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40 CFR Ch. I (7-1-04 Edition)

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

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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;

(3) Detailed descriptions of the structure of computer codes and complete listings of the source codes;

(4) Detailed descriptions of data collection procedures, sources of data, data reduction and analysis, and code input parameter development;

(5) Any necessary licenses; and

(6) An explanation of the manner in which models and computer codes incorporate the effects of parameter correlation.

(d) The Administrator or the Administrator's authorized representative may verify the results of computer simulations used to support any compliance application by performing independent simulations. Data files, source codes, executable versions of computer software for each model, other material or information needed to permit the Administrator or the Administrator's authorized representative to perform independent simulations, and access to necessary hardware to perform such simulations, shall be provided within 30 calendar days of a request by the Administrator or the Administrator's authorized representative.

§ 194.24 Waste characterization.

(a) Any compliance application shall describe the chemical, radiological and physical composition of all existing waste proposed for disposal in the disposal system. To the extent practicable, any compliance application shall also describe the chemical, radiological and physical composition of to-be-generated waste proposed for disposal in the disposal system. These descriptions shall include a list of waste components and their approximate quantities in the waste. This list may be derived from process knowledge, current non-destructive examination/assay, or other information and methods.

(b) The Department shall submit in the compliance certification application the results of an analysis which substantiates:

(1) That all waste characteristics influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The characteristics to be analyzed shall include, but shall not be limited to: Solubility; formation of colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment.