U.S. Department of Energy
Carlsbad Field Office

REMOTE-HANDLED TRU WASTE CHARACTERIZATION PROGRAM IMPLEMENTATION PLAN

DOE/WIPP-02-3214

Revision 5

Effective Date: November 1, 2023

This document supersedes DOE/WIPP-02-3214, Revision 4.
This document implements the WIPP DSA

U.S. Department of Energy
Carlsbad Field Office

REMOTE-HANDLED TRU WASTE CHARACTERIZATION PROGRAM IMPLEMENTATION PLAN

Effective Date: November 1, 2023

Approved by: _/signature on file/_____ Date: __November 1, 2023__
Kenneth E. Princen, Assistant Manager
Office of National TRU Program
Waste Certification and Disposal

CHANGE HISTORY SUMMARY

Revision Number	Date Issued	Description of Changes
4	02/07/2019	• Added Change History Summary table and formatted document in compliance with requirements of CBFO MP 4.4, *Document Preparation and Control.* • Modified the requirements for analytical batch data reports, incorporate neutron dose-to-curie and correct editorial errors.
5	11/01/2023	• Complete rewrite to correspond to the incorporation of the waste acceptance requirements into revision 10 of DOE/WIPP-02-3122, Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant and to limit the document to the programmatic requirements. • Delete programmatic requirements that are not derived from regulatory requirements documents including the Characterization Reconciliation Report, EPA AK Accuracy Report, and the Certification Plan which was replaced with the Certification Description.

Table of Contents

Contents

Acronyms and Abbreviations

AK	acceptable knowledge
ASME	American Society of Mechanical Engineers
CBFO	Carlsbad Field Office
CFR	Code of Federal Regulations
CH	contact-handled
DOE	U.S. Department of Energy
DQO	data quality objective
DTC	dose-to-curie
EPA	U.S. Environmental Protection Agency
LWA	Land Withdrawal Act
NTP	Office of the National TRU Program
QA	quality assurance
QAO	quality assurance objective
QAPD	Quality Assurance Program Document
QC	quality control
RCTR	Radiological Characterization Technical Report
RH	remote-handled
RTR	real-time radiography
SAP	Sampling and Analysis Plan
SPM	site project manager
TRU	transuranic
VE	visual examination
WAC	Waste Acceptance Criteria
WAP	WIPP Hazardous Waste Facility Permit Waste Analysis Plan
WCPIP	Waste Characterization Program Implementation Plan
WIPP	Waste Isolation Pilot Plant

1. Introduction

   Remote-handled (RH) transuranic (TRU) waste characterization, which involves obtaining radiological and physical data, is a primary component of ensuring compliance of the Waste Isolation Pilot Plant (WIPP) with regulatory requirements. This RH TRU Waste Characterization Program Implementation Plan (WCPIP) identifies the programmatic requirements necessary to ensure conformance with the requirements specified in Title 40 Code of Federal Regulations (CFR) Part 191 (Subparts B and C) and Part 194 (EPA, 1993; EPA, 1996), the U.S. Environmental Protection Agency (EPA) final certification decision (EPA, 1998), and the WIPP Land Withdrawal Act (LWA) (Public Law 102-579).

   Other important aspects of the overall RH TRU waste characterization program that are not covered in this document are:

   - WIPP Hazardous Waste Facility Permit Waste Analysis Plan (WAP)
   - Waste Acceptance Requirements contained in DOE/WIPP-02-3122, Transuranic Waste Acceptance Requirements for the Waste Isolation Pilot Plant (WAC)
   - Shipping requirements contained in the Contact-Handled Transuranic Waste Authorized Methods for Payload Control (CH-TRAMPAC) and the Remote-Handled Transuranic Waste Authorized Methods for Payload Control (RH-TRAMPAC)
   - Transportation requirements specified in the shipping package Safety Analysis Reports for Packaging and associated Certificates of Compliance
   - WIPP operations and safety requirements

2. Program Requirements

   This section describes the RH TRU waste characterization program requirements that must be met by RH TRU characterization programs prior to the shipment of RH TRU waste to the WIPP facility.

   Data quality objectives (DQOs) are qualitative and quantitative statements that specify the WIPP program technical and quality objectives. The associated DQOs are delineated in the WAC and the WAP.

   Quality assurance objectives (QAOs) are data characteristics used to determine whether the quality of the waste characterization data collected is acceptable. They include the following:

   - Data precision – A measure of the mutual agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation.
   - Data accuracy – The degree to which data agree with an accepted reference or true value.

- Data representativeness – The degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions.
- Data completeness – A measure of the amount of valid data obtained compared to the amount that was expected.
- Data comparability – A measure of the confidence with which one data set can be compared to another.

Although QAOs are used to assess the quality of analytical data, both quantitative and qualitative, they may not all be applicable to certain waste characterization methodologies.

3. Program Description

The nature of RH waste (material age, unique dose considerations, availability of acceptable knowledge [AK] information, site waste-handling capabilities, and potential opportunities to collect data by measurement), makes it necessary to develop waste stream-specific characterization approaches. The characterization approaches shall be selected/developed in consultation with Carlsbad Field Office (CBFO) and documented in a memorandum to the Office of the National TRU Program (NTP) Certification Manager.

3.1. AK Summary

The AK Summary Report will be prepared to describe existing AK information relating to the generating process(es), material inputs, and the physical and radiological properties of the waste stream. In conjunction with the development of the AK Summary Report, a waste stream certification approach is developed for each waste stream (or related waste streams) to determine the methods to be used to generate characterization data and qualify AK data used to meet the DQOs.

3.2. Nondestructive Examination (NDE)

A combination of these characterization methods may be utilized to meet the DQO for NDE:

- Real time radiography (RTR)
- Visual examination (VE)
- AK - existing RTR or VE data used in part or in whole to meet a DQO that was collected prior to the implementation of a quality assurance program pursuant to 40 CFR §194.22(a)(1) must be qualified using one of the AK qualification methods described in Section 3.6.

3.3. Radiological characterization:

To complete the radiological characterization, RH waste is typically measured through the dose-to-curie (DTC) process (a detailed description of the DTC process is included in the WAC). Other options for characterization include non-destructive assay, modeling, use of AK documentation, or a combination of the different techniques. Any AK data used in part or in whole to meet a DQO that was collected prior to the implementation of a quality assurance program pursuant to 40 CFR §194.22(a)(1) must be qualified using one of the AK qualification methods described in Section 3.6. For completion of the DTC process, the isotopic distribution must be determined. The methods used to determine the isotopic distribution include but are not limited to the following:

- Sampling
- Modeling
- AK
- Non-destructive assay

The details of the radiological characterization will be documented in the Radiological Characterization Technical Report (RCTR) for the waste stream (or related waste streams). This report presents the methodology and technical approach to be used for the radiological characterization for the waste stream. The RCTR serves as the roadmap to the calculation packages that contain the specific characterization evaluation and related results for the methodology selected. The RCTR includes the following:

- Detailed description of the technical approach, including characterization methodology and technical justification for the selection of the methodology
- Description of radiological materials and operations contributing to the waste stream contamination (type of fuels, reactors, fuel composition, burnup, etc.)
- Presentation of the generator AK information utilized for the radiological characterization method(s) selected for the waste stream
- Specific identification of additional data to be generated to characterize waste containers or qualify AK
- Presentation of method(s) and data used to qualify AK data used for characterization
- Total uncertainty analysis based upon the propagation of uncertainties present in all aspects of the determination of the isotopic content of the waste stream
- Presentation of waste stream-specific radiological parameters that address the required radiological DQOs
- Use of correlating or surrogate information generated for other materials or waste streams

If sampling is to be used, a Sampling and Analysis Plan (SAP) will be issued to delineate the sampling evolution and requirements for the associated analysis. Following completion of the analysis, the guidance provided in EPA QA/G-9S, Data Quality Assessments: Statistical Methods for Practitioners, shall be used in analyzing results of the sampling program. This post-sampling and analysis will be documented in a memorandum prepared for the Site Project Manager. The post-sampling analysis memorandum will contain the following:

- Review of objectives
  - Review of sampling program objectives
  - Review of sampling program QAOs
- Preliminary Evaluation of Data
  - Derivation of radiological characterization parameters from sample data
  - Derivation of statistical parameters
- Perform Statistical Analyses
  - Evaluate adequacy of the number of samples
  - Evaluate performance against QAOs
  - Perform other statistical tests, as required
- Verify Assumptions of Statistical Analyses
  - As applicable for the methods and analyses performed
- Draw Conclusions from the Data
  - Summarize results of sampling program and QAOs
  - Summarize radiological characterization parameters derived from sampling program

In addition, the post-sampling memorandum shall contain a description of the actual sampling event including any deviation from the original sampling plan. Significant or substantial deviation should be flagged and their potential effect evaluated.

3.3.1. Sampling to Confirm or Derive Radionuclide Distributions

Representative sampling of actual waste materials or of surrogate materials can be used to develop the radionuclide distribution for use in the DTC or Direct Assay methods. The sampling may involve the acquisition of a small portion of the actual waste or it may involve the removal of the contamination on the waste or surrogate surfaces such as work areas, tools, equipment, and floors by the use of what is termed a swipe or smear. The sampling results may be used by themselves to develop radionuclide ratios for all of the radionuclides required for the characterization of the waste. Alternatively, the sampling results may be used in conjunction with modeling to develop the required ratios. Such a case, for example, would be where two isotopes (e.g. 239Pu/240Pu) cannot be separated in a typical alpha spectrometry measurement, but their relative contributions may be determined from calculations using available AK information. The sample results may also be used to confirm the ratios derived from analytical modeling.

3.3.1.1. Sampling Plan

For TRU waste characterization programs that plan to use analytical results from sampling to develop either radionuclide ratios or concentrations, a sampling plan shall be prepared and documented for each RH TRU waste stream, or portion thereof. The sampling plan is a critical component in the development of representative samples and shall be developed consistent with the guidance provided in EPA QA/G-5S, *Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan,* including citing specific sections that are explicitly followed. The characterization program shall consider the best means for obtaining samples that are representative of the RH TRU content of a particular waste stream. The sampling plan shall be submitted to CBFO for review and approval prior to implementation.

At a minimum in the development and design of the sampling plan, the following shall be considered:

- The purpose and use of the sampling data (i.e., DQOs and QAOs).
- The sampling approach that will be employed based on an evaluation of the activities and facilities that generated the waste, the practicality of obtaining representative samples, the availability of waste, and the form, distribution, and type of waste comprising the RH TRU waste stream.
- The form, distribution, and type of waste comprising RH TRU waste.
  - The variety in operations and the nature of the generation of RH TRU waste are such that a single method of sampling the waste

cannot be applied across the U.S. Department of Energy (DOE) complex.

- The method used to collect the sample must be representative of the waste.
- RH TRU material embedded in concrete or other solids may require samples to be obtained from within the matrix.

- The use of surrogate samples such as swipes or smears of actual waste materials or work surfaces within the facility where the wastes were generated. The justification for the use of surrogate samples shall be documented.
- The number, types, and locations of samples as required to meet the established accuracy goal and to demonstrate representativeness and/or account for potential variations in the distribution within the waste.
- The sample collection, handling, and identification.
- The analytical methods to be used and the specific radionuclides to be measured.

3.3.1.2. Sampling Quality Assurance Objectives

The following QAOs are applied for the sampling activities:

- Precision QAO – Measuring precision for sampling using replicate samples would not provide useful data and is not practicable. Therefore, the precision QAO is not applicable for sampling.
- Accuracy QAO – Accuracy shall be achieved by the development of an appropriate sample design in the sampling plan approved by CBFO and by collecting an adequate number of samples such that the one-sigma uncertainty in the mean value of the sample-generated scaling factor is within a factor of two. Where AK supports a homogenous isotopic distribution a tighter variability may be developed that would allow for reducing the required number of samples thereby reducing cost and worker exposure.
- Representativeness QAO – Project-specific QAOs shall include methods to ensure representativeness and shall be described in each sampling plan. The specification of a factor of two in the one-sigma uncertainty in the mean provides an indication that the sampling plan is representative.
- Completeness QAO – Completeness will be ensured by meeting the QAO for a minimum set of radionuclides as specified in the sampling plan.

- Comparability QAO – Comparability is achieved by performing the sampling in accordance with the sample plan and documenting any required deviations in the Post Sampling Memorandum.

3.3.2. Sample Collection

The methods used to collect samples of RH TRU waste shall be such that the samples are representative of the waste from which they were taken. However, the diversity of RH TRU waste, as well as the dissimilarity of storage facilities (tanks, drums, hot cells, storage wells, underground caissons, etc.) and sampling equipment associated with them, preclude a detailed description of any specific sampling plan in this WCPIP. Consequently, the burden of responsibility for developing a technically sound sampling plan rests with the TRU waste characterization program at each site.

To minimize the quantity of waste derived from sampling, laboratories conducting the analytical work may require no more sample than is required for the analysis, based on the analytical methods. However, a sufficient number of samples shall be collected to adequately represent waste being sampled. All sampling will comply with the quality control (QC) requirements specified in this section.

Sampling equipment shall be cleaned or purchased clean. Sampling equipment, at least that portion that contacts the waste during sampling, shall be verified to be free of radiological contamination prior to use. This can be verified by normal radiological control survey techniques or by purchasing new equipment for each evolution. The results of cleanliness surveys of sampling equipment shall be traceable to sampling equipment batches.

Chain-of-custody on field samples (including field QC samples) will be initiated immediately after sample collection or preparation. Sample custody will be maintained by ensuring that samples are custody-sealed during shipment to the laboratory. If custody sealing is not practical due to radiological considerations associated with the sample, the generator site may implement administrative controls to ensure that samples are not tampered with. After samples are accepted by the analytical laboratory, custody is maintained by assuring the samples are in the possession of an authorized individual, in that individual's view, in a sealed or locked container controlled by that individual, or in a secure controlled-access location. Sample custody will be maintained until the sample is released by the site project manager (SPM) or until the sample is expended. The sampling plan or site-specific procedures shall include a copy of the sample chain-of-custody form and instructions for completing sample chain-of-custody forms. This form will include provisions for each of the following:

- Signature of individual initiating custody control, along with the date and time.
- Documentation of sample numbers for each sample under custody.
- Sample numbers will be referenced to a specific sampling event description that will identify the sampler(s) through signature, the date and time of sample collection, type/number of containers for each sample, sample matrix, preservatives (if applicable), requested methods of analysis, place/address of sample collection, and the waste container number (if applicable).
- For off-site shipping, method of shipping transfer, responsible shipping organization or corporation, and associated air bill or lading number.
- Signatures of custodians relinquishing and receiving custody, along with date and time of the transfer.
- Description of final sample container disposition, along with signature of individual removing sample container from custody.
- Comment section.
- Documentation of discrepancies, breakage, or tampering.

All samples and sampling equipment will be identified with unique identification numbers. Sampling equipment will be identified with unique equipment numbers to ensure that all sampling equipment is traceable to equipment cleanliness survey or purchase records.

All samples will be uniquely identified to ensure the integrity of the sample and to identify the generator/storage site and date of collection. Because of the high radiation dose rates associated with samples of RH TRU waste, traditional sample tags or labels may be impractical and are not required.

3.3.2.1. Sample Collection Quality Assurance Objectives

The following QAOs are applied for the sample collection:

- Precision QAO – Measuring precision for sampling using replicate samples would not provide useful data and is not practicable. Therefore, the precision QAO is not applicable for sampling.
- Accuracy QAO –Sampling accuracy in terms of the absence of cross-contamination will be measured. Sampling equipment will be verified as clean by the use of standard radiological control survey methods or purchasing new equipment for each sampling evolution.

- Representativeness QAO – Representativeness is the degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions. For sample collection, the samples are collected in the same location and in the manner directed by the sampling plan. Representativeness cannot be measured for sample collection and is therefore not applicable to sample collection.
- Completeness QAO – Completeness is a measure of the amount of valid data obtained compared to the amount that was expected. Data is not collected relative to the sample collection and the completeness QAO is therefore not applicable to sample collection.
- Comparability QAO – Comparability is a measure of the confidence with which one data set can be compared to another. Data is not collected relative to the sample collection and the comparability QAO is therefore not applicable to sample collection.

3.3.3. Modeling to Confirm or Derive Radionuclide Distributions

As an alternative to, or in addition to sampling, radionuclide distributions may be determined by modeling and/or calculations. Calculations of radionuclide activities are performed by considering their production and depletion during irradiation and radioactive decay and any removal in reprocessing or separations processes. Production of a radionuclide can continue after irradiation as a result of decay of another parent radionuclide. Sophisticated computer programs, such as ORIGEN, exist to calculate these radionuclide production and depletion effects. If the waste is to be characterized by modeling and/or calculations, the following requirements apply:

- The computer codes to be used shall be controlled under an appropriate software quality assurance program that tracks the installation and use of the codes, and requires comprehensive verification and validation prior to use.
- Calculations shall be performed using methods, including computer programs, which account for the pre-irradiation composition of the fuel or target used to produce the TRU radionuclides, the exposure of this fuel or target during irradiation, and the change in radionuclide activities following irradiation.
- The appropriate cross-sections shall be used or generated for each irradiation condition.
- The irradiation energy spectrum shall be known or calculated. The characteristics of the energy spectrum affect the effective cross-

sections for fission and transmutation. For many reactor types, these calculations have been performed and cross-section libraries exist.

- The fuel or target exposure history shall be used in the radionuclide generation and depletion calculation. RH TRU waste in a particular waste stream may have been produced as the result of numerous campaigns involving differing exposure and decay times and differing fuel properties.

Alternatively, in order to avoid calculating each campaign, a strategy may be developed to perform a set of calculations that represent the entire range of conditions leading to the generation of the RH TRU waste. The span of the evaluated parameters is considered AK information and will be compiled and documented for the waste under the AK process.

3.3.3.1. Modeling Quality Assurance Objectives

The following QAOs are applied for the modeling activities:

- Precision QAO – Precision is a measure of the mutual agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation. Comparable data sets are not generated and therefore, precision is not applicable to modeling.
- Accuracy QAO – Accuracy will be achieved by demonstrating that the modeling results compare to sample results within a factor of two or by using standardized and bench marked isotope generation and depletion computer codes.
- Representativeness QAO – Composition and burnup information for a minimum of 50% of the radioactive materials identified in the AK record involved in the generation of the waste shall be included in the modeling.
- Completeness QAO – Completeness is a measure of the amount of valid data obtained compared to the amount that was expected. Data is not collected relative to modeling and the completeness QAO is therefore not applicable to modeling.
- Comparability QAO – Comparability QAO – Comparability is a measure of the confidence with which one data set can be compared to another. Data is not collected relative to modeling and the completeness QAO is therefore not applicable to modeling.

3.3.4. AK to Confirm or Derive Radionuclide Distributions

Any AK data used in part or in whole to meet a DQO that was collected prior to the implementation of a quality assurance program pursuant to 40

CFR §194.22(a)(1) must be qualified using one of the AK qualification methods described in Section 3.6

3.3.5. NDA to Confirm or Derive Radionuclide Distributions

The requirements for NDA are included in DOE/WIPP-02-3122, Appendix A.

3.4. Calculation Packages

Calculation packages shall be prepared to document the calculations performed for the radiological characterization of the waste stream. At a minimum, the calculation packages shall include the following:

- the identification of the purpose of the calculation, the approach used to meet the purpose, the assumptions made in the calculational approach and, as appropriate, references cited for technical sources of information used in the calculation.
- the presentation of the actual numerical calculations along with the results and conclusions resulting from the calculations.

3.5. Certification Description:

The RH-TRU waste characterization and certification shall be described in the RH-TRU Waste Stream Certification Description developed to meet the requirements of 40 CFR Part 194. The Waste Stream Certification Description shall be prepared to describe the process for certification of the waste stream, including a description of the characterization methods selected for the waste stream and AK qualification method(s) described in Section 3.6. The Waste Stream Certification Description for each waste stream (or related streams) shall present the overall characterization strategy for the waste stream. At a minimum, the Waste Stream Certification Description shall include the following:

- Description of AK qualification and/or characterization methods selected to meet the DQOs, including the justification for the selection of the methods.
- Description of the QAOs for the selected methods.
- Detailed description for any characterization and testing method not currently approved. The description of the method must be sufficient to allow for the CBFO's approval prior to implementation of the method.
- Summary of the program documents to be prepared during the characterization and/or qualification methods selected for the waste stream.

Table 3.1 titled, "RH-TRU Documentation," lists the required RH-TRU program documents that depend on the specific radiological characterization method selected. The nature of RH-TRU waste, however, makes it necessary to develop

waste stream specific characterization approaches. The documents required for each approach will be recorded and justified as needed in the Waste Stream Certification description.

The listing of the documents is in the approximate order they are usually developed, and the order is generally dictated by the dependencies between the documents. Some documents are not strictly dependent on the finalization of a precedent document and can be completed based on a draft in advance of the final completion of a document. The dependencies are identified in the description of the documents. Documents must be in final form before submissions to CBFO for RH-TRU waste certification.

Table 3.1 RH-TRU Documentation

Required Documents	CBFO Approval Required Prior to Tier I Request
AK Source Document Summaries	No
List of AK Source Documents	Yes
AK Summary Report	No
*Sampling and Analysis Plan	Yes[1]
*Post-Sampling Memo	No
*Confirmation Test Plans	Yes[1]
*Request for Corroborating Data	Yes[1]
*Request for Peer Review Qualification	Yes[1]
*Equivalent Quality Assurance (QA) Program Evaluation	Yes[1]
Calculation Packages	No
*Dose-to-Curie (DTC) Radiological Characterization Spreadsheet & Calculation	No
Radiological Characterization Technical Report	Yes
*RH transuranic (TRU) Waste Correlation and Surrogate Summary Form	No
Waste Stream Certification Description	Yes

* Required Document Depending on the Selected Characterization Method

[1] CBFO approval required prior to executing the plans and evaluations.

3.6. AK Qualification Methods:

Any AK data used in part or in whole to meet a DQO that was collected prior to the implementation of a quality assurance program pursuant to 40 CFR §194.22(a)(1) must be qualified, including any information including characterization data generated prior to the characterization program establishing an approved QA program that implements the requirements of the CBFO Quality Assurance Program Document (QAPD). The CBFO QAPD incorporates the EPA-required QA elements from American Society of Mechanical Engineers (ASME) NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1) as required by 40 CFR §194.22. A QA program meeting these requirements must be applied to waste characterization activities performed under this WCPIP. 40 CFR §194.22 also allows qualification by CBFO QA of information generated prior to the establishment of a compliant QA program. AK information may be qualified by one or a combination of the following four methods:

- Peer review, conducted in a manner compatible with NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*, February 1988
- Corroborating data
- Confirmatory testing
- Evidence of a QA program that is equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1)

For all qualification methods, the following shall be considered:

- Qualifications of personnel or organizations generating the data
- Technical adequacy of the equipment and procedures used to collect and analyze the data
- Environmental conditions under which the data were obtained (if germane)
- Quality and reliability of the measurement control program under which the data were generated
- Extent to which data demonstrate properties of interest (e.g., physical or radiological)
- Extent to which conditions generating the data may partially meet requirements of the ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1).
- Prior uses of the data and associated verification processes

- Prior peer or other professional reviews of data and their results
- Extent and reliability of the documentation associated with the data
- Extent and quality of corroborating data or confirmatory testing results
- Degree to which data generating processes were independently audited

3.6.1. Peer Review

Peer reviews conducted to qualify AK characterization information must comply with the following requirements:

- RH TRU waste characterization programs must develop a peer review procedure that complies with the requirements of NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*, February 1988.
- The characterization program must obtain CBFO approval of the peer review procedure and the peer review plan prior to conducting the peer review.
- The peer review scope must explicitly define the waste characterization DQOs and QAOs that the peer review panel will be evaluating. The peer review scope must explicitly require the peer review panel to determine whether the data being reviewed satisfy the defined DQOs and QAOs.

The peer review shall be audited and approved by CBFO during each peer review process, and prior to shipping RH TRU waste that has been characterized using data qualified by peer review to the WIPP.

3.6.2. Corroborating Data

Corroborating data that could be used to qualify AK information includes, but is not limited to:

- Characterization data from a related waste source or from a different time period of generation.
- Data from a related RH or CH waste source.
- Direct analytical results from samples taken from the stream that are not adequate to address a given requirement (e.g., too few samples), but sufficient to meet the DQOs for other characterization parameters.
- Data from a similar waste process generated at a different site or facility.
- Data from similar source material (e.g., fuel test specimen or process input materials).
- Data that establishes the efficacy of a mathematical model.

Corroborating data will generally be either lacking a fully implemented QAPD QA program or not supported by the documentation necessary to complete a demonstration of an effectively equivalent QA program under Section 3.6.4. In order for corroborating data to be used to qualify AK information, the characterization program must present sufficient detail that establishes the quality and reliability of the data. For example, data generated by a laboratory that did not implement NQA-1 or DOE quality assurance programs would be acceptable if that laboratory operated under a regime of quality assurance and control measures that provide defensibility of the data. Corroborating data from other reliable and accredited sources such as government agencies, national laboratories, universities, or peer reviewed journals could be acceptable sources of qualification information.

The use of corroborating data will be described in a report (e.g., Radiological Technical Report) that will describe the source of the data, define the AK information that the data are intended to qualify, present or summarize the data, justify the use of the data, describe the reasons why the data are considered reliable, and explain any limitations associated with the data.

3.6.3. Confirmatory Testing

Use of the characterization methods (e.g., AK, NDE, radiological characterization) for AK qualification shall be described in Waste Stream Certification Description. If a Confirmation Test Plan proposes to qualify AK information by confirmatory testing methods other than the standard characterization approach, the Confirmation Test Plan must be approved by CBFO. Other methods that could be proposed include, but are not limited to:

- Qualification of existing VE or RTR audio/videotapes by the review of a percentage of the tapes by qualified operators.
- Qualification of existing radiological characterization data by analyzing representative samples of the waste.
- Qualification of existing waste container packaging records by VE or RTR of a representative subpopulation of the waste.
- Qualification of existing radiological sampling and analytical information by the use of confirmatory modeling (e.g., ORIGEN).
- A combination of methods can be used to meet a DQO and shall be defined in the Waste Stream Certification Description.

Characterization programs that propose to use other methods to qualify AK information must submit a confirmation testing approach to CBFO for

review and approval. This approach will be included in the Waste Stream Certification Description and must include:

- A description of the waste stream or waste stream lots to which the plan applies.
- An explicit description of the waste characterization DQOs and QAOs that will be satisfied with the data being qualified.
- A description of the proposed method, including the percentage of waste containers that will be subject to the method proposed.
- A description of how the tested subpopulation will be representative of the waste stream or waste stream lot.
- Quantitative acceptance criteria for determining that the AK information in question can be qualified as characterization information.

Prior to shipping waste to the WIPP that has been characterized using data qualified via the proposed method under this section, the proposed method shall be audited by the CBFO.

3.6.4. Equivalent QA Program

To qualify AK information using an equivalent QA program, the characterization program must be able to demonstrate that the program in use at the time the data were generated implemented requirements equivalent in effect to the applicable requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1). “Equivalent in effect” is defined as a program that results in confidence that the data generated is what it is purported to represent, although the data need not exactly match all of the QAPD requirements. For example, if individual training records for certain individuals cannot be recovered but evidence demonstrates that the program had a qualification and training program in place at the time, then it can be surmised that the historical program was equivalent in effect to the QAPD and that the training records existed but are unrecoverable. Implementation of the QA program on the waste characterization program that generated the AK information must be auditable. Examples of the type of records that should be identified and retrieved include:

- Evidence that the organization performing the work identified persons or organizations responsible for verifying quality with sufficient independence from cost and schedule considerations (e.g., organizational charts and QA policies).
- Training records for waste characterization and verification personnel.
- Assessment records (audits and surveillances).

- Nonconformance and corrective action records (if no nonconformances are identified, evidence that a process was in place to address nonconformances had they occurred).
- Procurement documentation for items and services that could affect the quality of the characterization data.
- Approved QA plans and programs.
- Standard operating procedures used for characterization and QA activities.
- Document control records that demonstrate that documents were reviewed and approved in accordance with procedural requirements.
- Calibration records.
- Software qualification records.
- Documented and verifiable evidence that a records program was in existence that required records important to quality be controlled, stored, maintained, and retrievable.
- Some records may have exceeded their specified retention time and may have been destroyed in accordance with the requirements of the QA program.

Characterization programs proposing to use the equivalent QA program method for qualifying AK information as characterization data shall submit a “procedure matrix” providing a crosswalk that identifies the plans and procedures that implemented the applicable requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1). Those ASME NQA elements that are determined to not be applicable to RH TRU waste characterization activities will be identified on the matrix along with a description of why the element is not applicable. The characterization program shall also submit plans and procedures referenced on the matrix for CBFO review during audits or upon request by CBFO. The matrix and associated plans and procedures should include the applicable document revisions that were in effect when the AK information was originally generated; exceptions shall be noted and justified (e.g., a prior or post revision with a declaration from a knowledgeable individual that the missing revision was essentially the same would be sufficient evidence of acceptability).

Prior to shipping waste that has been characterized using data qualified under an equivalent QA program to the WIPP, the documentation demonstrating an equivalent QA program was implemented shall be audited and approved by CBFO.

4. References

DOE (U.S. Department of Energy), 1996, Compliance Certification Application (CCA), DOE/CAO-1996-2184, U.S. Department of Energy, Carlsbad Area Office, Carlsbad, NM.

EPA (U.S. Environmental Protection Agency), 1993, 40 CFR Part 191 Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule, *Federal Register*, Vol. 58, No. 242, pp. 66398 – 66416, December 20, 1993, Office of Radiation and Indoor Air, Washington, D.C.

EPA (U.S. Environmental Protection Agency), 1996, 40 CFR Part 194: Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations; Final Rule, *Federal Register*, Vol. 61, No. 28, pp. 5224 – 5245, February 9, 1996, Office of Air and Radiation, Washington, D.C.

EPA (U.S. Environmental Protection Agency), 1998, Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations: Certification Decision; Final Rule, *Federal Register*, Vol. 63, No. 95, pp. 27353-27406, May 18, 1998, Washington, D.C.

New Mexico Environment Department, *Waste Isolation Pilot Plant Hazardous Waste Facility Permit*, NM4890139088-TSDF, Santa Fe, New Mexico

DOE-/WIPP-02-3122, *Transuranic Waste Acceptance Requirements for the Waste Isolation Pilot Plant*