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Quality Assurance Requirements for Certification of TRU Waste for Shipment to the Waste Isolation Pilot Plant

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WASTE ISOLATION PILOT PLANT



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QUALITY ASSURANCE REQUIREMENTS FOR CERTIFICATION
OF TRU WASTE FOR SHIPMENT TO THE
WASTE ISOLATION PILOT PLANT

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WESTINGHOUSE ELECTRIC CORPORATION
WIPP MANAGEMENT AND OPERATING CONTRACTOR

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QUALITY ASSURANCE REQUIREMENTS
FOR
CERTIFICATION OF TRU WASTE
FOR SHIPMENT TO THE WASTE ISOLATION PILOT PLANT

1.0 INTRODUCTION

This document presents the basic Quality Assurance (QA) requirements which shall be included in the QA Program established by sites planning to certify transuranic (TRU) waste to the Waste Isolation Pilot Plant (WIPP) Waste Acceptance Criteria (WAC). These QA requirements were modeled after ANSI/ASME NQA-1-1986 (Reference 1).

This document should be used in conjunction with References 2 through 7, and other available guidance documents, to develop the overall TRU Waste Certification Programs. The application of QA to Waste Certification Programs is required by WIPP-DOE-069 (Reference 2) and DOE Order 5700.6B (Reference 5), as implemented by DOE Order AL 5700.6B (Reference 7).

This document also furnishes guidance for definition of all those planned and systematic activities that provide adequate confidence that each site's TRU Waste Certification Program will perform satisfactorily. The definition of those activities is considered to be part of the site's QA Plan and, accordingly, each waste generator shall ensure that their QA/QC Program will result in only certified waste being shipped to WIPP.

Plans and actions to assure quality activities shall be established, implemented, and maintained with primary emphasis on achieving a high degree of operational success and with due consideration to health, safety, and environmental protection. The extent of quality program requirements and the level of associated QA activity will be commensurate with the scope and importance to the certification program.

2.0 REFERENCES

1. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities.
2. WIPP-DOE-069 (Current Rev.), TRU Waste Acceptance Criteria for the Waste Isolation Pilot Plant.
3. WIPP-DOE-114, (Current Rev.), TRU Waste Certification Compliance Requirements for Acceptance of Newly Generated, Contact-Handled Wastes to be Shipped to the WIPP.
4. WIPP-DOE-137, (Current Rev.), TRU Waste Certification Compliance Requirements for Acceptance of Contact-Handled Wastes Retrieved from Storage to be Shipped to the WIPP.
5. DOE Order 5700.6B, Quality Assurance.
6. WIPP-DOE-158, (Current Rev.), TRU Waste Certification Compliance Requirements for Remote-Handled Wastes for Shipment to the WIPP.
7. DOE Order AL 5700.6B, Quality Assurance.

3.0 DEFINITIONS

SITE QUALITY ASSURANCE PROGRAM. A system of activities defined by documents which implement a site's total QA Program. The QA Program should define, in written form, QA policy, requirements, authority and responsibility, organization, method of implementation, and activities required to establish and maintain QA. The QA Program should include: activities subject to control (e.g., design, processes, tests, procurement); nonconformance identification; corrective action requirements; records functions (identification, control, preservation, etc.); the QA documentation scheme; methods of independent verification (inspection, surveillance, and QA audit); procedures for implementing all aspects of the QA Program; and a method for assessing the QA Program's effectiveness.

TRU WASTE QUALITY ASSURANCE PLAN. A description of the quality-related requirements, responsibilities, activities, procedures, and methods of implementation which are applicable to the specific task of TRU waste certification and a description of how organization level QA programs, manuals, and procedures are effectively translated for use on that task. The QA Plan may invoke existing manuals and procedures (or parts thereof), or it may be a fully self-contained document. The QA Plan may be included in the site TRU Waste Certification Plan or it may be a separate document. In either event, the two must be completely integrated.

QUALITY-RELATED. Of or pertaining to quality or the process that assures quality, or having a cause-and-effect influence on quality or on a QA function. TRU waste certification quality-related activities are those important to public health and safety, environmental protection, and process equipment performance and reliability, with primary emphasis on achieving a high degree of operational success in those activities. These include activities considered part of the process for valid data acquisition, facility and equipment design, testing, peer group review, project monitoring, records management, planning, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, installing, inspecting, auditing, surveillance, measuring, documenting, analyzing, maintaining, repairing, and modifying.

4.0 QUALITY ASSURANCE PROGRAM ELEMENTS

4.1 Organization

The organizational structure, functional responsibilities, levels of authority, and lines of communication for those individuals and groups performing the TRU waste processing, handling, verification, and other certification activities shall be identified in a site's Waste Certification QA Program Plan.

Persons or organizations responsible for assuring that an appropriate Waste Certification QA Program is established and verifying that activities affecting certification have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to: identify certification problems; initiate, recommend, or provide solutions to certification problems through designated channels; verify effective implementation of solutions; and assure that further processing or shipment to the WIPP site is controlled until proper disposition of any nonconformance, deficiencies, or other unsatisfactory conditions has occurred.

Such person or organizations shall report to a management level such that required authority and organizational freedom necessary to comply with the requirements of the plan are provided, including sufficient independence from cost or schedule considerations.

4.2 Quality Assurance Program Plan

Each generator or storage site shall prepare, maintain, and implement a documented TRU Waste Certification QA Plan (or Program Plan) which is appropriate for the types of waste generation, waste processing, and waste certification activities being performed at the site. In preparing the plan, the site shall address the eighteen (18) QA Program elements presented in this document and determine which are applicable to the certification program. The Plan shall describe methods of compliance with the applicable elements, including justification for exclusions of those elements considered not to apply to the site's specific activity. A review of critical program aspects shall also be included to assure that certification quality requirements are adequately and correctly stated. The plan shall apply to all activities affecting the certification of TRU waste.

Each QA Program Plan and subsequent revisions shall be submitted to the WIPP Project Office for review and approval prior to implementation.

4.3 Design Control

Design activities associated with waste certification shall be performed in accordance with documented procedures which include the following control features, as a minimum:

- Provisions for applicable design inputs and interfaces to be identified, documented, and approved as part of the design verification process.
- Provisions for verifying the adequacy and correctness of designs by the performance of design reviews, alternate calculations, or qualification testing. The extent of design verification required is a function of the importance of the item being designed to the certification process, the complexity of the design, and the degree of similarity with previously proven designs.
- Provisions for changes to final designs, including shop or field changes, to be documented and evaluated by qualified personnel commensurate with those utilized for the original design.
- Provisions for drawing reviews, specification reviews, and audits of design activities.

4.4 Procurement Document Control

Procurement documents associated with the site's Waste Certification Program shall be prepared, reviewed, approved, issued, and controlled in accordance with documented procedures. Procurement

documents shall contain administrative, technical, and quality requirements, as appropriate, to assure conformance with applicable design requirements, waste acceptance and certification criteria, and other applicable codes and standards.

Procurement documents shall be reviewed to assure that quality requirements are adequate and correctly stated.

4.5 Instructions, Procedures, and Drawings

Waste certification activities such as waste treatment, inspection, testing, packaging, labelling, and other certification activities shall be appropriately prescribed by written instructions, work plans, task descriptions, drawings, or other procedures.

Documents which involve inspection, testing, or other types of verification activities shall include or reference appropriate qualitative and quantitative acceptance criteria, thereby establishing a mechanism for determining the acceptability of the activity. In those cases where verification steps are specified in work documents and/or procedures, the independent organizational unit responsible for performing the verification shall be clearly specified.

One example may be procedures controlling the segregation of waste streams to prevent the mixing of incompatible waste categories requiring different certification procedures.

4.6 Document Control

The generation, review, approval, distribution, and revision of documents related to waste certification shall be controlled through written document control procedures. These procedures shall ensure that the certification documents are valid, correct, and up to date. Documents shall be reviewed for adequacy and approved for release by independent qualified personnel.

The document control procedures shall also include the methods used to change documents. These methods shall assure that changes in documents are reviewed and approved by organizations responsible for the original review and other appropriate individuals, and that the changes are included in the documents prior to the implementation of the change in the activity.

4.7 Control of Purchased Items and Services

The procurement of items or services associated with waste certification shall be controlled, to the extent necessary, to assure conformance with specifications.

Such control of procured items and services shall provide for the following, as necessary: source evaluation and selection; bid evaluation of objective evidence of quality furnished by the supplier; source inspection; control of nonconformances; audit; and examination of items or services upon delivery or completion.

4.8 Identification and Control of Items

Identification requirements shall be established for waste, packages, containers, and other items associated with waste certification where loss of identification could invalidate certification efforts.

The method and location of the identification marking shall be unambiguous, indelible, and shall be directly maintained on the item or on records traceable to the item or process.

The correct identification of items involved in certification shall be verified and documented prior to the release of that item or process for testing, packaging, packing, or shipment.

4.9 Control of Processes

Certification processes shall be performed under controlled conditions in accordance with documented instructions, procedures, drawings, checklists, travelers, or other appropriate means.

Processes which are mainly dependent upon the expertise or skill of the personnel conducting the activity, such as remote welding or real time radiographic inspection, shall be considered special processes, and shall be identified in the site's QA Plan, together with methods for qualification of personnel performing those activities and control over the work performed.

Records shall be maintained for qualification of procedures, equipment, and personnel performing operations associated with special processes.

4.10 Inspection

Inspections shall be planned and performed at appropriate points in the certification process to assure conformance to applicable waste acceptance and certification criteria. Inspections shall be performed by qualified personnel, and the results of the inspections shall be documented. Procedures for inspection activities, including the responsible organizational unit and standards for acceptance/rejection, shall also be included.

Independent inspections, which are used to verify conformance to certification requirements, shall be performed by personnel other than those who performed or directly supervised the work being inspected. These inspections may also be performed or witnessed by assigned WIPP personnel during: 1) formal audit or re-audit activities being conducted by the Waste Acceptance Criteria Certification Committee (WACCC); or 2) subsequent on-site inspections conducted prior to shipment of the waste to WIPP.

Inspection records shall be prepared for all specified inspections and be maintained in accordance with the site's record retention program.

4.11 Test Control

Tests performed to provide verification data or acceptance for waste certification shall be planned, documented, and controlled, including test description, objectives, proposed frequencies, and rejection criteria. These tests shall be performed by qualified personnel and the results documented.

Test records shall be prepared for all specified tests and be maintained in accordance with the site's record retention program.

4.12 Control of Measuring and Test Equipment

Measuring and test equipment used for activities involving certification shall be controlled and calibrated at specified intervals in accordance with written procedures to maintain accuracy within acceptable limits.

Calibration and standardization shall be addressed in the QA Plan. These may consist of standards traceable to NBS, recognized industrial standards, or standards specifically developed for TRU waste certification. Measurement and test equipment control procedures shall provide for identification of equipment and calibration status, including methods to ensure that test equipment is properly calibrated when used.

Calibration records shall be prepared and maintained for measuring and test equipment and associated standards important to certification. These records shall be maintained in accordance with the site's record retention program.

4.13 Handling, Storage, and Shipping

Procedures or instructions shall be written and implemented to provide control of handling, storage, labeling, and preparation for shipping of waste packages, containers, packaging materials, and associated equipment significant to certification. The documents shall assure proper handling, storage, labeling, and preparations for shipping of TRU waste.

4.14 Inspection, Test, and Operating Status

The status of certification activities shall be identified either on the items (e.g., waste forms, waste packages, etc.) or in documents traceable to the items. It is necessary to assure that required inspections and/or tests are performed and to assure that items which have not passed the required inspections and/or tests are not later marked, certified, and shipped. Certification status shall be maintained through indicators, such as being placed in a specified location and tagged, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified.

4.15 Control of Nonconforming Items

Procedures shall be implemented by each waste generator for prompt detection, documenting, and dispositioning of waste, waste containers, waste packages, processes, etc., important to certification and which do not conform to specifications. The procedures shall assure that nonconformances are positively identified and that notification of their existence and proposed disposition are sent to all affected organizations. The procedures shall also require that nonconforming items be tagged or segregated to prevent inadvertent certification.

Nonconformances that result in waste which does not meet the WAC requirements shall result in such waste being non-certified. Such waste shall not be shipped to WIPP until it has been certified by procedures approved by the WACCC. Further, no subsequent waste generated by the nonconforming process or procedure can be certified until the nonconformance has been identified to the WACCC and appropriate corrective actions are approved by the WACCC. Nonconformances that may affect the certification status of waste already shipped to WIPP shall require the submittal (to the WACCC for approval) of proposed corrective actions that, as a minimum, either include a rationale for acceptance by WIPP or a plan for return shipment of the waste for certification at the generating facility.

Nonconformance shall be documented and copies of all nonconformance reports shall be maintained in accordance with the site's record retention program.

4.16 Corrective Action

Procedures shall be implemented to ensure conditions adverse to certification are promptly identified and corrected as soon as practical. In the case of a significant condition adverse to certification, the cause of the condition shall be determined and appropriate corrective action taken to preclude recurrence of the condition. The identification, cause, and corrective action for significant conditions adverse to certification shall be documented and reported to appropriate levels of management. Follow-up action shall be taken by responsible waste generator officials to verify implementation of corrective action. Nonconformances detected after shipment of the waste to WIPP shall result in suspension of certification activities until corrective action is approved by the WACCC.

4.17 Certification Records

Records shall be prepared to furnish documentary evidence of the verification of activities and items affecting certification. These records shall be identified, readily retrievable, and retained and protected against damage, loss, and deterioration as prescribed by documented procedures. The responsibilities and requirements for record preparation, review, transmittal, maintenance, and retention shall be specified. The organization and individuals responsible for the collection, review, storage and disposition of certification records, and the designation of the types of records to be maintained shall be specified.

Certification records may include, but are not limited to: inspection, test, nonconformance, and audit reports; results of routine assays of waste; operating logs; calibration records; equipment certifications; personnel qualification records; and other records which provide technical support for the validity of the certification.

Certification records shall be reviewed by the designated Certifying Official at the waste generating site. This individual will certify, by full signature, that the appropriate procedures have been followed and that the waste packages meet all WIPP criteria and requirements.

Certification records retention requirements fall into three (3) categories:

- Those relating to current operations (equipment calibrations, personnel qualifications) which must be available for periodic WACCC audits but which do not require retention beyond the next WACCC re-audit.

- Those which provide detailed information on the processing of the waste (e.g., routine assays and inspections of individual packages placed in a container, internal audit reports, nonconformance reports), which do not require retention after the waste is permanently emplaced in the WIPP. Waste is not considered permanently emplaced until (a) the waste is emplaced in the underground room; and (b) the demonstration period has ended and the facility has been declared a repository.
- Those which are basic to the certification process and should be considered permanent (i.e., retained 25 years or longer), such as a process batch or container inventory records, NDE/NDA records, and certification statements.

4.18 Audits

Planned and scheduled audits shall be conducted by appropriate site personnel to verify compliance with all aspects of waste certification. Audit responsibility and minimum frequency shall be defined in site QA Plans. Audit activities shall include: planning and performance of audits; evaluation of certification procedures and activities, with emphasis on implementation of controls; reporting of audit results to responsible management; assigning responsibility of correcting deficiencies; and follow up to assure that appropriate corrective action has been taken.

The site QA audit procedures shall specify how audits are planned, documented, implemented, and closed out.

All audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility in the areas being audited. Audit results shall be documented and reported to, and reviewed by responsible management. An appropriate level of management shall be responsible for assuring that necessary actions are taken to correct deficiencies.

Copies of all completed audit reports and associated responses shall be maintained in accordance with the site's record retention program.

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