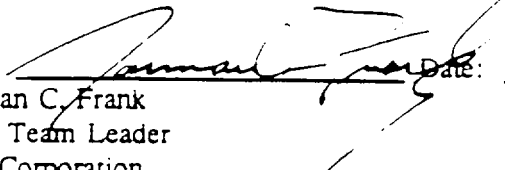
Attachments

cc:

S. Cowan, EM-30
M. Frei, EM-34
J. Hennessey, EM-343
K. Chacey, EM-343
F. Peters, RW-2
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J. Buckley, NRC, Washington, D.C.
R. J. Brackett, TESS, HQ (RW-3) FORS


U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT REPORT
OF
EM-343, VITRIFICATION PROJECTS BRANCH
AUDIT NO. HQ-91-003
AUGUST 26 THROUGH AUGUST 30, 1991

Prepared by:


Norman C. Frank
Audit Team Leader
CER Corporation

Date: 10/22/91

Approved by:


Donald G. Horton
Director
Office of Quality Assurance

Date: 10/22/91

EXECUTIVE SUMMARY

The audit team concluded that, in general, the quality assurance program for the Vitrification Projects Branch, EM-343, was not being fully implemented and for this reason was determined to be "not effective." Two of the 11 criteria audited were found to be effective. Two criteria were found to be indeterminate because insufficient work had been done to allow an evaluation. Seven criteria were found to be "not effective" for the work done. Nine Corrective Action Requests resulted from this audit. In addition, eight observations are presented to the auditee for consideration.

As a result of discussions among RW-3, EM-30 and EM-343 management, EM-30 has taken limited stop work action. Because of the general lack of compliance with the quality assurance program, the infrastructure needed to support the technical review activities is not adequate. Work on the technical review activities has been stopped until specified actions to ensure compliance with the quality assurance program and establish the infrastructure needed to support the technical activities have been taken. EM-343 has agreed to keep OCRWM apprised of the status of completion of prerequisite actions to resume work in this area.

1.0 Introduction

The Office of Civilian Radioactive Waste Management (OCRWM) performed a quality assurance audit (number HQ-91-003) of the Vitrification Projects Branch (EM-343) of the Waste Operations Division of the Office of Environmental Restoration and Waste Management. The audit was conducted by an audit team from the Headquarters Quality Assurance Division (HQAD) of the Office of Quality Assurance (OQA). The audit was performed in accordance with Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program," and the associated audit plan [reference letter from RW-3 to Associate Director, EM-30, dated July 29, 1991, "Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit HQ-91-003 of the Vitrification Projects Branch (EM-343)"].

2.0 Audit Scope

The audit evaluated compliance to and the effectiveness of the EM-343 QA program as described in the Environmental Restoration and Waste Management (EM) Quality Assurance Program Description (QAPD), DOE/EM/WO/01 and DOE/EM/WO/02 and their associated Standard Practice Procedures (SPPs).

The adequacy of the QAPD was evaluated separately and was not included as a component of this audit (Reference DOE letter from RW-3 to Chief, Vitrification Projects Branch, EM-343, dated April 8, 1991, "Review of EM QAPD, Revision 0"). The adequacy of the SPPs (revision 0) was not reviewed in detail because of the already identified weaknesses in the EM QAPD.

No previous audits of EM-343 had been performed by OCRWM. Although three surveillances had been performed by OCRWM within the past two months, only one surveillance report had been issued and EM-343 had not had time to respond to the report. The results of these surveillances (HQ-SR-91-011, HQ-SR-91-016, and HQ-SR-91-014) were taken into account when auditing the following SPPs:

- SPP 3.04, "Documentation of Surveillance and Review Personnel Qualifications" - qualifications of review personnel only
- SPP 4.05, "Administration of Technical Reviews"
- SPP 4.06, "Conduct of Technical Reviews"
- SPP 4.11, "Review of Waste Acceptance Process Technical Documents"
- SPP 4.12, "Review of Program Execution Guidance Documents"
- SPP 7.01, "Preparation, Transfer, and Receipt of Quality Records"
- SPP 7.02, "Quality Records Management"

The following procedure was not included in the audit because it was determined that it had been adequately covered during surveillance HQ-SR-91-014:

- SPP 3.03, "Certification of Quality Assurance Audit Personnel"

The programmatic elements audited are identified below:

QA PROGRAM ELEMENTS

- 1 - Organization
- 2 - Quality Assurance Program
- 3 - Design Control (including software and scientific investigation)
- 4 - Procurement Document Control
- 5 - Instructions, Procedures, and Drawings
- 6 - Document Control
- 7 - Control of Purchased Items and Services
- 15 - Control of Nonconforming Items
- 16 - Corrective Action
- 17 - Quality Assurance Reports
- 18 - Audits

The following programmatic elements were not reviewed during the audit because they are not included within the scope of the EM quality assurance program and no work had been done in these areas:

- 8 - Identification and Control of Items
- 9 - Control of Processes
- 10 - Inspection
- 11 - Test Control
- 12 - Control of Measuring and Test Equipment
- 13 - Handling, Storage, and Shipping
- 14 - Inspection, Test, and Operating Status

The audit of implementation and statements of effectiveness were based on the issued revisions of the QAPD and SPPs at the time of the audit.

The audit of technical areas was limited to a review of:

- 1. Qualifications of technical personnel
- 2. Understanding of procedural requirements as they pertain to the development and qualification of waste forms.

3.0 Audit Team and Observers

The following is a list of audit team members and observers.

Audit Manager Robert W. Clark
Audit Team Leader Norman C. Frank

DOE, Washington, D.C.
CER Corp., Arlington, VA

Auditors	R. Dennis Brown	CER Corp., Arlington, VA
	Robert G. Thomas	CER Corp., Arlington, VA
	Craig G. Walenga	CER Corp., Arlington, VA
	Clyde D. Morell	CER Corp., Arlington, VA
	Thomas E. Rodgers	CER Corp., Arlington, VA
	Louis Wade	WESTON, Washington, DC
Observers	John T. Buckley USNRC	
	James T. Conway	USNRC
	Frank E. Nash	Duke Eng/TESS

4.0 Summary of Audit Results

4.1 Program Effectiveness

The audit team concluded that, in general the quality assurance program for EM-343 was not being fully implemented and for this reason was determined to be "not effective." Two of the 11 criteria audited were found to be effective. Two criteria were found to be indeterminate because insufficient work had been done to allow an evaluation. Seven criteria were found to be "not effective" for the work done. Nine Corrective Action Requests resulted from this audit. In addition, eight observations are presented to the auditee for consideration.

4.2 Stop Work Action

As a result of discussions among RW-3, EM-30 and EM-343 management, EM-30 has taken limited stop work action. Because of the general lack of compliance with the quality assurance program, the infrastructure needed to support the technical review activities is not adequate. Work on the technical review activities has been stopped until specified actions to ensure compliance with the quality assurance program and establish the infrastructure needed to support the technical review activities have been taken. EM-343 has agreed to keep OCRWM apprised of the status of completion of prerequisite actions to resume work in this area.

4.3 Programmatic Audit Activities

Details of programmatic audit activities are provided in Attachment 1. A list of objective evidence reviewed during the audit is provided in Attachment 2.

4.4 Technical Activities

The qualifications of review personnel were evaluated during the audit. EM personnel's understanding of procedural requirements as they pertain to the development and qualification of waste forms was also evaluated during the audit. The results are included in this report.

4.5 Summary of Deficiencies

The audit team identified numerous deficiencies during the audit. These were consolidated into nine CARs. A synopsis of the CARs and observations is presented in Section 6.0. Information copies of the draft CARs are included in Attachment 3.

Of the nine CARs written, three represented significant failures of the EM personnel to understand and implement the quality assurance program, one represented insufficient definition of the quality assurance program, and five represented deficiencies in the implemented portion of the quality assurance program.

5.0 Audit Meetings and Personnel Contacted

The preaudit conference was held at EM-343 offices in the Trevion II building in Germantown, MD on August 26, 1991. A daily debriefing and coordination meeting was held with EM-343 management and staff. The postaudit conference was held in the Trevion I building in Germantown, MD on August 30, 1991. A list of personnel involved in the audit is included in Attachment 4.

6.0 Synopsis of Corrective Action Requests Issued and Observations Noted

6.1 Corrective Action Requests (CARs)

- HQ-91-035 Personnel demonstrated a general lack of compliance with the issued Standard Practice Procedures.
- HQ-91-036 The training program was inadequate and ineffective.
- HQ-91-037 No management assessments or internal QA program audits of EM-343 had been completed.
- HQ-91-038 The QARG-1 (SPP) did not: a) comply with the applicable SPPs or its own charter, nor b) adequately review the draft revision 1 or draft revision 0 SPPs.

- HQ-91-039 EM-343 has not established and implemented a systematic method for defining the work that is subject to the EM-343 QA program requirements. SPP 2.05, "Selective Application of Quality Assurance Activities," was not issued at the time of the audit. No method existed for the selective application of QA activities to EM-343 work.
- HQ-91-040 The EM-343 Branch Chief had not designated a person to fill the HLW Quality Assurance Program Manager position.
- HQ-91-041 Deficiencies identified in Surveillance Report 91EA-VP-S-003, dated 6/14/91, were not documented on deviation reports. In addition, no action had been taken to correct the identified deficiencies. The deficiencies had been included in the Quality Improvement Log rather than being documented on deviation reports. The surveillance report had not been "accepted" by EM-343.
- HQ-91-042 The administrative support contract for BDM does not require BDM to perform work in accordance with the SPPs or the EM-343 QAPD.
- HQ-91-043 EM-343 has not reviewed and accepted the West Valley or Richland Office implementing procedures.

6.2 Observations/Recommendations

1. Several of the existing SPPs are concerned with topics of an administrative/program management nature that, although needed, do not have to be included within the scope of the quality assurance program, yet are shown in the EM QAPD requirements matrix as being necessary to satisfy DOE/RW-0214 (QARD). These procedures are fairly prescriptive, and any flexibility in their implementation is forfeited by maintaining them as procedures that affect quality. Because they are auditable, implementation and compliance problems are inevitable. EM-343 should consider removing the following procedures from the EM QAPD requirements matrix:

- SPP 6.01 "Official HLW Office Files"
- SPP 6.02 "Preparation of Correspondence"
- SPP 6.03 "Incoming Mail"
- SPP 6.04 "Commitment Control"
- SPP 9.01 "Preparation and Maintenance of the Program Schedules"
- SPP 9.02 "HLW Monthly Progress Reporting"
- SPP 9.03 "Preparation and Maintenance of the Work Breakdown Structures (WBS)"

2. The procedures for corrective action, including the Deviation and Corrective Action Report (DCAR), quality improvements, and trending systems should be evaluated for unnecessary overlap of system function and definition of applicability. Consolidation of procedures with significant overlap is recommended.
3. Deficiencies identified during audits of the Savannah River Operations Office are not being promptly corrected. The response to DCARs issued as a result of a February 1991 audit was only recently received. Several DCARs from the June 1990 audit remain open. The audit team recognizes that considerable effort by EM has been made to obtain responses from Savannah River, but the audit team also recognizes that the responsibility rests with EM-343 for timeliness and for adequacy of responses.
4. The audit team was informed that the EM-343 working files are to contain a complete set of the working documents. However, the audit team identified numerous instances where complete working files were not present. Examples are:
 - personnel qualification and certification records for the WVDP technical review groups
 - complete working files for such areas as complete DCARs and completed audit checklists
 - training and qualification records for some audit team members.

The audit team recognizes that EM is now in the process of completing the working files.
5. The qualifications of two technical specialists used on audit 91EA-WV-AU-001 were reviewed. While their overall qualifications were excellent, a concern exists that the two technical specialists were not qualified for the areas of review that they were assigned. One technical specialist was assigned to sections 1, 2, 16, and 18 of the West Valley QAPD while the other technical specialist was assigned to sections 3, 5, 6, 10, 17, and 19. Since the audit report was deficient in addressing exactly what was audited, and the completed checklists of these two technical specialists were not available to the audit team, this concern could not be resolved. EM-343 should ensure that the qualifications of future technical specialists match the expertise needed to review areas assigned. It is further recommended that technical specialists be used to review the adequacy of work products and work performed.
6. The PEGD provides requirements to be met by the Operations Offices' QAPDs. The guide sheets (review plans) for the EM-343 reviews of Operations Office QAPDs do not list the PEGD as one of the base documents to be used during the review.

7. A trend analysis of DCARs has not been performed. There are approximately 40 DCARs that could be analyzed for trends. The audit team recognizes that a new system to track and analyze DCARs is now being developed.
8. There is no objective evidence that the Richland Operations Office has been sending quarterly "QA and Safety Status Reports" to EM-30 as required by the PEGD.

7.0 Required Actions

Responses to the CARs were requested in a separate memorandum that formally transmitted the CARs to EM-30. Responses will be evaluated and followup action will be performed in accordance with QAAP 16.1, "Corrective Action."

Responses to the recommendations are not required, but appropriate management attention and action should be taken.

8.0 List of Attachments

- Attachment 1: Audit Details
- Attachment 2: List of Objective Evidence Reviewed During the Audit
- Attachment 3: Information Copy of Draft CARs
- Attachment 4: Personnel Involved in the Audit

ATTACHMENT 1

Audit Details

The following is a summary of programmatic activity covered during the audit. A list of objective evidence reviewed during this audit and the full document identification number, revision status, and title for Standard Practice Procedures (SPPs) referenced below are given in Attachment 2.

1.0 Organization

The evaluation of Criterion 1 was based on personnel interviews and a review of the current organizational structure. The areas evaluated included:

- Organizational Responsibilities and Authority
- External and Internal Interfaces
- Differing Staff Opinions and Allegations (SPP 10.03)
- Control of Unsatisfactory Conditions (Stop Work Orders) (SPP 5.03)

The organization as depicted in the QAPD does not accurately describe lines of responsibilities and authority for the implementation of Standard Practice Procedures nor does it accurately describe the interfaces with other organizations, for example, EM-1, EM-20, EM-30, RW, WAC, MSC. This concern had been previously addressed in the formal comment review of the DOE/EM/WO/02 (QAPD) Rev.0.

The SPPs use titles for the "performer" that have not been defined within the EM-343 organization. Examples include: SPP Coordinator, Manager (Project or EM-343?), Approver, and Organizational Director (there is no "Director" in EM-343). As a consequence, personnel interviewed were unsure who was to perform the specified actions.

Deficiencies identified were included in Corrective Action Request HQ-91-035 and HQ-91-040.

An evaluation of SPP 10.03, "Differing Staff Opinions and Allegations," concluded that personnel are aware of the procedure and have been indoctrinated, however, to date no differing opinions or allegations have been identified.

An evaluation of SPP 5.03, "Control of Unsatisfactory Conditions (Stop Work Order)," concluded that to date, stop work authority had not been exercised. In addition, the evaluation revealed that no indoctrination or training had been presented to EM-343 personnel on SPP 5.03.

Based on the facts that organizational interfaces are not clearly defined and performers identified in SPPs have not been defined, Criterion 1 is found to be not effective in its implementation.

2.0 Quality Assurance Program

The evaluation of Criterion 2 was based on personnel interviews and review of objective evidence. The evaluation included:

- QA Program Documentation.
- Indoctrination and Training of Personnel
- Qualification and Certification of Personnel
- Surveillance and Assessments
- Review and Reporting of QA Program Status

The evaluation identified the following deficiencies that were included in Corrective Action Requests resulting from the audit.

1. Indoctrination and training (CAR HQ-91-036)
 - There were provisions for ensuring that people performing quality-affecting activities are indoctrinated/trained prior to performing the activity.
 - Of the 43 SPPs issued to implement the QA Program, only 16 have been identified as requiring indoctrination/training.
 - Lesson plans were not approved by the QA Specialist or the manager (Branch Chief) as required by procedure.
 - Personnel were not indoctrinated/trained on procedures for which they have responsibility to implement.
2. No annual assessments have been performed to date (CAR HQ-91-037).
3. Deviations identified in EM-343 Surveillance Report 91EA-VP-S-003 were not documented on deviation reports (CAR HQ-91-041).
4. The audit team evaluated the qualifications of the reviewers. Deficiencies were identified and included in CAR HQ-91-036. The evaluation of audit and surveillance personnel qualifications had been previously addressed in Surveillance Report HQ-SR-91-014 and resulted in the issuance of CAR HQ-91-034. However, the reviewers qualifications were not evaluated during the surveillance.

The following SPPs could not be audited due to insufficient activities occurring to demonstrate implementation:

- SPP 8.01, "Coordination of Reviews and Evaluation by Outside Organizations"
- SPP 9.01, "Preparation and Maintenance of the Program Schedules"
- SPP 9.02, "HLW Monthly Progress Reporting"
- SPP 9.03, "Preparation and Maintenance of the Work Breakdown Structure"
- SPP 10.01, "Identification and Analysis - Trends"

Based on the numerous instances of procedural noncompliance identified during the audit, Criterion 2 has been found to be not effective in its implementation.

3.0 Design Control

The implementation of SPPs related to design control were reviewed as follows:

SPP 4.05, "Administration of Technical Reviews", Rev. 0; and
SPP 4.06, "Conduct of Technical Reviews", Rev. 0

The audit team conducted interviews with the WVDP Program Manager and the Tech. Rev. Manager regarding the implementation of the SPPs.

The audit team reviewed the statement of work for both the WVDP Waste Form Compliance Plan (WCP) #1 and the WVDP Waste Form Qualification Report (WQR) #3. In addition, the Technical Review Group charter was reviewed for the WVDP WCP#1. The Review Log for the TRG Waste Acceptance Activities and the WVDP WQR TRG Log Sheet were also reviewed. The TRG Review and Comment Records were reviewed. In all cases, it appeared that the implementation of the two TRGs had been conducted in accordance with the controlling SPPs. The audit team considered that adequate review criteria existed between the statement of work and the TRG charter to support a meaningful review.

It was not possible to verify the qualifications and experience of the TRG review team due to the fact that those records were currently retained by the TRG Executive Secretary at Argonne National Laboratory. EM-343 personnel could not locate duplicate copies of these records in the working files for the subject TRGs.

Based on discussions held with the Assistant Program Manager for WVDP, it was determined that the EM-343 level of activity regarding facilities, software, and scientific investigation was in its beginning stages and did not yet warrant review. Consequently, the effectiveness of the implementation of Criterion 3 is not determinate.

4.0 Procurement Document Control

EM-343 has two types of procurement documents. The Program Execution Guidance Document (PEGD) is used to transmit EM-343 technical and QA requirements to West Valley, Hanford, and Savannah River Operations Offices. It was already identified in an

earlier surveillance that EM-343 was not reviewing the PEGD in accordance with Standard Practice Procedure (SPP) 4.12. The PEGD (FY1991) was found to be inadequate because the requirements of DOE/RW-0214 were not included in the PEGD.

The other procurement vehicle is a contract. EM-343 has a direct support services contract with BDM Corporation. The BDM/SAIC support team was under the direct supervision of EM-343 personnel. The audit team could not verify that support team personnel were contractually required to work to the QAPD or the SPPs. CAR HQ-91-042 was written for this deficiency.

The only other activity reviewed under this criterion was the work performed by PDC personnel. It was determined that PDC personnel are receiving contractual direction from the Richland Operations Office and technical direction from EM-343.

Based on the above, procurement document control was found to be not effective in its implementation.

5.0 Instructions, Procedures, and Drawings

The audit team reviewed the working files of seven revision 0 SPPs. The files were available at the PDC-Germantown offices. Each working file was neatly maintained and contained a copy of the original DWTM-HLW version of the respective SPP, an instruction file index for the working file, an approved-original section, an instruction coordination log section, a memo to file, a reviewer comment and disposition section, and a reference material section. For each of the seven working files, the instruction file index sheet was not completed, there was no approved original SPP in the working file, the coordination log had not been completed, and the reviewer comment and disposition forms were in various stages of completeness with no one form fully completed. These working files are to be maintained by the SPP Coordinator, who was identified as PDC. Numerous violations of SPP 2.01 requirements were noted in reviewing the incomplete working files. These procedural noncompliance problems have been addressed in CAR HQ-91-035.

The audit team was informed that though the SPPs were issued in February 1990 the entire process of procedural development and review was done prior to the approval of SPP 2.01, which accounts for the incompleteness of the working files. It appeared to the audit team that the completeness of the revision 0 SPP working files was a low priority to the SPP Coordinator as draft revision 1 SPPs have already been written and reviewed.

Criteria for the review of the SPPs were not found though an after-the-fact informal review of the SPPs against the DOE/RW-0214, QARD, Rev. 2, Requirements Matrix was performed.

The audit team did not find evidence in the working files that any EM-343 staff member was involved in the formal review process for the revision 0 and draft revision 1 SPPs audited.

A check for the establishment of any quality records packages showed that only the issued SPPs have been set up as quality records while the remaining quality records required by SPP 2.01 have not been created due to the incompleteness of the working files.

The audit team evaluated the preparation of the 47 draft SPPs of which most were modifications to the revision 0 SPPs. SPP 2.01 revision 0 was used to determine compliance. The same SPPs selected for the revision 0 review were selected for the revision 1 review along with SPP 2.05. The working files of these SPPs were presented to the audit team. The working files were similar in nature in that they contained something called a "document traveller" which replaced the SPP coordination log that had been used previously for revision 0 SPP working files. In general, the document traveller contained or could contain the information required by SPP 2.01 for each SPP. The document traveller identified the author of the SPP or SPP revision and had the signatures or initials of the reviewers. It was noted that for four SPPs of the eight evaluated, the author of the SPP was also listed as a reviewer.

The audit team did not find evidence that any EM-343 staff member was involved in the formal review process of the draft SPPs reviewed.

No reviewer comments or resolutions of the comments were present in the working files. Though SPP 2.01 revision 0 requires the maintenance of reviewer comments and comment resolutions, the SPP Coordinator stated that reviewer comments were no longer being kept although some [an unknown quantity] completed forms may still be available in Oak Ridge. After a review of the draft SPP 2.01 revision 1, the auditors noted that the SPP Coordinator was not complying with the existing SPP 2.01 revision 0 but was basically implementing the unapproved process described in draft SPP 2.01 revision 1.

While discussing the adequacy of these reviews, the PDC SPP Coordinator and support personnel informed the audit team that SPPs were also reviewed by a QARG and the documentation of their review comments and comment resolutions would show a thorough review. The audit team attempted to establish if the QARG review represented a quality assurance program review or was actually a management function that was performed outside of the quality assurance program because the EM-343 QAPD and the SPPs did not address this review group. The EM-343 Branch Chief informed the audit team that the QARG review of the SPP was done to meet the review requirements of the SPPs. The audit team was first told that the QARG review was not performed to comply with any SPP but was done in accordance with a charter. Later, SPPs 4.05 and 4.06 were identified as the applicable SPPs for the QARG. The charter and review documentation were provided to the audit team. It was noted that two members of the QARG-1 (SPP) were not members of the core group listed in the charter.

The adequacy of the QARG-1 (SPP) review was assessed based on the documentation provided in a March 5, 1991 letter from M.H. Campbell to W.J. Kehew that contained the agenda for the QARG-1 (SPP) meeting, review criteria, and the SPP review assignments. The results are included in CAR HQ-91-038.

To evaluate the adequacy of the QARG-1 (SPP) review, the audit team reviewed the draft SPP 2.01 revision 1 and draft SPP 2.05, revision 0 that had been reviewed by the QARG-1 (SPP) for compliance with DOE/RW-0214, QARD. The results are included in CAR HQ-91-038.

Based on the numerous instances of procedural noncompliance and inadequate reviews identified during the audit, Criterion 5 has been found to be not effective in its implementation.

6.0 Document Control

The audit team attempted to verify that the requirements contained within the EM QAPD for Document Control were adequately reflected within the SPPs to ensure adequate implementation. Several instances were identified in which QAPD requirements were not contained within the SPPs, thus jeopardizing their implementation. No objective evidence could be found that the following QAPD requirements had been satisfied:

The QA Program Manager and the QA Specialists have reviewed the document control system and have confirmed its readiness to function prior to implementation (Para. 6.1.1).

Controlled documents have been reviewed for adequacy by the QA Program Manager (Para. 6.1.3).

The Branch Chief has established an appropriate review schedule for the accepted controlled document (Para. 6.1.3).

The QA Program Manager participates in and monitors the execution of the document control system (Para. 6.1.5).

These results are not included in a CAR but are expected to be addressed in the next revision to the SPPs. The SPPs will be revised to also address changes to the QAPD necessitated by upgrading to meet Revision 4 of the QARD and to address deficiencies identified in the HQ review of the EM QAPD.

SPP 2.03, "Quality Assurance Program Description Preparation, Maintenance, and Control", Rev. 0

The audit team interviewed the PDC Program Manager and a BDM QA Support person regarding the implementation of SPP 2.03.

The audit team reviewed the working file for the preparation of the EM QAPD DOE/EM/WO/02, Rev. 0 which is currently in effect. The development of the QAPD appeared to comply with the requirements contained within the SPP. The establishment of formal review and acceptance criteria was not as formalized as it could have been. The Quality Assurance Review Group (QARG) used the review matrix for the NRC Standard

Review Plan and the 0214 Document for their review criteria. The EM-343 internal reviewers used an internal letter from the Branch Chief which basically stated to review the document relative to their areas of responsibility. Although the criteria provided could have been more specific, they are considered to have met the intent of the SPP. An opportunity exists for management to establish more definitive review and acceptance requirements for the upcoming Rev. 1 to the EM QAPD.

The audit team reviewed the Review and Comment Records as well as the annotated drafts. In all cases, comments appeared to have been adequately resolved. Mandatory comments were initialed by each reviewer indicating acceptance of the resolution.

The audit team reviewed the control and distribution of the EM QAPD. A distribution list, approved by the PDC Program Manager, was in effect. The list had been most recently revised on 8/26/91 to reflect two recent additions. The Document Transmittal/Receipt forms were randomly compared against the Distribution List to verify accuracy. No problems were noted. Two sets of EM-343 QAPDs were randomly pulled and verified to be accurately reflected on the Distribution List and the Transmittal/Receipt Forms.

SPP 2.04, "Control of the Standard Practice Procedures Manual", Rev. 0

The audit team interviewed the PDC Program Manager and a BDM QA Support person regarding the implementation and requirements of SPP 2.04.

PDC is responsible to EM-343 to perform document control responsibilities on their behalf. A PDC Oak Ridge person has been designated as the SPP Coordinator. She maintains the SPP Distribution List, which is approved by the PDC Program Manager. The latest Distribution List was issued 8/26/91 to reflect several current additions. The list appeared to be accurate and was in compliance with the requirements of the SPP. The audit team randomly sampled several individuals to verify distribution was as stated. No revisions have been made to any of the SPPs to date.

The Transmittal/Receipt Memorandums were reviewed to verify acknowledgement. In all but one case, which was still within the allowable 10 day time frame, the forms had been returned and were available for review.

The audit team verified that PDC Oak Ridge SPP Coordinator had received training on SPP 2.04.

SPP 2.05, "Selective Application of QA Activities", Rev. 0

This SPP existed in a draft form but had not yet been issued. As a result, no mechanism was in existence to support the implementation of the QAPD requirement [Paragraph 2.7.1.(1)] for the selective application of QA controls. This is included in CAR HQ-91-039.

SPP 6.01, "Official HLW Office Files", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary and a BDM QA Support person relative to the implementation and requirements of SPP 2.01. Both individuals demonstrated adequate knowledge of the procedure.

EM-343 Branch Chief has designated in writing his secretary as File Administrator. File numbers have been assigned to the HLW Office Files in accordance with DOE Order 1324.3 and Attachment A of the SPP. Alterations, additions, and deletions are tracked and reflected in periodic revisions to the file index. It was verified that the File Administrator had received training on SPP 6.01.

SPP 6.02, "Preparation of Correspondence", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary regarding the implementation and associated requirements of SPP 6.02. The Secretary was adequately familiar with the SPP requirements.

EM-343 outgoing correspondence is prepared within the guidelines of DOE Order 1325.1A and SPP 6.02, Attachment A. The following three letters were reviewed for compliance to the guidelines:

- EM-343 to the Secretary dated 8/16/91
- EM-343 to Murial Scarborough, PR-23, dated 8/16/91
- EM-343 to Corinne Macaluso, RW-331, dated 7/30/91

The above correspondence was found to comply with procedural requirements.

SPP 6.03, "Incoming Mail", Rev. 0

The implementation of SPP 6.03 was not verified because: 1) this SPP is scheduled for cancellation in the next revision, and 2) the process described is not necessary to be contained within the scope of the QA Program.

SPP 6.04, "Commitment Control", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary relative to the implementation of SPP 6.04. She was adequately familiar with the requirements of the SPP.

Several instances of procedural noncompliance were identified. These deficiencies are supporting elements for CAR HQ-91-035, which addresses the issue of procedural noncompliance.

The audit team verified that the Secretary had received training on SPP 6.04.

The audit team noted that SPP 6.01, SPP 6.02, SPP 6.03, and SPP 6.04, although necessary from an administrative standpoint, are not required to be included within the scope of the QA program.

SPP 6.05, "Controlled Documents", Rev. 0

The audit team interviewed PDC Program Manager and a BDM QA Support person regarding the implementation of SPP 6.05.

PDC, in the role of a direct support contractor to EM-343, performs the document control functions.

Controlled Document Master Lists have been developed and are maintained by PDC for each individual assignee. A sample of these lists was selected for the three EM-343 Program Managers and verified to be accurate regarding the controlled documents they actually had in their possession.

The audit team verified that the BDM SPP Coordinator and a BDM QA Support person had received training on SPP 6.05.

Although minor instances of noncompliance were noted with several administrative SPPs, controlled documents were found to be current and no obsolete/superseded procedures were found. Criterion 6 is considered to be effectively implemented.

7.0 Control of Purchased Items and Services

EM-343 oversees the quality affecting activities at the Operations Offices by reviewing their QAPDs and implementing procedures and by conducting QA audits and surveillance. The audit team evaluated activities in the QAPD and relevant implementing procedures. The log of review activities was current but did indicate several unreviewed documents. The auditors observed that EM-343 was using the QARG to perform the QAPD review required by SPP 4.10. However, these reviews were not performed in accordance with SPP 4.10. The Operations Office QAPDs did not include the requirements of the EM-343 QARD. The review plans did adequately address DOE Order 5700.6B, ASME NQA-1, and DOE/RW-0214. In addition, there was no evidence of DOE Project Managers approving review plans and review team compositions for Hanford and West Valley.

The auditors also reviewed the EM-343 review of Savannah River's QA implementing procedures. The review appears to have been adequate.

Based on the ineffective audit program (see Section 18.0) and the QAPD review irregularities, it can be concluded that Criterion 7 was not effective in its implementation.

15.0 Control of Nonconforming Items

EM-343 uses audits and surveillance to identify nonconforming items and conditions. They use a Deviation and Corrective Action Report (DCAR) form to document these nonconformances. PDC has recently developed a database for EM-343 to track the status of all DCARs and other nonconformances. The database is scheduled to be completed and ready for formal use on September 15, 1991.

The audit team reviewed files for eleven DCARs issued in the last two years. Most of the files were incomplete as the original records were being stored at PDC in Oak Ridge. However, based on records available for review, enough evidence existed to conclude that EM-343 was properly implementing the DCAR system. Criterion 15 is considered to be effectively implemented.

16.0 Corrective Action

EM-343 uses the DCAR form to document the corrective action activities required for nonconformances that are significantly adverse to quality. For the eleven DCARs reviewed the audit, there was not sufficient records to adequately review and evaluate the criterion. The lack of documentation in the working files made Criterion 16 not determinate.

17.0 Quality Assurance Records

Surveillance Report HQ-SR-91-016 covered the quality records system. Corrective Action Request HQ-91-033 issued as a result of this surveillance stated, "A Vitrification Projects Branch quality records system has not been established and implemented, and objective evidence does not exist that an effective quality records system has been implemented for or by any contractor that is required to comply with procedures SPP 7.01 and SPP 7.02."

Based on this surveillance, Criterion 17 was found to be not effective in its implementation.

18.0 Audits

SPP 4.02, "Administration of Quality Assurance Audits", Rev. 0, and SPP 4.03, "Conduct of Quality Assurance Audits", Rev. 0

The audit team assessed the implementation of SPPs 4.02 and 4.03. The third and fourth quarter 1991 evaluation plans were reviewed to verify the scheduling of audits. Audits were scheduled.

The audit team requested the working files for any conducted internal audits and was informed that EM-343 has not performed any internal audits. A CAR HQ-91-037 was written to address this condition.

Only three internal audits have been completed; two audits of Savannah River (SR) and one audit of West Valley (WV). The audit team chose to review the latest SR audit working file and the only West Valley audit working file. The certifications and qualifications of the lead auditors and auditors were not addressed as this area had been reviewed in surveillance HQ-SR-91-003.

Both audit working files contained an audit notification letter, audit plans, copies of the checklists that were to be used, and the audit report. The SPPs do not require the keeping of completed checklists as quality records.

Without the completed checklists as part of a quality records package, both audit reports were reviewed to assess the quality of the audit by evaluating the way the audit was conducted, the evidence reviewed, the assigned reviewers, and the overall conclusions made by the team. Both audit reports lack details as to what was reviewed, the depth and details of the areas reviewed, identification of the auditors to the areas reviewed, and the results of each of the areas audited. What was present was a description of only the negative findings and negative observations and effectiveness statements along with the usual information about the scope, attendees, and preaudit and postaudit conferences. This is contrary to SPP 4.03 Attachment B. This deficiency is included in CAR HQ-91-035.

The completed checklists were requested for the West Valley audit that was completed in June 1991. Only four completed checklists could be found in the working files. The four completed checklists were reviewed for completeness and content. The four checklists reflected various levels of completeness from very good to poor with the checklist of one previously qualified lead auditor being evaluated as poor because the documented information, in most cases, failed to identify who was interviewed and the details as to what was reviewed. The checklist also identified weaknesses that were not found to have been addressed in either the audit checklist or the audit report.

A review of the qualifications of two technical specialists was conducted. The two technical specialists had excellent technical qualifications; however, based on the audit plan and the audit report, it appeared that the technical specialists were either unneeded or were used in areas where they were not qualified or experienced to review. Completed checklists for these two technical specialists were not available for review and the audit report, as previously noted, was deficient in providing any details to support or dismiss this concern. An observation was written to address this concern.

No quality records had been created for the audits that have been performed.

SPP 4.13, "Participation in Evaluation Activities Led by External Organization", Rev. 0

The audit team interviewed an EM-343 QA Specialist and a PDC QA Specialist relative to the implementation of SPP 4.13 and the associated requirements.

EM-343 has participated in only one audit led by an external organization under the SPP 4.13 procedure. The EM-343 QA Specialist was originally scheduled to be the participant. However, just prior to the audit performance, a BDM person was substituted to act as EM-343's representative on the audit. ANL Audit # QA-91-07 was conducted 5/29-31/91. EM-343 took credit for this activity through the participation of the BDM person under Audit # 91-EA-AN-AU-001 of the Chemical Technology Division.

Both the EM-343 QA Specialist and the BDM person had received training on SPP 4.13, which was included in training modules 1, 2, & 3.

The audit team was unable to evaluate the BDM person's qualifications and experience in order to assess adequacy relative to the audit performed. These records were retained at PDC's Oak Ridge Office where he is normally assigned. However, based on interview, he appeared to be adequately experienced and qualified to participate on the audit.

An Audit Summary Report was not completed as required by SPP 4.13 requirements. However, the BDM person did file a Trip Report dated 5/31/91, which provided his assessment of the audit. This report is considered to adequately meet the intent of the Audit Summary Report since it contains the same type of information.

An External Evaluation Participation Record , Parts 1 & 2, had been completed and was contained in the audit working file. A quality records package for Audit # 91-EA-AN-AU-001 had not been prepared at the time of this audit.

Internal audits have not been performed, the audit reports do not contain the information required by the procedure and are insufficient to stand alone, and corrective action from Savannah River has not been received in what the audit team considers a timely manner. Based on this Criterion 18 is found to be not effective in its implementation.

ATTACHMENT 2

List of Objective Evidence Reviewed During the Audit

EM Quality Assurance Program Descriptions (QAPDs)

DOE/EM/WO/01, QAPD for High-Level Waste Processing

DOE/EM/WO/02, QAPD for High-Level Waste Form Development and Qualification

Standard Practice Procedures

- SPP 1.01, "Index of High-Level Waste Standard Practice Procedures for Quality Assurance", Revision 0
- SPP 2.01, "Standard Practice Procedures", Revision 0 and draft Revision 1
- SPP 2.03, "Quality Assurance Program Description Preparation Maintenance, and Control", Revision 0
- SPP 2.04, "Control of the Standard Practice Procedures Manual", Revision 0
- SPP 2.05, "Selective Application of QA Activities Manual", Draft Revision 0
- SPP 3.01, "Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation", Revision 0
- SPP 3.02, "Preparation and Conduct of Personnel Training, Indoctrination, and Orientation", Revision 0
- SPP 3.03, "Certification of Quality Assurance Audit Personnel", Revision 0
- SPP 3.04, "Documentation of Surveillance and Review Personnel Qualifications", Revision 0
- SPP 3.05, "Administration of Personnel Certification and Qualification Records", Revision 0
- SPP 4.01, "Planning and Scheduling of Evaluation Activities", Revision 0
- SPP 4.02, "Administration of Quality Assurance Audits", Revision 0
- SPP 4.03, "Conduct of Quality Assurance Audits", Revision 0
- SPP 4.04, "Administration and Conduct of Surveillance", Revision 0
- SPP 4.05, "Administration of Technical Reviews", Revision 0
- SPP 4.08, "Administration of Peer Reviews", Revision 0
- SPP 4.09, "Conduct of Peer Reviews", Revision 0
- SPP 4.10, "Review of Operations Offices Quality Assurance Program Descriptions and Procedures", Revision 0
- SPP 4.11, "Review of Waste Acceptance Process Technical Documents", Revision 0
- SPP 4.12, "Review of Program Execution Guidance Documents", Revision 0
- SPP 4.13, "Participation in Evaluation Activities Lead by External Organizations", Revision 0
- SPP 5.01, "Deviation Reporting and Disposition", Revision 0
- SPP 5.02, "Management Action Request", Revision 0
- SPP 5.03, "Control of Unsatisfactory Conditions (Stop Work Order)", Revision 0
- SPP 5.04, "Disposition of Deviations Identified By Outside Organizations", Revision 0
- SPP 5.05, "Review of Unusual Occurrences", Revision 0

- SPP 5.06. "Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations", Revision 0
- SPP 6.01. "Official HLW Office Files", Revision 0
- SPP 6.02. "Preparation of Correspondence", Revision 0
- SPP 6.03. "Incoming Mail", Revision 0
- SPP 6.04. "Commitment Control", Revision 0
- SPP 6.05. "Controlled Documents", Revision 0
- SPP 7.01. "Preparation, Transfer, and Receipt of Quality Records", Revision 0
- SPP 7.02. "Quality Records Management", Revision 0
- SPP 8.01. "Coordination of Reviews and Evaluations by Outside Organizations", Revision 0
- SPP 8.02. "Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness", Revision 0
- SPP 8.03. "Review and Reporting of Quality Assurance Program Progress and Status", Revision 0
- SPP 9.01. "Preparation and Maintenance of the Program Schedules", Revision 0
- SPP 9.02. "HLW Monthly Progress Reporting", Revision 0
- SPP 9.03. "Preparation and Maintenance of the Work Breakdown Structures (WBS)", Revision 0
- SPP 10.01. "Identification and Analysis of Adverse Quality Trends and Problems", Revision 0
- SPP 10.02. "Planning and Conduct of Quality Improvement", Revision 0
- SPP 10.03. "Differing Staff Opinions and Allegations", Revision 0

Working Files For:

- SPP 4.01, Revision 1, (Draft)
- SPP 4.02, Revision 1, (Draft)
- SPP 4.03, Revision 1, (Draft)
- SPP 7.01, Revision 1, (Draft)
- SPP 7.02, Revision 1, (Draft)
- SPP 2.01, Revision 1, (Draft)
- SPP 2.05, Revision 0, (Draft)
- SPP 4.05, Revision 1, (Draft)
- SPP 4.06, Revision 1, (Draft)
- SPP 4.01, Revision 0
- SPP 4.02, Revision 0
- SPP 4.03, Revision 0
- SPP 7.01, Revision 0
- SPP 7.02, Revision 0
- SPP 2.01, Revision 0
- Audit 91EA-SR-AU-001
- Audit 91EA-WV-AU-001

Organizational Charts

- Waste Acceptance Participants Organizational Chart Fig. 1.2.11(see QAPD).
- DOE EM Headquarters Organizational Chart - Fig. 1.0.1(see QAPD)
- DOE Waste Operations Organizational Chart - Fig. 1.0.2(see QAPD)
- Participants in High-Level Waste Processing Organizational Charts - Fig. 2.2.1-2

QA Planning

- FY 90-92 Long Range Plan and Schedule
- FY 89 4th Quarter Evaluation Plan and Schedule
- FY 90 1st Quarter Evaluation Plan and Schedule
- FY 91 2nd Quarter Evaluation Plan and Schedule
- FY 91 3rd Quarter Evaluation Plan and Schedule
- FY 91 4th Quarter Evaluation Plan and Schedule

Management Reports

- Management Assessment of EM-343 by PTSO (Draft) dated March 5, 1991

Monthly QA Program Status Reports

- EM-HLW, SR-HLWD and WSRC, dated May 14, 1991
- EM-343 HLW, dated June 25, 1991
- SR-HLWD, EM-HLW and WSRC, dated July 30, 1991

QA Program Reviews

- Letter dated July 30, 1991 from K. Chacey directing the implementation of SPPs effective October 31, 1990.
- Letter dated May 07, 1991 from K. Chacey acceptance of the HLW Form Producers Quality Assurance Program Interface Arrangements.
- Letter dated February 13, 1991 from W.J. Kehew addressing the review of the West Valley Demonstration Project QA Program.
- Letter dated July 30, 1991 from K. Chacey delegating authority to T. McIntosh, V. Trice and T. Gutmann.
- Letter dated April 8, 1991 from D. Horton transmitting formal comments on DOE/EM/VO/02 (QAPD)
- Letter dated October 23, 1990 from S. Cowan, conditionally accepting the SR/HLWD and WSRC Quality Assurance Program Descriptions.

Training

- Training Attendance Rosters
- Lesson Plans 03.901024.01 and HLW-9002
- Orientation to the QA Audit, dated 5/24-25/90
- QAMT Orientation to the SPPs, dated 10/16-18/90
- EM-343 QA Orientation, dated 10/29/90
- QA Orientation, dated 10/15/90
- QAMT Orientation to the SPPs, dated 12/12/90
- Needs Assessment Worksheets for K. Chacey, T. Gutmann, T. McIntosh, V. Trice and J. Hennessey
- Training Course Critique for QAMT Orientation to SPPs (Lesson HLW 9002) dated 10/18/90
- TI&O Status report for supporting contractor personnel, dated April 26, 1991.
- TI&O Status of EM-343 and Supporting Contractor Personnel (BDM/GER-RES 16027-91 to KA Chacey dated June 26, 1991)
- Description of SPP Training Modules #1, 2 & 3.
- QARG reviewer training records
 - QARG reviewer S. Marra (qualification records)
 - QARG reviewer D. Ryder
 - QARG reviewer R. Stockman
 - QARG reviewer M. Campbell
 - QARG reviewer B. Kehew
 - QARG reviewer J. Hummel
 - QARG reviewer J. Smith
 - Lesson plan for course #HLW 9101
 - Lesson plan for course #QARG 9001

Procurement Documents

- Fiscal Year 1991 Program Execution Guidance Document (PEGD).
- BDM/SAIC contractor support contract.

Control of Purchased Materials and Services

- EM-343 review documentation for the Hanford/Richland site Quality Assurance Program Description.
- EM-343 review documentation for the West Valley QAPD.
- EM-343 review documentation for the Savannah River site implementing procedures.

Technical Review Group Documentation

- Statement of Work for the TRG Evaluation of the WVDP Waste Form Compliance Plan, Rev. 0, dated 5/22/90

- Statement of Work for the TRG Evaluation of the WVDP Waste Qualification Report, Rev. 1, dated 5/11/90
- TRG Charter for the WVDP Waste Form Compliance Plan, Rev. 0, dated 5/22/90
- Review Log for the TRG Waste Acceptance Activities
- West Valley/WQR TRG Log Sheet

Nonconforming Items/Corrective Action

DCAR Nos. 91EA-SR-AU-001-003
91EA-SR-AU-001-005
91EA-SR-AU-001-009
QA90-EM-30-01-01
QA90-EM-30-01-06
90EA-SR-S-003-01
90EA-SR-S-003-02
91EA-SR-S-001-01
91EA-SR-S-001-02
91EA-WV-AU-001-03
91EA-WV-AU-001-05

Management Action Request #MAR-001, 5/9/91

Surveillances Reports

- 90EA-SR-S-002
- 90EA-SR-S-003
- 91EA-VP-S-003
- 91EA-SR-S-004
- 91EA-VP-S-006

Audit-Related Documents

- Audit 91EA-WV-AU-001 checklists for Lefman, Crawford, Stockman, and Ryder.
- Qualification Records for J. Flaherty, SAIC and M.H. Campbell, WHC

Audit Reports

Audit Report #90-15-03-1006 (external)
Audit Report #91-15-03-1012 (external)

Audit Report #91EA-AN-AU-001 (internal, BDM participated only)
Audit Report #91EA-WV-AU-001 (internal)
Audit Report #91EA-SR-AU-001 (internal)

Record Files

EM-343 Quality Records File located at the EM-343 offices

Correspondence

- M.H. Campbell to Mr. W.J. Kehew, March 5, 1991 Subject: QARG-1 SPP Review
- EM-343 Memorandum to Corinne Macaluso, RW-331, dated 6/30/91
- EM-343 Memorandum to the Secretary dated 8/16/91
- EM-343 Memorandum to Murial Scarborough, PR-23, dated 8/16/91
- Assignment Letter - BDM/GER-KJM-11480-91 dated August 23, 1991

Miscellaneous

Commitment Summary Log dated 8/27/91
WGWA Charter dated July 18, 1990
Position description for a Quality Assurance Specialist - not dated (Position Announcement)
QARG Charter
Quarterly QA Status Report for Hanford site
Quarterly QA Status Report for Savannah River site
Quality Improvement Log
Commitment Tracking & Reporting Log

ATTACHMENT 3

Information Copies of Draft

Corrective Action Requests

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ-91-035
DATE _____
SHEET 25 OF 25
QA
WBS NO. 5.07

CORRECTIVE ACTION REQUEST

¹ Controlling Document DOE/EM/WO/02, dated 10/90		² Related Report No. Audit HQ-91-003	
³ Responsible Organization EM-343		⁴ Discussed With K. Chacev, J. Hennessey, H. Nguyen	
⁵ Response Due EM-343		⁶ Responsibility for Corrective Action EM-343	
⁷ Requirement: Subparagraph 5.1.1: "Waste Operations has established a management procedures system. The procedures prescribe methods for performing quality-related activities in support of development and qualification activities." Subparagraph 6.1.2: "Verification Projects Branch documents that are related to quality or that affect quality assurance activities are controlled by procedures. These procedures address the following: ...4. Initial issuance of documents for use at locations where the activity will be performed prior to commencing the work."		⁸ Stop Work Order Y or N See Note	
⁹ Adverse Condition: Personnel demonstrated a general lack of compliance with the issued Standard Practice Procedures. This finding is supported by the following: <ol style="list-style-type: none"> 1. The preparation and review process of Revision 0 and of draft Revision 1 of the SPPs did not comply with SPP 2.01. The approval of Revision 0 did not comply with SPP 2.01. Details of deficiencies are contained in audit report HQ-91-003. 2. A "Gold Sheet" system was used to make major changes to procedures. This process bypassed the requirements in SPP 2.01 that revisions to SPPs follow the same steps used to develop the originals. 			
¹⁰ Recommended Action(s): Identify the remedial actions taken or to be taken to correct the specific deficiencies noted in Block 6. Investigate the			
¹¹ Initiator N. O. Frank	¹² Date: 8/29/91	¹³ Severity Level: 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	¹⁴ Approved by OQA
¹⁵ Verification of Corrective Action:			
¹⁶ Corrective Action Completed and Accepted: OAR _____ Date _____		¹⁷ Closure Approved By: OQA _____	

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ-91-003

DATE

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CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 6 (continued)

QARG reviews were being used by EM-343 to satisfy the review processes defined in SPPs 2.00, 4.05, 4.06, 4.10, 4.11, and 4.12. It was stated that these reviews were being performed in accordance with the QARG charter (see also CAR HQ-91-038). Other than the procedures, the QARG charter and review process are not defined or controlled within these SPPs.

Records for audits 91EA-SR-AU-001 and 91EA-WV-AU-001 did not meet the requirements of SPP 4.03 regarding content (see SPP 4.03 Attachment B) or issuance within 30 days of the postaudit conference.

SPP 4.12 was not used to control the development of the Program Execution Guidance Document. As a consequence, the requirement to meet DOE BW-0274 was not included.

SPP 4.04 was not followed for the documentation, followup, and close out of deficiencies identified in Surveillance Report 91EA-VF-S-003 dated 6/14/91 (see CAR HQ-91-041 for details).

The audit team selected for audit two people who had performed a review. Neither had supporting documentation in the file to illustrate that their qualifications were reviewed against applicable task requirements.

The SPPs use titles for the "performer" that have not been defined within the EM-343 organization. Examples include: SPP Coordinator, Manager, Project or EM-343, Approver, and Organizational Director. There is no "Director" in EM-343. Personnel interviewed were unsure who was to perform the specified actions.

Note: SPP 7.01 and SPP 7.02 were previously identified as not being complied with during HQ surveillance HQ-SR-91-016.

SPP 3.03 and SPP 3.04 were previously identified as not being complied with during HQ surveillance HQ-SR-91-014.

Block 7 (continued)

Implementation of the QA program for additional instances of lack of compliance with the QA program and identify remedial actions to correct the additional deficiencies identified during the investigation. Identify the cause of each deficiency and the overall cause that permitted the adverse condition to occur. Identify the corrective actions necessary to prevent the recurrence of each deficiency and the adverse condition. Provide the responsible person and planned completion date for each identified action.

OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

¹ CAR NO. HQ-91-036
DATE
SHEET OF
QA
WBS NO. 607

CORRECTIVE ACTION REQUEST

¹ Controlling Document DOE/EMWO/02, SPP 3.01, and SPP 3.02, Revs. 0		² Related Report No. Audit HQ-91-003
³ Responsible Organization EM-343	⁴ Discussed With Tom Gutmann	
⁵ Response Due	Responsibility for Corrective Action EM-343	⁶ Stop Work Order Y or N See Note.

⁷ Requirement:

Paragraph 2.7.1(2) of DOE/EMWO/02, requires, in part, the establishment and implementation of a method of selecting, indoctrinating, and training personnel who perform or verify activities affecting quality and before assigning personnel to perform activities affecting quality the Vittrification Projects Branch ensures the positions are evaluated and that quality-affecting responsibilities are documented and used as a basis for personnel selection.

SPP 3.01 and SPP 3.02 require that managers ensure that people performing activities affecting quality or activities assuring quality are indoctrinated, trained, and oriented prior to performing the activity.

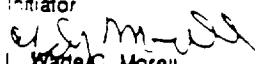
⁸ Adverse Condition:

The training program was inadequate and ineffective. This finding is supported by the following:

- Thirteen of 20 personnel interviewed demonstrated a general lack of knowledge of the content of the procedures and, in many cases, were not aware that procedures covering their activities existed.
- TI&O Plans and Schedules were not issued to EM-343 project managers by December 31, 1990 as required by SPP 3.01. The only TI&O Plan and Schedule presented to the audit team for review was included in letter BDM/GER-RES 16027 from BDM & BDM/SAIC to K. A. Chacev, dated June 26, 1991. It was not issued by EM-343.

⁹ Recommended Action(s):

Identify the remedial actions taken or to be taken to correct the specific deficiencies noted in Block 6. Investigate the

¹⁰ Initiator  L. Wade C. Morell	Date: 8/29/91	¹¹ Severity Level - 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	¹² Approved by OQA	Date:
¹³ Verification of Corrective Action:				
¹⁴ Corrective Action Completed and Accepted: QAR <u> </u> Date <u> </u>			¹⁵ Closure Approved By: OQA <u> </u>	

OFFICE OF CIVILIAN
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CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 6 (continued)

3. No objective evidence could be presented to substantiate that subject matter experts had reviewed and commented on lesson plans (03.901024.01 and HLW 9002) as required by SPP 3.02, Paragraph 5.a.5.
4. Lesson plans reviewed had not been approved by the QA Specialist nor the manager (Branch Chief) as required by SPP 3.02, Paragraph 5.a.7. The lesson plans reviewed (03.901024.01 and HLW 9002) were signed by a course developer, a training coordinator, and a QA Manager (see also CAR HQ-91-040).
5. Only 16 of the 43 SPPs were covered by training modules. Work governed by the SPPs not covered by the modules was being done.
6. Individuals who functioned as QARs members performed reviews of QARs from outside organizations had not received training on SPP 4.10 which governs such reviews prior to conducting the reviews.
7. "Needs Assessment Worksheets" were provided over three months after the training "needed by" date. The Branch Chief's Needs Assessments Worksheet does not require any T&O even though he is performing activities affecting quality. Training for one project manager had been completed over a month after the specified "needed by" date.

Block 7 (continued)

"Implementation of the training program for additional instances of inadequacies and ineffectiveness and identify remedial actions taken or to be taken to correct the additional deficiencies identified during this investigation. Identify the cause of each deficiency and the overall cause that permitted the adverse condition to occur. Identify the corrective actions necessary to prevent recurrence of each deficiency and the adverse condition. Provide the responsible person and planned completion date for each identified action."

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAP NO. HQ-91-037

DATE

SHEET

OF

QA

WBS NO.

507

CORRECTIVE ACTION REQUEST

Controlling Document

DOE/EM/WO/02, Rev. 0, dated 10/90

Related Report No.

Audit HQ-91-003

Responsible Organization
EM-343

Discussed With

J. Hennessey, K. Chacev

Response Due

Responsibility for Corrective Action
EM-343

Stop Work Order Y or N

See Note

Requirement

Subparagraph 18.1.6. "The activities and practices which carry out these procedures are audited upon implementation and at least annually thereafter."

Subparagraph 2.2.2. "The Office for Environmental Quality Assurance/Quality Control performs an annual assessment of the scope, status, adequacy and compliance of the quality assurance program with DOE RW-0214. Resultant corrective measures are reported to the affected organizations for completion; the corrective actions are tracked to completion."

Adverse Condition

No management assessments or internal QA program audits of EM-343 have been completed.

1. No internal audits of EM-343 had been performed as of August 30, 1991.
2. No management assessments had been "issued" as of August 30, 1991. One assessment report transmitted from M.H. Campbell Projects Technical Support Office, to K.A. Chacev, EM-343, dated March 5, 1991 had been presented to EM-343 management but had not been issued and the Branch Chief indicated that it would not be issued. As a consequence, no action had been taken to address the assessment's findings.

Recommended Action(s):

Identify the remedial actions taken or to be taken to correct the specific deficiencies noted in Block 6. Identify the

Initiator

Date:

Severity Level -

Approved by

Date:

L. Wade/C. Morell

8/29/91

☐ 1 ☐ 2 ☒ 3 ☐ 4

OQA

Verification of Corrective Action:

Corrective Action Completed and Accepted:

OAR

Date

Closure Approved By:

OQA

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RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ-91-037

DATE

SHEET 1 OF

CORRECTIVE ACTION REQUEST
(continuation sheet)Block 7 (continued)

cause of the adverse condition and the planned corrective action to prevent recurrence. Provide the responsible person and planned completion date for each identified action.

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RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

¹⁴ CAR NO. HQ-91-038
DATE _____
SHEET _____ OF _____
QA
WBS NO. 8.07

CORRECTIVE ACTION REQUEST

¹ Controlling Document DOE/EM/WO/02, dated 10/90		² Related Report No. Audit HQ-91-003
³ Responsible Organization EM-343	⁴ Discussed With J. Smith, J. Hessesey	
¹⁵ Response Due	¹¹ Responsibility for Corrective Action EM-343	¹² Stop Work Order Y or N See Note

⁵ Requirement:


DOE/EM/WO/02, Paragraph 5.1.1 states that EM-343 has developed a management procedures system to perform quality-affecting activities. The EM-343 Branch Chief told the audit team that the Quality Assurance Review Group (QARG) performs the quality-affecting activities of procedure reviews.

⁶ Adverse Condition:

1. The QARG-1 (SPP) did not:
 - a. comply with the applicable SPPs or its own charter
 - b. adequately review the draft revision 1 or draft revision 0 SPPs.
2. Discussion:
 - a. The audit team was told that the QARG-1 (SPP) performed its function in accordance with a Charter. This Charter did not include full compliance with SPPs 4.05 and 4.06. Though the Charter addressed a process similar to SPPs 4.05 and 4.06, the Review Coordinator (SPP) responsibilities were not accomplished by the

Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiencies noted in Block 6 under "Discussion." Identify

⁷ Initiator  C. G. Walenga	Date: 8/29/91	⁸ Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	¹³ Approved by OQA _____	Date: _____
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¹⁵ Verification of Corrective Action:

¹⁶ Corrective Action Completed and Accepted:

QAR _____ Date _____

¹⁷ Closure Approved By:

OQA _____

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

CAR NO. HQ-91-038

DATE

SHEET 2 OF

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 6 (continued)

Program Manager as described in the Charter and it was noted that two members of the QARG-1 (SPP) were not members of the core group listed in the Charter.

- 2 The audit team assessed the adequacy of the QARG-1 (SPP) review based on a March 5, 1991 letter from M.H. Campbell to W.J. Kehew that contained the agenda for the QARG-1 (SPP) meeting, review criteria, and the SPP review assignments. The QARG-1 (SPP) consisted of six members (four reviewers, an Executive Chairman, and an Executive Secretary). The agenda called for reviewing 47 SPPs during a two-day period. The Executive Chairman and the Executive Secretary were not assigned to perform any formal reviews. Each of the remaining four members were assigned approximately 20 SPPs to review and were to document their comments prior to attendance at the meeting. Twelve SPPs were assigned to all four reviewers while the remaining 35 SPPs had only one assigned reviewer. The agenda stated that the reviewers were to randomly check assigned procedures for the given criteria. The purpose of the two-day meeting was to discuss only the reviewers comments to see if the comments had merit and to consolidate the comments.

It appeared that the position taken by the QARG-1 for 35 of the SPPs was not based on a thorough review of the SPPs by all the QARG-1 (SPP) members, but consisted of random checks by one member whose comments were only reviewed and concurred with by the entire QARG-1 (SPP).

The audit team reviewed the draft SPP 2.01 revision 1 that had been reviewed by the QARG-1 (SPP) for compliance with DOE/RW-0214 QARD. The audit team noted that the draft SPP 2.01, revision 1 is not adequate and not complete because 1) contrary to ASME NQA-1-1989, Supplement 6S-1, Paragraph 2.b SPP 2.01 does not identify who is responsible for assigning the reviewers; 2) contrary to Paragraph 2.c SPP 2.01 does not require that documents be reviewed for adequacy, completeness, and correctness; and 3) contrary to Section 3 SPP 2.01 does not address major or minor changes, does not require that the reviewing organization have access to pertinent background data or information upon which to base their approval, and does not require that the same organization who performed the original review also review revisions unless another organization is specifically designated.

The audit team also reviewed SPP 2.05, revision 0 that had been reviewed by the four review team members. The SPP was not adequate in that it failed to provide a method with objective criteria on how to determine and document work that is subject to quality assurance program requirements. This violates the QARD requirement that "a method shall be developed to identify items and activities to which the quality assurance program applies." The SPP fails to satisfy the "Purpose" section of the SPP, which states that "this procedure describes the measures required to delineate the quality-affecting activities to be performed..." Also, the SPP provides an incomplete definition of "items and activities important to safety and waste isolation." The definition never defines "important to waste isolation" (reference NUREG-1318). However, the major concern with the adequacy of the SPP is that even if the definition was correct, the definition has no clear relevancy to the establishment of criteria for determining EM-343 work that is subject to quality assurance program requirements.

Block 7 (continued)

the cause of the adverse condition and the planned corrective action to prevent recurrence. Provide the responsible person and planned completion date for each identified action.

OFFICE OF CIVILIAN
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WASHINGTON, D.C.

CAR NO. HQ 91-039
DATE _____
SHEET _____ OF _____
QA
WBS NO. 507

CORRECTIVE ACTION REQUEST

Controlling Document DOE/EM/WO/02, Rev. 0 dated 10/90		Related Report No. Audit HQ-91-003
Responsible Organization EM-343	Discussed With J. Standifer, J. Smith, J. Hennessey	
Response Due	Responsibility for Corrective Action EM-343	Stop Work Order Y or N See Note

Requirement:
Subparagraph 2.7.1, "Additional quality assurance program activities for waste acceptance process activities of high-level waste form development and qualification leading to production have been established and implemented to satisfy the requirements of DOE/RW-0214. These include the following: (1) Establishing and implementing a systematic method by which quality assurance activities are selected and applied to waste acceptance process activities of high-level waste form development and qualification."

Adverse Condition:
EM-343 has not established or implemented a systematic method for defining the work that is subject to the EM-343 QA program requirements. SPP 2.05, "Selective Application of Quality Assurance Activities," was not issued at the time of the audit. No method existed for the selective application of QA activities to EM-343 work.

Recommended Action(s):
Identify the remedial actions taken or to be taken to correct the specific deficiencies noted in Block 6. Investigate the

Initiator C.G. Walenga	Date: 8/29/91	Severity Level - <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	Approved by OQA _____	Date: _____
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Verification of Corrective Action:

Corrective Action Completed and Accepted: OAR _____ Date _____	Closure Approved By: OQA _____
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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

DAR NO. HQ 91-003

DATE

SHEET 1 OF 1

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 7 (continued)

Impact that the lack of having a grading system had on the work performed to date, and identify remedial actions taken or to be taken to correct the additional deficiencies identified during this investigation. Identify the cause of each deficiency and the overall cause that permitted the adverse condition to occur. Identify the corrective actions necessary to prevent recurrence of each deficiency and the adverse condition. Provide the responsible person and planned completion date for each identified actions.

OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.CAR NO. HQ-91-040
DATE _____
SHEET 3 OF 3
QA
WBS NO. 607

CORRECTIVE ACTION REQUEST

Controlling Document DOE/EM/WO/02, Rev. 0, dated 10/90		Related Report No. Audit HQ-91-003	
Responsible Organization EM-343		Discussed With K. Chacev, R. Torro, R. Stockman	
Response Due		Responsibility for Corrective Action EM-343	Stop Work Order Y or N See Note
Requirement: Paragraph 2.2 states, "The Verification Projects Branch Chief is assisted in managing and directing HLW quality assurance programs by support services contractors, who provide a HLW Quality Assurance Program Manager..."			
Adverse Condition: The Verification Projects Branch Chief has not filled the HLW Quality Assurance Program Manager position.			
Recommended Action(s): Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Identify the cause of the			
Initiator C. Mohr		Date: 11/29/91	Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>
Approved by OQA		Date:	
Verification of Corrective Action:			
Corrective Action Completed and Accepted: QAR _____ Date _____		Closure Approved By: OQA _____	

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ-91-040

DATE

SHEET 1 OF 1

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 7 continued

adverse condition and the planned corrective action to prevent recurrence. Provide the responsible person and planned completion date for each identified action.

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WASHINGTON, D.C.

CAR NO. HQ-91-041

DATE

SHEET

QA

WBS NO. 507

CORRECTIVE ACTION REQUEST

Controlling Document

SPP 4 04, Rev. 0, dated 2/2/90

Related Report No.

Audit HQ-91-003

Responsible Organization

EM-343

Discussed With

T. McIntosh

Response Due

Responsibility for Corrective Action

EM-343

Stop Work Order Y or N

See Note

Requirement

Paragraph 5 b.7: "The Evaluator documents any deviations on a deviation report in accordance with SPP 5 01."

Adverse Condition

Deficiencies identified in Surveillance Report 91EA-VP-S-003, dated 6/14/91, were not documented on deviation reports. In addition, no action had been taken to correct the identified deficiencies. The deficiencies had been included in the Quality Improvement Log rather than being documented on deviation reports. The surveillance report had not been "accepted" by EM-343.

Details: Six significant deficiencies were identified by the surveillance team in the areas of QA program definition (including lack of an EM-343 QA Program Manager), implementation and conformance to procedures, records and records management, orientation/training, document control, and inattention to detail. The surveillance team commented, "It also appeared to the surveillance team that implementation may be slowed by an apparent lack of a comprehensive understanding of the QA Program by EM-343 personnel and in-house resources."

Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Identify the cause of the

Initiator:

Date:

Severity Level:

Approved by

Date:

L. Wade

8/29/91

1 ☐ 2 ☒ 3 ☐

OQA

Verification of Corrective Action:

Corrective Action Completed and Accepted:

Closure Approved By:

OAR

Date

OQA

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. HQ 91-041

DATE

SHEET 1 OF 1

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 7 (continued)

adverse condition and the planned corrective action to prevent recurrence. Provide the responsible person and planned completion date for each identified action.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

¹⁴ CAR NO. HQ-91-042
DATE _____
SHEET _____ OF _____
QA
WBS NO. 607

CORRECTIVE ACTION REQUEST

¹ Controlling Document Each SPP and DOE/EM/WO/02, Rev. 0, dated 10/91		² Related Report No. Audit HQ-91-003	
³ Responsible Organization EM-343		⁴ Discussed With K. Chacey, R. Stockman, R. Torro	
⁵ Response Due	¹¹ Responsibility for Corrective Action EM-343	¹² Stop Work Order Y or N See Note	
<p>⁶ Requirement:</p> <p>The Scope of each Standard Practice Procedure states, "The provisions of this ... SPP apply only to the organization(s) that has ... had it invoked by contractual or other means."</p> <p>DOE/EM/WO/02, Subparagraph 4.1.1(2): "Administrative support contracts are the vehicle through which Headquarters obtains technical support in carrying out its management duties. Such contracts specify both the technical and quality assurance requirements as well as administrative and financial considerations."</p>			
<p>⁷ Adverse Condition:</p> <p>The administrative support contract for BDM does not require BDM to perform work in accordance with the SPPs or the EM-343 QAPD.</p>			
<p>⁸ Recommended Action(s):</p> <p>Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Provide the responsible</p>			
⁹ Initiator <i>R. D. Brown</i> R. D. Brown	Date: 8/29/91	¹⁰ Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/>	¹³ Approved by OQA _____ Date: _____
<p>¹⁵ Verification of Corrective Action:</p>			
<p>¹⁶ Corrective Action Completed and Accepted:</p> <p>OAR _____ Date _____</p>		<p>¹⁷ Closure Approved By:</p> <p>OQA _____</p>	

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RADIOACTIVE WASTE MANAGEMENT
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CAR NO. HQ-91-042

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SHEET 2 OF

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 7 (continued)

person and planned completion date for each identified action.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.CAR NO. HQ-91-043
DATE _____
SHEET _____ OF _____
QA
WBS NO. 607

CORRECTIVE ACTION REQUEST

¹ Controlling Document
DOE/EM/WO/02, Rev. 0, dated 10/90² Related Report No.
Audit HQ-91-003³ Responsible Organization
EM-343⁴ Discussed With
H. Walter, J. Smith¹⁰ Response Due¹¹ Responsibility for Corrective Action
EM-343¹² Stop Work Order Y or N
See Note⁵ Requirement:

Subparagraph 2.7.1 (3): "The overview practice includes the following activities: Review and acceptance of Operations Offices quality assurance plans and implementing procedures."

⁶ Adverse Condition:

EM-343 has not reviewed and accepted the West Valley or Richland Operations Office implementing procedures.

Note: West Valley's QAPD had been conditionally accepted. The QAPDs for Richland Operations Office and Westinghouse (performing contractor) had been rejected.

⁷ Recommended Action(s):

Identify the remedial actions taken or to be taken to correct the specific deficiencies noted in Block 6. Provide the

⁸ Initiator <i>R.D. Brown</i> R.D. Brown	Date: 8/29/91	⁹ Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/>	¹³ Approved by OQA _____	Date:
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¹⁵ Verification of Corrective Action:¹⁶ Corrective Action Completed and Accepted:

QAR _____ Date _____

¹⁷ Closure Approved By:

OQA _____

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
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CAR NO. HQ-91-043

DATE

SHEET 2 OF

CORRECTIVE ACTION REQUEST
(continuation sheet)

Block 7 (continued)

responsible person and planned completion date for each identified action.

ATTACHMENT 4
 WASTE VITRIFICATION PROJECTS BRANCH
 HQ-91-003 AUDIT PERSONNEL LIST

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PRE-AUDIT</u>	CONTACTED <u>DURING</u> <u>AUDIT</u>	<u>POST-AUDIT</u>
H.P. Brown	PDC	Staff Advisor	X		
R.D. Brown	CER	QA Spec/Auditor	X	X	X
J.T. Buckley	USNRC	QA Engr/Obs.	X		X
K. Carter	EM-343	Secretary		X	
K. Chacey	EM-343	WVP Branch Chief	X	X	
R.W. Clark	OCRWM OQA	Director, HQAD	X		X
J.T. Conway	USNRC	SR WA Engr/Obs.	X		X
S.L. Crawford	BDM/SAIC	SR QA Engr.	X		X
A. Dasu	BDM/SAIC	QA Support	X	X	X
J.P. Dreis	BDM/SAIC	Engr.	X	X	X
N.C. Frank	CER	Lead QA Spec/ATL	X		X
T.S. Gutmann	EM-343	Prog. Mgr.-DWPF	X	X	
J.E. Hennessey	EM-343	Ast. Prog. Mgr.-HWVP	X	X	X
D.G. Horton	RW-3	Director, OQA			X
J.E. Irvin	WHC	EM	X		
I.J. Lefman	SAIC	Mgr. QA Group	X		
W.J. McClanahan	BDM/SAIC	Sr. QA Engr.	X	X	X
T. McIntosh	EM-343	Prog. Mgr.-WVDP	X	X	X
C.D. Morell	CER	QA Spec/Auditor	X		
F.E. Nash	Duke Eng/TESS	QA Audit Mgr/Obs	X		X
H.P. Nguyen	EM-343	Ast Prog Mgr DWPF	X	X	
C.J. Payton	PDC	Staff Advisor		X	X
K.G. Picha, Jr.	BDM/SAIC	Sr. Staff Mbr.	X		X
T.E. Rodgers	CER	QA Spec/Auditor	X		X
S. Rodick	PDC	Principal Eng.		X	
J.L. Smith	PDC	Staff Adv.	X	X	X
J. Standifer	PDC	Program Manager		X	
R.E. Stockman	BDM/SAIC	Dpty. QA Mgr.	X	X	X
R.G. Thomas	CER	QA Spec/Auditor	X		X
R. Toro	BDM/SAIC	QA Support	X	X	X
V. Trice	EM-343	Prog. Mgr.-HWVP	X	X	
O. Truskett	EM-343	Tech. Rev. Mgr.	X	X	X
L.R. Wade	Weston	Sr. Qual. Engr/Audt	X		X
C.G. Walenga	CER	QA Spec/Auditor	X		X
H.F. Walter	EM-343	Phy. Scientist	X	X	
J.C. Yocum	BDM/SAIC	Staff Member	X		X
J.A. Youmans	BDM/SAIC	QA Support	X	X	X