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**Title 40 CFR Part 191  
Subparts B and C  
Compliance Recertification Application 2014  
for the  
Waste Isolation Pilot Plant**

**Quality Assurance  
(40 CFR § 194.22)**



**United States Department of Energy  
Waste Isolation Pilot Plant**

**Carlsbad Field Office  
Carlsbad, New Mexico**

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**Compliance Recertification Application 2014**  
**Quality Assurance**  
**(40 CFR § 194.22)**

**Table of Contents**

22.0 Quality Assurance (40 CFR § 194.22)..... 1

    22.1 Requirements..... 1

    22.2 Background ..... 1

    22.3 1998 Certification Decision..... 2

    22.4 Changes in the CRA-2004..... 3

    22.5 EPA’s Evaluation of Compliance for the 2004 Recertification ..... 4

        22.5.1 NQA Standards .....4

        22.5.2 Audits of QA Plan Implementation .....4

        22.5.3 Audits of QA Programs at Lower-Tier Organizations.....4

        22.5.4 NUREG-1297 for Peer Reviews .....5

        22.5.5 Assessments of Data Quality Characteristics .....5

        22.5.6 Data Qualifications .....5

    22.6 Changes or New Information Between the CRA-2004 and the CRA-2009  
 (Previously: Changes or New Information Since the 2004 Recertification) ..... 6

        22.6.1 Changes to the QAPD.....6

        22.6.2 Changes to CBFO/DOE Procedures .....7

        22.6.3 Updated List of Waste Generator Sites Certified under the QA  
 Program.....8

    22.7 EPA’s Evaluation of Compliance for the 2009 Recertification ..... 8

        22.7.1 NQA Standards .....9

        22.7.2 Audits of QA Plan Implementation .....9

        22.7.3 Audits of QA Programs at Lower-Tier Organizations.....9

        22.7.4 NUREG-1297 for Peer Reviews.....10

        22.7.5 Assessments of Data Quality Characteristics .....10

        22.7.6 Data Qualifications .....10

    22.8 Changes or New Information Since the CRA-2009..... 10

        22.8.1 Changes to QAPD.....11

        22.8.2 Changes to DOE/CBFO Procedures .....11

        22.8.3 Updated List of Waste Generator Sites Certified under the QA  
 Program.....12

    22.9 References ..... 13

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### **Acronyms and Abbreviations**

ANL	Argonne National Laboratory
ASME	American Society of Mechanical Engineers
BAPL	Bettis Atomic Power Laboratory
CARD	Compliance Application Review Document
CBFO	Carlsbad Field Office
CCA	Compliance Certification Application
CCP	Central Characterization Project
CFR	Code of Federal Regulation
CRA	Compliance Recertification Application
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
GEVNC	General Electric Vallecitos Nuclear Center
INL	Idaho National Laboratory
LANL	Los Alamos National Laboratory
MP	management procedure
NQA	Nuclear Quality Assurance
ORNL	Oak Ridge National Laboratory
QA	quality assurance
QAPD	Quality Assurance Program Document
RL	Hanford-Richland
RH-TRU	remote-handled transuranic
SRS	Savannah River Site
TP	team procedure
TRU	transuranic
WIPP	Waste Isolation Pilot Plant

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1 **22.0 Quality Assurance (40 CFR § 194.22)**

2 **22.1 Requirements**

§ 194.22 Quality Assurance

(a)(1) As soon as practicable after April 9, 1996, the Department shall adhere to a quality assurance program that implements the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c), and Section 17.1). (Incorporation by reference as specified in § 194.5.)

(2) Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:

- (i) Waste characterization activities and assumptions;
- (ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
- (iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;
- (iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;
- (v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;
- (vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
- (vii) The collection of data and information used to support compliance application(s); and
- (viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

(b) Any compliance application shall include information which demonstrates that data and information collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section have been qualified in accordance with an alternate methodology, approved by the Administrator or the Administrator's authorized representative, that employs one or more of the following methods: Peer review, conducted in a manner that is compatible with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," published February 1988 (incorporation by reference as specified in § 194.5); corroborating data; confirmatory testing; or a quality assurance program that is equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1). (Incorporation by reference as specified in § 194.5.)

(c) Any compliance application shall provide, to the extent practicable, information which describes how all data used to support the compliance application have been assessed for their quality characteristics, including:

- (1) Data accuracy, i.e., the degree to which data agree with an accepted reference or true value;
- (2) Data precision, i.e., a measure of the mutual agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation;
- (3) Data representativeness, i.e., the degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions;
- (4) Data completeness, i.e., a measure of the amount of valid data obtained compared to the amount that was expected; and
- (5) Data comparability, i.e., a measure of the confidence with which one data set can be compared to another.

(d) Any compliance application shall provide information which demonstrates how all data are qualified for use in the demonstration of compliance.

(e) The Administrator will verify appropriate execution of quality assurance programs through inspections, record reviews and record keeping requirements, which may include, but may not be limited to, surveillance, audits and management systems reviews.

3

4 **22.2 Background**

5 40 CFR § 194.22 (U.S. EPA 1996) establishes quality assurance (QA) requirements for the  
6 Waste Isolation Pilot Plant (WIPP). The QA process enhances the reliability of technical data

1 and analyses used for the U.S. Department of Energy’s (DOE’s) Compliance Certification  
 2 Application (CCA) (U.S. DOE 1996), and subsequent Compliance Recertification Applications  
 3 (CRAs) (U.S. DOE 2004 and 2009a) and this CRA, which demonstrate compliance with U.S.  
 4 Environmental Protection Agency (EPA) disposal standards. Section 194.22 requires the DOE  
 5 to (1) establish and execute a QA program for all items and activities important to the  
 6 containment of waste in the disposal system, (2) qualify data that are collected prior to  
 7 implementation of the required QA program, (3) assess data for their quality characteristics, to  
 8 the extent practicable, (4) demonstrate how data are qualified for use, and (5) allow verification  
 9 of the above measures through EPA inspections and audits. The DOE’s QA program is required  
 10 to adhere to specific Nuclear Quality Assurance (NQA) standards issued by the American  
 11 Society of Mechanical Engineers (ASME) NQA-1-1989, NQA-2a-1990 addenda part 2.7, and  
 12 NQA-3-1989 (ASME 1989; ASME 1990a; ASME 1990b).

### 13 **22.3 1998 Certification Decision**

14 The EPA’s Certification Decision was provided in *Federal Register* vol. 63 (U.S. EPA 1998),  
 15 pp. 27353–406, “40 CFR Part 194 Criteria for the Certification and Recertification of the Waste  
 16 Isolation Pilot Plant’s Compliance with the Disposal Regulations: Certification Decision; Final  
 17 Rule.” A complete description of the EPA’s 1998 Certification Decision for section 194.22 is  
 18 contained in Docket A-93-02, Items V-A-1 and V-B-2 (U.S. EPA 1998).

19 The EPA performed three types of assessments during review of the CCA to determine  
 20 compliance with section 194.22:

- 21 1. Determine if the DOE correctly established and implemented QA programs for items and  
 22 activities important to the long-term isolation of transuranic (TRU) waste in the disposal  
 23 system (40 CFR § 194.22(a))
- 24 2. Determine if the DOE qualified all data, including existing data collected prior to the  
 25 implementation of QA programs (40 CFR §§ 194.22(b) and (d))
- 26 3. Determine if the DOE assessed the CCA data for their quality characteristics (40 CFR §  
 27 194.22(c))

28 The EPA took two general steps to perform each of the three assessments listed above. First, the  
 29 EPA reviewed the CCA and associated references to determine if the DOE provided a  
 30 satisfactory description of compliance with the QA requirements. During this stage, the EPA  
 31 requested and reviewed additional information.

32 In the second step, the EPA conducted formal audits at WIPP-related facilities to verify  
 33 compliance with the requirements of section 194.22. These audits were conducted under the  
 34 authority of 40 CFR § 194.22(e) and were essential to verifying implementation of the QA  
 35 requirements. Each WIPP-related facility generated much activity and documentation, and it  
 36 was not practical to visit each facility to witness proper implementation of QA programs.  
 37 Neither was it considered adequate to assess proper QA program implementation at each facility  
 38 based solely on documents provided by the DOE. Therefore, the EPA auditors went to four  
 39 DOE facilities to witness the proper implementation of the QA requirements of section 194.22.

1 As a result of the audits, the EPA approved the WIPP’s QA programs at the DOE Carlsbad Field  
 2 Office (CBFO), the WIPP site (managed by Washington TRU Solutions, LLC), Sandia National  
 3 Laboratories, and Los Alamos National Laboratory (LANL). These four WIPP-related facilities  
 4 are all located in New Mexico.

5 At that time (1996–1998), other WIPP-related facilities located outside of New Mexico were not  
 6 approved by the EPA. 40 CFR § 194.22(a)(2)(i) requires the DOE to apply QA programs for  
 7 waste characterization activities prior to certification. The criteria in 40 CFR § 194.24(c)(3) and  
 8 40 CFR § 194.24(c)(5) cross-reference the QA requirements set forth in section 194.22(a)(2)(i).  
 9 The CCA indicated that waste generator sites outside New Mexico would not begin waste  
 10 characterization until after 1997 and that it was not reasonable to implement QA programs at that  
 11 time for future waste characterization. The EPA applied a condition to the approval of the CCA  
 12 that sites without approved QA programs could not dispose of TRU waste at the WIPP. After  
 13 the approval of the CCA, each unapproved site would have to be audited to verify compliance  
 14 prior to shipping waste.

15 The EPA examined the application of QA for waste characterization at one waste generator site  
 16 as part of the CCA review. After the DOE informed the EPA that LANL was ready for an audit,  
 17 the EPA auditors reviewed the LANL QA Plan to verify establishment of QA requirements, and  
 18 later to verify proper implementation of the QA Plan. Based on the audit samples taken, the  
 19 EPA determined that LANL had properly established and implemented a QA program for its  
 20 waste characterization. The other waste generator sites required EPA audits of their individual  
 21 QA programs before the EPA could allow them to send waste to the WIPP.

22 After the EPA approved the CCA, the agency conducted periodic audits at the four approved  
 23 facilities to verify continued compliance. The EPA also began to audit other facilities that had  
 24 not been ready to perform work at the time of the CCA.

25 **22.4 Changes in the CRA-2004**

26 The 2004 Compliance Recertification Application (CRA-2004) (U.S. DOE 2004a), Chapter 5.0,  
 27 like the CCA, Chapter 5.0, discussed the QA programs for the WIPP. The DOE extensively  
 28 revised the CRA-2004, Chapter 5.0 to make it clearly match the structure of the NQA standards  
 29 and to update information. Changes to the QA portions of the CRA-2004 reflected a maturing  
 30 and expansion of the CBFO QA program since the CCA. The QA programs that were new at the  
 31 time of the CCA had increased their effectiveness over time. Between 1998 and 2004, new  
 32 waste generator sites were added, thus adding more QA programs.

33 The QA document that establishes the NQA standards for the WIPP is the CBFO *Quality*  
 34 *Assurance Program Document* (QAPD). As in the CCA, Appendix QAPD-2004 contained the  
 35 current QAPD at the time. The DOE revised the QAPD between the CCA and the CRA-2004 to  
 36 more clearly establish each of the applicable NQA elements and to update the DOE  
 37 organizational structure. Appendices PEER-2004 and AUD-2004 were also updated to include  
 38 peer reviews and audits performed since the CCA.

## 1 **22.5 EPA’s Evaluation of Compliance for the 2004 Recertification**

2 The EPA’s Recertification Decision was published in *Federal Register* vol. 71 (2006), pp.  
3 18010–021 (U.S. EPA 2006a), “40 CFR Part 194 [EPA–HQ–OAR–2004–0025; FRL–8055–1]  
4 Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant’s Compliance  
5 with the Disposal Regulations: Recertification Decision.” Detailed technical evaluation of the  
6 CRA-2004, Chapter 5.0, Quality Assurance, was provided in Compliance Application Review  
7 Document (CARD) 22 (U.S. EPA 2006b). The following is a summary of the EPA’s evaluation  
8 of compliance with section 194.22 (CRA-2004, Chapter 5.0, and Appendices PEER-2004 and  
9 AUD-2004), as contained in the EPA documents mentioned above.

### 10 **22.5.1 NQA Standards**

11 The CRA-2004 provided information on the DOE’s implementation of the NQA standards.  
12 ASME NQA-1-1989 (ASME 1989) requirements were addressed in the CRA-2004, Chapter 5.0,  
13 Sections 5.3.1 through 5.3.19. ASME NQA-2a-1990 addenda part 2.7 (ASME 1990a) was  
14 addressed in the CRA-2004, Chapter 5.0, Section 5.3.20. ASME NQA-3-1989 (ASME 1990b)  
15 was addressed in the CRA-2004, Chapter 5.0, Sections 5.3.21, 5.3.22, and 5.3.23 (Docket A-93-  
16 02 Items V-A-1 and V-B-2).

17 The CBFO QA document that implemented the NQA standards, the QAPD, was provided in  
18 Appendix QAPD-2004. Since the CCA, the EPA periodically audited the QAPD to verify the  
19 continued proper establishment of the NQA standards.

20 The EPA found that the CBFO QAPD (Appendix QAPD-2004) properly established the  
21 applicable elements of the NQA standards invoked under section 194.22 for items and activities  
22 important to the long-term isolation of TRU waste.

### 23 **22.5.2 Audits of QA Plan Implementation**

24 The CRA-2004 provided information on internal and external auditing of the implementation of  
25 the CBFO QAPD in the CRA-2004, Chapter 5.0, Sections 5.3.19 and 5.7. The CRA-2004,  
26 Chapter 5.0, Section 5.7 described the CBFO audit process that covered internal and external  
27 audits, audit schedules, and audit team leader qualification requirements. Appendix AUD-2004,  
28 Table AUD-10, provided a summary of audits conducted on the CBFO QAPD.

29 The EPA determined that the CRA-2004 provided references to general and auditable  
30 information regarding internal and external audits to verify proper implementation of the CBFO  
31 QAPD. Further, the EPA conducted periodic audits since the CCA to verify the proper  
32 implementation of the CBFO QAPD.

### 33 **22.5.3 Audits of QA Programs at Lower-Tier Organizations**

34 The CRA-2004, Chapter 5.0, Section 5.3.19 addressed internal and external auditing of the  
35 CBFO QAPD as a requirement of NQA-1-1989, and the CRA-2004, Chapter 5.0, Section 5.7  
36 described the CBFO audit process that covers internal and external audits, audit schedules, and  
37 audit team leader qualification requirements. An audit history of assessments of TRU waste

1 generator sites and suppliers performing quality-affecting work between 1999 and 2003 is  
 2 located in Appendix AUD-2004, Tables AUD-1 through AUD-11. All audits were assigned an  
 3 audit number, which allowed traceability.

4 Audited suppliers included the CBFO Technical Assistance Contractor, Argonne National  
 5 Laboratory (ANL) – East, Battelle Columbus Laboratories, Mobile Characterization Services,  
 6 LLC, and the Carlsbad Environmental Monitoring and Research Center.

7 The EPA found that the CRA-2004 contained general and auditable information describing an  
 8 active CBFO auditing program of lower-tier and supplier organizations. Further, the EPA had  
 9 conducted periodic audits since the CCA to verify the proper execution of QA programs at the  
 10 lower-tier organizations.

#### 11 **22.5.4 NUREG-1297 for Peer Reviews**

12 U. S. Nuclear Regulatory Commission NUREG-1297 (NRC 1988) provides guidance on the  
 13 definitions of peer reviews, the area for which peer review is appropriate, the acceptability of  
 14 peers, and the conduct and documentation of peer reviews. The CBFO peer review process was  
 15 outlined in the CRA-2004, Chapter 9.0, Section 9.2, which is broken into Sections 9.2.1 through  
 16 9.2.8 that generally mirror the topics in NUREG-1297 (NRC 1988). The remainder of the CRA-  
 17 2004, Chapter 9.0 discussed the results of peer reviews conducted prior to 2004.

18 CBFO Management Procedure (MP) 10.5 defines the process for conducting peer reviews for  
 19 compliance with the requirements of NUREG-1297(NRC 1988). The EPA evaluated MP 10.5  
 20 and its description in the CRA-2004, Chapter 9.0, Sections 9.2.1 through 9.2.8, and found it to be  
 21 acceptable.

#### 22 **22.5.5 Assessments of Data Quality Characteristics**

23 The CRA-2004 provided information that described how all data used to support the compliance  
 24 application were assessed for accuracy, precision, representativeness, completeness, and  
 25 comparability.

26 The DOE applied the data quality characteristics to tasks involving the quantification of specific  
 27 constituents in an environmental medium through sampling and analysis, and applied these data  
 28 quality characteristics to activities such as the determination of the presence or absence of  
 29 constituents within TRU waste streams. In these cases, the performance measurement is the  
 30 concentration of the constituent of interest. Data quality measures are found in the CRA-2004,  
 31 Chapter 5.0, Section 5.3.22.

32 The EPA found that the CRA-2004 provided information that describes how all data used to  
 33 support the compliance application were assessed for their quality characteristics.

#### 34 **22.5.6 Data Qualifications**

35 The CRA-2004, Chapter 5.0, Section 5.3.23 provided information on how all data were qualified  
 36 for use in the demonstration of compliance by applying one or more of five methods. Audits

1 were conducted to verify that data not qualified by one of these methods were not used for  
2 demonstrating compliance. The EPA found that the CRA-2004 provided information describing  
3 how all data used to support the compliance application were qualified.

4 Based on a review and evaluation of the CRA-2004 and supplemental information provided by  
5 the DOE, the EPA determined that the DOE continued to comply with the requirements of  
6 section 194.22.

## 7 **22.6 Changes or New Information Between the CRA-2004 and the CRA-2009** 8 **(Previously: Changes or New Information Since the 2004 Recertification)**

9 Changes between the CRA-2004 and CRA-2009 (U.S. DOE 2009a) reflected maturation and  
10 expansion of the CBFO QA program since the CCA. The QA programs that were new at the  
11 time of the CCA had increased their effectiveness over time. As was the case between the CCA  
12 and CRA-2004, new waste generator sites were added between the CRA-2004 and CRA-2009,  
13 thus adding more QA programs.

14 The QA document that establishes the NQA standards for the WIPP is the QAPD. Appendix  
15 QAPD-2009, as in the CRA-2004, contained the current QAPD at the time. The DOE revised  
16 the QAPD between the CRA-2004 and the CRA-2009 to more clearly establish each of the  
17 applicable NQA elements and to update the DOE organizational structure. Appendix AUD-2009  
18 was updated to identify the audits performed since the CRA-2004.

### 19 **22.6.1 Changes to the QAPD**

20 Changes to the QAPD between CRA-2004 and CRA-2009, as noted in the revision histories, are  
21 summarized below. Document citations were added to include remote-handled transuranic (RH-  
22 TRU) waste packaging. The detailed changes were incorporated within the document.

23 In October 2004, Revision 6 of the QAPD (U.S. DOE 2004b) implemented the restructured  
24 CBFO organization.

25 In July 2005, changes implemented in Revision 7 of the QAPD (U.S. DOE 2005) were the direct  
26 result of DOE Headquarters (DOE EM 3-2) comments relative to compliance with DOE Order  
27 414.1B.

28 The changes implemented in Revision 8 of the QAPD (U.S. DOE 2006), effective November  
29 2006, were made to address 13 minor findings and 1 concern from an EPA inspection of the  
30 CBFO QA program. Document citations were added to include RH-TRU waste packaging. The  
31 exemption of National Environmental Policy Act–related software from the requirements of the  
32 QAPD was deleted. The applicability of software QA to safety software was clarified. Editorial  
33 changes related to the June 26, 2006, reorganization of the CBFO were also incorporated.

34 In December 2007, Revision 9 of the QAPD (U.S. DOE 2007) clarified that reliance on  
35 administrative controls alone is not sufficient for differentiating between waste that is acceptable  
36 for shipment to the WIPP and waste that does not meet the WIPP waste acceptance criteria. The  
37 classification of conditions adverse to quality related to the Hazardous Waste Facility Permit was

1 also clarified. The language regarding reporting nonconformances was revised to comply with  
2 the November 16, 2006, Permit Modification. The requirements for records disposition were  
3 revised to comply with the Class 1 Permit Modification that took effect on September 13, 2007.

#### 4 **22.6.2 Changes to CBFO/DOE Procedures**

5 The following CBFO procedures were revised between the CRA-2004 and CRA-2009:

- 6 • MP 1.2, *Selection of Quality Levels*
- 7 • MP 3.1, *Corrective Action Reports*
- 8 • MP 4.1, *Preparation and Maintenance of CBFO Procedures*
- 9 • MP 4.2, *Document Review*
- 10 • MP 4.4, *Document Preparation and Control*
- 11 • MP 4.10, *Processing of TRU Waste Site Documents*
- 12 • MP 5.2, *TRU Waste Site Certification/Recertification*
- 13 • MP 7.1, *QA Requirements for Procurement of Services*
- 14 • MP 9.1, *Management Assessments*
- 15 • Team Procedure (TP) 10.1, *Qualification of Audit Personnel and Certification of Lead*  
16 *Auditors*
- 17 • MP 10.2, *Surveillances*
- 18 • MP 10.3, *Audits*
- 19 • MP 10.5, *Peer Review*
- 20 • TP 10.7, *Operational Assessments*

21 The following CBFO procedures were added between the CRA-2004 and CRA-2009:

- 22 • MP 3.2, *Trend Identification and Reporting* (changed from a TP to an MP)
- 23 • MP 3.4, *CBFO Manager Actions upon Notification of Potential Noncompliant Waste*  
24 *Identified During the Waste Confirmation Process*
- 25 • TP 3.3, *Protocol for CBFO Observers at Baseline Inspections*
- 26 • MP 4.11, *Safety Basis Review Procedure*

- 1 • MP 4.12, *National Environmental Policy Act Compliance*
- 2 • MP 4.14, *Review of Acceptable Knowledge Sufficiency Determination Requests*
- 3 • MP 5.4, *Orders Compliance Program Implementation*

4 The following procedure was inactivated:

- 5 • MP 2.1, *Personnel Qualification and Training*

### 6 **22.6.3 Updated List of Waste Generator Sites Certified under the QA** 7 **Program**

8 The contact-handled TRU waste generator sites certified between the CRA-2004 and CRA-2009  
9 under the QA program included:

- 10 • LANL Central Characterization Project (LANL/CCP)
- 11 • Hanford-Richland (RL/CCP)
- 12 • Idaho National Laboratory (INL/CCP)
- 13 • Savannah River Site (SRS/CCP)
- 14 • Advanced Mixed Waste Treatment Project (AMWTP)
- 15 • Oak Ridge National Laboratory (ORNL/CCP)

16 Between the CRA-2004 and the CRA-2009, two RH-TRU waste generator sites, INL/CCP and  
17 ANL/CCP, were certified (see CRA-2009, Section 8, Approval Process of Waste Shipment from  
18 Waste Generator Sites for Disposal at the WIPP). Four peer reviews were conducted between the  
19 CRA-2004 and the CRA-2009 (see Section 27, Peer Review). A listing of audits and  
20 surveillances performed by CBFO can be found in Appendix AUD-2009.

21 The changes identified to the QAPD and its implementing procedures represented normal  
22 evolution and improvement in the CBFO QA program. The CBFO QA program was effectively  
23 managed and maintained as demonstrated through CBFO audits and surveillances (see Appendix  
24 AUD-2009), and met the provisions of section 194.22.

### 25 **22.7 EPA's Evaluation of Compliance for the 2009 Recertification**

26 The EPA's Recertification Decision was published in *Federal Register* vol. 75 (2010), pp.  
27 70584–595 (U.S. EPA 2010a), as “40 CFR Part 194 [EPA–HQ–OAR–2009–0330; FRL–9227–  
28 4], Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's  
29 Compliance with the Disposal Regulations: Recertification Decision.” Detailed technical  
30 evaluation of the CRA-2009, Section 22, Quality Assurance, was provided in CARD 22 (U.S.  
31 EPA 2010b). The following is a summary of the EPA's evaluation of compliance with section

1 194.22 (CRA-2009, Section 22, and Appendices AUD-2009 and QAPD-2009) as contained in  
2 the EPA documents mentioned above.

### 3 **22.7.1 NQA Standards**

4 The CRA-2009 provided information on the DOE's implementation of the NQA standards.  
5 ASME NQA-1-1989 (ASME 1989), ASME NQA-2a-1990 addenda part 2 (ASME 1990a), and  
6 ASME NQA-3-1989 (ASME 1990b) requirements were addressed in Appendix QAPD-2009.

7 The DOE QA document that implemented the NQA standards, the QAPD, was provided in  
8 Appendix QAPD-2009. Since the CCA, the EPA periodically audited the QAPD to verify the  
9 continued proper establishment of the NQA standards.

10 The EPA found that the CBFO QAPD (Appendix QAPD-2009) properly established the  
11 applicable elements of the NQA standards invoked under section 194.22 for items and activities  
12 important to the long-term isolation of TRU waste.

### 13 **22.7.2 Audits of QA Plan Implementation**

14 The CRA-2009 provided information on internal and external auditing of the implementation of  
15 the CBFO QAPD in Appendix AUD-2009. Appendix QAPD-2009, Section QAPD-4.2.2  
16 described the CBFO audit process that covered internal and external audits, audit schedules, and  
17 audit team leader requirements. Appendix AUD-2009 provided a summary of audits conducted  
18 on the CBFO QAPD. The EPA determined that the CRA-2009 provided references to general  
19 and auditable information regarding internal and external audits to verify proper implementation  
20 of the CBFO QAPD. Further, the EPA conducted periodic audits since the CRA-2004 to verify  
21 the proper implementation of the CBFO QAPD.

### 22 **22.7.3 Audits of QA Programs at Lower-Tier Organizations**

23 Appendix QAPD-2009, Section QAPD-4.2.2 addressed internal and external auditing of the  
24 CBFO QAPD as a requirement of NQA-1-1989, and described the CBFO audit process. An  
25 audit history of assessments of TRU waste generator sites and suppliers performing quality-  
26 affecting work between 2003 and 2008 were located in Appendix AUD-2009. All audits were  
27 assigned an audit number, which allowed traceability.

28 Audited suppliers included the Carlsbad Environmental Monitoring and Research Center,  
29 Environmental Resource Associates, L&M Technologies (project records services), and Portage  
30 Environmental, Inc.

31 The EPA found that the CRA-2009 contained general and auditable information describing an  
32 active auditing program by the CBFO of lower-tier and supplier organizations. Further, the EPA  
33 conducted periodic audits since the CRA-2004 to verify the proper execution of QA programs at  
34 the lower-tier organizations.

1 **22.7.4 NUREG-1297 for Peer Reviews**

2 U. S. Nuclear Regulatory Commission NUREG-1297 (NRC 1988) provides guidance on the  
3 definitions of peer reviews, the area for which peer review is appropriate, the acceptability of  
4 peers, and the conduct and documentation of peer reviews. The CBFO peer review process was  
5 outlined in the CRA-2009, Section 27.0, which also documented the results of peer reviews  
6 conducted since the CRA-2004.

7 CBFO MP 10.5 defines the process for conducting peer reviews for compliance with the  
8 requirements of NUREG-1297 (NRC 1988). The EPA evaluated MP 10.5 and its description in  
9 the CRA-2009, Section 27.0, and found it to be acceptable.

10 **22.7.5 Assessments of Data Quality Characteristics**

11 The CRA-2009 provided information that described how all data used to support the compliance  
12 application were assessed for accuracy, precision, representativeness, completeness, and  
13 comparability.

14 The DOE applied the data quality characteristics to tasks involving the quantification of specific  
15 constituents in an environmental medium through sampling and analysis. The DOE also applied  
16 these data quality characteristics to activities such as the determination of the presence or  
17 absence of constituents within TRU waste streams. In these cases, the performance  
18 measurement is the concentration of the constituent of interest. Data quality measures were  
19 found in Appendix QAPD-2009, Section QAPD-6.3.

20 The EPA found that the CRA-2009 provided information that described how all data used to  
21 support the compliance application were assessed for their quality characteristics.

22 **22.7.6 Data Qualifications**

23 Appendix QAPD-2009, Section QAPD-6.3 provided information on how all data were qualified  
24 for use in the demonstration of compliance by applying one or more of five methods. Audits  
25 were conducted to verify that data not qualified by one of these methods were not used for  
26 demonstrating compliance. The EPA found that the CRA-2009 provided information describing  
27 how all data used to support the compliance application have been qualified.

28 Based on a review and evaluation of the CRA-2009, the EPA determined that the DOE continued  
29 to comply with the requirements of section 194.22 (U.S. EPA 2010a; U.S. EPA 2010b).

30 **22.8 Changes or New Information Since the CRA-2009**

31 Changes to the QAPD since the CRA-2009, additions and changes to the CBFO implementing  
32 procedures, and an updated list of waste generator sites certified as of the CRA-2009 under the  
33 QA program are described in this section.

1 **22.8.1 Changes to QAPD**

2 Two revisions to the QAPD occurred since the CRA-2009, as summarized below.

3 In April 2009, Revision 10 of the QAPD (U.S. DOE 2009b) addressed the following:

- 4 • CBFO Corrective Action Report 08-026 regarding the adequacy of the test control  
5 requirements as stated in Revision 9 of the QAPD
- 6 • Requirements for the use of administrative controls to differentiate waste that is acceptable  
7 for shipment to the WIPP to address “as low as reasonably achievable” considerations for  
8 remote-handled waste
- 9 • Editorial revisions to the reference document sections to address changes to documents since  
10 the last revision of the QAPD
- 11 • Minor clarifications in response to comments during CBFO internal review and to address a  
12 recent reorganization of CBFO

13 In May 2010, Revision 11 of the QAPD (U.S. DOE 2011) addressed the April 1, 2010, WIPP  
14 Hazardous Waste Facility Permit modification for the time allowed for reporting  
15 nonconformances to data quality objectives first identified at the Site Project Manager level.

16 **22.8.2 Changes to DOE/CBFO Procedures**

17 The following CBFO procedures were added since the CRA-2009:

- 18 • MP 2.2, *Lessons Learned*
- 19 • MP 5.5, *CBFO Telework Requirements*
- 20 • MP 5.6, *Subcontract Consent Reviews*
- 21 • MP 5.7, *CBFO Injury/Illness Reporting*
- 22 • TP 9.2, *CBFO Work Control Oversight*
- 23 • MP 10.7, *CBFO Oversight Evaluation*

24 The following CBFO procedures were revised since the CRA-2009:

- 25 • MP 1.2, *Selection of Quality Levels*
- 26 • MP 3.1, *Corrective Action Reports*
- 27 • MP 3.4, *CBFO Manager Actions Upon Notification of Potential Noncompliant Waste*  
28 *Identified During The Waste Confirmation Process*

- 1 • MP 4.1, *Preparation and Maintenance of CBFO Procedures*
- 2 • MP 4.2, *Document Review*
- 3 • MP 4.4, *Document Preparation and Control*
- 4 • MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*
- 5 • MP 4.6, *Records Filing, Inventorying, Scheduling, and Dispositioning*
- 6 • MP 4.7, *Disposal of Nonpermanent Records*
- 7 • MP 4.8, *Records Transfer and Retrieval*
- 8 • MP 4.9, *Quality Assurance Records*
- 9 • MP 4.11, *Safety Basis Review Procedure*
- 10 • MP 4.12, *National Environmental Policy Act Compliance*
- 11 • MP 4.14, *CBFO Review of Acceptable Knowledge Sufficiency Determination Requests*
- 12 • MP 5.1, *Approval of Contractor-Generated Confirmation Data Packages*
- 13 • MP 5.2, *TRU Waste Site Certification/Recertification*
- 14 • MP 5.4, *Directives Compliance Program*
- 15 • MP 9.1, *Management Assessments*
- 16 • MP 10.3, *Audits*
- 17 The following procedures have been cancelled since the CRA-2009:
- 18 • OP 10.3, *Operational Evaluations*
- 19 • TP 10.7, *Operational Evaluations*

### 20 **22.8.3 Updated List of Waste Generator Sites Certified under the QA** 21 **Program**

22 The TRU waste sites approved by the EPA to ship contact-handled TRU waste to the WIPP in  
23 accordance with the requirements of section 194.8 since CRA-2009 are as follows: Advanced  
24 Mixed Waste Treatment Project, RL/CCP, INL/CCP, LANL/CCP, ORNL/CCP and SRS/CCP.  
25 Since the CRA-2009, suspension of CH waste characterization activities occurred at ORNL/CCP  
26 and RL/CCP.

1 The TRU waste sites approved by the EPA to ship RH-TRU waste to the WIPP in accordance  
2 with the requirements of section 194.8 since CRA-2009 are as follows: ANL/CCP, Bettis Atomic  
3 Power Laboratory (BAPL/CCP), General Electric Vallecitos Nuclear Center (GEVNC)/CCP,  
4 INL/CCP, ORNL/CCP and SRS/CCP. Since the CRA-2009, suspension of RH waste  
5 characterization activities occurred at the following sites: BAPL/CCP, GEVNC/CCP, RL/CCP,  
6 and ORNL/CCP.

7 A listing of audits and surveillances performed by CBFO can be found in Appendix AUD-2014.

8 The results of audits and surveillances performed by CBFO concluded that the DOE continues to  
9 comply with all the requirements of section 194.22.

10 The changes identified to the QAPD and its implementing procedures represent normal evolution  
11 and improvement in the CBFO QA program. The current CBFO QA program is effectively  
12 managed and maintained as demonstrated by the CBFO audit and surveillance program (see  
13 Appendix AUD-2014), and meets the provisions of section 194.22.

## 14 **22.9 References**

15 (\*Indicates a reference that has not been previously submitted.)

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