

§ 194.21

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 subsequent 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

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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 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 deemed to accurately portray performance of the disposal system.

(3) Documentation that:

(i) Conceptual models and scenarios reasonably represent possible future states of the disposal system;

(ii) Mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models;

(iii) Numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions;

(iv) Computer models accurately implement the numerical models; i.e., computer codes are free of coding errors and produce stable solutions;

(v) Conceptual models have undergone peer review according to § 194.27.

(b) Computer codes used to support any compliance application shall be documented in a manner that complies with the requirements of ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition. (Incorporation by reference as specified in § 194.5.)

(c) Documentation of all models and computer codes included as part of any compliance application performance assessment calculation shall be provided. Such documentation shall include, but shall not be limited to:

(1) Descriptions of the theoretical backgrounds of each model and the method of analysis or assessment;

(2) General descriptions of the models; discussions of the limits of applicability of each model; detailed instructions for executing the computer codes, including hardware and software requirements, input and output formats with explanations of each input and output variable and parameter (e.g., parameter name and units); listings of input and output files from a sample computer run; and reports on code verification, benchmarking, validation, and quality assurance procedures;