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ASME (American Society of Mechanical Engineers)., 1989a. Quality Assurance Program Requirements for Nuclear Facilities. ASME NQA-1-1989, September 15, 1989. The American Society of Mechanical Engineers, New York, NY.

INTRODUCTION, 1 PURPOSE, p 1;

" This Standard sets forth requirements for the establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. Nonmandatory guidance is provided in the Appendices."



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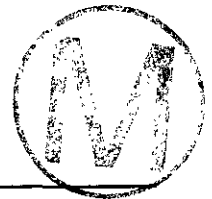
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ASME (American Society of Mechanical Engineers), 1989b. "Part 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," Quality Assurance Requirements for Nuclear Facility Applications. ASME NQA-2a-1990, Part 2.7. May 31, 1990. ASME, New York, NY.

Part 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications, 1 GENERAL, p 58.3;

" Part 2.7 provides requirements for the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities. It supplements the requirements of ASME NQA-1 and shall be used in conjunction with applicable Basic and Supplementary Sections of ASME NQA-1 when and to the extent specified by the organization invoking this Part."





ASME (American Society of Mechanical Engineers). 1989c. Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories. ASME NQA-3-1989. March 23, 1990. American Society of Mechanical Engineers, New York, NY.

FOREWORD, p iii;

" Early in 1975, the American National Standards Institute (ANSI) assigned overall responsibility for coordination among technical societies, development, and maintenance of nuclear power quality assurance standards to the American Society of Mechanical Engineers (ASME). The ASME Committee on Nuclear Quality Assurance was constituted on October 3, 1975, and began operating under the ASME Procedures for Nuclear projects. The ASME Committee on Nuclear Quality Assurance currently operates under the ASME Operating Procedures and Practices for Nuclear Codes and Standards Development Committees. This committee prepared ANSI/ASME NQA-1, Quality Assurance Program requirements for Nuclear facilities and ANSI/ASME NQA-2, Quality Assurance Requirements for Nuclear facility Applications. The need for a document like ASME NQA-3 was established after extensive studies by the ASME Nuclear Quality Assurance Subcommittee on Nuclear Waste Management, and after contractors and government agencies experienced difficulty in implementing NQA-1 as the Quality Assurance Program standard on the unique type of work involved in a high-level nuclear waste management program.

In 1984, the NQA Subcommittee on Nuclear Waste management was assigned responsibility for developing a Quality Assurance Program standard appropriate to site characterization of high-level nuclear waste repositories. This Subcommittee prepared ASME NQA-3, Quality Assurance Program requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories.

NQA-3 is to be used in conjunction with NQA-1 to set forth Quality Assurance Program requirements and nonmandatory guidance for the collection of scientific and technical information for site characterization of high-level nuclear waste repositories. It contains an Introduction, Basic Requirements, and Supplements. In addition, nonmandatory guidance is provided in the appendices, which do not set forth requirements. The requirements of NQA-1 and NQA-3 are intended to meet and clarify the criteria of 10CFR50, Appendix B and 10CFR60, Subpart G (Repository Quality Assurance Requirements) for high-level nuclear waste repositories.

The arrangements of the basic and supplementary requirements of these standards permit judicious application of the entire documents or only portions of the documents. The extent to which these documents should be applied, either wholly or in part, will depend upon the nature and scope of the work to be performed and the relative importance of the items being produced or services being provided. The extent of application is to be determined by the organization imposing this document. For example, it may only involve the Basic Requirements, or the Basic Requirements in combination with Supplements and Nonmandatory Appendices. These documents may be modified, as appropriate, or they may be applied in their entirety. These documents are written to allow application to any structure, system, component, or activity that

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is essential to the satisfactory completion of site characterization of high-level nuclear waste repositories. . . ."





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EPA (U.S. Environmental Protection Agency). 1993. 40 CFR Part 191 Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule. Federal Register, Vol. 58, No. 242, pp. 66398-66416, December 20, 1993, Office of Radiation and Indoor Air, Washington, D.C. WPO 39133.

**PREAMBLE: SUMMARY;**

" The U.S. Environmental Protection Agency (EPA) is promulgating amendments to the environmental standards for the disposal of spent nuclear fuel, high-level and transuranic wastes (40 CFR 191.15 and Subpart C).

EPA originally promulgated these standards in 1985 pursuant to the Agency's authorities and responsibilities under the Nuclear Waste Policy Act of 1982, as amended, the Atomic Energy Act of 1954, as amended, and §2(a)(6) of Reorganization Plan No. 3 of 1970 (5 USC app. 1). In 1987, following a legal challenge, the U.S. Court of Appeals for the First Circuit (hereinafter referred to as 'the First Circuit' or 'the court') remanded subpart B of the 1985 standards to the Agency for further consideration. *Natural Resources Defense Council, Inc. v. United States Environmental Protection Agency*, 824 F.2d 1258 (1st Cir. 1987). Recently enacted legislation, (Pub. L. 102-579) known as the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA), however, reinstates the 1985 disposal standards except 'the 3 aspects of §§191.15 and 191.16 of such [standards] that were subject of the remand ordered' by the First Circuit. The WIPP LWA directs EPA to expedite issuance of final disposal standards and specifies that such regulations shall not be applicable to the characterization, licensing, construction, operation, or closure of any site required to be characterized under §113(a) of Public Law 97-425, the Nuclear Waste Policy Act of 1982.

Today's action represents the Agency's response to this legislation and to the issues raised by the court pertaining to individual and ground-water protection requirements. After considering the relevant comments received on the February 10, 1993 proposed rulemaking, the Agency has taken this final action in the form of amendments to parts 191 of title 40 of the Code of Federal Regulations. In so doing, EPA has not revised any of the regulations reinstated by the WIPP LWA.

**DATES:** These amendments will become effective on January 19, 1994. These amendments will be promulgated for purposes of judicial review at 1 p.m. eastern standard time on December 20, 1993. "

**STATUTORY AND REGULATORY BACKGROUND;**

" **The WIPP Land Withdrawal and Nuclear Waste Policy Acts**

As noted above, today's action responds to the directive in section 8 of the WIPP LWA that EPA conduct a rulemaking to issue certain radioactive waste disposal regulations at 40 CFR Part 191, subpart B. The EPA initially promulgated subpart B in 1985 (50 FR 38084 (Sept. 19, 1985)), but those regulations were subsequently vacated in whole as part of a remand order issued by the First Circuit in 1987 (discussed further above and below). See *NRDC v. EPA*, 824 F.2d 1258 (1st Cir. 1987).

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Section 8(a)(1) of the WIPP LWA reinstates those portions of subpart B except §§191.15 and 191.16 (which were the bases of remand by the First Circuit). Accordingly, section 8(a)(2)(A) of the WIPP LWA exempts the requirements at 40 CFR 191.15 (individual protection) and 191.16 (ground-water protection) from the statutory reinstatement. Section 8(b)(2) addresses these non-reinstated provisions by directing the EPA promulgate final regulations. Today's action responds to that directive by revising the individual protection requirements in 40 CFR 191.15, discussed above, and by adding new ground-water protection standards as 40 CFR part 191, subpart C (discussed below)."

Federal register, Vol. 58 No. 242, p 66398, dated December 20, 1993

"191.15 Individual protection requirements.

(a) Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 millirems (150 microsieverts).

(b) Annual committed effective doses shall be calculated in accordance with appendix B of this part.

(c) Compliance assessments need not provide complete assurance that the requirements of paragraph (a) of this section will be met. Because of the long time period involved and the nature of the processes and events of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved.

(d) Compliance with the provisions in this section does not negate the necessity to comply with any other applicable Federal regulations or requirements.

(e) The standards in this section shall be effective on January 19, 1994."

"Subpart C-Environmental Standards for Ground-Water Protection

. . .191.23 General provisions.

(a) Determination of compliance with this subpart shall be based upon underground sources of drinking water which have been identified on the date the implementing agency determines compliance with subpart C of this part.

191.24 Disposal standards.

(a) Disposal systems.

(1) General. Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR part 141 as they exist on January 19, 1994.

(2) Disposal systems above or within a formation which within one-quarter ( 1/4) mile





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contains an underground source of drinking water. [Reserved]

(b) Compliance assessments need not provide complete assurance that the requirements of paragraph (a) of this section will be met. Because of the long time period involved and the nature of the processes and events of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved. . . ."

§191.27. Effective date: p. 66415, col. 3;

"Appendix A to Part 191--Table for Subpart B

9. Appendix B is redesignated as Appendix C to part 191 and the heading is revised as follows:

Appendix C to Part 191--Guidance for Implementation of Subpart B."

50 FR 38088, p. 38088, col. 2;

" Appendix B--Guidance for Implementation of Subpart B

[Note: The supplemental information in this appendix is not an integral part of 40 CFR Part 191. Therefore, the implementing agencies are not bound to follow this guidance. However, it is included because it describes the Agency's assumptions regarding the implementation of Subpart B. This appendix will appear in the Code of Federal Regulations]"

" Scope of Performance Assessments.

Section 191.13 requires the implementing agencies to evaluate compliance through performance assessments as defined in § 191-12(q). The Agency assumes that such performance assessments need not consider categories of events or processes that are estimated to have less than one chance in 10,000 of occurring over 10,000 years. Furthermore, the performance assessments need not evaluate in detail the releases from all events and processes estimated to have a greater likelihood of occurrence. Some of these events and processes may be omitted from the performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changes by such omissions."



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EPA (U.S. Environmental Protection Agency). 1996. 40 CFR Part 194: Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations; Final Rule. Federal Register, Vol. 61, No. 28, pp. 5224-5245, February 9, 1996. Office of Air and Radiation, Washington, D.C. In NWM Library as KF70.A35.C751 1996 (Reference).

SUMMARY, p. 5224, col. 1;

" The Environmental Protection Agency (EPA) is promulgating criteria for determining if the Waste Isolation Pilot Plant (WIPP) will comply with EPA's environmental radiation protection standards for the disposal of radioactive waste. If the Administrator of the EPA determines that the WIPP will comply with the standards for disposal, then the Administrator will issue to the Secretary of Energy a certification of compliance which will allow the emplacement of transuranic waste in the WIPP to begin, provided that all other statutory requirements have been met. If a certification is issued, EPA will also use this final rule to determine if the WIPP has remained in compliance with EPA's environmental radiation protection standards, once every five years after the initial receipt of waste for disposal at the WIPP. This rulemaking was mandated by the WIPP Land Withdrawal Act of 1992.

EFFECTIVE DATE: These regulations are effective April 9, 1996."

p. 5238, col. 2;

" §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. Such description shall include, at a minimum:

(i) Existing fluids and fluid hydraulic potential, including brine pockets, in and near the disposal system; and

(ii) Existing higher permeability anhydrite interbeds located at or near the horizon of the waste.

(3) The presence and characteristics of potential pathways for transport of waste from the disposal system to the accessible environment including, but not limited to: Existing boreholes, solution features, breccia pipes, and other potentially permeable features, such as interbeds.

(4) The projected geophysical, hydrogeologic, and geochemical conditions of the disposal system due to the presence of waste including, but not limited to, the effects of production of heat or gases from the waste."

p. 5240, col. 2;

" §194.24 Waste characterization.



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(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."

p. 5243, Assurance Requirements, col. 3;

" §194.44 Engineered barriers.

(a) Disposal systems shall incorporate engineered barrier(s) designed to prevent or substantially delay movement of water or radionuclides toward the accessible environment."



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NRC (U.S. Nuclear Regulatory Commission). 1988. Qualification of Existing Data for High-Level Nuclear Waste Repositories. NUREG-1298, February 1988.

ABSTRACT, p iii;

" This document provides guidance on methods of qualifying data not initially collected under a 10 CFR Part 60, Subpart G quality assurance (QA) program. The license applicant for a geologic repository must demonstrate that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a QA program.

Some data which have not been initially generated under a 10 CFR Part 60, Subpart G QA program may be needed to support a license application to construct and operate a geologic repository. This document provides guidance on the use and qualification of data not initially collected under a Subpart G, QA program."



**BIBLIOGRAPHY DOCUMENTS**



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NRC (U.S. Nuclear Regulatory Commission). 1988a. Peer Review for High-Level Nuclear Waste Repositories. NUREG-1297. February 1988.

ABSTRACT, p iii;

" This document provides guidance on the use of the peer review process in the high-level nuclear waste repository program. The applicant must demonstrate in the license application that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a quality assurance (QA) program as described in 10 CFR Part 60, Subpart G.

Peer reviews may be used as part of the QA actions necessary to provide adequate confidence in the work being reviewed. Because of several unique conditions inherent in the geologic repository program, expert judgement will need to be utilized in assessing the adequacy of work. Peer reviews are a mechanism by which these judgements may be made.

This document provides guidance on areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review."



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Knight, J.P. 1989. Memorandum. " Waste Isolation Pilot Plant Safety Evaluation Report," on EH-30 Safety Evaluation Report (SER) for the Waste Isolation Pilot Plant (WIPP) plus attachment.

NOTE: The above listed document was not available for inclusion in the Reference Expansion as of the printing date. Page changes will be provided as the above document becomes available for inclusion.



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