
**Title 40 CFR Part 191
Subparts B and C
Compliance Recertification Application 2019
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 2019
Quality Assurance
(40 CFR 194.22)

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Acronyms and Abbreviations

ASME	American Society of Mechanical Engineers
CBFO	Carlsbad Field Office
CCA	Compliance Certification Application
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
SRS	Savannah River Site
TP	technical procedure
TRU	transuranic
WIPP	Waste Isolation Pilot Plant

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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 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 for the U.S. Department of Energy's (DOE's) Compliance Certification Application (CCA) ([U.S. DOE 1996](#)), subsequent Compliance Recertification Applications (CRAs) ([U.S. DOE 2004](#), [2009](#), and [2014](#)), and this CRA, which demonstrate compliance with U.S. Environmental Protection Agency (EPA) waste disposal standards. 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 is required to adhere to specific Nuclear Quality Assurance (NQA) standards issued by the American Society of Mechanical Engineers (ASME). These include NQA-1-1989, 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) and other CBFO programmatic documents (e.g., DOE/CBFO-17-3580, *CBFO Federal Employee Training Program*, DOE/CBFO-16-3563, *Waste Isolation Pilot Plant Generator Site Technical Review Plan*, and DOE/CBFO-14-3540, *Quality Assurance Implementation Plan and Requirements Flow-down*). The QAPD is implemented through a series of management procedures (MPs), office procedures (OPs), and team procedures (TPs). Since the CCA, the DOE periodically revises the QAPD to more clearly address each of the applicable NQA standards and to update the organizational structures. Two revisions have been made since the CRA-2014, as discussed in Section 22.3.1.

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-2014 ([U.S. DOE 2014](#)).

22.3 Changes or New Information Since the CRA-2014

Changes to the QAPD since the CRA-2014, additions and changes to the CBFO implementing procedures, and an updated list of waste generator sites, certified as of the CRA-2014 under the QA program, are described in this section.

22.3.1 Changes to the QAPD

Two revisions to the QAPD occurred since the CRA-2014. They are summarized as follows:

In August 2015, Revision 12 of the QAPD ([U.S. DOE 2015](#)) addressed updates/revisions to the acronyms list, CBFO organizational position description changes, consistent use of the term “HWFP” for references to the Hazardous Waste Facility Permit or Resource Conservation and Recovery Act language, updates to requirements/commitment documents, addition of the Transuranic Package Transporter-III and associated certificate of compliance, identification of the current management and operating contractor, management of non-conformances, procurement requirements, additions/corrections to the glossary, additions/corrections to the references list, and minor editorial/grammatical changes throughout the document.

In April 2017, Revision 13 of the QAPD ([U.S. DOE 2017](#)) addressed changes to section 6, *Software Requirements*. The basis of changes was software applicability defined in ASME NQA-2-1990 Part 2.7 ([ASME 1990a](#)) and DOE Order 414.1D, *Quality Assurance* ([U.S. DOE 2013](#)). Major changes to section 6 include the applicability of software to the QAPD. Software is classified based on the impact of the software output on intended usage (i.e., impact on design, impact on equipment operations, impact on other intended usage of the software application). Requirements for software procurement have been revised requiring the organization providing software services to provide a software quality assurance plan that is to be reviewed and approved by the purchaser. Requirements for software used in design analysis have been added. Other changes were made to sections covering commercial grade dedication for software, software developed under other QA programs, the software development life cycle, software verification and validation, software configuration management, documentation, problem reporting and corrective action, access control, and support software. Minor editorial/grammatical changes were also incorporated throughout the document.

22.3.2 Changes to DOE/CBFO Procedures

The following CBFO procedures were added since the CRA-2014:

- TP 1.3, *CBFO Quality Assurance Compliance with WIPP Documented Safety Analysis, Chapter 18*
- MP 3.6, *Management of Reviews Conducted by External Organizations*
- 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 Judgments of Need Identified by the Accident Investigation Boards*
- MP 4.15, *Review of TRU Waste Acceptable Knowledge Documents*
- MP 4.17, *CBFO Review and Approval of Waste Stream Profile Forms*

- OP 5.9, *Facility Representative Duties, Responsibilities, and Routine Activities*
- OP 5.10, *ICE Program Administrator Responsibilities*
- MP 5.11, *CBFO Approval for Emplacement of Waste Received up to February 14, 2014*
- MP 8.1, *CBFO Issue Collection and Evaluation Software Test Acceptance*
- OP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors* (note: this procedure was converted from TP 10.1)
- OP 10.4, *Surveillances*
- OP 10.13, *Audits*
- MP 10.9, *Surveillance, Operational Awareness, and Issues Management*

The following CBFO procedures were revised since the CRA-2014:

- MP 1.2, *Grading Activities and Determination of Quality Levels* (note: this is a new title with Revision 5. Previous title was *Selection of Quality Levels*)
- MP 3.1, *Corrective Action Reports*
- OP 3.2, *Deficiency Trending and Reporting* (note: formerly MP 3.2)
- TP 3.3, *Protocol for CBFO Observers at U.S. Environmental Protection Agency Inspections* (note: this is a new title with Revision 1. Previous title was *Protocol for CBFO Observers at Baseline Inspections*)
- MP 3.4, *CBFO Manager Actions Upon Notification of Potential Noncompliant Waste Identified During The Waste Confirmation Process*
- MP 4.1, *Preparation and Maintenance of CBFO Procedures*
- MP 4.2, *Document Review and Approval* (note: this is a new title with Revision 13. Previous title was *Document Review*)
- MP 4.4, *Document Preparation and Control*
- MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*
- MP 4.6, *Records Filing, Inventorying, Scheduling, and Dispositioning*
- MP 4.7, *Disposal of Temporary/Nonpermanent Records*
- MP 4.8, *Records Transfer and Retrieval*
- MP 4.9, *Quality Assurance Records*
- MP 4.11, *Safety Basis Review Procedure*
- MP 4.12, *National Environmental Policy Act Compliance*
- MP 5.1, *Approval of Contractor-Generated Confirmation Data Packages*
- MP 5.2, *TRU Waste Program Certification/Recertification*
- TP 5.6, *Subcontract Consent Review*
- MP 7.1, *Quality Assurance Requirements for Procurement Services*
- MP 9.1, *Management Assessments*
- MP 10.5, *Peer Review*

The following procedures have been cancelled and/or replaced since the CRA-2014:

- MP 3.2, *Deficiency Trending and Reporting* (note: MP 3.2 was converted to OP 3.2. See entry for OP 3.2 above)

- OP 5.8, *On-Call/On-Watch Facility Representative Duties* (note: this procedure was cancelled on October 25, 2016 after its content was incorporated into and consolidated with OP 5.9. See entry for OP 5.9 above)
- TP 9.2, *CBFO Work Control Oversight*
- TP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors* (note: TP 10.1 was converted to OP 10.1. See entry for OP 10.1 above)
- MP 10.2, *Surveillances* (note: MP 10.2 was cancelled and replaced with OP 10.4. See entry for OP 10.4 above)
- MP 10.3, *Audits* (note: MP 10.3 was cancelled and replaced with OP 10.13. See entry for OP 10.13 above)
- MP 10.7, *CBFO Oversight Evaluation*
- TP 10.7, *Operational Evaluations* (note: TP 10.7 was cancelled and replaced with MP 10.7, which was subsequently cancelled on January 30, 2017. See entry for MP 10.7 above)
- OP 10.8, *Operational Awareness Activities* (note: OP 10.8 was cancelled and replaced with MP 10.9. See entry for MP 10.9 above)
- MP 10.10, *Technical Review of TRU Waste Generator Site Processes*

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

The transuranic (TRU) waste sites approved by the EPA to ship contact-handled TRU (CH-TRU) waste to the WIPP in accordance with the requirements of 40 CFR 194.8 since CRA-2014 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, and Savannah River Site (SRS)/CCP. Since the CRA-2014, no suspension of CH-TRU waste characterization activities occurred at any of these sites.

The TRU waste sites approved by the EPA to ship remote-handled TRU (RH-TRU) waste to the WIPP in accordance with the requirements of 40 CFR 194.8 since CRA-2014 are as follows: Argonne National Laboratory/CCP, INL/CCP, ORNL/CCP, and SRS/CCP. Since the CRA-2014, no suspension of RH-TRU waste characterization activities occurred at any of these sites.

The changes identified to the QAPD and its implementing 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-2019). 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.

22.4 References

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

U.S. Department of Energy (DOE). 1996. Title 40 CFR Part 191 Compliance Certification Application for the Waste Isolation Pilot Plant (October). 21 vols. Carlsbad, NM: Carlsbad Area Office. DOE/CAO 1996-2184.

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U.S. Environmental Protection Agency (EPA). 1996. 40 CFR Part 194: Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance With the 40 CFR Part 191 Disposal Regulations; Final Rule. *Federal Register*, vol. 61 (February 9, 1996): 5223-5245.

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The American Society of Mechanical Engineers (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.