
**Title 40 CFR Part 191
Subparts B and C
Compliance Recertification
Application
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**

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

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Acronyms and Abbreviations

ANL	Argonne National Laboratory
ASME	American Society of Mechanical Engineers
CARD	Compliance Application Review Document
CBFO	Carlsbad Field Office
CCA	Compliance Certification Application
CCP	Central Characterization Project
CRA	Compliance Recertification Application
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
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
RH-TRU	remote-handled transuranic
SNL	Sandia National Laboratories
SRS	Savannah River Site
TRU	transuranic
WIPP	Waste Isolation Pilot Plant
WTS	Washington TRU Solutions

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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 (2004) establishes quality assurance (QA) requirements for the Waste Isolation
6 Pilot Plant (WIPP). QA is a process for enhancing the reliability of technical data and analyses

1 used for the U.S. Department of Energy’s (DOE) Compliance Certification Application (CCA)
2 (U.S. Department of Energy 1996) and 2004 Compliance Recertification Application (CRA-
3 2004) (U.S. Department of Energy 2004) that demonstrate compliance with the U.S.
4 Environmental Protection Agency’s (EPA’s) disposal standards. Section 194.22 requires the
5 DOE 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 their use, and (5) allow
9 verification of the above measures through the EPA inspections and audits. The DOE’s QA
10 program is required to adhere to specific Nuclear Quality Assurance (NQA) standards issued by
11 the American Society of Mechanical Engineers (ASME) (NQA-1-1989, NQA-2a-1990 addenda
12 part 2.7, and NQA-3-1989).

13 **22.3 1998 Certification Decision**

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

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 mentioned above.
29 First, the 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 witness proper implementation of QA programs away from each facility
37 based solely on documents provided by the DOE. Therefore, the EPA auditors went to four
38 DOE facilities to witness the proper implementation of the QA requirements of section 194.22.
39 As a result of the audits, the EPA approved the WIPP’s QA programs at the DOE Carlsbad Field
40 Office (CBFO), the WIPP site (managed by Washington TRU Solutions [WTS]), Sandia

1 National Laboratories (SNL), and Los Alamos National Laboratory (LANL). These four WIPP-
2 related facilities are all located in New Mexico.

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

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

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

23 **22.4 Changes in the CRA-2004**

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

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

36 **22.5 EPA’s Evaluation of Compliance for the 2004 Recertification**

37 The EPA’s Recertification Decision was published in *Federal Register* vol. 71 (2006), pp.
38 18010–021, (U.S. Environmental Protection Agency 2006a) as “40 CFR Part 194 [EPA–HQ–
39 OAR–2004–0025; FRL–8055–1] Criteria for the Certification and Recertification of the Waste

1 Isolation Pilot Plant’s Compliance with the Disposal Regulations: Recertification Decision.”
2 Detailed technical evaluation of the CRA-2004, Chapter 5.0, Quality Assurance, was provided in
3 Compliance Application Review Document (CARD) 22 (U.S. Environmental Protection Agency
4 2006b). The following is a summary of the EPA’s evaluation of compliance with section 194.22
5 (CRA 2004, Chapter 5.0 and Appendices PEER-2004 and AUD-2004), as contained in the EPA
6 documents mentioned above.

7 **22.5.1 NQA Standards**

8 The CRA-2004 provides information on the DOE’s implementation of the NQA standards.
9 ASME NQA-1-1989 requirements are addressed in the CRA-2004, Chapter 5.0, Sections 5.3.1
10 through 5.3.19. ASME NQA-2a-1990 addenda part 2.7 is addressed in the CRA-2004, Chapter
11 5.0, Section 5.3.20. ASME NQA-3-1989 is addressed in the CRA-2004, Chapter 5.0, Sections
12 5.3.21, 5.3.22, and 5.3.23 (Docket A-93-02 Items V-A-1 and V-B-2).

13 The DOE QA Plan that implements the NQA standards, the QAPD, is provided in the CRA-2004
14 as Appendix QAPD. Since the CCA, the EPA periodically audited the QAPD to verify the
15 continued proper establishment of the NQA standards.

16 The EPA found that the CBFO QA Plan (the CRA-2004, Appendix QAPD) properly established
17 the applicable elements of the NQA standards invoked under section 194.22 for items and
18 activities important to the long-term isolation of TRU waste.

19 **22.5.2 Audits of QA Plan Implementation**

20 The CRA-2004 provides information on internal and external auditing of the implementation of
21 the CBFO QAPD in the CRA-2004, Chapter 5.0, Sections 5.3.19 and 5.7. The CRA-2004,
22 Chapter 5.0, Section 5.7 describes the CBFO audit process that covers internal and external
23 audits, audit schedules, and audit team leader requirements. The CRA-2004, Appendix AUD-
24 2004, Table AUD-10 provides a summary of audits conducted on the CBFO QA Plan.
25 The EPA determined that the CRA-2004 provided references to general and auditable
26 information regarding internal and external audits to verify proper implementation of the CBFO
27 QA Plan. Further, the EPA conducted periodic audits since the CCA to verify the proper
28 implementation of the CBFO QA Plan.

29 **22.5.3 Audits of QA Programs at Lower-Tier Organizations**

30 The CRA-2004, Chapter 5.0, Section 5.3.19 addresses internal and external auditing of the
31 CBFO QA Plan as a requirement of NQA-1-1989, and the CRA-2004, Chapter 5.0, Section 5.7
32 describes the CBFO audit process that covers internal and external audits, audit schedules, and
33 audit team leader requirements. An audit history of assessments of TRU waste generator sites
34 and suppliers performing quality-affecting work between 1999 and 2003 is located in CRA-
35 2004, Appendix AUD-2004, Tables AUD-1 through AUD-11. All audits are assigned an audit
36 number, which allows traceability.

1 Audited suppliers included CBFO Technical Assistance Contractor, Argonne National
2 Laboratory (ANL) – East, Battelle Columbus Lab, Mobile Characterization Services, LLC, and
3 Carlsbad Environmental Monitoring and Research Center.

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

8 **22.5.4 NUREG-1297 for Peer Reviews**

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

15 CBFO Management Procedure (MP) 10.5 defines the requirements of NUREG-1297. The EPA
16 evaluated MP 10.5 and its description in the CRA-2004, Chapter 9.0, Sections 9.2.1 through
17 9.2.8 and found it to be acceptable.

18 **22.5.5 Assessments of Data Quality Characteristics**

19 The CRA-2004 provides information that describes how all data used to support the compliance
20 application have been assessed for accuracy, precision, representativeness, completeness, and
21 comparability.

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

28 The EPA found that the CRA-2004 provides information that describes how all data used to
29 support the compliance application have been assessed for their quality characteristics.

30 **22.5.6 Data Qualifications**

31 The CRA-2004, Chapter 5.0, Section 5.3.23 provides information on how all data are qualified
32 for use in the demonstration of compliance. This section provides information on how all data
33 used are qualified by using one or more of five methods. Audits were conducted to verify that
34 data not qualified by one of these methods were not used for demonstrating compliance. The
35 EPA found that the CRA-2004 provides information describing how all data used to support the
36 compliance application have been qualified.

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

4 **22.6 Changes or New Information Since the 2004 Recertification**

5 Changes to the QAPD since the CRA-2004, additions and changes to the CBFO implementing
6 procedures, and an updated list of waste generator sites certified under the QA program are
7 described below.

8 **22.6.1 Changes to QAPD**

9 Revisions to the QAPD identified below are a summary of changes as noted in the revision
10 history. The detailed changes are incorporated within the document.

11 In October 2004, Rev. 6 of the QAPD implemented the restructured CBFO organization.

12 In July 2005, changes implemented in Rev. 7 of the QAPD were the direct result of the DOE
13 Headquarters (DOE EM 3-2) comments relative to compliance with the DOE Order (DOE O
14 414.1B).

15 The changes implemented in Rev. 8 of the QAPD, effective November 2006, were made to
16 address 13 minor findings and 1 concern from an EPA inspection of the CBFO QA program.
17 Document citations were added to include remote-handled (RH) transuranic (TRU) (RH-TRU)
18 waste packaging. The exemption of National Environmental Policy Act–related software from
19 the requirements of the QAPD was deleted. The applicability of software QA to safety software
20 was clarified. Editorial changes related to the June 26, 2006, reorganization of the CBFO were
21 also incorporated.

22 In December 2007, Rev. 9 of the QAPD clarified that reliance on administrative controls alone is
23 not sufficient for differentiating between waste that is acceptable for shipment to the WIPP and
24 waste that does not meet the WIPP waste acceptance criteria. The classification of conditions
25 adverse to quality related to the Hazardous Waste Facility Permit was also clarified. The
26 language regarding reporting nonconformances was revised to comply with the November 16,
27 2006, Permit Modification. The requirements for records disposition were revised to comply
28 with the Class 1 Permit Modification that took effect on September 13, 2007.

29 **22.6.2 Changes to CBFO/DOE Procedures**

30 The following CBFO procedures have been added since the CRA-2004:

- 31 • MP 3.2, “Trend Identification and Reporting” (changed from a Team Procedure to an MP)
- 32 • MP 3.4, “CBFO Manager Actions upon Notification of Potential Noncompliant Waste
33 Identified During the Waste Confirmation Process”
- 34 • TP 3.3, “Protocol for CBFO Observers at Baseline Inspections”

- 1 • MP 4.11, “Safety Basis Review Procedure”
- 2 • MP 4.12, “National Environmental Policy Act Compliance”
- 3 • MP 4.14, “Review of Acceptable Knowledge Sufficiency Determination Requests”
- 4 • MP 5.4, “Orders Compliance Program Implementation”

5 The following procedure has been inactivated:

- 6 • MP 2.1, “Personnel Qualification and Training”

7 **22.6.3 Updated List of Waste Generator Sites Certified under the QA** 8 **Program**

9 The contact-handled TRU waste generator sites currently certified under the QA program
10 include:

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

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

22 The following CBFO procedures were revised since the CRA-2004:

- 23 • MP 1.2, “Selection of Quality Levels”
- 24 • MP 3.1, “Corrective Action Reports”
- 25 • MP 4.1, “Preparation and Maintenance of CBFO Procedures”
- 26 • MP 4.2, “Document Review”
- 27 • MP 4.4, “Document Preparation and Control”

- 1 • MP 4.10, “Processing of TRU Waste Site Documents”
- 2 • MP 5.2, “TRU Waste Site Certification/Recertification”
- 3 • MP 7.1, “QA Requirements for Procurement of Services”
- 4 • MP 9.1, “Management Assessments”
- 5 • TP 10.1, “Qualification of Audit Personnel and Certification of Lead Auditors”
- 6 • MP 10.2, “Surveillances”
- 7 • MP 10.3, “Audits”
- 8 • MP 10.5, “Peer Review”
- 9 • TP 10.7, “Operational Assessments”

10 The changes identified to the QAPD and its implementing procedures since the CRA-2004
11 represent normal evolution and improvement in the DOE QA program. The current WIPP QA
12 program is effectively managed and maintained as demonstrated by the CBFO audit and
13 surveillance program (see Appendix AUD-2009), and meets the provisions of section 194.22.

14 **22.7 References**

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20 Carlsbad, NM: Carlsbad Field Office.

21 U.S. Department of Energy (DOE). 2005. *Management Procedure: Peer Review* (Rev. 6,
22 Effective July 25, 2005 to July 25, 2007). CBFO MP 10.5. Carlsbad, NM: Carlsbad Field
23 Office.

24 U.S. Environmental Protection Agency (EPA). 1998. “40 CFR Part 194: Criteria for the
25 Certification and Recertification of the Waste Isolation Pilot Plant’s Compliance with the
26 Disposal Regulations: Certification Decision; Final Rule.” *Federal Register*, vol. 63 (May 18,
27 1998): 27353–406.

28 U.S. Environmental Protection Agency (EPA). 2006a. “40 CFR Part 194: Criteria for the
29 Certification and Recertification of the Waste Isolation Pilot Plant’s Compliance with the
30 Disposal Regulations: Recertification Decision” (Final Notice). *Federal Register*, vol. 71
31 (April 10, 2006): 18010–021.

- 1 U.S. Environmental Protection Agency (EPA). 2006b. "Recertification CARD No. 22: Quality
2 Assurance." *Compliance Application Review Documents for the Criteria for the Certification
3 and Recertification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191
4 Disposal Regulations: Final Recertification Decision* (March) (pp. 22-1 through 22-17).
5 Washington, DC: Office of Radiation and Indoor Air.

- 6 U.S. Nuclear Regulatory Commission (NRC). 1988. *Peer Review for High-Level Nuclear
7 Waste Repositories: Generic Technical Position*. NUREG-1297. Washington, DC: U.S.
8 Nuclear Regulatory Commission.