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APPENDIX B5

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QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

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3 B5-1 Quality Assurance Project Plans

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

15 The Permittees shall ensure that prior to the implementation of characterization activities at
16 participating sites, standard operating procedures (**SOPs**) were developed for all activities which
17 affect the quality of the waste characterization program elements specified in the WAP. For the
18 purposes of the quality assurance program, the term SOP refers to any site-specific implementing
19 document. Compliance with SOPs will ensure that tasks are performed in a consistent manner
20 that results in achieving the quality required for the quality assurance program. The organization,
21 format, content, and designation of SOPs shall be described in the QAPjPs. Site-specific SOPs
22 will be reviewed for consistency with the QAPjP according to the Permittees' Audit and
23 Surveillance Program specified in Permit Attachment B6.

24 B5-2 Document Review, Approval, and Control

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

37 At a minimum, the Permittees shall ensure that revisions to documents that implement the
38 requirements of the WAP are denoted by including the current revision number on the document

1 title page, the revised signature page, and each page that has been revised. Only revised pages
2 need to be reissued. Changes to documents, other than those defined as editorial changes or
3 minor changes, shall be reviewed and approved by the same functional organizations that
4 performed the original review and approval, unless other organizations are specifically
5 designated in accordance with approved procedures. Editorial or minor changes may be made
6 without the same level of review and approval as the original or otherwise changed document.
7 The following items are considered editorial or minor changes:

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

16 A change in an organizational title accompanied by a change in the responsibilities is not
17 considered an editorial change. Changes to the text shall be clearly indicated in the document.
18 The Permittees shall provide the QAPjP for each site and all revisions to NMED upon approval
19 by the Permittees.

20 The Permittees shall ensure that QAPjPs include a detailed description of the reporting and
21 approval requirements for changes to approved QA documents and SOPs, including procedures
22 for implementing changes to these documents. All members of the site project staff are
23 responsible for reporting any obsolete or superseded information to the site project manager. All
24 site-specific changes shall be evaluated and approved by the site project manager before
25 implementation. The site project manager shall notify the appropriate personnel and the affected
26 documents shall be revised as necessary. The site project manager shall also be responsible for
27 notifying the DOE field office of the changes. The Permittees shall ensure that changes that
28 affect performance criteria or data quality, such as sample handling and custody requirements,
29 sampling and analytical procedures, quality assurance objectives, calibration requirements, or
30 QC sample acceptance criteria comply with the WAP (Permit Attachment B) and shall not be
31 made without prior approval of the Permittees.