

Recertification CARD No. 8
Approval Process for Waste Shipment from Waste Generator Sites
for Disposal at the WIPP

BACKGROUND

The requirements of Section 194.8 apply to the process used by the U.S. Environmental Protection Agency (EPA or Agency) to approve the disposal of transuranic (TRU) waste from U.S. Department of Energy (DOE or Department) waste generator sites at Waste Isolation Pilot Plant (WIPP).

This requirement was established at the time of EPA's 1998 Certification Decision to address compliance of site-specific Quality Assurance (QA) programs and requirements for use of process knowledge and a system of controls at waste characterization (WC) sites.

REQUIREMENTS

(a) "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 docket, as described in §194.67.”

(b) “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 designated 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 the 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) "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 forth below. 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.”

1998 CERTIFICATION DECISION

At the time of the 1998 Certification Decision, EPA’s WIPP Compliance Criteria were appended to include the requirements of Section 194.8, Approval Process for Waste Shipment from Waste Generator Sites for Disposal at the WIPP.

Conditions 2 and 3 of the 1998 Certification Decision relate to activities conducted at waste generator sites that produce the transuranic waste proposed for disposal in the WIPP. The WIPP compliance criteria (§§194.22 and 194.24) require DOE to have, in place, a system of controls to measure and track important waste components, and to apply QA programs to inspect the reliability/quality of those controls. At the time of EPA’s proposed certification decision, the Los Alamos National Laboratory (LANL) was the only site to demonstrate the proper execution of the required QA programs and the implementation of the required waste characterization system of controls. Therefore, EPA’s 1998 Certification Decision allowed only LANL to ship the retrievably-stored (legacy) debris waste for disposal at the WIPP. This decision was based

on EPA's inspection of the applicable system of controls for characterizing the waste contents and tracking waste components of this waste type.

As described in the 1998 Certification Decision and before other waste may be shipped for disposal at the WIPP, EPA must separately approve the QA programs at other generator sites (Condition 2) and the waste characterization system of controls for other waste streams (Condition 3). The approval process includes an opportunity for public comment, and an inspection (of a DOE audit) or audit of the waste generator site by EPA. The Agency's approval of WC systems of controls and QA programs were to be conveyed by letter from EPA to DOE.

As part of the 1998 Certification Decision, EPA's approval processes for waste generator site programs have been incorporated into the body of the WIPP compliance criteria, in a new section at §194.8.

CHANGES IN THE CRA

DOE added a discussion of the requirements for Section 194.8 to the 2004 Compliance Recertification Application (2004 CRA). The 2004 CRA notes that "[b]ased on the [EPA] acceptance of the site-specific waste characterization and QA program, the CBFO Manager is responsible for granting and revoking the program certification that allows the TRU waste site to characterize and to ship waste to WIPP" (See 2004 CRA, Chapter 4, page 4-41), but also adds that "[c]onsistent with the provisions of section 194.8, the EPA also has a role in the approval process. The EPA determines compliance with requirements for site-specific QA programs." (See 2004 CRA, Chapter 4, Page 4-42). In addition to determination of QA compliance, EPA also approves the waste characterization programs at generator sites to ensure that the system of controls required to track important components is technically adequate.

The 2004 CRA notes that according to the WWIS, the following five (5) sites had approved QA and WC programs under the Section 194.8 requirements, as of September 30, 2002: Hanford-RL, Idaho National Engineering and Environmental Laboratory (INEEL), LANL, Rocky Flats Environmental Technology Site (RFETS), and the Savannah River Site (SRS). Additionally, the DOE's Central Characterization Project (CCP) had been approved to ship waste from SRS, Argonne National Laboratory-East (ANL-E), and the Nevada Test Site (NTS) (See 2004 CRA, Chapter 4, Table 4-3).

EVALUATION OF COMPLIANCE FOR RECERTIFICATION

EPA regulations governing the disposal of TRU waste at the WIPP require EPA to inspect and approve waste characterization activities at DOE waste generator sites. Before waste is sent to WIPP for disposal, EPA conducts inspections at the generator sites to verify that the waste characterization program can measure and track how much waste goes to WIPP and what that waste contains.

In July 2004, EPA finalized changes to the requirements of Section 194.8(b). These changes were made to add flexibility and focus to our oversight of the waste characterization

approval process. The changes allow EPA to issue a single approval for each waste generator site, followed by ongoing EPA inspections and reporting of important changes by DOE. The current requirements of Section 194.8(b) provide for public comment on EPA's proposed approval decisions instead of focusing on plans and procedures prepared by DOE. These changes do not effect EPA's technical approach used during an independent inspection and they do not lessen the requirements that DOE must meet in order to dispose of waste at WIPP.

EPA is continually evaluating compliance with the requirements of Section 194.8 through QA and WC inspections, observations and technical reviews. Table 1 lists all EPA-Section 194.8(b) inspections through September 2005. These WC inspection reports and approval letters are available from the Docket A-98-49, Items II-A4-1 through 28. Table 2 lists all EPA- Section 194.8(a) QA audits through September 2005.

The 2004 CRA did not identify instances where waste had been shipped to WIPP from a generator site prior to approval of its QA and waste characterization programs by EPA prior to the 2004 CRA cut off date of September, 2002. However, instances have occurred where waste was shipped prior to approval of instrumentation or techniques used to characterize that waste (e.g., INEEL-Summer 2001 and Hanford-Summer 2004). At one site (LANL- Fall 2003), the waste shipped was characterized using a Nondestructive Assay (NDA) device for which calibration was problematic. In all cases, DOE discontinued shipment of the waste under investigation until EPA completed its inspection and approval. The issues associated with errors were ultimately resolved and corrective actions were taken to avoid future occurrences.

EPA did not receive any public comments on DOE's continued compliance with the approval process for waste shipment from WIPP waste generator sites for disposal at the WIPP requirements of Section 194.8.

Table CARD 8-1: EPA Waste Characterization Inspections - May 1998 - September 2005

Date of Inspection	EPA Inspection No.	Site	Approval Date
July 28-30, 1998	EPA-INEEL-7.98-8	INEEL	February 1999
July 23-25, 1998	EPA-RFETS-6.98-8	RFETS	March 1999
January 20-22, 1999	EPA-LANL-1.99-8	LANL	-*
April 27-28, 1999	EPA-RFETS-4.99-8	RFETS	June 1999
June 15-17, 1999	EPA-LANL-6.99-8	LANL	July 1999
May 18-20, 1999	EPA-INEEL-5.99-8	INEEL	August 1999
June 8-10, 1999	EPA-NTS-6.99-8	NTS	October 1999
July 13-15, 1999	EPA-Hanford-7.99-24	Hanford	August 1999
August 24-26, 1999	EPA-SRS-8.99-24	SRS	-
September 14-16, 1999	EPA-RFETS-9.99-24	RFETS	-
November 16-18, 1999	EPA-RFETS-11.99-8	RFETS	January 2000
January 25-27, 2000	EPA-HAN-1.00-8	Hanford Site	February 2000
April 25-27, 2000	EPA-INEEL-4.00-8	INEEL	July 2000
September 19-21, 2000	EPA-RFETS-9.00-8	RFETS	November 2000
December 5-7, 2000	EPA-INEEL-12.00-8	INEEL	April 2001
November 7-9 and 14-16,	EPA-SRS-11.00-8	SRS	April 2001

2000			
January 30 – February 1, 2001	EPA-RFETS-1.01-8	RFETS	-
May 15-17, 2001	EPA-RFETS-5.01-8	RFETS	December 2001
June 12-14, 2001	EPA-Hanford-6.01-24	Hanford	August 2001
July 2-3, 2001	EPA-INEEL-7.01-24	INEEL	August 2001
July 24-26, 2001	EPA-INEEL-7.01-8	INEEL	August 2001
September 25-27, 2001	EPA-SRS-CCP-9-01-8	SRS	-
October 16-18, 2001	EPA-SRS-CCP-10.01-8	SRS	February 2002
October 30- November 1, 2001	EPA-INEEL-10-01-8	INEEL	-
December 18-20, 2001	EPA-HAN-12.01-8	Hanford Site	April 2002
April 9-11, 2002	EPA-INEEL-4.02-8	INEEL	May 2002
December 11-13, 2001	EPA-SRS-12.01-8	SRS	July 2002 and December 2002
February 5-7, 2002	EPA-RFETS-2.02-24	RFETS	-
February 26- 28, 2002	EPA-LANL-2.02-8	LANL	August 2002
June 4-6, 2002	EPA-RFETS-6.02-8	RFETS	July 2002
June 25-27, 2002	EPA-HAN-6.02-8	Hanford Site	August 2002
August 27-29, 2002	EPA-LANL-8.02-8	LANL	December 2002
September 10-12, 2002	EPA-ANL-E-CCP-9.02-8	ANL- E	December 2002
September 24-26, 2002	EPA-NTS-CCP-9.02-8	NTS	December 2002
February 11-13, 2003	EPA-ANL-E-CCP-2.03-8	ANL-E	May 2003
March 5-7, 2003	EPA-RFETS-3.03-24	RFETS	May 2003
March 25-27, 2003	EPA-SRS-CCP-3.03-8	SRS	September 2003
June 17-19, 2003	EPA-Hanford-8.03-8 and 24	Hanford	August 2003
July 22-24, 2003	EPA-RFETS-7.03-8	RFETS	November 2003
August 19-21, 2003	EPA-AMWTP-8.03-8	AMWTP	January 2004
September 9-11, 2003	EPA-Hanford-CCP-9.03-8	Hanford	March 2005
October 15-17, 2003	EPA-AMWTP-10.03-24	AMWTP	January 2004
October 21-23, 2003	EPA-SRS-CP-10.03-24	SRS	March 2004
March 1-3, 2004	EPA-AMWTP-3.05-8	AMWTP	October 2005
April 27-29, 2004	EPA-LANL-CCP- 4.04-8	LANL	August 2004
June 15-17, 2004	EPA-Hanford-6.04-24	Hanford	August 2004
August 17-19, 2004	EPA-AMWTP-8.04-24	AMWTP	June 2005
September 8-9, 2004	EPA-SRS-CCP-9.04-24	SRS	December 2004
October 26-28, 2004	EPA-SRS-CCP-10.04-8	SRS	June 2005
December 20-21, 2004	EPA-RFETS-12.04-8	RFETS	March 2005
April 12-14, 2005	EPA-LANL-CCP-4.05-8	LANL	August 2005
May 2-5, 2005	EPA-INL-CCP-5.05-8	INL-CCP	November 2005
May 5-7, 2005	EPA-LLNL-CCP-5.04.8	LLNL	August 2004
June 21-23, 2005	EPA-Hanford-6.05-8	Hanford	September 2005

* - Not issued

Table CARD 8-2: EPA Quality Assurance Audits by Site - May 1998 - September 2005*

Site	Date	Purpose
Hanford	January 24-24, 2000	Initial audit of Hanford's QA program per 194.8(a)(1)&(2) and inspection of DOE's Certification Audit A-00-05
	January 16, 2001	Subsequent audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4) and inspection of DOE's Surveillance Audit S-01-04
	June 12-15, 2001	Subsequent Audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4) and inspection of DOE's Audit A-01-03 and A-01-16
	June 24-26, 2002	Subsequent Audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4) and inspection of DOE's Audit A-02-23
	June 25-27, 2003	Subsequent Audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4) and inspection of DOE Audit
	July 29-31, 2003	Follow-up audit to the June audit. Expand audit sample and verify correction of non-conformances
	September 9-11, 2003	Follow-up Audit to July audit to verify correction of non-conformances and initial audit of Hanford CCP's QA program
	June 2004	Subsequent audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4)
	June 2005	Subsequent audit to verify proper maintenance of Hanford's QA program per 194.8(a)(4)
RFETS	June 22-25, 1998	Initial Audit of RFETS's QA Program per 40 CFR 194.8(a)(1)&(2) and inspection of DOE Audit A-98-26. Also reviewed records of CBFO Audit A-97-03, A-98-04 and A-98-06 of RFET
	March 2-4, 1999	Subsequent audit to verify maintenance of RFETS QA program per 40 CFR 194.8(a)(4) and Inspection of DOE's Certification Audit A-99-07
	March 24, 1999	Follow-up to A-99-07. Expand audit sample; inspect DOE Audit A-99-13, which assessed Canberra's software QA program
	April 28, 1999	Follow-up t A-99-07: inspect CBFO Audit A-99-16, which assessed TRU waste characterization of

		LECO crucible
	March 7-8, 2000	Subsequent Audit to verify proper maintenance of RFETS's QA program per 40 CFR 194.8(a)(4) and inspection of DOE Audit A-00-10
	January 29 – February 1, 2001	Subsequent audit to verify proper maintenance of RFETS's QA Program per 40 CFR 194.8(a)(4) and Inspection of DOE Audit
	February 4-8, 2002	Subsequent audit to verify proper maintenance of RFETS's QA program per 40 CFR 194.8(a)(4) and Inspection of CBFO Audit A-02-07 for maintenance of WIPP support QA program
	March 26-27, 2002	Follow-up audit to verify completion of DOE CAR 02-050
	March 4-5, 2003	Subsequent audit to verify proper maintenance of RFETS's QA Program per 40 CFE 194/8(a)(4) and Inspection of DOE Audit
SRS	October 15-18, 2001	Initial audit of SRS CCP's QA program as required under §194.8(a)(1) and (2)
	December 2-4, 2003	Subsequent audit to verify proper maintenance of SRS CCP's QA program per 40 CFR 194.8(a)(4)
	October 26-28, 2004	Subsequent audit to verify proper maintenance of SRS CCP's QA program per 40 CFR 194.8(a)(4)
	November 6-8, 2005	Subsequent audit to verify proper maintenance of SRS CCP's QA program per 40 CFR 194.8(a)(4)
NTS	September 24, 2002	Initial audit of NTS CCP's QA program and inspection of DOE's Audit A-02-15
ANL-E	September 9-10, 2002	Initial audit of ANL-E CCP's QA program and inspection of DOE Audit A-02-03
LANL	April 27-29, 2004	Initial audit of LANL CCP's QA program per 40 CFR 194.8(a)(1) & (2)
	April 12-15, 2005	Subsequent audit to verify proper maintenance of LANL's CCP QA program per 40 CFR 194.8(a)(4)
LLNL	May 5-7, 2004	Initial audit of LLNL's QA program per 40 CFR 194.8(a)(1) & (2)

*EPA audits of the CBFO QA programs can be found in Docket A-98-49, Category II-A1.

RECERTIFICATION DECISION

Based on a review and evaluation of the 2004 CRA, supplemental information provided by DOE (FDMS Docket ID No. EPA-HQ-OAR-2004-0025, Air Docket A-98-49) and EPA inspections and audits, EPA determines that DOE continues to comply with the requirements for Section 194.8