

Environmental Protection Agency

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system and how these conditions are expected to change over the regulatory time frame.

(j) The information required elsewhere in this part or any additional information, analyses, tests, or records determined by the Administrator or the Administrator's authorized representative to be necessary for determining compliance with this part.

§ 194.15 Content of compliance re-certification application(s).

(a) In submitting documentation of continued compliance pursuant to section 8(f) of the WIPP LWA, the previous compliance application shall be updated to provide sufficient information for the Administrator to determine whether or not the WIPP continues to be in compliance with the disposal regulations. Updated documentation shall include:

(1) All additional geologic, geophysical, geochemical, hydrologic, and meteorologic information;

(2) All additional monitoring data, analyses and results;

(3) All additional analyses and results of laboratory experiments conducted by the Department or its contractors as part of the WIPP program;

(4) An identification of any activities or assumptions that deviate from the most recent compliance application;

(5) A description of all waste emplaced in the disposal system since the most recent compliance certification or re-certification application. Such description shall consist of a description of the waste characteristics and waste components identified in §§ 194.24(b)(1) and 194.24(b)(2);

(6) Any significant information not previously included in a compliance certification or re-certification application related to whether the disposal system continues to be in compliance with the disposal regulations; and

(7) Any additional information requested by the Administrator or the Administrator's authorized representative.

(b) To the extent that information required for a re-certification of compliance remains valid and has been submitted in previous certification or re-certification application(s), such information need not be duplicated in subse-

quent applications; such information may be summarized and referenced.

Subpart C—Compliance Certification and Re-certification

GENERAL REQUIREMENTS

§ 194.21 Inspections.

(a) The Administrator or the Administrator's authorized representative(s) shall, at any time:

(1) Be afforded unfettered and unannounced access to inspect any area of the WIPP, and any locations performing activities that provide information relevant to compliance application(s), to which the Department has rights of access. Such access shall be equivalent to access afforded Department employees upon presentation of credentials and other required documents.

(2) Be allowed to obtain samples, including split samples, and to monitor and measure aspects of the disposal system and the waste proposed for disposal in the disposal system.

(b) Records (including data and other information in any form) kept by the Department pertaining to the WIPP shall be made available to the Administrator or the Administrator's authorized representative upon request. If requested records are not immediately available, they shall be delivered within 30 calendar days of the request.

(c) The Department shall, upon request by the Administrator or the Administrator's authorized representative, provide permanent, private office space that is accessible to the disposal system. The office space shall be for the exclusive use of the Administrator or the Administrator's authorized representative(s).

(d) The Administrator or the Administrator's authorized representative(s) shall comply with applicable access control measures for security, radiological protection, and personal safety when conducting activities pursuant to this section.

§ 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

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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.

§ 194.23 Models and computer codes.

(a) Any compliance application shall include:

(1) A description of the conceptual models and scenario construction used to support any compliance application.

(2) A description of plausible, alternative conceptual model(s) seriously considered but not used to support such application, and an explanation of the reason(s) why such model(s) was not