

# CCP-QP-036

Revision 4

## CCP

### Qualification of Acceptable Knowledge for Remote-Handled Transuranic Waste Through a Quality Assurance Equivalency Demonstration

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Mike Sensibaugh

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RECORD OF REVISION

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1	05/05/2006	Revised to address CBFO comments.
2	06/14/2006	Revised in response to concerns raised during audit A-06-21.
3	02/12/2009	Revised to address changes identified during annual review.
4	04/13/2009	Revised in response to Carlsbad Field Office (CBFO) Corrective Action Request (CAR) 09-010 to assure Quality Assurance (QA) review and approval of QA Equivalency Documents.

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## 1.0 PURPOSE

This document provides instructions to ensure compliance with DOE/WIPP-02-3214, *Remote-Handled TRU Waste Characterization Program Implementation Plan (WCPIP)*, programmatic requirements for the qualification of acceptable knowledge (AK) and historical remote-handled (RH) transuranic (TRU) waste characterization data through a Quality Assurance (QA) Equivalency Demonstration. Sites electing to qualify RH TRU AK information through a demonstration of QA equivalency must complete a procedure matrix that addresses the requirements in DOE/CBFO-94-1012, *U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document (QAPD)*. The QAPD incorporates the U.S. Environmental Protection Agency (EPA)-required QA elements from American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-1989 edition, *Quality Assurance Program Requirements for Nuclear Facilities*; ASME NQA-2A-1990 addenda, Part 2.7, of ASME NQA-2-1989 edition, *Quality Assurance Program Requirements for Nuclear Facilities*; and ASME NQA-3-1989 edition, *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*, (excluding Section 2.1(b) and (c) and Section 17.1). The procedure matrix must identify applicable documents that implement each applicable requirement of the QAPD. The procedure matrix must specifically reference the applicable portion of the procedure or document that meets the Carlsbad Field Office (CBFO) QAPD requirement.

### 1.1 Scope

This document provides guidance for documenting the decision process, the criteria for qualifying data through this method, and the criteria used for qualifying the data for their intended use. This document also addresses the documentation needed to develop a procedure matrix providing a cross walk that identifies the generator site plans and procedures that implement the applicable requirements of the QAPD as identified in Section 1.0. The demonstration of QA equivalency, in effect, ensures RH TRU waste characterization information generated under a historic QA program complies with the applicable Data Quality Objectives (DQOs) and programmatic requirements specified in the WCPIP, Section 4.3 and step 4.3.4.

### 1.2 Applicability

This document applies to Sites electing to qualify AK information in accordance with the WCPIP requirements, Section 4.3 and step 4.3.4, and CCP-PO-002, *CCP Transuranic Waste Certification Plan*.

## 2.0 REQUIREMENTS

### 2.1 References

#### Referenced Documents

- DOE/CBFO-94-1012, *U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document*
- DOE/WIPP-02-3214, *Remote-Handled TRU Waste Characterization Program Implementation Plan*
- ASME NQA-1-1989, *Quality Assurance Program Requirements for Nuclear Facilities*
- ASME NQA-2-1989, *Quality Assurance Program Requirements for Nuclear Facilities*
- ASME NQA-3-1989, *Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*
- CCP-AK-LANL-503, *Central Characterization Project Los Alamos National Laboratory Quality Assurance Equivalency Report and Procedure Matrix for Remote-Handled Transuranic Debris Waste*
- CCP-PO-002, *CCP Transuranic Waste Certification Plan*
- CCP-QP-002, *CCP Training and Qualification Plan*
- CCP-QP-008, *CCP Records Management*
- CCP-QP-010, *CCP Document Preparation, Approval and Control*
- CCP-TP-005, *CCP Acceptable Knowledge Documentation*

2.2 Quality Assurance Requirements

2.2.1 The QA equivalency demonstration is achieved by meeting the WCPIP requirements, Section 4.3 and step 4.3.4. To comply with these requirements, the Site must complete a procedure matrix using applicable Site programmatic documents, Standard Operating Procedures (SOPs), and records. Applicable documents are those in existence and utilized when the waste was characterized initially, packaged, or stored. Completion of the procedure matrix demonstrates the degree of equivalency to NQA Standards: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2A-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1).

2.3 Training Requirements

2.3.1 Personnel performing this document will be trained and qualified in accordance with CCP-QP-002, *CCP Training and Qualification Plan*, prior to performing this procedure.

2.4 Equipment List

2.4.1 None.

2.5 Prerequisite Actions

2.5.1 None.

2.6 Definitions

2.6.1 None.

### 3.0 RESPONSIBILITIES

#### 3.1 Acceptable Knowledge (AK) Personnel

3.1.1 Collects and evaluates source documents relevant to QA equivalency.

3.1.2 Prepares the AK Summary Report that documents the QA Equivalency Report.

#### 3.2 Acceptable Knowledge Expert (AKE)

3.2.1 Reviews the QA Equivalency Report.

3.2.2 Ensures referenced source documents are included in the AK record.

3.2.3 Ensures the source documents cited in the QA Equivalency Report have been included in the AK record in accordance with CCP-TP-005, *CCP Acceptable Knowledge Documentation*.

#### 3.3 Quality Assurance Manager

3.3.1 Reviews and approves the QA Equivalency Report and forwards it to the AKE.

#### 3.4 Document Control

3.4.1 Processes the QA Equivalency Report as an AK document in accordance with CCP-QP-010, *CCP Document Preparation, Approval and Control*.

#### 4.0 PROCEDURE

##### AK Personnel

#### 4.1 Collection of Relevant Source Documents

4.1.1 With the assistance of Site personnel, collect source documents related to the historical RH TRU waste characterization and packaging operations.

4.1.2 Collect programmatic documents and procedures that specify how waste characterization and packaging activities were conducted at the time the waste was generated. Programmatic documents and procedures may include:

[A] QA manuals, QA plans, and waste certification plans.

[B] Procedures used for characterization and QA activities that may include design procedures, procurement procedures, document control procedures, operating manuals, work instructions, inspection and test procedures, calibration procedures, training procedures, and assessment procedures.

[C] Records that demonstrate the completion of waste characterization and QA activities. Records may include, but are not limited to:

[C.1] Management and organizational records (e.g., organizational charts, mission statements, and roles and responsibility matrices)

[C.2] Design records (e.g., drawings, design change requests, design change notifications, and design reviews)

[C.3] Procurement records (e.g., source evaluations, source selection records, approved-vendor lists, source inspection records, and receiving inspection and test records)

[C.4] Certificates of Compliance, purchase orders, design specifications, and supplier inspection records

- [C.5] Document management records (e.g., document control records)
- [C.6] Waste package records (e.g., waste travelers, waste characterization data, inspection tags, travelers, stamp accountability records, nonconformance reports [NCRs], and corrective action requests [CARs])
- [C.7] Operational records (e.g., process flow diagrams, laboratory notebooks, weld specifications, and waste technical reports)
- [C.8] Inspection and test records (e.g., inspection and test records, inspection and test specifications, measurement and test equipment calibration records, calibration source certificates, and calibration recall schedules)
- [C.9] Training records (e.g., personnel training records, attendance sheets, and training logs)
- [C.10] Assessment records (e.g., audit and surveillance schedules, plans and reports, and interviews)

#### 4.2 Review and Classification of Source Documents

- 4.2.1 Review the relevant source documents to determine the classification of the source documents and to determine the agreement of the source document contents to the requirements of the QAPD.
- 4.2.2 Review the contents of relevant source documents to demonstrate implementation of applicable NQA-1, NQA-2, or NQA-3 requirements based on the document type (as described in step 4.1.2) and the extent of comparability (as outlined in Section 4.4).

#### 4.3 Indexing of Source Documents

- 4.3.1 Assign source document numbers using CCP-TP-005.
- 4.3.2 Submit source documents to the AKE.

## AKE

4.3.3 Maintain source documents in accordance with CCP-TP-005.

## AK Personnel

4.4 Completion of the Procedure Matrix

4.4.1 Develop a procedure matrix template. For an example, refer to Section 2.1, References, of CCP-AK-LANL-503, *Central Characterization Project Los Alamos National Laboratory Quality Assurance Equivalency Summary Report and Procedure Matrix for Remote-Handled Transuranic Debris Waste*.

4.4.2 Review the source documents and reference the appropriate source document section(s) on the procedure matrix for each of the requirement(s) for which compliance can be demonstrated. In addition, identify those requirements that are not applicable to the Site's characterization activities and justify their non-applicability.

4.4.3 For each item on the procedure matrix, use the criteria below to indicate whether a source document complies with, partially complies with, or does not comply with a given requirement. Criteria for determining whether a source document partially complies with a given requirement may include use of programmatic documents without support of implementing procedures or the use of procedures that address the requirement, but are outside the time frame of interest.

[A] NQA-1 Section 1: Organization

[A.1] To demonstrate equivalency to NQA-1 Section 1, document the organizational hierarchy and infrastructure of the Site's facilities, divisions, groups, and/or individuals associated with the RH TRU waste characterization, packaging, and QA organizations.

The basis for compliance is to document, either textually or graphically, the cooperation of the QA organization with, but independent from, the waste management organizations.

To demonstrate compliance, source documents shall:

- Show that organizations had sufficient authority, organizational freedom, and access to responsible management.
- Demonstrate that these organizations implemented adequate procedures and processes to ensure the quality of the RH TRU waste characterization data.
- Describe the roles and responsibilities of the waste management and QA organizations.

[B] NQA-1 Section 2: Quality Assurance Program

[B.1] To demonstrate equivalency to NQA-1 Section 2, document the Site's QA infrastructure, roles, and responsibilities.

The basis for compliance is to demonstrate that the responsible management had implemented a QA program equivalent, in effect, to the NQA requirements.

To demonstrate compliance, source documents shall:

- Demonstrate that the Site's QA program provided adequate planning and oversight for the accomplishment of the RH TRU waste characterization and packaging activities.
- Ensure that these activities were performed under properly controlled conditions that included appropriate instrumentation, adequate procedures, and necessary indoctrination of personnel.

[B.2] NQA-1, Supplement 2S-1: Qualification of Inspection and Test Personnel

- (a) To demonstrate equivalency to NQA-1 Supplement 2S-1, document the qualification and certification of inspection and test personnel as part of the overall implementation of a Site's QA program.

The basis for compliance is to document that qualified and certified inspection and test personnel performed RH TRU waste characterization and packaging operations.

Source documents shall demonstrate that inspection and test personnel were qualified to specific certification requirements to include the content and frequency of the certification program.

[B.3] NQA-1, Supplement 2S-2: Qualification of Nondestructive Examination (NDE) Personnel

- (a) To demonstrate equivalency to NQA-1, Supplement 2S-2, document the qualification and certification of NDE personnel as part of the overall implementation of a Site's QA program.

The basis for compliance is to document that qualified and certified NDE personnel performed RH TRU waste characterization operations.

Source documents shall demonstrate that NDE personnel were qualified to specific certification requirements.

[C] NQA-1 Section 3: Design Control

- [C.1] To demonstrate equivalency to NQA-1 Section 3, document design control of RH TRU waste characterization items, such as metrology instrumentation, and packaging configuration.

The basis for compliance is documentation of Site-designed items associated with the RH TRU waste characterization and packaging operations.

Source documents shall demonstrate documentation of design controls, including the design specifications and standards, design process, configuration control, and design verification.

[D] NQA-1 Section 4: Procurement Documentation Control

- [D.1] To demonstrate equivalency to NQA-1 Section 4, document the control of procurement documentation related to RH TRU waste characterization equipment and packaging items.

The basis for compliance is to document that the Site had adequate procurement documentation control procedures and records to ensure that procured items met defined specifications as part of the implementation of a Site's QA program.

Source documents shall demonstrate procurement documentation control for those items that affect the quality of the RH TRU waste characterization.

[E] NQA-1 Section 5: Instructions, Procedures and Drawings

- [E.1] To demonstrate equivalency to NQA-1 Section 5, document the collection, review, classification, and indexing of relevant source documents.

The basis for compliance is to document that the Site had adequate controls for instructions, procedures, and drawings.

Source documents shall demonstrate that adequate historic programmatic documents and procedures were developed and implemented to ensure that RH TRU waste characterization and packaging activities were performed in accordance with applicable regulatory standards and QA practices of the time.

[F] NQA-1 Section 6: Document Control

- [F.1] To demonstrate equivalency to NQA-1 Section 6, document the Document Control processes.

The basis for compliance is to demonstrate the Site's ability of development, implementation, and control of document control procedures as part of the Site's QA program.

Source documents shall demonstrate document control processes, procedures, and records addressing the preparation, revision, issuance, and archival of documents related to RH TRU waste characterization and packaging operations.

[G] NQA-1 Section 7: Procurement

[G.1] To demonstrate equivalency to NQA-1 Section 7, document the control processes ensuring that procured items met defined specifications as part of the implementation of a Site's QA program.

The basis for compliance is to demonstrate the control of the procurement of items and services to ensure conformance with specified requirements. Source documents shall demonstrate adequate procurement control procedures and records for those items that affect the quality of RH TRU waste characterization and packaging activities.

[H] NQA-1 Section 8: Identification and Control of Items

[H.1] To demonstrate equivalency to NQA-1 Section 8, document that processes for the identification and control of items associated with RH TRU waste characterization and packaging activities were part of the implementation of a Site's QA program.

The basis for compliance is to demonstrate that processes for the identification and control of items are traceable, accepted, and used.

Source documents shall demonstrate that controls were established to ensure that only correct and accepted items were used or installed.

[I] NQA-1 Section 9: Control of Processes

[I.1] To demonstrate equivalency to NQA-1 Section 9, document that processes affecting quality of items or services are controlled.

The basis for compliance to NQA-1 Section 9 is the Site's ability to demonstrate that sufficient programmatic documents and SOPs ensured adequate control of RH TRU waste characterization and packaging operations.

Source documents shall identify those activities affecting the quality of the RH TRU waste characterization or packaging, and document the control of processes and performance of special processes.

[J] NQA-1 Section 10: Inspections

- [J.1] To demonstrate equivalency to NQA-1 Section 10, document that adequate inspection processes, procedures, instrumentation, and records were part of the implementation of a Site's QA program.

The basis for compliance is to demonstrate that inspections required to verify conformance of an item or activity to specified requirements were planned and executed.

Source documents shall demonstrate adequate inspection processes, procedures, instrumentation, and records for those items that affect the RH TRU waste activities.

[K] NQA-1 Section 11: Test Control

- [K.1] To demonstrate equivalency to NQA-1 Section 11, document that testing operations associated with RH TRU waste characterization were performed in accordance with defined specifications and were performed by qualified personnel.

The basis for compliance is to demonstrate tests required to verify conformance to an RH TRU waste characterization item or computer program to specified requirements were performed.

Source documents shall demonstrate that adequate testing processes, procedures, instrumentation, and records were part of the implementation of a Site's QA program.

[L] NQA-1 Section 12: Measurement & Test Equipment (M&TE)

- [L.1] To demonstrate equivalency to NQA-1 Section 12, document the control of M&TE processes, procedures, instrumentation, and calibration sources.

The basis for compliance is to demonstrate the calibration, control, handling, and storage of M&TE was implemented.

Source documents shall include SOPs and records that demonstrate adequate control of M&TE processes and instrumentation.

[M] NQA-1 Section 13: Handling, Storage and Shipping

- [M.1] To demonstrate equivalency to NQA-1 Section 13, document the control of handling, storage, and shipping of RH TRU characterization items to prevent damage or loss.

The basis for compliance is to demonstrate the Site's ability to control the RH TRU debris waste to prevent damage or loss and to minimize deterioration of the packaging configuration for those activities affecting the quality of the RH TRU waste packaging.

To demonstrate compliance, source documents shall:

- Document the implementation of procedures and processes ensuring the proper handling, storage, and transportation of the RH TRU waste.
- Demonstrate continuity of waste characterization information, and ensure adequacy of the waste packaging configuration as part of the implementation of a Site's QA program.

[N] NQA-1 Section 14: Inspection, Test and Operational Status

- [N.1] To demonstrate equivalency to NQA-1 Section 14, document the status of inspections and tests related to the RH TRU waste characterization and packaging configuration were maintained sufficiently.

The basis for compliance is to demonstrate the status of inspection and that test activities were identified and performed and the results were identified and controlled.

Source documents shall demonstrate that adequate inspection and testing procedures, personnel, and inspection and testing records were part of the implementation of a Site's QA program.

[O] NQA-1 Section 15: Control of Nonconforming Items

[O.1] To demonstrate equivalency to NQA-1 Section 15, document items that do not conform to specified requirements are controlled to prevent inadvertent installation or use.

The basis for compliance is to demonstrate the control of nonconforming items to prevent mischaracterization of RH TRU waste and to document deficient packaging configuration.

Source documents shall demonstrate compliance by documenting that the Site had procedures for the identification, control, documenting, evaluation, reporting, segregation, and trending of nonconforming items as part of the implementation of a Site's QA program.

[P] NQA-1 Section 16: Corrective Action

[P.1] To demonstrate equivalency to NQA-1 Section 16, document that conditions adverse to quality were identified promptly and corrected as soon as possible.

The basis for compliance is to demonstrate that sufficient procedures and mechanisms were in place for the identification, classification, documentation, and reporting of conditions adverse to quality related to the characterization and packaging of RH TRU waste.

Source documents shall demonstrate compliance by documenting the implementation of corrective actions and the planning and implementation of action(s) taken to verify the remediation of any nonconforming waste items as part of the implementation of a Site's QA program.

[Q] NQA-1 Section 17: Quality Assurance Records

[Q.1] To demonstrate equivalency to NQA-1 Section 17, document records that furnish documentary evidence of quality were specified, prepared, and maintained.

The basis for compliance is to demonstrate QA records were specified, maintained, and prepared for the RH TRU waste activities that were performed.

Source documents shall demonstrate the implementation for the RH TRU waste characterization and packaging activities as part of the implementation of a Site's QA program.

[R] NQA-1 Section 18: Audits and Assessments

[R.1] To demonstrate equivalency to NQA-1 Section 18, document that planned and scheduled audits were performed to verify compliance with all aspects of the QA program and to determine effectiveness.

The basis for compliance is to demonstrate the scheduling, planning, performance, and documenting of management, internal, and third-party assessments related to RH TRU waste characterization, packaging, and QA operations.

Source documents shall demonstrate the assessment history and results for waste management activities and other related quality, technical, and administrative activities.

[S] NQA-2: Software Requirements

[S.1] To demonstrate equivalency to NQA-2, document the planning, performance, and documentation of software QA activities.

The basis for compliance is to demonstrate software QA activities were part of the implementation of a Site's QA program.

Source documents shall address the planning, performance, and documentation of software QA activities as part of the Site's QA program.

[T] NQA-3: Sample Control and Performance of Scientific Investigations

[T.1] To demonstrate equivalency to NQA-3, document the control of samples and the performance of scientific and technical investigations.

The basis for compliance is to demonstrate the collection of samples and the performance of scientific and technical investigations as part of the implementation of a Site's QA program.

Source documents shall demonstrate the control of samples and the performance of scientific and technical investigations related to RH TRU waste characterization activities.

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4.5 Reporting of QA Equivalency

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**NOTE**

The QA Equivalency Report must ensure that program equivalence is demonstrated for all quality-related activities having an influence on the AK information to be qualified, not just those activities directly associated with generation of the data. For example, a QA Equivalency Report for qualification of analytical data from smear samples would have to demonstrate equivalence for the program used to collect and maintain the samples, as well as the program for the analytical laboratory producing the data.

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**AK Personnel**

4.5.1 Generate a QA Equivalency Report, which includes a procedure matrix, to summarize the results of the qualification of AK information through QA equivalency. Describe the factors and rationale that explain why a QA equivalency is acceptable for the subject waste stream. Ensure that there is adequate discussion in the "comments" column of the procedure matrix that explains the adequacy decisions for each relevant QAPD item. At a minimum, the QA Equivalency Report shall address the following issues for each of the NQA sections:

- [A] A statement as to the NQA section addressed and how the requirements relate to the Site's waste characterization inventory.
- [B] A definition, textual or tabular, as to which QAPD section(s) are related to each of the NQA sections.
- [C] A statement as to which section(s) of the procedure matrix are applicable, which section(s) are not, and a justification for identifying these sections as not applicable.
- [D] A statement as to which source document(s) address each of the NQA sections. Each section should reference the programmatic documents, implementing procedures, and the records, as applicable, evidencing the performance of the waste characterization process.
- [E] A conclusion within each of the NQA sections about the equivalency.
- [F] Attachments showing the quantitative representation of QA Equivalency and the procedures matrix.

4.5.2 Submit the QA Equivalency Report to the QA Manager for processing.

**QA Manager**

4.5.3 Review the QA Equivalency Report for completeness and accuracy.

4.5.4 Approve the QA Equivalency Report and submit it to the AKE for final review prior to submittal to Central Characterization Project (CCP) Document Control.

**AKE**

4.5.5 Ensure the source documents cited in the QA Equivalency Report have been included in the AK record in accordance with CCP-TP-005.

4.5.6 Submit the QA Equivalency Report to CCP Document Control.

**CCP Document Control**

4.5.7 Process the QA Equivalency Report as an AK document in accordance with CCP-QP-010.

## 5.0 RECORDS

5.1 Records generated during the performance of this procedure are maintained as QA records in accordance with CCP-QP-008, *CCP Records Management*. The records are the following:

### 5.1.1 QA/Lifetime

[A] QA Equivalency Report

[B] AK Source Documents