

Office of Civilian Radioactive Waste Management

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Office of Geologic Repositories  
**Quality Assurance Requirements  
for High-Level Waste Form  
Production  
(OGR/B-14)**

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February 1988

U.S. Department of Energy  
Office of Civilian Radioactive Waste Management

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U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

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SPECIFICATION

QUALITY ASSURANCE REQUIREMENTS  
FOR  
HIGH-LEVEL WASTE FORM PRODUCTION

August 28, 1987

Approval

A. H. Kale

Date

1/25/88

S. H. Kale, Associate Director  
Office of Geologic Repositories  
Office of Civilian Radioactive  
Waste Management

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**APPENDIX**

- A. Guidelines for Preparation of a Quality Assurance Program Description for High-Level Waste Form Production**
- B. Review Plan for Quality Assurance Programs for High-Level Waste Form Production**
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## FOREWORD

This specification of quality assurance requirements for high-level waste form production was prepared by the DOE Quality Assurance Work Group on Waste Acceptance. This group included representatives or organizations involved in processing of high-level radioactive waste into canistered waste forms for disposal in a licensed Federal Repository. They represent what is being referred to as the waste form producer organizations.

There will be several waste form producer organizations; one associated with each of the high-level waste form production activities of DOE (e.g., Savannah River, West Valley, Hanford, and Idaho). A waste form producer organization is a composite of elements of DOE and their contractors. It is expected that the major participants in a waste form producer organization will be:

- DOE Headquarters
- DOE Operations Office
- DOE Project Office (If separate from an operations office)
- Operating Contractors

It is further expected that these major participants will be associated through organizational, administrative or contractual arrangements such that a vertical tier relationship exist between the individual participants. For example, the waste form producer for Savannah River activities is an organization made up through a vertical relationship which connects downward from the DOE Defense Programs Office (DOE/DP) in Headquarters to the DOE Operations Office at Savannah River (DOE/SR) and through its Defense Waste Processing Facility (DWPF) Project Office to the E.I. DuPont de Nemours and Company (DuPont). DuPont is the operating contractor for waste form production in the DWPF on the Savannah River site. In this arrangement, the DOE Office of Civilian Radioactive Waste Management (OCRWM), also referred to as DOE/RW, is the recipient for the canistered waste forms (products) from the waste form producer. They are responsible for receipt at the waste form production site and transportation to and disposal in the repository.

The specific organizational units of DOE and the operating contractors will vary depending upon which of the waste form producers is involved.

The waste form producer organizations and the DOE/OCRWM are pursuing an integrated strategy for ensuring that canistered waste forms are acceptable for disposal in a licensed Federal Repository. This strategy involves the preparation of an initial specification which outlines the administrative and technical requirements to be met by each canistered waste form. This initial specification is called the Waste Acceptance Preliminary Specification (WAPS). Updated versions of this specification will be issued at key points in the CRWM Program. Hereafter in this specification, it will be referred to as simply the Waste Acceptance Specification (WAS). The second step is the preparation and implementation of a plan that assures that the processes, methods and techniques that

have been developed for waste form production provide canistered waste forms that meet each point of the WAS. This plan is called the Waste Form Compliance Plan (WCP). The third step is the collection of information and data resulting from the execution of the WCP and preparing a composite report which demonstrates that canistered waste forms can meet all aspects of the WAS. This report is called the Waste Form Qualification Report (WQR). Further, the WQR is expected to demonstrate that high-level waste form production can be accomplished with confidence that final canistered waste forms (product) will meet the WAS in all respects. The last step in this process is the collection of information and data resulting from actual production of canistered waste forms and the assembly of a Production Records Package (PR) for each canister of waste which ultimately demonstrates conformance with the WAS. This four-step strategy is referred to as Waste Acceptance Process Activities.

The quality assurance program of a particular waste form producer will ultimately be the composite of the quality assurance programs of each of the major participant organizations. In this arrangement there will be an overall program of the waste form producer made up of constituent programs of each of the major participants in the composite organization. In most cases the major participants may already have quality assurance programs in place, and they may be providing satisfactory results for other DOE projects and programs. To the extent that these programs meet the requirements of this specification and the participant chooses to apply these programs to Waste Acceptance Process Activities, they are expected to be acceptable. In those cases however where no previous program exist or where the participant chooses to not extend its present program to cover Waste Acceptance Process Activities, programs or portions of programs are expected to be developed to implement the provisions of this specification on Waste Acceptance Process Activities of high-level waste form production. As a consequence, the overall quality assurance program of the waste form producer will implement this specification.

Ultimately the quality assurance programs, program descriptions, and program results will be influential in supporting the acceptability of the product to DOE/RW and DOE/RW's ultimate disposal of that product in the licensed Federal Repository. It is expected therefore that these quality assurance programs, program descriptions, and program results related to the waste acceptance process activities will be concurred in by the DOE/RW organization in order to support its repository licensing activities with regard to the canistered waste form.

To facilitate DOE's repository licensing activities the waste form producers will prepare their quality assurance program descriptions in a format and having content that can be used by DOE/RW in its repository license application. Program description documents will be prepared by each waste form producer such that they can be incorporated in the Repository Safety Analysis Report at the proper time. At that time it is expected that these program descriptions will be evaluated by the U.S. Nuclear Regulatory Commission (NRC) against the applicable criteria of the NRC Review Plan for Quality Assurance Programs for High-Level Nuclear Waste Repositories (HLNWR).

To ensure that the program descriptions of waste form producers will be acceptable to the NRC, guidelines on the preparation of such program descriptions have been prepared and placed in the specification as Appendix A. To provide further confidence in their acceptability, a comprehensive evaluation of the program descriptions has been required by the specification. This evaluation

**QUALITY ASSURANCE REQUIREMENTS**  
**FOR**  
**HIGH-LEVEL WASTE FORM PRODUCTION**

**1.0 GENERAL**

This specification identifies the basic requirements for quality assurance programs applied to Waste Acceptance Process Activities of high-level waste form production. It also provides supplementary requirements and guidance on selected activities that have unique importance to Waste Acceptance Process Activities of high-level waste form production. These supplementary requirements are to be applied in conjunction with the requirements embodied or referenced in the basic requirements specified.

**2.0 PURPOSE**

The purpose of this specification is to define requirements for the quality assurance programs of organizations that are responsible for or involved in high-level waste form production as part of the established waste acceptance process activities.

**3.0 SCOPE**

The requirements of this specification are for quality assurance activities that are to be performed in Waste Acceptance Process Activities of high-level waste form production. In high-level waste form production, radioactive waste is converted to a waste form and canistered such that the canistered waste form will be acceptable at a Federal Repository licensed by the Nuclear Regulatory Commission (NRC) for disposal of high-level radioactive waste.

The requirements apply to activities of The Department of Energy (DOE) and to operating contractors of DOE facilities who are assigned responsibilities for performing and verifying activities affecting quality in Waste Acceptance Process Activities of high-level waste form production.

The specific organizational units of DOE and the operating contractors will vary depending upon which waste production facility is involved (e.g., Savannah River, West Valley, Hanford, or Idaho). These organizations will be referred to hereafter as "major participants" in Waste Acceptance Process Activities of high-level waste form production. They are to establish and implement quality assurance programs in accordance

with this specification to assure and demonstrate that canistered waste forms meet the technical and administrative requirements of the Waste Acceptance Specification (WAS). This will include activities associated with: research and development that is essential to qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms; and processing operations that are essential to the certification of canistered waste forms.

#### 4.0 DEFINITIONS

The following terms and their definitions are provided to ensure a uniform understanding of these terms as they are used in defining the requirements and guidance contained herein.

- 4.1 Waste Form - The radioactive waste materials and any encapsulating or stabilizing matrix (10CFR60.2).
- 4.2 Canistered Waste Form - The waste form and the surrounding canister as well as any secondary canisters applied by the producer.
- 4.3 Waste Acceptance Process Activities - The activities through which documentation and data are collected and prepared to support compliance with the Waste Acceptance Preliminary Specification. This includes activities associated with: research and development that is essential to qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms; and processing operations that are essential to the certification of canistered waste forms.
- 4.4 Waste Acceptance Specification (WAS) - Identifies the properties and requirements the high-level waste form must meet in order to be accepted for disposal in a Federal Repository.
- 4.5 Waste Form Compliance Plan (WCP) - The document that describes the producer's plan for demonstrating compliance with each Waste Acceptance Specification in the WAS. The WCP includes descriptions of the tests, analyses and process controls to be performed by producer.
- 4.6 Waste Form Qualification Report (WQR) - A compilation of results from waste form testing and analysis which develops in detail the case for compliance with each Waste Acceptance Specification.
- 4.7 Production Records (PR) - The documentation, provided by the producer, that describes the actual canistered waste forms.

- 4.8 Computer Code (Scientific and Engineering) - Instructions written in a computer language for the processing of mathematical models developed for use in scientific and engineering analysis, design, safety analysis, process or equipment control and other activities dependent upon a computer for solution or control. Computer code development includes preparation of instructions for the input data format and use of the code.
- 4.9 Readiness Review - A structured method for determining that an activity is ready to operate or proceed to the next phase, and includes, as a minimum, a comprehensive review of the readiness of the plant and hardware, personnel, and procedures. The review includes a determination of compliance with all requirements.
- 4.10 Technical Review - A documented, traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to that needed to perform the original work. Technical reviews are in-depth, critical reviews, analyses and evaluations of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness that are within the existing state of current technology.
- 4.11 Peer Review - A documented critical review performed by personnel who are independent of those who performed the work but who have technical expertise at least equivalent to that needed to perform the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions, or material or data contained in a report which generally includes elements that go beyond the existing state of current technology.
- 4.12 Independent (Personnel) - A condition characterizing an individual or group of individuals who are qualified to analyze, review, inspect, test, audit or otherwise evaluate activities and work results because:
- A. They had no direct responsibility for or involvement in performing the activity or work.
  - B. They are not accountable for the activity or work result.
  - C. They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated.
- 4.13 Overview - An analysis and assessment by management of the scope, status, adequacy and effectiveness of quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

- 4.14 Verification - The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specification requirements. Also, the documented determination that work under review conforms to specified requirements.
- 4.15 Validation - The documented confirmation of the adequacy (suitability for its intended purpose) of the work under review.
- 4.16 Indoctrination - To instruct in fundamentals so as to provide understanding of principles involved.
- 4.17 Training - In-depth instruction to develop proficiency in the application of requirements, methods, and procedures. Such instruction may be internal or external classroom sessions, courses, or informal on-the-job assignments.
- 4.18 Quality Record - A completed document that furnishes evidence of quality of items and/or activities affecting quality. Lifetime quality records related to waste form production are those quality records that are turned over to the repository operator for preservation as required for the canistered waste form to which they relate.
- 4.19 Surveillance - The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.
- 4.20 Audit - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

## 5.0 REQUIREMENTS

Quality assurance programs are to be established and implemented in Waste Acceptance Process Activities of high-level waste form production. These programs shall contain the activities and meet the criteria for those activities as defined in the basic and supplementary requirements defined hereafter.

### 5.1 Basic Requirements

The basic quality assurance requirements to be implemented in the quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production are defined in national consensus standards and DOE directives as identified in this section.

### **5.1.1 National Consensus Standard**

- (1) **ANSI/ASME NQA-1, 1986, "Quality Assurance Program Requirements for Nuclear Facilities," Sections I, II, and III.**

This standard contains basic and supplementary requirements and nonmandatory guidance for establishing and implementing quality assurance programs for nuclear facilities. (Note the nonmandatory guidance has not been invoked in the above reference.)

### **5.1.2 Department of Energy (DOE) Orders and Guidance**

- (1) **DOE 5000.3 "Unusual Occurrence Reporting System"**

This directive sets forth policy, responsibilities, criteria, and instructions for preparing, analyzing, and disseminating unusual occurrence reports.

- (2) **DOE 5700.6B "Quality Assurance"**

This directive provides policy, sets forth principles, and designates responsibility for the implementation of DOE plans and actions necessary to ensure quality achievement.

- (3) **Guidelines for Application of Readiness Reviews to Department of Energy Activities, January, 1987.**

This document contains guidelines for planning, staffing and conducting readiness reviews for assuring that all necessary activities and actions have been satisfactorily completed before subsequent activity initiation is authorized.

### **5.1.3 Relationship to Other Requirements and Guidance**

- (1) **10 CFR Part 60, "Disposal of High-Level Radioactive Waste in Geologic Repositories." Subpart G, "Quality Assurance," defines basic and supplemental requirements for quality assurance programs for CRWM program participants. Major participants in Waste Acceptance Process Activities of high-level waste form production will fulfill the applicable requirements of 10CFR Part 60, Subpart G, through implementation of quality assurance programs that meet the basic and supplementary requirements defined herein.**

- (2) DOE/RW-0005, "Mission Plan for Civilian Radioactive Waste Management," Section 5.6, also identifies the basic requirements for quality assurance programs for CRWM program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will implement the applicable requirements of Section 5.6 of DOE/RW-0005 as a consequence of implementing the basic requirements defined herein.
- (3) DOE/RW-0032, "OCRWM Quality Assurance Management Policies and Requirements," also identifies basic and supplementary requirements for quality assurance programs for CRWM program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will also implement the applicable requirements of DOE/RW-0032 as a consequence of implementing the basic and supplementary requirements defined herein.
- (4) DOE/RW-0043, "Program Management System Manual," Chapter 5, also identifies basic and supplementary requirements for quality assurance programs for CRWM program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will also implement the applicable requirements of Chapter 5 of DOE/RW-0043 as a consequence of implementing the basic and supplementary requirements defined herein.
- (5) DOE/RW-0095, "Quality Assurance Plan for High-Level Radioactive Waste Repositories (OGR/B-3)," also identifies basic and supplementary requirements for quality assurance programs for CRWM program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will also implement the applicable requirements of DOE/RW-0095 as a consequence of implementing the basic and supplementary requirements defined herein.

## **5.2 Supplemental Requirements**

There are several areas in Waste Acceptance Process Activities of high-level waste form production in which quality assurance activities are required in addition to those contained in the basic requirements identified in Section 5.1. These activities are identified in this section and the requirements for each activity are defined. These activities, as applicable, are to be developed and implemented as integral parts of the quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production.

### **5.2.1 Control of Essential Software**

Software that is essential to meeting the WAS is to be developed, implemented, documented and controlled as defined hereafter.

- A. Software to be controlled shall be identified in the WCP and documented. The documentation shall appropriately reflect the provisions of NUREG-0856 (see Appendix C).
- B. Software control activities shall include as appropriate:
  - (1) Identification of the organization and responsible individuals that influences the quality of software.
  - (2) Methods and procedures for design and development, including mathematical modeling and technical review of computer codes.
  - (3) Methods and procedures for verification of computer codes.
  - (4) Methods and procedures for validation of computer codes.
  - (5) Methods and procedures for configuration control of computer codes including the user's manual and the computer operations' manual.
  - (6) Identification of all support software and the computer equipment to be used.
  - (7) Methods and procedures for reporting, tracking and resolving software problems.
  - (8) Methods and procedures for safely storing verified computer codes and data.
  - (9) Methods and procedures for code custody and transfer control.

### **5.2.2 Peer Review**

Peer reviews are to be conducted for items or data significant to Waste Acceptance Process Activities of high-level waste form production. As a minimum, peer reviews shall include activities that go beyond the existing technology or where conclusions or assumptions have not been clearly validated

(e.g., disagreement exists between experts) by conventional means. Such peer reviews are to be identified and are to be planned, conducted and controlled as defined hereafter.

- A. Peer reviews shall be accomplished by qualified reviewers having qualifications at least equivalent to that needed to perform the work being reviewed.
- B. Peer reviews shall address the following areas as applicable:
  - (1) Validity of basic assumptions or functional requirements.
  - (2) Appropriateness of methodology.
  - (3) Verification of calculations or computer software.
  - (4) The review process and reviewer responsibilities.
  - (5) Handling of comment resolutions.
  - (6) Reporting minority positions.
  - (7) Involvement of the quality assurance organization.
  - (8) Review of new documents and changes to previously peer-reviewed documents.
  - (9) Re-review of revised documents.
  - (10) Records of revised documents.
  - (11) Review individual(s) qualifications for the review(s).
- C. The need for and extent of additional peer reviews shall be determined and accomplished following the revision of a previously peer-reviewed document whenever the technical content or results presented in the document are revised.
- D. Peer review records shall include qualifications of the reviewers, results of the review, and disposition or replies to reviewer comments. The peer review records shall be retained commensurate with the retention requirements of the data or documents which they support.

### **5.2.3 Control of Experiments and Developmental Activities**

Experiments and developmental activities to support Waste Acceptance Process Activities of high-level waste form production are to be controlled and documented in a manner which ensures that:

- (1) The data will be suitable for its intended use.
  - (2) Independent reconstruction and evaluation of the activities can be performed.
- A. The controls for experiments and developmental activities shall address the following:
- (1) Responsibility for initiating experiments and developmental activity.
  - (2) Selection and qualification of personnel.
  - (3) Review and approval of procedures.
  - (4) Surveillance and auditing of experiments and developmental activities.
  - (5) Review and evaluation of the results of experiments and developmental activities.
  - (6) Documentation of experiments and developmental activities and results.
  - (7) Responsibility for preparation and retention of documentation.
- B. While in progress, experiments and developmental activities shall be documented on a day-to-day basis and be maintained in a retrievable form.
- C. The experimental or developmental record shall be sufficiently detailed so that the following can be clearly identified, either directly or by reference.
- (1) Purpose of the experiment or developmental activity.
  - (2) The person(s) initiating the experiment or developmental activity.
  - (3) The person(s) performing the experiment or developmental activity.

- D. The experimental or developmental record shall also identify equipment, materials, and procedures actually used in sufficient detail to allow an individual skilled in the technology to reproduce the results.
- E. The experimental or developmental record shall also include original records of data or facsimiles of the original records.
- F. The experimental or developmental records shall be signed by the person performing the experiment or developmental activity.
- G. Any summaries, reports, or evaluations of the experiments, developmental activities or their results that are used for Waste Acceptance Process Activities shall clearly reference the experimental records.
- H. The experimental or developmental records of Waste Acceptance Process Activities are to be collected and maintained as quality records.

#### 5.2.4 Qualification of Data

Data or data interpretations in support of Waste Acceptance Process Activities of high-level waste form production are to be acquired or produced under a quality assurance program that meets the requirements defined herein. Data or data interpretations that were generated outside of a quality assurance program, as defined by this document, may be accepted based upon the results of a peer review or may be qualified through corroborating data, confirmatory testing or by having been acquired or produced under an equivalent quality assurance program. Such reviews or other qualification activities are to be conducted as further specified hereafter.

- A. Peer reviews shall be performed in accordance with the provisions of Subsection 5.2.2 under a quality assurance program meeting the requirements defined herein.
- B. Corroborating data shall be collected, processed and reported to demonstrate the properties of interest (e.g., physical, chemical, scientific, mechanical). Inferences drawn to corroborate non-qualified data shall be clearly identified and presented in a written justification of qualification which includes an analysis of the strengths of the quality assurance program under which the data was developed.

- C. Confirmatory tests shall be accomplished in accordance with a quality assurance program meeting the requirements defined herein to demonstrate the properties of interest (e.g., physical, chemical, scientific, mechanical).
- D. An equivalent quality assurance program is one that can be shown to be equivalent to the requirements defined herein. A determination of equivalence shall be based upon a demonstration which includes an assessment of differences between the two quality assurance programs and how these differences may bear on the intended use of the data.
- E. Documentation generated to support qualification of data shall be collected and maintained as quality records.

#### 5.2.5 Archival of Samples

Archival samples used for waste form qualification or for certification of canistered waste forms are to be prepared and controlled as follows:

- A. Sample preparation and use shall be planned and documented. The planning shall identify the following:
  - (1) What samples are to be used (number, size, origin or other characteristics).
  - (2) Where and when they are to be taken or prepared.
  - (3) Where and how they are to be kept.
  - (4) Where and how they are to be analyzed.
  - (5) When and how the results are to be used.
- B. Methods and procedures for sample preparation, maintenance and use shall be prepared and used. These shall cover the following as a minimum:
  - (1) Sample taking or preparation.
  - (2) Logging and labeling or otherwise identifying.
  - (3) Packing, packaging and handling.
  - (4) Locating, storage and monitoring.

- (5) Retrieval.
  - (6) Analysis.
  - (7) Treatment of data and results.
- C. Documentation and other forms of evidence necessary to demonstrate the performance of activities essential to the integrity of sample use shall be collected and maintained as quality records.

#### 5.2.6 Control of Special Processes

Production processes that have a significant effect on quality characteristics of the canistered waste form and that produce results that cannot be readily verified by inspection or testing of the final product are to be identified in the WCP and controlled. The controls to be established and implemented on such processes shall be performed by qualified personnel using qualified procedures in accordance with specified requirements and shall include:

- A. Process requirements shall be specified and maintained in controlled documentation.
- B. Process procedures or instructions shall be prepared and maintained as controlled documents with unique identification and revision status and be readily available in the work area when the process is being performed. These procedures or instructions shall consider the following as a minimum:
  - (1) Identification of required equipment and instrumentation.
  - (2) Identification of control parameters and the operating limits for those parameters.
  - (3) Environmental conditions and requirements.
  - (4) Instrument calibration frequency.
  - (5) Reference to applicable codes, standards and specifications.

These procedures or instructions may be included in other controlled documents, such as drawings, checklists, travelers, work orders, or specifications.

- C. Personnel shall be selected, trained, and indoctrinated in accordance with subsection 5.2.10.
- D. Copies of process requirements, procedures or instructions, and documentation of personnel qualifications shall be collected and maintained as quality records.

#### **5.2.7 Product Certification**

The waste form producers are to develop and provide for retention, the records necessary to provide evidence of the acceptability of the canister and waste form which includes the canistered waste form. The WCP and/or WQR are to identify the types of records that will be developed during the waste form production process. The WQR is to identify the quality records required to be a permanent part of the overall canistered waste form product certification package. These documents are to be identified, collected, managed and delivered in accordance with the requirements of subsection 5.2.12.

#### **5.2.8 Readiness Review**

Readiness reviews are to be planned, scheduled and conducted at significant transitional events in Waste Acceptance Process Activities leading up to and during high-level waste form production to assure that all necessary activities and actions have been satisfactorily completed before subsequent activity initiation is authorized. Readiness reviews shall be performed in accordance with DOE Guidelines for Application of Readiness Reviews to Department of Energy Activities, dated January, 1987.

#### **5.2.9 Selective Application of Program Activities (Quality Levels)**

A systematic method by which quality assurance activities are selected and applied to Waste Acceptance Process Activities of high-level waste form production is to be established and implemented.

The selective application method implemented shall be described in the WCP.

### **5.2.10 Selection, Indoctrination, and Training of Personnel**

Personnel who perform or verify activities affecting quality in waste acceptance process activities of high-level waste form production are to be proficient in the activities that they perform. A systematic practice for achieving and assuring the required proficiency is to be established and implemented. Prior to assigning personnel to perform activities affecting quality, they shall receive appropriate training and indoctrination as defined in ANSI/ASME NQA-1, Supplement 2S-4.

- A. Personnel who perform verification activities that require qualification (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) are to be certified in accordance with the detailed requirements specified in ANSI/ASME NQA-1 and referenced codes and standards.**
- B. Other personnel who perform activities that require qualification are to have their qualification requirements defined and their qualifications determined and documented as follows.**
  - 1. Types of positions or tasks requiring qualified personnel shall be identified and procedures established for the following:**
    - (a) Selection of personnel.**
    - (b) Training and indoctrination of personnel.**
    - (c) Proficiency evaluation.**
    - (d) Recording of qualifications.**
  - 2. Position or task descriptions shall be prepared which define the minimum education and experience requirements for each type of position or task requiring qualification.**
  - 3. Personnel selected to fill positions or perform tasks requiring qualification shall be evaluated to determine that they are qualified. Such determinations shall be documented by managers or supervisors responsible for the activities to be performed.**

### **5.2.11 Overview of Quality Assurance Activities**

Each major participant in Waste Acceptance Process Activities of high-level waste form production is to establish and implement a systematic overview of quality assurance activities performed by organizations over which they have contractual or administrative overview responsibilities. Each organization's overview practice is to include an appropriate combination of the following activities:

- (1) The review and approval of participant quality assurance plans and administrative procedures.**
- (2) Surveillance of participant activities affecting quality to verify compliance with requirements.**
- (3) Performance of quality assurance audits to verify the adequacy and effectiveness of participant quality assurance program activities.**

These activities are to be planned and performed in accordance with procedures as described hereafter:

- A. Procedures shall be established for the review of participant quality assurance programs to verify adequacy, completeness and relevance. The overview procedures shall identify the types of documents to be submitted by the participant for review and approval; shall assign project responsibility for reviews; and shall identify the methods for documenting review and approval actions.**
- B. Procedures shall be established for planning, scheduling, performing, and documenting surveillance of participant activities related to quality. Surveillance activities shall be performed by personnel who are not directly responsible for performing the work to be monitored or observed in the surveillance activity. Surveillance actions shall be performed to written checklists or plans whenever practicable. All deficiencies, non-conformances and potential quality problems identified during the surveillance shall be documented and monitored until verification of disposition or corrective action is accomplished.**
- C. Procedures shall be established for the planning, scheduling, performing and reporting of quality assurance audits of participant quality assurance programs. Audit schedules shall be developed annually and updated as changes occur. Audits of organizations common to more than one project shall be coordinated whenever practicable to conserve resources and maintain consistency.**

Audit teams should include, whenever possible, a representative that is trained and/or qualified in the technology being audited.

- D. Documentation of overview activities shall be retained as quality records.

#### 5.2.12 Quality Records

Documentation sufficient to demonstrate canistered waste form compliance with the WAS and implementation of this specification is to be prepared and maintained as quality records. These records are to be collected and maintained as follows.

- A. Documentation sufficient to demonstrate satisfactory implementation of the WCP shall be collected and maintained as lifetime quality records by the major participant that generated or caused to be generated the documentation. Copies of these records shall be made available to the Federal Repository Operator at the time the repository is ready to begin accepting canistered waste forms from the waste form producer. Such records will be maintained by the Federal Repository Operator to satisfy any repository requirements. Other documentation generated during preparation and implementation of the WCP shall be collected and maintained as nonpermanent quality records.
- B. Documentation sufficient to support preparation of the WQR shall be collected and maintained as lifetime quality records by the major participant that generated or caused to be generated the documentation. Copies of these records shall be made available to the Federal Repository Operator at the time the repository is ready to begin accepting canistered waste forms from the waste form producer. Such records will be maintained by the Federal Repository Operator to satisfy any repository requirements. Other documentation generated during preparation and maintenance of the WQR shall be collected and maintained as nonpermanent quality records.
- C. Production documentation shall be identified in a manner that facilitates positive-direct correlation between documents and canistered waste forms to which they relate.
- D. Production documentation shall be declared lifetime quality records and transferred to the Federal Repository Operator with the canistered waste forms to which they relate.

- E. Copies of production documentation shall be kept and maintained by the waste form producer as non-permanent quality records. These records shall be kept for a minimum of 10 years after the canistered waste forms they represent are transferred to the Federal Repository Operator or as otherwise directed by DOE.

#### 5.2.13 Modification Control

Controls are to be established and implemented by the appropriate major participant to assure that only approved modifications are made in Waste Acceptance Process Activities of high-level waste form production. These controls shall include the following:

- A. Application to items and activities that are essential to canistered waste form certification and acceptance as defined in the WAS including the following as appropriate.
  - (1) The waste form.
  - (2) The waste canister.
  - (3) The canistered waste form.
  - (4) The production process.
  - (5) Processing equipment.
  - (6) Processing supplies and consumables.
  - (7) Processing plans and procedures.
  - (8) Maintenance plans and procedures.
  - (9) Process control plans and procedures.
- B. A controlled listing of the documentation that defines items and activities under modification control.
- C. Procedures defining elements of the modification control process that address:
  - (1) Change proposals (including deviation requests and waiver request).
  - (2) Change review and approval.

**(3) Change implementation.**

**(4) Change incorporation and issue of changed documentation and records.**

**D. Provisions for assessing the need for and accomplishing any needed requalification resulting from modifications.**

#### **5.2.14 Effectiveness Evaluation**

Each major participant in Waste Acceptance Process Activities of high-level waste form production is to establish and implement methods and procedures for evaluating the effectiveness of its quality assurance program in ensuring conformance with the WAS. The effectiveness evaluation practice is to include the following:

- A. A clear identification of the quality characteristics to be achieved in meeting the requirements of the WAS.**
- B. The identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved.**
- C. A performance measuring process using review, surveillance, inspection, tests, audit or other techniques to monitor performance indicators.**
- D. An analysis process in which performance data are trended and problem areas identified.**
- E. A reporting practice in which program effectiveness information is prepared and fed back to top management.**

### **5.3 Quality Assurance Program Description**

The quality assurance program applied to Waste Acceptance Process Activities of high-level waste form production is to be described in a document that provides guidance and direction for program implementation and a concise description of what the program contains and how it is to function.

#### **5.3.1 General**

- A. The description shall cover the basic and supplementary requirements identified in Sections 5.1 and 5.2 of this specification in sufficient detail to provide a**

knowledgeable reviewer with confidence that an adequate response to all quality assurance requirements have been identified and fully developed in the quality assurance program.

B. The description shall also provide a formal statement by the management of the organization of its commitment to:

(1) Implement the quality assurance program activities for which it is responsible.

(2) Review the program periodically and revise it as necessary to keep it current and effective.

### 5.3.2 Structure

The program description is to be a composite of the program descriptions of each of the major participants in Waste Acceptance Process Activities of high-level waste form production tied together by an umbrella description that identifies the major participants, their roles and responsibilities and how they interface and work together. This structural concept is illustrated in Figure 1. Figure 2 shows how such a waste form producer program description can be used to support The Federal Repository's licensing activities.

### 5.3.3 Format and Content

The format and content of each of the constituent program descriptions of the major participants are to be as described in Appendix A, Guidelines for Preparation of a Quality Assurance Program Description for High-Level Waste Form Production.

### 5.3.4 Approval and Maintenance

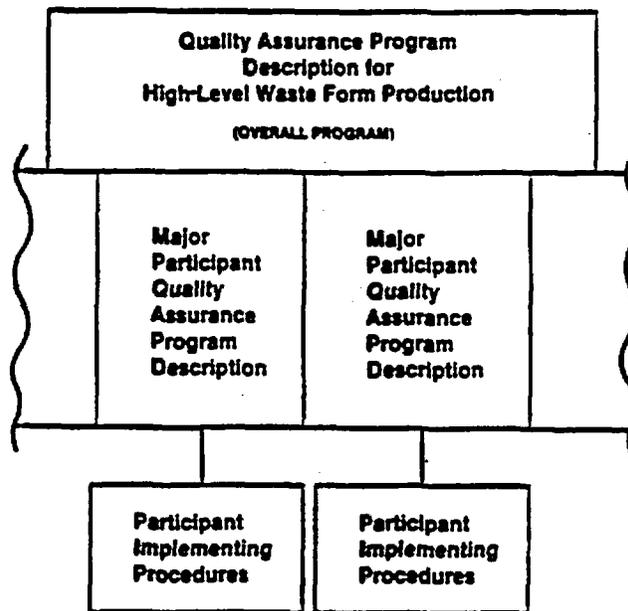
A. The program description is to be made a part of the WCP.

B. Procedures shall be prepared and implemented for the program description approval and subsequent change control that satisfy DOE approval and change control requirements. These procedures may be an integral part of the procedures for approval and maintenance of the WCP or they may be separate.

#### **5.4 Program Description Evaluation**

Quality assurance programs applied to Waste Acceptance Process Activities of high-level waste form production are expected to be evaluated by DOE/RW, as the repository licensing applicant, for licensing purposes against the applicable criteria of the NRC Review Plan for Quality Assurance Programs for High-Level Nuclear Waste Repositories (HLNWR). To ensure the acceptability of these quality assurance programs, the program descriptions prepared as defined in Section 5.3 of this specification shall be evaluated against the criteria in Appendix B, Review Plan for Quality Assurance Programs for High-Level Waste Form Production. As a minimum, this evaluation shall be performed as an internal evaluation by the organization preparing the program description. Alternatives to the Appendix B criteria may be necessary to address unique HLNWR situations. They shall be identified and justified in the WCP. The quality assurance program description in the WCP shall address any modifications to the criteria of Appendix B.

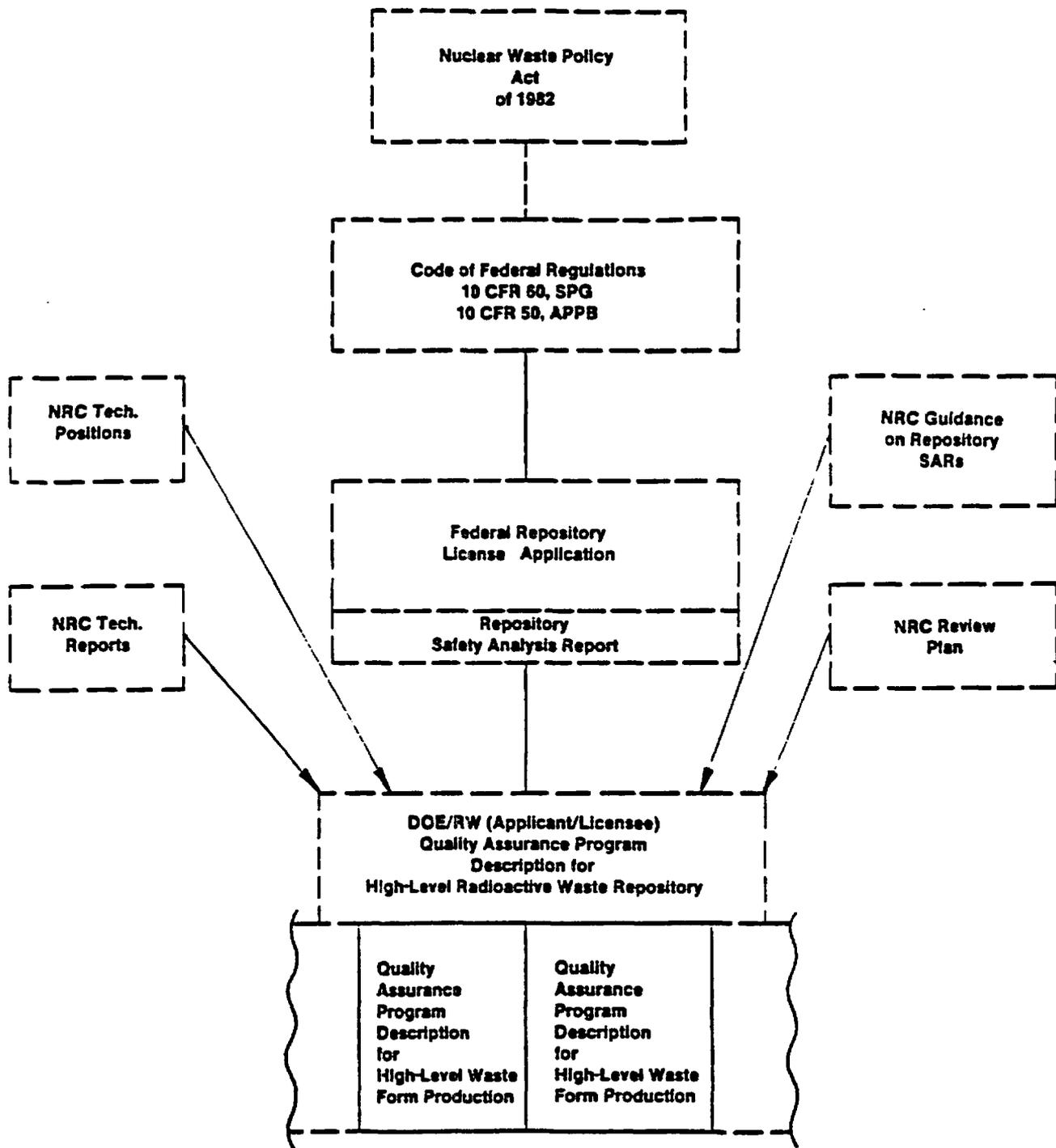
# COMPOSITE QUALITY ASSURANCE PROGRAM DESCRIPTION FOR A TYPICAL HIGH-LEVEL WASTE FORM PRODUCTION ACTIVITY



**Major Participants  
(High-Level Waste Form Production)**

- DOE-HQ
- DOE-OPS Office
- DOE-PO
- OP Contractor

**FIGURE 1**



**TYPICAL RELATIONSHIP OF QUALITY ASSURANCE PROGRAM DESCRIPTIONS TO SUPPORT REPOSITORY LICENSING**

**FIGURE 2**

**APPENDICES**

**APPENDIX A**  
**GUIDELINES**  
**FOR**  
**PREPARATION OF A QUALITY ASSURANCE PROGRAM DESCRIPTION**  
**FOR**  
**HIGH-LEVEL WASTE FORM PRODUCTION**

**1.0 INTRODUCTION**

This appendix has been prepared as a guide to assist high-level waste form producer organizations in the preparation of their quality assurance program descriptions in response to the requirements of Section 5.3 of this specification. The quality assurance program described in the program description is intended to be the program implemented in Waste Acceptance Process Activities of high-level waste form production. The program described may be more broadly applied if the organization wishes and such expanded scope should be clearly identified in such a way as to make it very clear as to which activities apply to Waste Acceptance Process Activities of high-level waste form production and which activities are applied beyond that scope.

The guidance contained in this appendix is a customized version of NRC Regulatory Guide 1.70.6. The guide was developed by NRC many years ago to assist applicants with water reactor construction projects in the preparation of their quality assurance program descriptions. These descriptions were intended to be included in license applications as Chapter 17 of The Safety Analysis Report. At that time NRC required the applicant to prepare its description in the format (including paragraph numbering and titles) as shown in the guide. For this reason the guide has been left showing the Chapter 17 format as though the resulting program description would become a part of Chapter 17 in The Safety Analysis Report of the repository license application.

**17.0 QUALITY ASSURANCE**

The quality assurance program being described should be established at the earliest practical time consistent with the schedule for accomplishing the activity. Where some portions of the quality assurance program have not yet been established at the time the Program Description is prepared, (because the activity will be performed in the future) the description should also provide a schedule for implementation.

In order to facilitate the presentation of information about the quality assurance program, the major participants in the waste form producer organization that are involved in executing the quality assurance program should include the information described (either separately for each organization or integrally for all organizations) in accordance with the outline presented below.

## **17.2 Quality Assurance During Production**

### **17.2.1 Organization**

**17.2.1.1** The Program Description should describe clearly the authority and duties of persons and organizations performing the quality assurance functions of assuring that the quality assurance program is established and executed and of verifying that an activity has been correctly performed. The Program Description should provide organization charts and functional responsibility descriptions that denote the lines of responsibility and areas of authority within each of the major participant organizations in Waste Acceptance Process Activities of high-level waste form production including DOE headquarters, DOE operation offices, DOE project offices, and operating contractors of DOE facilities. Hereafter, these organizations are referred to collectively as the "waste form producer". These charts and descriptions should present the structure of quality assurance organizations involved as well as other functional organizations performing activities affecting quality in preparation of waste forms, acquisition of waste canisters and canistering of waste forms with clear delineation of their responsibility, authority, and relationship to corporate management. In addition, a single, overall project organization chart should be included showing how the major organizations or companies working directly as the waste form producer interrelate with one another.

**17.2.1.2** The Program Description should describe the level of management responsible for establishing the quality assurance policies, goals, and objectives and should describe the continuing involvement of this management level in quality assurance matters. The Program Description should tell what position has overall authority and responsibility for the quality assurance program and tell what position is responsible for final review and approval of the quality assurance program and related manuals. The qualification requirements of the principal quality assurance and quality control positions should be described.

**17.2.1.3** The Program Description should describe those measures which assure that persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to (1) identify quality problems, (2) initiate, recommend, or provide solutions, and (3) verify implementation of solutions. The Program Description should describe the measures which assure that persons and organizations assigned the responsibility for checking, auditing, inspecting or otherwise verifying that an activity has been correctly performed report to a management level such that this required authority and organizational freedom, including sufficient independence from the pressures of production, are provided. Irrespective of the organizational structure, the Program Description should describe how the individual or individuals with primary responsibility for assuring effective implementation of the quality assurance program at any location where activities subject to the control of the quality assurance program are being performed will have direct access to such levels of management as may be necessary to carry out this responsibility. The Program Description should indicate from whom the persons performing quality assurance functions receive technical direction for performing quality assurance

tasks and administrative control (salary review, hire/fire, position assignment). The Program Description should identify those positions or organizations which have written delegated responsibility and authority to stop work or control further processing, use or delivery of nonconforming items until proper disposition of the deficiency has been approved.

The Program Description should describe how requirements will be imposed on other organizations including contractors and subcontractors to assure that individuals or groups within their organizations performing quality assurance functions have sufficient authority and organizations freedom to effectively implement their respective quality assurance programs.

**17.2.1.4** The Program Description should describe the extent to which the organization will delegate to other organizations the work of establishing and executing the quality assurance program or any part thereof. A clear delineation of those quality assurance functions which are implemented within the organization and those which are delegated to other organizations should be provided in the Program Description. The Program Description should describe the method by which the organization will retain responsibility for and maintain control over those portions of the quality assurance program delegated to other organizations and should identify the organization responsible for verifying that delegated quality assurance functions are properly carried out. The Program Description should identify major work interfaces for activities affecting quality and describe how clear and effective lines of communication exist between the organization and other major participants in the waste form producer organization to assure necessary coordination and control of the quality assurance program.

## **17.2.2 Quality Assurance Program**

**17.2.2.1** The quality assurance program in the Program Description should cover each of the criteria in Appendix B to 10 CFR Part 50 (see Note 1) in sufficient detail to permit a determination as to whether and how all of the requirements of Appendix B will be satisfied. The Program Description should (1) describe the extent to which the quality assurance program will conform to various provisions of ANSI/ASME NQA-1 and NRC regulatory guides that provide guidance on acceptable methods of implementing portions of the quality assurance program and (2) identify the organizational element responsible for implementing these provisions. If the waste form producer elects not to follow the above guidance, the Program Description should describe in detail equivalent to that furnished in this instruction the alternative methods that will be used and the manner of implementing them and should indicate the organizations responsible for their implementation.

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Note 1 - The Federal Repository including the waste package to be placed in the repository is to comply with 10CFR Part 60. Subpart G of this regulation subsequently requires compliance with Appendix B of 10CFR Part 50.

**17.2.2.2** The Program Description should identify the items and activities of the Waste Acceptance Process Activities of high-level waste form production to be controlled by the quality assurance program.

**17.2.2.3** The Program Description should describe the measures which assure that the quality assurance program was or is being established at the earliest practicable time consistent with the schedule for accomplishing activities affecting quality in Waste Acceptance Process Activities of high-level waste form production. That is, the Program Description should describe how the quality assurance program is being established in advance of the activity to be controlled and how it will be implemented as the activity proceeds. Those activities affecting quality initiated prior to the development of the waste form producer Quality Assurance Program, such as establishing information required to be included in the Program Description; performing research and development that is essential to the qualification of the waste form; control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms; and processing operations that are essential to the certification of canistered waste forms should be identified in the Program Description. The Program Description should describe how these activities are controlled by a quality assurance program which complies with this specification.

**17.2.2.4** The Program Description should describe how the quality assurance program is documented by written policies, procedures, or instructions and how it will be implemented in accordance with these policies, procedures, or instructions. The procedures list should identify which requirements of the specification are implemented by each procedure. In the event certain required procedures are not yet established, a schedule for their preparation should be provided in the Program Description.

**17.2.2.5** The Program Description should summarize the corporate quality assurance policies, goals, and objectives; and it should describe how disputes involving quality are resolved.

**17.2.2.6** The Program Description should describe the program that provides adequate indoctrination and training of personnel performing activities affecting quality in Waste Acceptance Process Activities of high-level waste form production to assure that suitable proficiency is achieved and maintained. The Program Description should describe how the indoctrination and training program will assure that:

1. Personnel performing activities affecting quality are appropriately trained in the principles and techniques of the activity being performed,
2. Personnel performing activities affecting quality are instructed as to purpose, scope, and implementation of governing manuals, policies, and procedures,

3. Appropriate training procedures are established, and
4. Proficiency of personnel performing activities affecting quality is maintained.

**17.2.2.7** The Program Description should describe the qualification requirements for the position or positions responsible for assuring effective implementation of the quality assurance program of the major participants in the waste form producer organization.

**17.2.2.8** The Program Description should describe the measures that assure that activities affecting quality will be accomplished under suitable controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity; e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given process or activity.

**17.2.2.9** The Program Description should describe the measures that assure that there is regular management review of the quality assurance program to assess its effectiveness and the adequacy of its scope, and implementation. The Program Description should describe the provisions for reviews by management above or outside the quality assurance organization to assure achieving an objective program assessment. The Program Description should describe the measures that assure that the quality assurance unit of the organization will (1) review and document agreement with the quality assurance programs of subtier participants in the waste form producer organization and (2) conduct or have conducted audits of the subtier participants.

**17.2.2.10** The Program Description should provide a summary description of the advanced planning that demonstrates control of quality-related activities including management and technical interfaces between the participant and other major participants in the waste form producer organization during research and development that is essential to qualification of the waste forms; control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms; and processing operations that are essential to the certification of canistered waste forms.

**17.2.2.11** The Program Description should describe provisions for maintaining the quality assurance Program Description current.

### **17.2.3 Design Control**

**17.2.3.1** The Program Description should describe the design control measures that assure that (1) applicable requirements for important items and activities essential to the certification of canistered waste forms are correctly

translated into operating and production processing specifications, drawings, procedures, and instructions, or for any modifications that become necessary, (2) appropriate quality standards are specified in design documents, and (3) deviations from such standards are controlled.

**17.2.3.2** The Program Description should describe measures to control operations, maintenance and modifications that assure that adequate review and selection for application suitability is conducted for production materials, parts, equipment, and processes that affect features of the canistered waste form with regard to its conformance with the Waste Acceptance Specification (WAS). The Program Description should describe provisions that assure that standard commercial or so-called "off-the-shelf" materials, parts, and equipment also receive adequate application review and selection before use in production processing that could affect canistered waste form compliance with the WAS.

**17.2.3.3** The Program Description should describe the program for applying design control measures to such aspects of production as processing; process design, development and qualification; production materials compatibility; product design, inspection, and testing and should describe measures for delineation of acceptance criteria for inspections and tests.

**17.2.3.4** The Program Description should describe measures that assure verification or checking of design adequacy, such as by design reviews, use of alternative calculational methods, or performance of a qualification testing program under the most adverse design conditions. The Program Description should identify the positions or organizations responsible for design verification or checking and should describe how design verification or checking is performed by individuals or groups other than those who performed the original design, but who may be from the same organization.

**17.2.3.5** The Program Description should describe measures for identifying and controlling design interfaces, both internal and external, and for coordination between participating design organizations. The Program Description should describe measures in effect between participating design organizations for review, approval, release, distribution, collection, and storage of documents involving design interfaces and changes thereto. The Program Description should describe how these measures will assure that these design documents are controlled in a timely manner to prevent inadvertent use of superseded design information.

**17.2.3.6** The Program Description should describe the measures that will be employed to assure that design changes, including field changes, are subject to the same design controls that were applied to the original design and are reviewed and approved by the organization that performed the original design unless the originating organization designates another responsible organization.

#### **17.2.4 Procurement Document Control**

**17.2.4.1** The Program Description should describe measures that assure that documents, and changes thereto, for procurement of material, equipment, and services, whether purchased by the waste form producer or contractors or sub-contractors, correctly include or reference the following as necessary to achieve required quality:

1. Codes, standards and design requirements,
2. Quality assurance program requirements,
3. Requirements for supplier documents such as instructions, procedures, drawings, specifications, inspection and test records, and supplier QA records to be prepared, submitted, or made available for purchaser review or approval,
4. Requirements for the retention, control, and maintenance of supplier quality assurance records,
5. Provision for purchaser's right of access to supplier's facilities and work documents for inspection and audit, and
6. Provision for supplier reporting and disposition of nonconformances from procurement requirements.

**17.2.4.2** The Program Description should describe (1) measures that clearly delineate the control responsibilities and action sequence to be taken in the preparation, review, approval, and issuance by competent personnel of procurement documents and (2) measures that assure that changes or revisions of procurement documents are subject to the same review and approval requirements as the original documents.

**17.2.4.3** The Program Description should describe measures that assure (1) that procurement documents require suppliers to have and implement a documented quality assurance program for purchased materials, equipment, and services to an extent consistent with their importance, (2) that the purchaser has evaluated the supplier before the award of the purchase order or contract to assure that the supplier can meet the procurement requirements, and (3) that procurement documents for spare or replacement items will be subject to controls at least equivalent to those used for the original supplies or equipment.

#### **17.2.5 Instructions, Procedures, and Drawings**

**17.2.5.1** The Program Description should describe measures that assure that activities affecting quality such as production processing, equipment maintenance, modifications, repair, testing, and inspection, and product handling are prescribed by appropriately documented instructions, procedures, or drawings and that these activities will be conducted in accordance with these documents.

**17.2.5.2** The Program Description should describe the system whereby the documented instructions, procedures, and drawings will include appropriate quantitative (such as dimensions, tolerance, and operating limits) and qualitative (such as workmanship samples) acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

#### **17.2.6 Document Control**

**17.2.6.1** The Program Description should describe those measures established to control the issuance of documents such as instructions, procedures, and drawings, including changes thereto, that prescribe all activities affecting quality in Waste Acceptance Process Activities of high-level waste form production. The description should cover control measures that assure that:

1. Documents are reviewed for adequacy (i.e., information is clearly and accurately stated) and are approved by authorized personnel for issuance and use at locations where the prescribed activity will be performed before the activity is started,
2. Means such as use of updated master document lists exist to assure that obsolete or superseded documents are replaced in a timely manner by updated applicable document revisions, and
3. Document changes are reviewed and approved by the same organizations that performed the original review and approval unless delegated by the originating organization to another responsible organization.

**17.2.6.2** The Program Description should identify the types of documents to be controlled and the group responsible for review, approval, and issuance of documents and changes thereto.

#### **17.2.7 Control of Purchased Material, Equipment, and Services**

**17.2.7.1** The Program Description should describe those measures that assure that material, equipment, and services purchased directly by the waste form producer or subcontractors will conform to procurement document requirements. The Program Description should describe the measures that provide, as appropriate for:

1. Evaluation and selection of sources of supply before the award of the procurement order or contract,
2. Surveillance at the supplier's facility by the purchaser or his representative in accordance with written procedures during design, manufacture, inspection, and test of the procured item or service to verify compliance with quality requirements,

3. Source and/or receipt inspection in accordance with written procedures and acceptance criteria of procured items furnished by the supplier,
4. Documentary evidence at the production facility from the supplier that procured items meet procurement quality requirements such as codes, standards, or specifications. The Program Description should describe measures established by waste form producer to (a) examine and indicate acceptance of this documented evidence during source or receipt inspection and (b) assure that this documented evidence is available at the production facility prior to installation or use of the procured item and that the documentation will be retained at the production facility, and
5. Periodic verification of supplier's certificates of conformance to assure that they are meaningful.

**17.2.7.2** The Program Description should describe measures whereby the waste form producer or his designated representative will audit and evaluate the effectiveness of the control of quality related activities of contractors and subcontractors at a frequency and extent consistent with the importance to safety, complexity, and quantity of the item or service being furnished.

**17.2.8 Identification and Control of Materials, Parts, and Components** The Program Description should describe measures established to identify and control processing materials, supplies, canisters, canistered waste forms, including partially filled assemblies, to prevent use of incorrect or defective feed material or loss of tracability between canistered waste forms and documentation. The Program Description should describe measures that assure (1) that identification of the item (i.e., heat number, part number, serial number, or other appropriate marking) is maintained either on the item or on records traceable to the item and verified, as required, throughout production, processing and (2) that the method and location of the identification does not affect the function or quality of the item being identified.

**17.2.9 Control of Special Processes** The Program Description should describe measures established to control special processes such as glass melting, welding, cleaning, and testing and to assure that they are accomplished by qualified personnel using written procedures qualified in accordance with applicable codes, standards, specifications, or other special requirements. The Program Description should describe those measures that assure that qualifications of special processes, personnel performing special processes, and equipment are kept current and that record files thereof are maintained.

## **17.2.10 Inspection**

**17.2.10.1** The Program Description should describe the measures that assure that a program for inspection is established and implemented by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The Program Description should describe measures that assure that (1) inspection personnel are appropriately qualified and are independent of the individual or group performing the activity being inspected, (2) inspections or tests are performed for each work operation or process activity as necessary to verify quality, (3) indirect control by monitoring processing methods, equipment, and personnel is used if direct inspection of processed material or products is impossible or disadvantageous, and (4) both inspection and process monitoring are used when control is inadequate without both. The Program Description should describe measures that assure that (1) inspection procedures and instructions are made available with necessary drawings and specifications for use prior to performing the inspections, (2) inspectors' qualifications or certifications are kept current, (3) replaced or reworked items are inspected in accordance with original inspection requirements, and (4) modified or repaired items are inspected by methods that are equivalent to the original inspection method.

**17.2.10.2** The Program Description should describe the system whereby appropriate documents will identify any mandatory sampling or inspection hold-points that require witnessing or inspecting by the waste form producer or his designated representative and beyond which work may not proceed without the consent of his designated representative.

## **17.2.11 Test Control**

**17.2.11.1** The Program Description should describe the measures that establish a test program that (1) identifies all testing required to demonstrate that items and services will conform to specified requirements, (2) is conducted by trained and appropriately qualified personnel in accordance with written test procedures that incorporate or reference the requirements and acceptance limits contained in applicable design documents, and (3) includes testing that will be performed in the Product and Process Qualification Phases.

**17.2.11.2** The Program Description should describe the measures that assure test procedures have provisions for assuring that:

1. All prerequisites for the given test have been met,
2. Adequate instrumentation and equipment are available, and
3. The test is performed under suitable environmental conditions and with appropriate test methods.

**17.2.11.3** The Program Description should describe the system whereby test results are documented and evaluated to assure that test requirements have been satisfied.

**17.2.12 Control of Measuring and Test Equipment**

The Program Description should describe the measures established to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly identified, controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. The Program Description should describe measures that assure (1) that these devices are adjusted and calibrated against certified equipment or reference transfer standards having known valid relationships to nationally recognized standards or (2) that if no national standards exist, the basis for calibration is documented. The Program Description should describe the measures that assure that the error of calibration standards is less than the error of production measuring and test equipment. The Program Description should describe provisions that will apply if measuring and test equipment is found out of calibration (1) for evaluating the validity of previous inspection or test results and the acceptability of items inspected or tested since the last calibration check and (2) for repeating original inspections or tests using calibrated equipment where necessary to establish acceptability of suspect items. The Program Description should describe measures that assure the maintenance of records that indicate the calibration status of all items under the calibration system and that identify the measuring and test equipment.

**17.2.13 Handling, Storage, and Shipping**

The Program Description should describe the measures established to control the handling, storage, shipping, cleaning, and preservation of canistered waste forms including processing material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. The Program Description should describe the measures for specifying and providing, when necessary for particular process steps, special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels.

**17.2.14 Inspection, Test, and Operating Status**

The Program Description should describe measures established to indicate by the use of markings such as stamps, tags, labels, routing cards, or other suitable means the status of inspections and tests performed on individual items or activities of the canistered waste form throughout waste form production. The Program Description should describe measures that provide for the identification of items and services that have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of such inspections and tests. The Program Description should describe the measures established for indicating the operating status of structures, systems, and components of the processing equipment and its support facilities and equipment. Such measures shall include, for example, tagging valves and switches to prevent inadvertent operation.

#### **17.2.15 Nonconforming Materials, Parts, or Components**

The Program Description should describe the measures established to control materials, parts, components or canistered waste forms that do not conform to requirements in order to prevent their inadvertent use or delivery. The Program Description should describe measures that provide for, as appropriate, identification, documentation, segregation, disposition, and notification to affected organizations. The Program Description should describe measures that assure that nonconforming items are reviewed and dispositioned in accordance with documented procedures. The Program Description should describe measures that control further processing or delivery pending proper disposition of the deficiency. The Program Description should describe measures established by the waste form producer (1) for contractors to report to him those nonconformances concerning departures from procurement requirements that are dispositioned "use as is" or "repair" and (2) to make such nonconformance reports part of the documentation required at the waste form production site or to include description of the nonconformance and its disposition on certificates of conformance that are provided to the site prior to use of material or equipment. The Program Description should state whether periodic analyses of nonconformance reports are performed to show quality trends and whether such analyses are forwarded to management.

#### **17.2.16 Corrective Action**

**17.2.16.1** The Program Description should describe the measures that assure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconforming in process and completed products are promptly identified and corrected.

**17.2.16.2** The Program Description should describe how, in the case of significant conditions adverse to quality, the cause of the condition is determined, corrective action is taken to preclude repetition, and the problem with its determined cause and corrective action is documented and reported to appropriate levels of management.

#### **17.2.17 Quality Assurance Records**

**17.2.17.1** The Program Description should describe the measures that assure that sufficient records are maintained to furnish evidence of activities affecting quality. The Program Description should describe how the content of such records (1) includes at least the following: test logs; results of reviews, drawings, inspections, tests, audits, monitoring of work performance, and materials and product analyses; and such data as qualifications of personnel, procedures, and equipment; (2) identifies the type of operation, and inspector or data recorder, the results, the acceptability, and action taken to correct any deficiencies noted; and (3) provides sufficient information to permit identification of the record with the item or activity to which it applies.

**17.2.17.2** The Program Description should describe the measures that assure that records will be identifiable and retrievable.

**17.2.17.3** The Program Description should describe the measures that establish requirements (consistent with regulatory requirements and responsibilities concerning record submittal and retention, security, and storage facilities) for protecting records from destruction by fire, flooding, tornadoes, insects, and rodents and from deterioration by extremes in temperature and humidity.

#### **17.2.18** Audits

The Program Description should describe the program of the waste form producer for conducting comprehensive planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

The Program Description should describe the program features that cover the functions listed below and should identify the positions or organizations that perform these functions.

1. External audits to be performed by the waste form producer or suppliers,
2. Internal audits to be performed by the waste form producer within their respective organizations,
3. The planning and scheduling of audits to assure that they are regularly scheduled on the basis of the status and safety importance of the activities being performed and are initiated early enough to assure effective quality assurance during production processing; equipment maintenance, modification, repair, inspection, and testing; or product inspection, handling, storing and shipping.
4. Conduct of audits in accordance with written procedures or checklists by appropriately trained and qualified personnel not having direct responsibility in the area being audited, and
5. Documentation of audit results with review by management responsible for the area audited and, where indicated, followup action taken, including re-audit of the deficient areas.

**APPENDIX B**  
**REVIEW PLAN**  
**FOR**  
**QUALITY ASSURANCE PROGRAMS FOR HIGH-LEVEL WASTE FORM PRODUCTION**

**1.0 INTRODUCTION**

This appendix has been prepared for use by organizations that are major participants in Waste Acceptance Process Activities of high-level waste form production. It is intended to be used as a checklist or review plan for evaluating the adequacy of the organization's quality assurance program in meeting the requirements for that program as defined in this specification. Its purpose is to facilitate the program evaluation required by Subsection 5.4 of this specification.

The quality assurance program required by this specification is expected to be evaluated at some point in the Federal Repository licensing procedure by the NRC. In order to develop the highest confidence level possible in its being found acceptable by the NRC at that time, this checklist or review plan has been prepared using the NRC's review plans for quality assurance programs for nuclear facility design, construction, and operations; repository site characterization; and waste packaging and transportation. Also considered were generic technical positions and other guidance that has been made available from the NRC. Since the evaluation by the NRC is expected to be made using their review plan for quality assurance programs for High-Level Nuclear Waste Repositories (HLNWR), this checklist or review plan has been prepared using concepts and language similar to that which would be expected to be in the NRC's review plan. Further, since the NRC's review plan is expected to be strongly oriented toward repository design, construction and operation, the checklist or review plan contained herein is also oriented in language to facility design, construction and operation even though the intended scope and application of the required quality assurance program is strictly Waste Acceptance Process Activities of high-level waste form production. This bias has been purposefully placed in the checklist or review plan to cause the evaluation process by the major participant's organization to consider the features of the program description from the same reference points expected of the NRC evaluation.

## **2.0 GENERAL**

The quality assurance program description must describe the quality assurance program that will be established, maintained, and implemented in the accomplishment of Waste Acceptance Process Activities of high-level waste form production.

The required quality assurance program is to be described in sufficient detail to allow a review and determination of acceptability with regard to the acceptance criteria defined herein.

### **3.0 ACCEPTANCE CRITERIA**

These acceptance criteria are to be used to evaluate the quality assurance program of a waste form producer that is proposed for accomplishing Waste Acceptance Process Activities of high-level waste form production.

The evaluation is to also determine if the implementation of commitments to specified requirements has been described in inspectable terms.

- I. **The organizational elements responsible for the quality assurance program are acceptable if:**
  - A. **The responsibility for the overall program for Waste Acceptance Process Activities of high-level waste form production is retained and exercised by the appropriate DOE organization.**
  - B. **The waste form producer describes any delegation of work involved in establishing and implementing the quality assurance program.**
  - C. **The waste form producer evaluates the performance of delegated work.**
  - D. **Qualified individual(s) or organization(s) within the waste form producer's organization are responsible for the quality of work prior to initiation of activities.**
  - E. **The waste form producer has established effective lines of communication between participants for quality assurance activities.**
  - F. **Organization charts clearly identify all organizational elements which function under the cognizance of the quality assurance program and identifies the lines of responsibility.**
  - G. **The quality assurance responsibilities of organizational elements are described.**
  - H. **The quality assurance organization is involved in the aspects of Waste Acceptance Process Activities of high-level waste production that affects safety-related and waste isolation features of canistered waste forms.**
  - I. **The waste form producer identifies the management position that retains the overall responsibility and authority for the quality assurance program.**
  - J. **Verification of conformance to established requirements is accomplished by individuals or groups within the quality assurance organization.**

K. Persons or organizations performing quality assurance functions are identified and have direct access to management levels which will assure the ability to:

1. Identify quality problems.
2. Initiate, recommend or provide solutions through designated channels.
3. Verify implementation of solutions.
4. Stop or control further execution of unsatisfactory work.

These responsibilities are designated in writing.

L. Provisions are established for the resolution of disputes involving quality arising from differing opinions between quality assurance and other participating organizations.

M. Policies regarding quality assurance program implementation are documented and mandatory.

II. Activities related to the quality assurance program are acceptable if:

- A. The quality assurance program includes all Waste Acceptance Process Activities of high-level waste form production associated with features of the waste form and canistered waste form that are important to safety or waste isolation. The rationale is provided for determining how the items or activities were identified.
- B. The quality assurance program includes a commitment that control and use of computer software will be conducted in accordance with the quality assurance program.
- C. The software types which support Waste Acceptance Process Activities of high-level waste form production are specified.
- D. Software and computer codes are verified and validated.
- E. Management commits to regularly assess the effectiveness of the quality assurance program.
- F. Peer reviews and readiness reviews are conducted on items and data significant to Waste Acceptance Process Activities of high-level waste form production in accordance with an approved documented program.
- G. Provisions are established to assure that implementing technical and quality assurance procedures are consistent with quality assurance program requirements.

- H. Measures are provided to assure that personnel responsible for performing quality-affecting activities in Waste Acceptance Process Activities of high-level waste form production are indoctrinated, trained, and qualified in the principles, techniques and requirements of the activities being performed.
- I. The quality assurance organization reviews and documents concurrence with quality-related procedures and revisions thereto.
- J. Provisions are established to control the distribution of quality assurance manuals and revisions thereto.
- K. A description is provided on how management (outside of the quality assurance organization) regularly assesses the scope, status, adequacy, and compliance of the quality assurance program applicable to Waste Acceptance Process Activities of high-level waste form production to 10 CFR 50, Appendix B, and ANSI/ASME NQA-1, 1986.
- L. A description of the control system for experimental or developmental work associated with Waste Acceptance Process Activities of high-level waste form production is provided and it clearly identifies how it was validated.
- M. Experimental research activities are accomplished in accordance with written procedures.
- N. Management monitors the performance of individuals involved in quality-affecting activities and determines the need for retraining and/or replacement.

III. Activities related to design control are acceptable if:

- A. Measures are established to carry out design and design modification activities associated with Waste Acceptance Process Activities of high-level waste form production in a planned, controlled, and systematic manner.
- B. Measures are established to correctly translate design or regulatory requirements into specifications, drawings, procedures and instructions.
- C. Quality standards are specified in design documents, and deviations from these quality standards are controlled.
- D. Organizational responsibilities are defined for preparing, reviewing, approving, verifying and validating designs, design changes and design information documents.
- E. Errors and deviations in approved design and design information documents are documented, and action is taken to assure that they are promptly corrected.

- F. Interface controls among organizations involved in design and design modification activities are described.
- G. Procedures require that design drawings, specifications, criteria and analysis be reviewed by the quality assurance organization to assure that the documents are prepared or revised, reviewed and approved in accordance with approved procedures and quality assurance requirements.
- H. Procedures shall describe the accomplishment of the design verification process through design reviews, alternate calculations or qualification testing.
- I. Procedures are established to assure that verified computer codes are certified for use and that their use is specified.
- J. Design and specification changes are subject to the same design or design modification controls and the same approvals that were applicable to the original design or specification.
- K. Individuals or groups responsible for design or design modification verification are other than the original designer and normally other than the designer's immediate supervisor. The verifier is qualified and not directly responsible for the design.
- L. For design or design modification activities which involve the use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review is conducted in accordance with established procedures.

IV. Activities related to procurement document control are acceptable if:

- A. Procedures are established that delineate the actions to be accomplished in the preparation, review, approval, and control of procurement documents associated with Waste Acceptance Process Activities of high-level waste form production.
- B. Procedures are established for the review of procurement documents to determine that quality assurance requirements are correctly stated, inspectable, and controllable; and there are adequate acceptance/rejection criteria.
- C. The review and approval of procurement documents are documented prior to release.

**D. Organizational responsibilities are described for:**

- o Procurement planning
- o Preparation, review, approval and control of procurement documents
- o Supplier selection
- o Bid evaluation
- o Review and acceptance of supplier quality assurance programs

**E. Procurement documents contain or reference regulatory requirements, design bases, and other technical requirements.**

**V. Activities related to instructions, procedures and drawings are acceptable if:**

**A. Organizational responsibilities are described for assuring that activities affecting quality in Waste Acceptance Process Activities of high-level waste form production are:**

- o Prescribed by documented instructions, procedures and drawings.
- o Accomplished through the implementation of these documents.

**B. Instructions, procedures and drawings include quantitative and qualitative acceptance criteria.**

**C. Methods for complying with each of the applicable quality assurance criteria are specified in instructions, procedures and drawings.**

**VI. Activities related to document control are acceptable if:**

**A. The scope of the document control system is described, and the types of controlled documents in Waste Acceptance Process Activities of high-level waste form production are identified.**

**B. Procedures are established for the review, approval, issuance, and revision of documents.**

**C. Procedures are established to assure that documents are available at the location where the activity will be performed prior to initiating work.**

**D. Procedures are established to assure obsolete documents are removed and replaced in a timely manner.**

**E. A master list is established to identify the current revision of documents that are controlled.**

**F. Data or data interpretations generated outside the quality assurance program are qualified.**

**G. Data qualification reviews are accomplished in accordance with written procedures.**

- H. Review and acceptance of data as qualified is based upon an independent review by at least two qualified individuals, a peer review or conformation tests.
- I. The establishment and implementation of the document control system is reviewed prior to implementation to confirm its readiness to function.

**VII. Activities related to control of purchased material, equipment and services are acceptable if:**

- A. Organizational responsibilities and interfaces are described for the control of purchased material, equipment and services associated with Waste Acceptance Process Activities of high-level waste form production.
- B. Qualified personnel evaluate a supplier's capability to provide acceptable services and products prior to the award of a contract. Quality assurance and technical personnel participate in the evaluation.
- C. The results of supplier evaluations are documented.
- D. Surveillance of supplier activities during the contract life is planned and accomplished in accordance with written procedures.
- E. Supplier documentation requirements are specified in the contract for procurement of material, equipment or services.
- F. Supplier's certificates of conformance are periodically evaluated by audits, independent inspections or tests to assure that they are valid and the results are documented.
- G. Receiving inspection of supplier-furnished material, equipment and services is performed to assure that the supplied item is properly identified, satisfies predetermined inspection requirements, and the required documentation is correct and available. Acceptance requirements are described in the purchaser's quality assurance program.

**VIII. Activities related to identification and control of materials, parts and components is acceptable if:**

- A. Procedures are established to identify and control materials, parts and components (including consumables) in Waste Acceptance Process Activities of high-level waste form production.
- B. Procedures are established to assure identification of items is maintained on items or records traceable to the item.
- C. Correct identification of an item is verified and documented prior to release for processing or shipment.

**IX. Activities related to control of special processes are acceptable if:**

- A. Special processes associated with Waste Acceptance Process Activities of high-level waste form production are procedurally controlled. A listing of these special processes is provided. Special processes are generally those processes where direct inspection is impossible or disadvantageous.**
- B. Organizational responsibilities are described for the qualification of special processes, equipment and personnel.**
- C. Procedures, equipment and personnel associated with special processes are qualified in accordance with applicable codes, standards and/or specifications. Qualification records are filed and kept current.**
- D. Special processes are performed by qualified personnel in accordance with written instructions, and the results recorded.**

**X. Activities related to inspection are acceptable if:**

- A. An inspection practice is established to verify conformance of quality-affecting activities in Waste Acceptance Process Activities of high-level waste form production with requirements. The inspections are performed in accordance with controlled procedures.**
- B. Organizational inspection responsibilities are documented. Inspection personnel are independent from those performing the activity being inspected.**
- C. A qualification practice for inspection personnel is established and documented. Inspection personnel qualification and certification records are kept current.**
- D. Comprehensive inspection procedures, instructions or checklists are provided for inspection activities.**
- E. Provisions are established that identify mandatory inspection hold-points for witness by designated inspection personnel.**
- F. Inspection results are documented and evaluated and their acceptability determined by a responsible individual.**

**XI. Activities related to test control are acceptable if:**

- A. A test program to demonstrate that processes, items and activities associated with Waste Acceptance Process Activities of high-level waste form production will meet predetermined requirements is established, documented and accomplished in accordance with controlled procedures.**

**B. Test procedures incorporate or reference:**

- (1) Test requirements and acceptance limits
- (2) Instructions for performing the test
- (3) Test prerequisites
- (4) Mandatory inspection hold-points
- (5) Acceptance/rejection criteria
- (6) Methods of documenting or recording test data or results
- (7) Method of data analysis

**C. Test results are documented, evaluated and their acceptability determined by a responsible individual or group.**

**XII. Activities related to control of measuring and test equipment are acceptable if:**

- A. The scope of the program for the control of measuring and test equipment used in Waste Acceptance Process Activities of high-level waste form production is described, and the types of equipment to be controlled are identified.**
- B. Organizational responsibilities are documented for establishing, implementing and assuring the continuing effectiveness of the calibration system.**
- C. Procedures are established for calibration, maintenance and control of measuring and test equipment.**
- D. Measuring and test equipment is identified and traceable to calibration test data.**
- E. Measuring and test equipment is labeled or otherwise identified to indicate the due date of the next calibration and to provide traceability to calibration records.**
- F. Measuring and test equipment is calibrated at specified intervals based on required accuracy, purpose, usage, stability, and other attributes which could affect measurement.**
- G. Calibration standards are traceable to nationally recognized standards. Where these standards do not exist, provisions are established to document the basis for calibration.**
- H. When measuring and test equipment is found out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration.**
- I. The complete status of all items under the calibration system is documented and maintained.**

**XIII. Activities relating to handling, storage and shipping are acceptable if:**

- A. Special handling, preservation, storage, cleaning, packaging and shipping requirements are established in accordance with predetermined work and inspection instructions for Waste Acceptance Process Activities of high-level waste form production. They are accomplished by qualified individuals.**
- B. Procedures are prepared in accordance with design and specification requirements to preclude damage, loss or deterioration.**

**XIV. Activities relating to inspection, test and operating status are acceptable if:**

- A. Procedures are established to indicate the status of inspections and tests on individual items and activities associated with Waste Acceptance Process Activities of high-level waste form production.**
- B. The application and removal of status indicators is procedurally controlled.**
- C. The status of discrepant items and activities is documented, and the item or activity is identified to prevent inadvertent use or inappropriate processing or continuation.**

**XV. Activities relating to nonconforming materials, parts or components are acceptable if:**

- A. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities (including computer codes) associated with Waste Acceptance Process Activities of high-level waste form production.**
- B. Organizational responsibilities relating to nonconformance control is described in writing.**
- C. Provisions are established identifying individuals or organizations delegated the responsibility and authority to disposition and close out nonconformances.**
- D. Nonconformance reports are analyzed to show quality problems and to aid in identifying root causes of nonconformances. Results are reported to senior management for action as applicable.**

**XVI. Activities relating to corrective action are acceptable if:**

- A. Conditions adverse to quality in Waste Acceptance Process Activities of high-level waste form production are evaluated in accordance with established procedures to determine the need for corrective action.**

- B. Corrective action is documented and initiated following a nonconformance to preclude recurrence.
- C. Timely follow-up actions are conducted to verify implementation of corrective actions and to close out the corrective action documentation.
- D. Significant conditions adverse to quality are documented and reported to cognizant levels of management for action to remedy the conditions and preclude repetition.

**XVII. Activities relating to quality assurance records are acceptable if:**

- A. The scope of the records program is defined such that sufficient records are maintained to provide documentary evidence of the quality of canistered waste forms and Waste Acceptance Process Activities of high-level waste form production related to the quality of canistered waste forms.
- B. Organizational responsibilities are identified and described relating to quality assurance records.
- C. Records are identified and retrievable.
- D. Responsibilities and requirements for record creation, transmittal, retention, and maintenance consistent with applicable codes, standards, and procurement documents are detailed in procedures.
- E. Inspection and test records contain the following where applicable:
  - (1) A description of the type of observation.
  - (2) The date and results of the inspection or test.
  - (3) Information related to conditions adverse to quality.
  - (4) Inspector or data recorder identification.
  - (5) Evidence as to acceptability of the results.
  - (6) Actions taken to resolve any discrepancies noted.
- F. Suitable facilities for the storage of records are described and utilized.
- G. Work not directly associated with the records program is prohibited within the records storage facility.
- H. Smoking, eating, or drinking is prohibited throughout the records storage facility.

**XVIII. Activities relating to audits are acceptable if:**

- A. Audits are performed to assure that procedures and activities comply with the overall quality assurance program applicable to Waste Acceptance Process Activities of high-level waste form production.

- B. Audits are conducted in accordance with established procedures or checklists and conducted by trained and qualified personnel not having direct responsibilities in the area being audited.**
- C. Audit results are documented and then reviewed with management having responsibility in the area audited.**
- D. Audits are regularly scheduled on the basis of the status and the importance to safety or waste isolation of the activities being performed to assure effective quality assurance during the total life of Waste Acceptance Process Activities of high-level waste form production.**
- E. Audit deficiency data are analyzed, tracked and trended. Resultant reports indicating trends and quality assurance program effectiveness are provided to management for review, assessment, corrective action, and follow-up.**

**APPENDIX C**  
**REFERENCE DOCUMENTS**

The following list of documents has been referred to in DOE-OCRWM Specification, "Quality Assurance Requirements for High-Level Waste Form Production".

- (1) Appendix B - 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants".
- (2) 10 CFR Part 60, "Disposal of High Level Radioactive Waste in Geologic Repositories," Subpart G, "Quality Assurance".
- (3) ANSI/ASME NQA-1, 1986, "Quality Assurance Program Requirements for Nuclear Facilities".
- (4) DOE 5000.3, "Unusual Occurrence Reporting System".
- (5) DOE 5700.6B, "Quality Assurance".
- (6) DOE/RW-0005, "Mission Plan for the Civilian Radioactive Waste Management Program".
- (7) DOE/RW-0032, "OCRWM Quality Assurance Management Policies and Requirements".
- (8) DOE/RW-0043, "Program Management Systems Manual".
- (9) DOE/RW-0095, "Quality Assurance Plan for High-Level Radioactive Waste Repositories (OGR/B-3)."
- (10) "Guidelines for Application of Readiness Reviews to Department of Energy Activities," January 1987 Draft.
- (11) NUREG 0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management".
- (12) DOE/RW-0125, Waste Acceptance Preliminary Specification for The Defense Waste Processing Facility High-Level Waste Form (OGR/B-8).

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