40 CFR Part 191
Subparts B and C
Compliance Recertification Application 2026
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

Compliance Recertification Application 2026
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ACRONYMS AND ABBREVIATIONS

ANL	Argonne National Laboratory
ASME	American Society of Mechanical Engineers
CBFO	Carlsbad Field Office
CCP	Central Characterization Program
CFR	Code of Federal Regulations
CH-TRU	contact-handled transuranic
CRA	Compliance Recertification Application
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
INL	Idaho National Laboratory
MP	management procedure
NQA	Nuclear Quality Assurance
OP	operating procedure
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
TP	technical procedure
TRU	transuranic
WIPP	Waste Isolation Pilot Plant

22.0 QUALITY ASSURANCE (40 CFR 194.22)

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.

22.2 Background

Title 40 Code of Federal Regulations (CFR) 194.22 (U.S. EPA 1996) establishes quality assurance (QA) requirements for the Waste Isolation Pilot Plant (WIPP). The QA process enhances the reliability of technical data and analyses used by the U.S. Department of Energy (DOE) to demonstrate compliance with U.S. Environmental Protection Agency (EPA) waste disposal standards (U.S. DOE 1996, 2004, 2009, 2014, and 2019). Title 40 CFR 194.22 requires the DOE to (1) establish and execute a QA program for all items and activities important to the containment of waste in the disposal system; (2) qualify data that are collected prior to implementation of the required QA program; (3) assess data for their quality characteristics, to the extent practicable; (4) demonstrate how data are qualified for use; and (5) allow verification of the above measures through EPA inspections and audits. The DOE's QA program must adhere to specific Nuclear Quality Assurance (NQA) standards issued by the American Society of Mechanical Engineers (ASME). These include NQA-1-+, NQA-2a-1990 addenda part 2.7, and NQA-3-1989 (ASME 1989; ASME 1990a; ASME 1990b).

The NQA standards for the WIPP are established through the Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD) (U.S. DOE 2023) and other CBFO programmatic documents. The QAPD is implemented through a series of management procedures (MPs), office procedures (OPs), and team procedures (TPs). The DOE periodically revises the QAPD to address each of the applicable NQA standards more clearly and to update the organizational structure.

The U.S. Nuclear Regulatory Commission's technical report designation, NUREG-1297, provides guidance for conducting and documenting peer reviews for nuclear waste repositories (U.S. NRC 1988). Section 27 of the CRA-2026 outlines the CBFO peer review process.

Information and data from previous compliance certification and recertification applications that form the basis of past DOE compliance positions and past EPA decision documents are found in the CRA-2019 (U.S. DOE 2019).

22.3 Changes or New Information Since the CRA-2019

Any changes to the QAPD and its implementing procedures, an updated list of approved transuranic (TRU) waste generator sites under the QA program, and peer review activities since the CRA-2019 data cut-off date of January 8, 2018, are described in this section.

Any changes to the QAPD and its implementation procedures represent normal evolution and improvement in the CBFO QA program. The current CBFO QA program is effectively managed and maintained as demonstrated by the CBFO audit and surveillance program (see Appendix AUD-2026). The results of audits and surveillances performed by CBFO concluded that the DOE continues to comply with all the requirements of 40 CFR 194.22.

22.3.1 Changes to the QAPD

One revision to the QAPD occurred since the CRA-2019 data cut-off date. The QAPD was revised in November 2023 (U.S. DOE 2023) to address management assessment results, audit results from DOE's Office of Environmental Management, and updates to EM-QA-001, "Office of Environmental Management Quality Assurance Program." Revisions were also made to address the newly published DOE transportation and records management orders. Finally, the QAPD was updated following the CBFO reorganization.

22.3.2 Changes to the CBFO Procedures

The following CBFO procedures were added since the CRA-2019 data cut-off date:

- MP 4.20, *Land Withdrawal Act TRU Waste Volume Tracking and Reporting*
- MP 5.16, *CBFO Software Quality Assurance of Non-Safety Software*
- MP 5.17, *Independent Technical Review*
- OP 10.14, *National TRU Program Compliance and Operations Oversight Functions*
- OP 10.15, *Office of the Waste Isolation Pilot Plant Implementation of the Carlsbad Field Office Contractor Oversight Plan*

The following CBFO procedures were revised since the CRA-2019 data cut-off date:

- TP 1.3, *CBFO Quality Assurance Compliance with WIPP Documented Safety Analysis, Chapter 18*
- MP 1.2, *Grading Activities and Determination of Quality Levels*
- OP 3.2, *Deficiency Trending and Reporting*
- TP 3.3, *Protocol for CBFO Observers at U.S. Environmental Protection Agency Inspections*
- MP 3.6, *Management of Assessments Conducted by External Organizations*
- MP 4.2, *Document Review and Approval*
- MP 4.10, *The Processing of WIPP Certified Program Documents*
- MP 4.12, *National Environmental Policy Act Compliance*
- MP 4.23, *Document Control*
- MP 5.1, *Approval of Contractor-Generated Confirmation Data Packages*
- MP 5.2, *TRU Waste Program Certification/Recertification*
- MP 8.1, *CBFO Software Test Acceptance*
- OP 5.9, *Facility Representative Duties, Responsibilities, and Routine Activities*
- MP 9.1, *Management Assessments*
- MP 10.5, *Peer Review*
- OP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*
- OP 10.4, *Surveillances*
- MP 10.9, *Surveillance, Operational Awareness, and Issues Management*
- OP 10.13, *Audits*

The following procedures have been canceled and/or replaced since the CRA-2019 data cut-off date:

- MP 3.7, *Management of Corrective Actions Responsive to Judgments of Need Identified by the Accident Investigation Boards*
- MP 3.8, *Management of Nuclear Waste Partnership LLC Corrective Actions Responsive to Judgements of Need Identified by the Accident Investigation Boards*
- MP 4.14, *CBFO Review of Acceptable Knowledge Sufficiency Determination Requests*
- MP 4.15, *Review of TRU Waste Acceptable Knowledge Documents*
- MP 4.17, *CBFO Review and Approval of Waste Stream Profile Forms*
- MP 5.5, *CBFO Telework Requirements*
- MP 5.11, *CBFO Approval for Emplacement of Waste Received up to February 14, 2014*
- MP 7.1, *Quality Assurance Requirements for Procurement of Services*

22.3.3 Updated List of Transuranic Waste Generator Sites Certified under the QA Program

The TRU waste generator sites, approved by the EPA to ship contact-handled TRU (CH-TRU) waste to the WIPP facility in accordance with the requirements of 40 CFR 194.8, as of the CRA-2019 data cut-off date are as follows: Advanced Mixed Waste Treatment Project, Idaho National Laboratory (INL)/Central Characterization Program (CCP), Los Alamos National Laboratory/CCP, Oak Ridge National Laboratory (ORNL)/CCP, Savannah River Site (SRS)/CCP, Lawrence Livermore National Laboratory/CCP, and Argonne National Laboratory (ANL)/CCP. Transuranic waste characterization field activities at the SRS were suspended in 2014 and continued to be suspended until 2020 when the SRS/CCP resumed characterization activities in Area E (U.S. DOE 2021a).

The TRU waste generator sites, approved by the EPA to ship remote-handled TRU (RH-TRU) waste to the WIPP facility in accordance with the requirements of 40 CFR 194.8, since the CRA-2019 data cut-off date are as follows: ANL/CCP, INL/CCP, ORNL/CCP, SRS/CCP, and Sandia National Laboratories (SNL)/CCP. The SNL has not performed waste characterization in the field since 2015 (U.S. DOE 2021b). Since the last shipment in 2012, there has been no characterization or certification of RH-TRU canisters at the SRS and no shipment of RH-TRU waste to the WIPP from the SRS (U.S. DOE 2025).

22.3.4 NUREG-1297 for Peer Reviews

The DOE has conducted one peer review since the CRA-2019 cut-off date of January 8, 2018. The WIPP Additional Panels Performance Assessment Changed Conceptual Models Peer Review evaluated changes to three conceptual models required to support a performance assessment that represented two new transuranic waste disposal panels (Panels 11 and 12) in the western area of the WIPP repository. Detailed information related to this peer review is provided in Section 27 of the CRA-2026.

In conclusion, the DOE believes it has demonstrated continued compliance with all provisions of 40 CFR 194.22.

22.4 References

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

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ASME. 1990b. Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories. ASME/NQA-3-1989.