

APPENDIX C10
QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS





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C10-1 Quality Assurance Project Plans

Each participating site shall develop and implement a quality assurance project plan (QAPjP) that addresses all the requirements specified in Waste Isolation Pilot Plant waste analysis plan and implemented in the Transuranic Waste Characterization Quality Assurance Program Plan (QAPP)(CAO-94-1010, April 30, 1995). These QAPjPs shall include or reference the appropriate management and technical criteria of the quality assurance program, as well as qualitative or quantitative criteria for determining that waste characterization program activities are being satisfactorily performed. QAPjPs shall identify the organization(s) and position(s) responsible for their implementation. The QAPjPs shall also reference site-specific documentation that details how each of the required elements of the characterization program will be performed.

Prior to the implementation of characterization activities at participating sites, standard operating procedures (SOP) will be developed for all activities affecting waste characterization program quality that require written instructions or procedures. For the purposes of the quality assurance 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 quality assurance program. The organization, format, content, and designation of SOPs must be described in the QAPjPs. Site-specific SOPs will be reviewed for consistency with the QAPjP during the Generator/Storage Site Waste Screening and Acceptance Audit Program.

C10-2 Document Review, Approval, and Control

The preparation, issue, and change to documents that specify quality requirements or prescribe activities affecting quality for the transuranic waste characterization program shall be controlled to assure that correct and current documents are used and referenced. The QAPjPs shall include the document control format implemented by the QAPP consisting of a unique document identification number in the upper left-hand corner of each page, and the section number, current revision number, date, and page number placed in the upper right-hand corner of each page. All quality documents for the waste characterization program shall be reviewed prior to approval and issuance by qualified and independent individuals. This review shall consider, as appropriate, the technical adequacy, completeness, and correctness of the documents and the inclusion of appropriate quality requirements. Approval shall be indicated by a signature and date page included in the front of each document. Table C10-1 shows the parties responsible for document review, review/approval, implementation, change approval, and change control. Whenever the quality assurance (QA) documents are revised, review and approval of the revision shall be conducted by the same level of approval authority and in accordance with the requirements of review as the original documents.

At a minimum, revisions to QA documents shall be 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. A vertical bar, indicating the change to the

1 text, shall be included along the left-hand margin of the page. Revised document submittals
2 shall also identify the changes, the reason for the changes, and the justification for concluding
3 that the revised contents continue to satisfy the requirements of the quality assurance program.

4
5 The QAPP shall be controlled by the U.S. Department of Energy Carlsbad Area Office National
6 Transuranic Program (NTP) team leader and distributed by this position to the applicable DOE
7 field offices. A distribution list for the QAPP shall be used to control the issuance of revisions
8 and shall be maintained by the NTP team leader.

9
10 The QAPP shall be initially reviewed, approved, and concurred with by those positions indicated
11 in Table C10-1, and thereafter reviewed by the NTP team leader at least annually to ensure it
12 addresses the current needs of the waste characterization quality assurance program. If
13 changes to the QAPP are required, the NTP team leader shall be responsible for scheduling and
14 coordinating the review and approval of the revised document. Changes shall be reported by
15 the NTP team leader to the DOE field office managers for notification to the sites. Each site
16 project manager shall be responsible for the revision of the QAPjP and SOPs in accordance with
17 the approved changes to the QAPP.

18
19 Each site must have a document control system to control the review and approval of controlled
20 documents. The NTP team leader, the applicable DOE field office, the site project manager, and
21 the site project QA officer are responsible for the initial review and approval of the QAPjPs.
22 Thereafter, the QAPjPs shall be reviewed at least annually by the site project manager. If
23 changes to the QAPjP are required, the site project manager shall be responsible for scheduling
24 and coordinating the review and approval of the revised document. The QAPjPs shall include
25 a description of the organization(s) or person(s) responsible for distributing revisions to those
26 plans.

27
28 The QAPjPs shall include a detailed description of the reporting and approval requirements for
29 changes to approved QA documents and SOPs, including procedures for implementing changes
30 to these documents. All members of the site project staff are responsible for reporting any
31 obsolete or superseded information to the site project manager. All site-specific changes shall
32 be evaluated and approved by the site project manager and the site project QA officer before
33 implementation. The site project manager shall notify the appropriate personnel and the affected
34 documents shall be revised as necessary. The site project manager shall also be responsible
35 for notifying the DOE field office of the changes. No changes that affect performance criteria or
36 data quality; such as sample handling and custody requirements, sampling, and analytical
37 procedures, quality assurance objectives, calibration requirements, or QC sample acceptance
38 criteria; shall be made without prior approval of the DOE field office and the NTP team leader.
39 However, minor changes to QAPjPs and SOPs that do not affect the transuranic waste
40 characterization quality assurance program performance criteria or data quality may be made
41 without prior notification of the DOE field office and the NTP team leader.

**TABLE C10-1
 REQUIREMENTS FOR REVIEW, APPROVAL, IMPLEMENTATION,
 AND CONTROL OF THE QAPP AND QAPJPs**

	Responsible Party							
	Deputy Assistant Secretary, EM-30	Manager, CAO	Manager, Office of Regulatory Compliance	Manager, CAO Quality Assurance	Team Leader, National TRU Program	DOE Field Office	Site Project Manager	Site Project QA Officer
QAPP								
Review	X							
Review/Concurrence			X	X	X			
Review/Approval		X						
Implementation					X			
Change Approval		X	X	X	X			
Change Control					X			
QAPJPs								
Review/Approval				X	X	X	X	X
Implementation							X	
Change Approval				X		X	X	X
Change Control							X	

