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**RENEWAL APPLICATION
APPENDIX B5**

QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

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1 **RENEWAL APPLICATION**
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3 **QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS**

4 **B5-1 Quality Assurance Project Plans**

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7 Prior to management, storage, or disposal of a generator/storage transuranic (TRU) waste site's
8 TRU mixed waste at the Waste Isolation Pilot Plant (WIPP) WIPP, the Permittees shall require
9 that each participating site certified characterization program develops and implements a quality
10 assurance project plan (QAPjP) that addresses all the applicable requirements specified in Waste
11 Isolation Pilot Plant Renewal Application Chapter B waste analysis plan (Waste Analysis Plan
12 (WAP) in Permit Attachment B. The Permittees will approve QAPjPs from all generator/storage
13 sites certified characterization programs and Permittee approved laboratories that intend to send
14 TRU mixed waste to the Waste Isolation Pilot Plant. The Permittees shall ensure that these
15 QAPjPs include the qualitative or quantitative criteria for determining whether waste
16 characterization program activities are being satisfactorily performed. The Permittees shall also
17 ensure that QAPjPs identify the organization(s) and position(s) responsible for their
18 implementation. Additionally, the QAPjPs shall also reference certified characterization
19 program site-specific documentation that details how each of the required elements of the
20 characterization program will be performed.

21 The Permittees shall ensure that prior to the implementation of characterization activities ~~at~~ by
22 ~~participating sites~~ certified characterization programs, standard operating procedures (SOPs)
23 ~~were~~ are developed for all activities which affect the quality of the waste characterization
24 program elements specified in ~~the WAP~~ Renewal Application Chapter B. For the purposes of
25 the quality assurance (QA) program, the term SOP refers to any certified characterization
26 program site-specific implementing document. Compliance with SOPs will ensure that tasks are
27 performed in a consistent manner that results in achieving the quality required for the quality
28 assurance QA program. The organization, format, content, and designation of SOPs shall be
29 described in the QAPjPs. Certified characterization program Site-specific SOPs will be
30 reviewed for consistency with the QAPjP according to ~~the~~ Renewal Application Appendix B6
31 (Waste Isolation Pilot Plant Permittees' Audit and Surveillance Program) ~~specified in Permit~~
32 Attachment B6.

33
34 **B5-2 Document Review, Approval, and Control**

35 The Permittees shall ensure that the preparation, issuance, and change to documents that specify
36 quality requirements or prescribe activities affecting quality for the transuranic TRU mixed
37 waste characterization program elements specified in ~~the WAP~~ Renewal Application Chapter B
38 be controlled to assure that correct and current documents are used and referenced. The QAPjPs
39 shall include a document control format consisting of a unique document identification number,
40 current revision number, date, and page number which will be placed on the individual pages of
41 the document. All quality documents for the waste characterization program shall be reviewed
42 prior to approval and issuance by qualified and independent individuals. The QAPjP review

1 shall consider the technical adequacy, completeness, and correctness of the QAPjP, and the
2 inclusion of and compliance with the requirements established by ~~the WAP (Permit Renewal~~
3 ~~Application Chapter B)~~. The Permittees shall ensure that appropriate QAPjP approval is
4 indicated by a signature and date page (including unique document number and revision)
5 included in the front of each document.

6
7 At a minimum, the Permittees shall ensure that revisions to documents that implement the
8 requirements of ~~the WAP~~ Renewal Application Chapter B are denoted by including the unique
9 document number, current revision number, and date on the document title page, the revised
10 signature page, and each page that has been revised. Only revised pages need to be reissued.
11 Changes to documents, other than those defined as editorial changes or minor changes, shall be
12 reviewed and approved by the same functional organizations that performed the original review
13 and approval, unless other organizations are specifically designated in accordance with approved
14 procedures. Editorial or minor changes may be made without the same level of review and
15 approval as the original or otherwise changed document. The following items are considered
16 editorial or minor changes:

- 17
- 18 • Correcting grammar or spelling (the meaning has not changed)
 - 19 • Renumbering sections or attachments
 - 20 • Updating organizational titles
 - 21 • Changes to nonquality-affecting schedules
 - 22 • Revised or reformatted forms, providing the original intent of the form has not been
23 altered
 - 24 • Attachments marked “Example,” “Sample,” or exhibits that are clearly intended to be
25 representative only

26 A change in an organizational title accompanied by a change in the responsibilities is not
27 considered an editorial change. Changes to the text shall be clearly indicated in the document.
28 The Permittees shall provide the QAPjP for each site certified characterization program and all
29 revisions to the New Mexico Environment Department ~~NMED~~ upon approval by the Permittees.

30
31 The Permittees shall ensure that QAPjPs include a detailed description of the reporting and
32 approval requirements for changes to approved QA documents and SOPs, including procedures
33 for implementing changes to these documents. ~~All members of the site project~~ Certified
34 certification program staff are responsible for reporting any obsolete or superseded
35 information to the certified characterization program Site Project Manager ~~site project manager~~.
36 ~~All~~ Certified characterization program ~~site-specific~~ changes shall be evaluated and approved by
37 the certified characterization program Site Project Manager ~~site project manager~~ before
38 implementation. The certified characterization program Site Project Manager ~~site project~~
39 ~~manager~~ shall notify the appropriate personnel and the affected documents shall be revised as
40 necessary. ~~The site project manager shall also be responsible for notifying the DOE field office~~

1 ~~of the changes.~~ The Permittees shall ensure that changes that affect performance criteria or data
2 quality, such as sample handling and custody requirements, sampling and analytical procedures,
3 quality assurance objectives, calibration requirements, or quality control QC sample acceptance
4 criteria comply with ~~the WAP (Permit Renewal Application Chapter B)~~ and shall not be made
5 without prior approval of the Permittees.

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