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§ 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 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 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]

Subpart B—Compliance Certification and Re-certification Applications

§ 194.11 Completeness and accuracy of compliance applications.

Information provided to the Administrator in support of any compliance application shall be complete and accurate. The Administrator's evaluation for certification pursuant to section 8(d)(1)(B) of the WIPP LWA and evaluation for recertification pursuant to section 8(f)(2) of the WIPP LWA shall not begin until the Administrator has notified the Secretary, in writing, that a complete application in accordance with this part has been received.

§ 194.12 Submission of compliance applications.

Unless otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of any compliance application(s), any accompanying materials, and any amendments thereto shall be submitted in a printed form to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. In addition, DOE shall submit 10 copies of the complete application in alternative format (e.g., compact disk) or other approved format, as specified by the Administrator's authorized representative.

[69 FR 42582, July 16, 2004]

§ 194.13 Submission of reference materials.

Information may be included by reference into compliance applications(s), provided that the references are clear specific and that unless, otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of reference information are submitted to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. Reference materials that are widely available in standard text books or reference books need not to be submitted. Whenever possible, DOE shall submit 10 copies of reference materials in alternative format (e.g., compact disk) or other approved format, as specified by the Administrator's authorized representative.

[69 FR 42582, July 16, 2004]

§ 194.14 Content of compliance certification application.

Any compliance application shall include:

(a) A current description of the natural and engineered features that may affect the performance of the disposal system. The description of the disposal system shall include, at a minimum, the following information:

(1) The location of the disposal system and the controlled area;

(2) A description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity and how these conditions are expected to change and interact over the regulatory time frame.