

ATTACHMENT C5
QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

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QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

C5-1 Quality Assurance Project Plans

Prior to management, storage, or disposal of a generator/storage site's transuranic (**TRU**) mixed waste at the Waste Isolation Pilot Plant (**WIPP**) facility, the Permittees shall require that each participating site develops and implements a quality assurance project plan (**QAPjP**) that addresses the applicable requirements specified in the waste analysis plan (**WAP**) in Permit Attachment C. The U.S. Department of Energy (**DOE**) will approve QAPjPs from the generator/storage sites that intend to send TRU mixed waste to the WIPP facility. The DOE shall ensure that these QAPjPs include the qualitative or quantitative criteria for determining whether waste characterization program activities are being satisfactorily performed. The DOE shall also ensure that QAPjPs identify the organization(s) and position(s) responsible for their implementation. Additionally, the QAPjPs shall also reference site-specific documentation that details how each of the required elements of the characterization program will be performed.

The DOE shall ensure that prior to the implementation of characterization activities at participating sites, standard operating procedures (**SOPs**) were developed for the activities which affect the quality of the waste characterization program elements specified in the WAP. For the purposes of the quality assurance (**QA**) program, the term SOP refers to any site-specific implementing document. Compliance with SOPs will ensure that tasks are performed in a consistent manner that results in achieving the quality required for the QA program. The organization, format, content, and designation of SOPs shall be described in the QAPjPs. Site-specific SOPs will be reviewed for consistency with the QAPjP according to the Audit and Surveillance Program specified in Permit Attachment C6.

C5-2 Document Review, Approval, and Control

The DOE shall ensure that the preparation, issuance, and change to documents that specify quality requirements or prescribe activities affecting quality for the TRU mixed waste characterization program elements specified in the WAP be controlled to assure that correct and current documents are used and referenced. The QAPjPs shall include a document control format consisting of a unique document identification number, current revision number, date, and page number which will be placed on the individual pages of the document. Quality documents for the waste characterization program shall be reviewed prior to approval and issuance by qualified and independent individuals. The QAPjP review shall consider the technical adequacy, completeness, and correctness of the QAPjP, and the inclusion of and compliance with the requirements established by the WAP (Permit Attachment C). The DOE shall ensure that appropriate QAPjP approval is indicated by a signature and date page included in the front of each document.

At a minimum, the DOE shall ensure that revisions to documents that implement the requirements of the WAP are denoted by including the current revision number on the document title page, the revised signature page, and each page that has been revised. Only revised pages need to be reissued. Changes to documents, other than those defined as editorial changes or minor changes, shall be reviewed and approved by the same functional organizations that performed the original review and approval, unless other organizations are specifically

designated in accordance with approved procedures. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The following items are considered editorial or minor changes:

- Correcting grammar or spelling (the meaning has not changed)
- Renumbering sections or attachments
- Updating organizational titles
- Changes to nonquality-affecting schedules
- Revised or reformatted forms, providing the original intent of the form has not been altered
- Attachments marked “Example,” “Sample,” or exhibits that are clearly intended to be representative only

A change in an organizational title accompanied by a change in the responsibilities is not considered an editorial change. Changes to the text shall be clearly indicated in the document. The DOE shall provide the QAPjP for each site and subsequent revisions to the New Mexico Environment Department upon approval by the DOE.

The DOE shall ensure that QAPjPs include a detailed description of the reporting and approval requirements for changes to approved QA documents and SOPs, including procedures for implementing changes to these documents. Members of the site project staff are responsible for reporting any obsolete or superseded information to the Site Project Manager (**SPM**). Site-specific changes shall be evaluated and approved by the SPM before implementation. The SPM shall notify the appropriate personnel and the affected documents shall be revised as necessary. The site project manager shall also be responsible for notifying the DOE field office of the changes. The DOE shall ensure that changes that affect performance criteria or data quality, testing procedures, quality assurance objectives, calibration requirements, or quality control sample acceptance criteria comply with the WAP and shall not be made without prior approval of the DOE.