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

**Approval Process for Waste Shipment From
Waste Generator Sites for Disposal at the
WIPP
(40 CFR § 194.8)**



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

**Carlsbad Field Office
Carlsbad, New Mexico**

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Acronyms and Abbreviations

ANL	Argonne National Laboratory
CARD	Compliance Application Review Document
CCP	Central Characterization Project
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
LANL	Los Alamos National Laboratory
LLNL	Lawrence Livermore National Laboratory
NTS	Nevada Test Site
ORNL	Oak Ridge National Laboratory
QA	quality assurance
RFETS	Rocky Flats Environmental Technology Site
RH-TRU	remote-handled transuranic
RL	Hanford-Richland
SRS	Savannah River Site
TRU	transuranic
WIPP	Waste Isolation Pilot Plant
WWIS	WIPP Waste Information System

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1 **8.0 Approval Process for Waste Shipment From Waste Generator** 2 **Sites for Disposal at the WIPP (40 CFR § 194.8)**

3 **8.1 Requirements**

§ 194.8 Approval Process for Waste Shipment From Waste Generator Sites for Disposal at the WIPP

(a) *Quality Assurance Programs at Waste Generator Sites.* The Agency will determine compliance with requirements for site-specific quality assurance programs as set forth below:

(1) Upon submission by the Department of a site-specific quality assurance program plan the Agency will evaluate the plan to determine whether it establishes the applicable Nuclear Quality Assurance (NQA) requirements of § 194.22(a)(1) for the items and activities of §§ 194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5). The program plan and other documentation submitted by the Department will be placed in the dockets described in § 194.67.

(2) The Agency will conduct a quality assurance audit or an inspection of a Department quality assurance audit at the relevant site for the purpose of verifying proper execution of the site specific quality assurance program plan. The Agency will publish a notice in the FEDERAL REGISTER announcing a scheduled inspection or audit. In that or another notice, the Agency will also solicit public comment on the quality assurance program plan and appropriate Department documentation described in paragraph (a)(1) of this section. A public comment period of at least 30 days will be allowed.

(3) The Agency's written decision regarding compliance with the requisite quality assurance requirements at a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No such compliance determination shall be granted until after the end of the public comment period described in paragraph (a)(2) of this section. A copy of the Agency's compliance determination letter will be placed in the public dockets in accordance with § 194.67. The results of any inspections or audits conducted by the Agency to evaluate the quality assurance programs described in paragraph (a)(1) of this section will also be placed in the dockets described in § 194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (a)(3) of this section, the Agency intends to conduct inspections, in accordance with §§ 194.21 and 194.22(e), to confirm the continued compliance of the programs approved under paragraphs (a)(2) and (a)(3) of this section. The results of such inspections will be made available to the public through the Agency's public dockets, as described in § 194.67.

(b) *Waste characterization programs at transuranic waste sites.* The Agency will establish compliance with Condition 3 of the certification using the following process:

(1) DOE will implement waste characterization programs and processes in accordance with § 194.24(c)(4) to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of § 194.24(c). Waste characterization processes will include the collection and use of acceptable knowledge; destructive and/or nondestructive techniques for identifying and measuring waste components; and the validation, control, and transmittal to the WIPP Waste Information System database of waste characterization data, in accordance with § 194.24(c)(4).

(2) The Agency will verify the compliance of waste characterization programs and processes identified in paragraph (b)(1) of this section at sites without EPA approval prior to October 14, 2004, using the following process:

(i) DOE will notify EPA by letter that a transuranic waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs. DOE also will provide the relevant waste characterization program plans and documentation. EPA may request additional information from DOE.

(ii) EPA will conduct a baseline compliance inspection at the site to verify that adequate waste characterization program plans and technical procedures have been established, and that those plans and procedures are effectively implemented. The inspection will include a demonstration or test by the site of the waste characterization processes identified in paragraph (b)(1) of this section. If an inspection does not lead to approval, we will send an inspection report to DOE identifying deficiencies and place the report in the public docket described in § 194.67. More than one inspection may be necessary to resolve compliance issues.

(iii) The Agency will announce in the FEDERAL REGISTER a proposed Baseline Compliance Decision to accept the site's compliance with § 194.24(c)(4). We will place the inspection report(s) and any supporting documentation in the public docket described in § 194.67. The site inspection report supporting the proposal will describe any limitations on approved waste streams or waste characterization processes. It will also identify (through tier

designations in accordance with paragraph (b)(4) of this section) what changes to the approved waste characterization processes must be reported to and approved by EPA before they can be implemented. In the notice, we will solicit public comment (for a minimum of 45 days) on the proposed Baseline Compliance Decision, including any limitations and the tier designations for future changes or expansions to the site's waste characterization program.

(iv) Our written decision regarding compliance with the requirements for waste characterization programs and processes described in paragraph (b)(1) of this section will be conveyed in a letter from the Administrator's authorized representative to DOE. EPA will not issue a compliance decision until after the end of the public comment period described in paragraph (b)(2)(iii) of this section. EPA's compliance decision will respond to significant and timely-received comments. A copy of our compliance decision will be placed in the public docket described in § 194.67. DOE will comply with any requirements identified in the compliance decision and the accompanying inspection report.

(3) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Agency intends to conduct inspections, in accordance with § 194.24(h), to confirm the continued compliance of approved waste characterization programs and processes at transuranic waste sites. EPA will make the results of these inspections available to the public in the dockets described in § 194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Department must report changes or expansions to the approved waste characterization program at a site in accordance with the tier designations established in the Baseline Compliance Decision.

(i) For changes or expansions to the waste characterization program designated as "Tier 1," the Department shall provide written notification to the Agency. The Department shall not ship for disposal at WIPP any waste that has been characterized using the new or revised processes, equipment, or waste streams until EPA has provided written approval of such new or revised systems.

(ii) For changes or expansions to the waste characterization program designated as "Tier 2," the Department shall provide written notification to the Agency. Waste characterized using the new or revised processes, equipment, or waste streams may be disposed at WIPP without written EPA approval.

(iii) EPA may conduct inspections in accordance with § 194.24(h) to evaluate the implementation of Tier 1 and Tier 2 changes or expansions to the waste characterization program at a site.

(iv) Waste characterization program changes or expansions that are not identified as either "Tier 1" or "Tier 2" will not require written notification by the Department to the Agency before implementation or before shipping waste for disposal at WIPP.

(5) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iii) of this section, EPA may revise the tier designations for approving changes or expansions to the waste characterization program at a site using the following process:

(i) The Agency shall announce the proposed tier changes in a letter to the Department. The letter will describe the Agency's reasons for the proposed change in tier designation(s). The letter and any supporting inspection report(s) or other documentation will be placed in the dockets described in § 194.67.

(ii) If the revised designation entails more stringent notification and approval requirements (e.g., from Tier 2 to Tier 1, or from undesignated to Tier 2), the change shall become effective immediately and the site shall operate under the more stringent requirements without delay.

(iii) If the revised designation entails less stringent notification and approval requirements, (e.g., from Tier 1 to Tier 2, or from Tier 2 to undesignated), EPA will solicit comments from the public for a minimum of 30 days. The site will continue to operate under the more stringent approval requirements until the public comment period is closed and EPA notifies DOE in writing of the Agency's final decision.

(6) A waste generator site that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, may continue characterizing and disposing such waste at the WIPP under paragraph (c) of this section until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision under paragraph (b)(2) of this section.

(i) Until EPA provides a Baseline Compliance Decision for such a site, EPA may approve additional transuranic waste streams for disposal at WIPP under the provisions of paragraph (c) of this section. Prior to the effective date of EPA's Baseline Compliance Decision for such a site, EPA will continue to conduct inspections of the site in accordance with § 194.24(c).

(ii) EPA shall conduct a baseline compliance inspection and issue a Baseline Compliance Decision for such previously approved sites in accordance with the provisions of paragraph (b) of this section, except that the site shall not be required to provide written notification of readiness as described in paragraph (b)(2)(i) of this section.

(c) *Waste characterization programs at waste generator sites with prior approval.* For a waste generator site

that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, the Agency will determine compliance with the requirements for use of process knowledge and a system of controls at waste generator sites as set in this paragraph (c). Approvals for a site to characterize and dispose of transuranic waste at WIPP will proceed according to this section only until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision for a site under paragraph (b)(2) of this section.

(1) For each waste stream or group of waste streams at a site, the Department must:

(i) Provide information on how process knowledge will be used for waste characterization of the waste stream(s) proposed for disposal at the WIPP; and

(ii) Implement a system of controls at the site, in accordance with § 194.24(c)(4), to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of § 194.24(c). The implementation of such a system of controls shall include a demonstration that the site has procedures in place for adding data to the WIPP Waste Information System (“WWIS”), and that such information can be transmitted from that site to the WWIS database; and a demonstration that measurement techniques and control methods can be implemented in accordance with § 194.24(c)(4) for the waste stream(s) proposed for disposal at the WIPP.

(2) The Agency will conduct an audit or an inspection of a Department audit for the purpose of evaluating the use of process knowledge and the implementation of a system of controls for each waste stream or group of waste streams at a waste generator site. The Agency will announce a scheduled inspection or audit by the Agency with a notice in the FEDERAL REGISTER. In that or another notice, the Agency will also solicit public comment on the relevant waste characterization program plans and Department documentation, which will be placed in the dockets described in § 194.67. A public comment period of at least 30 days will be allowed.

(3) The Agency’s written decision regarding compliance with the requirements for waste characterization programs described in paragraph (b)(1) of this section for one or more waste streams from a waste generator site will be conveyed in a letter from the Administrator’s authorized representative to the Department. No such compliance determination shall be granted until after the end of the public comment period described in paragraph (b)(2) of this section. A copy of the Agency’s compliance determination letter will be placed in the public dockets in accordance with § 194.67. The results of any inspections or audits conducted by the Agency to evaluate the plans described in paragraph (b)(1) of this section will also be placed in the dockets described in § 194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(3) of this section, the Agency intends to conduct inspections, in accordance with §§194.21 and 194.24(h), to confirm the continued compliance of the programs approved under paragraphs (b)(2) and (b)(3) of this section. The results of such inspections will be made available to the public through the Agency’s public dockets, as described in § 194.67.

[63 FR 27404, May 18, 1998, as amended at 69 FR 42581, July 16, 2004]

1

2 **8.2 Background**

3 The requirements of 40 CFR § 194.8 (U.S. Environmental Protection Agency 2004a) apply to
 4 the process used by the U.S. Environmental Protection Agency (EPA) to approve the disposal of
 5 transuranic (TRU) waste from U.S. Department of Energy (DOE) waste generator sites to the
 6 Waste Isolation Pilot Plant (WIPP).

7 The requirements were established at the time of the EPA’s 1998 Certification Decision to
 8 address compliance of site-specific quality assurance (QA) programs and a system of waste
 9 characterization and controls at waste generation sites.¹

¹ The dose rate of transuranic waste to be shipped to WIPP is measured at the generator sites to determine if the waste is remote-handled transuranic (RH-TRU) waste or contact-handled transuranic (CH-TRU) waste and the waste is certified in accordance with these measurements. Radionuclide dose rates of waste assemblies (i.e., drum seven packs, ten drum over pack) are measured at the WIPP site for worker health and safety issues only.

1 **8.3 1998 Certification Decision**

2 In order to clarify the EPA’s original intent for the compliance criteria regarding approval of
3 site-specific activities, the EPA amended the compliance criteria at 40 CFR Part 194 to include
4 the site-specific approval process (U.S. Environmental Protection Agency 1998, pp. 27404–406).
5 Appendix A of the EPA’s Certification Decision contains the requirements for the approval
6 process and four certification-related conditions. Two of the four conditions included in this
7 appendix are related to QA and waste characterization. Condition 2 specifies that no waste
8 generator site other than the Los Alamos National Laboratory (LANL) shall be allowed to ship
9 waste for disposal at the WIPP until the EPA determines that the site has established and
10 executed a QA program in accordance with 40 CFR §§ 194.22(a)(2)(i) (U.S. Environmental
11 Protection Agency 1996), 194.14(c)(3) (U.S. Environmental Protection Agency 1996), and
12 194.24(c)(5) (U.S. Environmental Protection Agency 2004a) for waste characterization activities
13 and assumptions. Condition 3 specifies that no waste from any additional LANL waste streams
14 (other than the ones already certified) or from any waste generator site other than LANL shall be
15 shipped for disposal at the WIPP until the EPA has approved the process for characterizing those
16 waste streams for shipment using the process set forth in section 194.8. The approval process
17 includes an opportunity for public comment and an inspection (of a DOE audit) or audit of the
18 waste generator site by the EPA. The procedures for demonstrating compliance with Conditions
19 2 and 3 of the EPA’s 1998 Certification Decision were incorporated in the final rule as a new
20 section to section 194.8, “Approval Process for Waste Shipment from Waste Generator Sites for
21 Disposal at the WIPP.”

22 For both QA and waste characterization programs, the approval process includes placement in
23 the docket of site-specific documentation submitted by the DOE, publication of a *Federal*
24 *Register* notice by the EPA announcing a scheduled inspection or audit, a period of at least 30
25 days for the public to comment on information placed in the docket, and the EPA’s written
26 decision regarding the approval of these programs in the form of a letter from the EPA to the
27 DOE. The EPA proposed to approve QA programs on a site-wide basis and to approve waste
28 characterization measures and controls on the basis of waste streams or, where multiple waste
29 streams may be characterized by the same waste characterization processes and techniques,
30 groups of waste streams.

31 **8.4 Changes in the CRA-2004**

32 A discussion of the requirements for section 194.8 was added to the Compliance Recertification
33 Application of 2004 (CRA-2004) (U.S. Department of Energy 2004, Chapter 4.0). The CRA-
34 2004 notes, “based on EPA acceptance of the site-specific TRU waste characterization and QA
35 program, the Carlsbad Field Office Manager is responsible for granting and revoking the
36 program certification that allows the TRU waste site to characterize and to ship waste to WIPP”
37 but also adds, “consistent with the provisions of section 194.8, EPA also has a role in the
38 approval process. The EPA determines compliance with requirements for site-specific QA
39 programs.” In addition to determining QA compliance, the EPA also approves the waste
40 characterization programs at generator sites to ensure that the system of controls required to track
41 important components is technically adequate.

1 The CRA-2004 notes that according to the WIPP Waste Information System (WWIS), as of
2 September 30, 2002, the following five sites had approved QA and waste characterization
3 programs under section 194.8 requirements: Hanford-Richland (RL), the Idaho National
4 Engineering and Environmental Laboratory (now called the Idaho National Laboratory [INL]),
5 LANL, the Rocky Flats Environmental Technology Site (RFETS), and the Savannah River Site
6 (SRS). Additionally, the DOE's Central Characterization Project (CCP) had been approved to
7 characterize and ship waste from SRS, Argonne National Laboratory (ANL), and the Nevada
8 Test Site (NTS).

9 **8.5 EPA's Evaluation of Compliance for the 2004 Recertification**

10 The CRA-2004 did not identify instances where waste had been shipped to the WIPP from a
11 generator site prior to approval of its waste characterization programs by the EPA before the
12 CRA-2004 cutoff date of September 22, 2002. However, instances have occurred where waste
13 was shipped before approval of instrumentation or techniques used to characterize that waste by
14 the EPA Compliance Application Review Document (CARD) 8 (U.S. Environmental Protection
15 Agency 2006a). In these cases, the DOE discontinued shipment of the waste under investigation
16 until the EPA completed its inspection and approval. The EPA received no public comments on
17 the DOE's continued compliance with the approval process for waste shipment from waste
18 generator sites for disposal at the WIPP.

19 Based on its review and evaluation of the CRA-2004, supplemental information provided by the
20 DOE, and the EPA inspections and audits, the EPA determined that the DOE continued to
21 comply at that time with the requirements for section 194.8 (U.S. Environmental Protection
22 Agency 2006b).

23 **8.6 Changes or New Information Since the 2004 Recertification**

24 The TRU waste sites approved by the EPA to ship contact-handled (CH) transuranic (TRU) (CH-
25 TRU) waste to the WIPP in accordance with the requirements of section 194.8 are as follows:
26 RL, INL/CCP, Advanced Mixed Waste Treatment Project, SRS/CCP, Oak Ridge National
27 Laboratory (ORNL)/CCP (EPA-ORNL-CCP-CH-11.07-8) (U.S. Environmental Protection
28 Agency 2008a), and LANL/CCP. The TRU waste sites identified in the CRA-2004 that have
29 shipped CH-TRU waste to the WIPP but are not currently active are Lawrence Livermore
30 National Laboratory (LLNL), NTS, ANL, and RFETS. RFETS has completed shipping its TRU
31 waste. LLNL was certified after the CRA-2004 was submitted (EPA-LANL-CCP-5.04-8) (U.S.
32 Environmental Protection Agency 2004b).

33 Since the CRA-2004, TRU waste characterization at LANL, SRS, and INL that was previously
34 performed using site resources is now being performed by CCP resources. An inspection was
35 performed by the EPA in April 2004 at LANL/CCP (EPA-LANL-CCP-4.04-08) (U.S.
36 Environmental Protection Agency 2004c). Approval was granted in August 2004 for the CCP to
37 characterize and ship CH-TRU waste from LANL. The EPA conducted a baseline inspection
38 and QA audit of INL/CCP in May 2005. Approval was granted by the EPA on November 1,
39 2005, for the CCP to characterize and ship CH-TRU waste from the INL.

1 On March 26, 2004, the EPA announced its final decision (Marcinowski 2004) to approve the
2 DOE's *Remote-Handled TRU Waste Characterization Program Implementation Plan* (U.S.
3 Department of Energy 2003a and 2003b). The EPA stated that on-site inspections and approval
4 of site-specific, remote-handled (RH) transuranic (TRU) (RH-TRU) waste characterization
5 programs will be conducted under the authority at section 194.8 or 40 CFR § 194.24, as
6 appropriate. Since then, four sites have been approved for RH-TRU waste characterization and
7 shipment to the WIPP. The EPA conducted a baseline inspection at INL/CCP in June and
8 August 2006 (U.S. Environmental Protection Agency 2007a) and approved the characterization
9 program on January 12, 2007 (U.S. Environmental Protection Agency 2007a). The baseline
10 approval designated the initiation of the WWIS for RH-TRU waste as a Tier 1 change (as
11 defined in section 194.8). The EPA approved a Tier 1 change request in January 2008 to add K-
12 Cell waste to the RH-TRU Waste Certification for INL/CCP (U.S. Environmental Protection
13 Agency 2008b). The EPA also conducted a QA program inspection and baseline inspection
14 (Inspection Number EPA-ANL-CCP-RH-09.06-08) at ANL/CCP in September 2006 (U.S.
15 Environmental Protection Agency 2007b). The QA program was approved on December 20,
16 2006 (Reyes 2006), and the characterization program was approved on January 16, 2007 (U.S.
17 Environmental Protection Agency 2007b). As with INL/CCP, the baseline approval designated
18 the initiation of the WWIS for RH-TRU waste as a Tier 1 change. A review of WWIS data entry
19 and waste component tracking was conducted by the EPA on November 21, 2006. The WWIS
20 system was determined to be adequate for RH-TRU waste characterized by INL/CCP and
21 ANL/CCP, as described by EPA correspondence dated January 17, 2007 (Reyes 2007). The
22 EPA approved a Tier 1 change request in July 2008 to add newly-packaged waste to the RH-
23 TRU Waste Certification for ANL/CCP (U.S. Environmental Protection Agency 2008c). In
24 February 2008, the EPA approved the baseline for RH-TRU Waste Characterization for
25 LANL/CCP (Inspection Number EPA-LANL-CCP-RH-05.07-8) (U.S. Environmental Protection
26 Agency 2008d). In August 2008, the EPA approved the baseline for RH-TRU Waste
27 Characterization for SRS-BCL/CCP (Inspection Number EPA-SRS-CCP-RH-07.07-8) (U.S.
28 Environmental Protection Agency 2008e). The EPA conducted a baseline inspection (July 2008)
29 of the RH-TRU Waste Characterization process at ORNL/CCP. Approval of the inspection has
30 not been received at this time. The DOE continues to comply with the requirements of section
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