SUBCHAPTER F—RADIATION PROTECTION PROGRAMS

PART 190—ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR NUCLEAR POWER OPERATIONS

Subpart A—General Provisions

Sec.

Subpart B—Environmental Standards for the Uranium Fuel Cycle

AUTHORITY: Atomic Energy Act of 1954, as amended; Reorganization Plan No. 3, of 1970.

SOURCE: 42 FR 2860, Jan. 13, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 190.01 Applicability.

The provisions of this part apply to radiation doses received by members of the public in the general environment and to radioactive materials introduced into the general environment as the result of operations which are part of a nuclear fuel cycle.

§ 190.02 Definitions.

(a) *Nuclear fuel cycle* means the operations defined to be associated with the production of electrical power for public use by any fuel cycle through utilization of nuclear energy.

(b) *Uranium fuel cycle* means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel, to the extent that these directly support the production of electrical power for public use utilizing nuclear energy, but excludes mining operations, operations at waste disposal sites, transportation of any radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and by-product materials from the cycle.

(c) *General environment* means the total terrestrial, atmospheric and aquatic environments outside sites upon which any operation which is part of a nuclear fuel cycle is conducted.

(d) *Site* means the area contained within the boundary of a location under the control of persons possessing or using radioactive material on which is conducted one or more operations covered by this part.

(e) *Radiation* means any or all of the following: Alpha, beta, gamma, or X-rays; neutrons; and high-energy electrons, protons, or other atomic particles; but not sound or radio waves, nor visible, infrared, or ultraviolet light.

(f) *Radioactive material* means any material which spontaneously emits radiation.

(g) *Curie* (Ci) means that quantity of radioactive material producing 37 billion nuclear transformations per second. (One millicurie (mCi) = 0.001 Ci.)

(h) *Dose equivalent* means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its spatial distribution in the body. The unit of dose equivalent is the ''rem.'' (One millirem (mrem)= 0.001 rem.)

(i) *Organ* means any human organ exclusive of the dermis, the epidermis, or the cornea.

(j) *Gigawatt-year* refers to the quantity of electrical energy produced at the busbar of a generating station. A gigawatt is equal to one billion watts. A gigawatt-year is equivalent to the amount of energy output represented by an average electric power level of one gigawatt sustained for one year.

(k) *Member of the public* means any individual that can receive a radiation dose in the general environment, whether he may or may not also be exposed to radiation in an occupation associated with a nuclear fuel cycle. However, an individual is not considered a member of the public during any

period in which he is engaged in carrying out any operation which is part of a nuclear fuel cycle.

(l) *Regulatory agency* means the government agency responsible for issuing regulations governing the use of sources of radiation or radioactive materials or emissions therefrom and carrying out inspection and enforcement activities to assure compliance with such regulations.

Subpart B—Environmental Standards for the Uranium Fuel Cycle

§ 190.10 Standards for normal operations.

Operations covered by this subpart shall be conducted in such a manner as to provide reasonable assurance that:

(a) The annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as the result of exposures to planned discharges of radioactive materials, radon and its daughters excepted, to the general environment from uranium fuel cycle operations and to radiation from these operations.

(b) The total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle, per gigawatt-year of electrical energy produced by the fuel cycle, contains less than 50,000 curies of krypton-85, 5 millicuries of iodine-129, and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year.

§ 190.11 Variances for unusual operations.

The standards specified in § 190.10 may be exceeded if:

(a) The regulatory agency has granted a variance based upon its determination that a temporary and unusual operating condition exists and continued operation is in the public interest, and

(b) Information is promptly made a matter of public record delineating the nature of unusual operating conditions, the degree to which this operation is expected to result in levels in excess of the standards, the basis of the variance, and the schedule for achieving conformance with the standards.

§ 190.12 Effective date.

(a) The standards in § 190.10(a) shall be effective December 1, 1979, except that for doses arising from operations associated with the milling of uranium ore the effective date shall be December 1, 1980.

(b) The standards in § 190.10(b) shall be effective December 1, 1979, except that the standards for krypton-85 and iodine-129 shall be effective January 1, 1983, for any such radioactive materials generated by the fission process after these dates.

PART 191—ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES

Subpart A—Environmental Standards for Management and Storage

Sec.

Subpart B—Environmental Standards for Disposal

Subpart C—Environmental Standards for Ground-Water Protection

AUTHORITY: The Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011–2296; Reorganization Plan No. 3 of 1970, 5 U.S.C. app. 1; the Nuclear Waste Policy Act of 1982, as amended, 42 U.S.C. 10101–10270; and the Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. 102–579, 106 Stat. 4777.

SOURCE: 50 FR 38084, Sept. 19, 1985, unless otherwise noted.

Subpart A—Environmental Standards for Management and Storage

§ 191.01 Applicability.

This subpart applies to:

(a) Radiation doses received by members of the public as a result of the management (except for transportation) and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at any facility regulated by the Nuclear Regulatory Commission or by Agreement States, to the extent that such management and storage operations are not subject to the provisions of part 190 of title 40; and

(b) Radiation doses received by members of the public as a result of the management and storage of spent nuclear fuel or high-level or transuranic wastes at any disposal facility that is operated by the Department of Energy and that is not regulated by the Commission or by Agreement States.

§ 191.02 Definitions.

Unless otherwise indicated in this subpart, all terms shall have the same meaning as in Subpart A of Part 190.

(a) *Agency* means the Environmental Protection Agency.

(b) *Administrator* means the Administrator of the Environmental Protection Agency.

(c) *Commission* means the Nuclear Regulatory Commission.

(d) *Department* means the Department of Energy.

(e) *NWPA* means the Nuclear Waste Policy Act of 1982 (Pub. L. 97–425).

(f) *Agreement State* means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919).

(g) *Spent nuclear fuel* means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

(h) *High-level radioactive waste*, as used in this part, means high-level radioactive waste as defined in the Nuclear Waste Policy Act of 1982 (Pub. L. 97–425).

(i) *Transuranic radioactive waste*, as used in this part, means waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes, with half-lives greater than twenty years, per gram of waste, except for: (1) High-level radioactive wastes; (2) wastes that the Department has determined, with the concurrence of the Administrator, do not need the degree of isolation required by this part; or (3) wastes that the Commission has approved for disposal on a case-by-case basis in accordance with 10 CFR Part 61.

(j) *Radioactive waste*, as used in this part, means the high-level and transuranic radioactive waste covered by this part.

(k) *Storage* means retention of spent nuclear fuel or radioactive wastes with the intent and capability to readily retrieve such fuel or waste for subsequent use, processing, or disposal.

(l) *Disposal* means permanent isolation of spent nuclear fuel or radioactive waste from the accessible environment with no intent of recovery, whether or not such isolation permits the recovery of such fuel or waste. For example, disposal of waste in a mined geologic repository occurs when all of the shafts to the repository are backfilled and sealed.

(m) *Management* means any activity, operation, or process (except for transportation) conducted to prepare spent nuclear fuel or radioactive waste for storage or disposal, or the activities associated with placing such fuel or waste in a disposal system.

(n) *Site* means an area contained within the boundary of a location under the effective control of persons possessing or using spent nuclear fuel or radioactive waste that are involved in any activity, operation, or process covered by this subpart.

(o) *General environment* means the total terrestrial, atmospheric, and aquatic environments outside sites within which any activity, operation, or process associated with the management and storage of spent nuclear fuel or radioactive waste is conducted.

(p) *Member of the public* means any individual except during the time when that individual is a worker engaged in any activity, operation, or process that is covered by the Atomic Energy Act of 1954, as amended.

(q) *Critical organ* means the most exposed human organ or tissue exclusive of the integumentary system (skin) and the cornea.

§ 191.03 Standards.

(a) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities regulated by the Commission or by Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from: (1) Discharges of radioactive material and direct radiation from such management and storage and (2) all operations covered by Part 190; shall not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other critical organ.

(b) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities for the disposal of such fuel or waste that are operated by the Department and that are not regulated by the Commission or Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from discharges of radioactive material and direct radiation from such management and storage shall not exceed 25 millirems to the whole body and 75 millirems to any critical organ.

§ 191.04 Alternative standards.

(a) The Administrator may issue alternative standards from those standards established in §191.03(b) for waste management and storage activities at facilities that are not regulated by the Commission or Agreement States if, upon review of an application for such alternative standards:

(1) The Administrator determines that such alternative standards will prevent any member of the public from receiving a continuous exposure of more than 100 millirems per year dose equivalent and an infrequent exposure of more than 500 millirems dose equivalent in a year from all sources, excluding natural background and medical procedures; and

(2) The Administrator promptly makes a matter of public record the degree to which continued operation of the facility is expected to result in levels in excess of the standards specified in §191.03(b).

(b) An application for alternative standards shall be submitted as soon as possible after the Department determines that continued operation of a facility will exceed the levels specified in §191.03(b) and shall include all information necessary for the Administrator to make the determinations called for in §191.04(a).

(c) Requests for alternative standards shall be submitted to the Administrator, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

[50 FR 38084, Sept. 19, 1985, as amended at 65 FR 47325, Aug. 2, 2000]

§ 191.05 Effective date.

The standards in this subpart shall be effective on November 18, 1985.

Subpart B—Environmental Standards for Disposal

§ 191.11 Applicability.

(a) This subpart applies to:

(1) Radioactive materials released into the accessible environment as a result of the disposal of spent nuclear fuel or high-level or transuranic radioactive wastes;

(2) Radiation doses received by members of the public as a result of such disposal; and

(3) Radioactive contamination of certain sources of ground water in the vicinity of disposal systems for such fuel or wastes.

(b) This subpart does not apply to:

(1) Disposal directly into the oceans or ocean sediments;

(2) Wastes disposed of before November 18, 1985; and

(3) The characterization, licensing, construction, operation, or closure of any site required to be characterized under section 113(a) of Public Law 97–425, 96 Stat. 2201.

[50 FR 38084, Sept. 19, 1985, as amended at 58 FR 66414, Dec. 20, 1993]

§ 191.12 Definitions.

Unless otherwise indicated in this subpart, all terms shall have the same meaning as in subpart A of this part.

Accessible environment means: (1) The atmosphere; (2) land surfaces; (3) surface waters; (4) oceans; and (5) all of the lithosphere that is beyond the controlled area.

Active institutional control means: (1) Controlling access to a disposal site by any means other than passive institutional controls; (2) performing maintenance operations or remedial actions at a site, (3) controlling or cleaning up releases from a site, or (4) monitoring parameters related to disposal system performance.

Annual committed effective dose means the committed effective dose resulting from one-year intake of radionuclides released plus the annual effective dose caused by direct radiation from facilities or activities subject to subparts B and C of this part.

Aquifer means an underground geological formation, group of formations, or part of a formation that is capable of yielding a significant amount of water to a well or spring.

Barrier means any material or structure that prevents or substantially delays movement of water or radionuclides toward the accessible environment. For example, a barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides.

Controlled area means: (1) A surface location, to be identified by passive institutional controls, that encompasses no more than 100 square kilometers and extends horizontally no more than five kilometers in any direction from the outer boundary of the original location of the radioactive wastes in a disposal system; and (2) the subsurface underlying such a surface location.

Disposal system means any combination of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal.

Dose equivalent means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its spatial distribution in the body; the unit of dose equivalent is the ''rem'' (''sievert'' in SI units).

Effective dose means the sum over specified tissues of the products of the dose equivalent received following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. This allows the various tissue-specific health risks to be summed into an overall health risk. The method used to calculate effective dose is described in appendix B of this part.

Ground water means water below the land surface in a zone of saturation.

Heavy metal means all uranium, plutonium, or thorium placed into a nuclear reactor.

Implementing agency means:

(1) The Commission for facilities licensed by the Commission;

(2) The Agency for those implementation responsibilities for the Waste Isolation Pilot Plant, under this part, given to the Agency by the Waste Isolation Pilot Plant Land Withdrawal Act (Pub. L. 102–579, 106 Stat. 4777) which, for the purposes of this part, are:

(i) Determinations by the Agency that the Waste Isolation Pilot Plant is in compliance with subpart A of this part;

(ii) Issuance of criteria for the certifications of compliance with subparts B and C of this part of the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iii) Certifications of compliance with subparts B and C of this part of

the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iv) If the initial certification is made, periodic recertification of the Waste Isolation Pilot Plant's continued compliance with subparts B and C of this part;

(v) Review and comment on performance assessment reports of the Waste Isolation Pilot Plant; and

(vi) Concurrence by the Agency with the Department's determination under §191.02(i) that certain wastes do not need the degree of isolation required by subparts B and C of this part; and

(3) The Department of Energy for any other disposal facility and all other implementation responsibilities for the Waste Isolation Pilot Plant, under this part, not given to the Agency.

International System of Units is the version of the metric system which has been established by the International Bureau of Weights and Measures and is administered in the United States by the National Institute of Standards and Technology. The abbreviation for this system is ''SI.''

Lithosphere means the solid part of the Earth below the surface, including any ground water contained within it.

Passive institutional control means: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

Performance assessment means an analysis that: (1) Identifies the processes and events that might affect the disposal system; (2) examines the effects of these processes and events on the performance of the disposal system; and (3) estimates the cumulative releases of radionuclides, considering the associated uncertainties, caused by all significant processes and events. These estimates shall be incorporated into an overall probability distribution of cumulative release to the extent practicable.

Radioactive material means matter composed of or containing radionuclides, with radiological half-lives greater than 20 years, subject to the Atomic Energy Act of 1954, as amended.

SI unit means a unit of measure in the International System of Units.

Sievert is the SI unit of effective dose and is equal to 100 rem or one joule per kilogram. The abbreviation is ''Sv.''

Undisturbed performance means the predicted behavior of a disposal system, including consideration of the uncertainties in predicted behavior, if the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events.

Waste, as used in this subpart, means any spent nuclear fuel or radioactive waste isolated in a disposal system.

Waste form means the materials comprising the radioactive components of waste and any encapsulating or stabilizing matrix.

[50 FR 38084, Sept. 19, 1985, as amended at 58 FR 66414, Dec. 20, 1993]

§191.13 Containment requirements.

(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system shall:

(1) Have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to Table 1 (appendix A); and

(2) Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (appendix A).

(b) Performance assessments need not provide complete assurance that the requirements of §191.13(a) will be met. Because of the long time period involved and the nature of the events and processes 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 §191.13 (a) will be achieved.

§191.14 Assurance requirements.

To provide the confidence needed for long-term compliance with the requirements of §191.13, disposal of spent nuclear fuel or high-level or transuranic wastes shall be conducted in accordance with the following provisions, except that these provisions do not apply to facilities regulated by the Commission (see 10 CFR Part 60 for comparable provisions applicable to facilities regulated by the Commission):

(a) Active institutional controls over disposal sites should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess isolation of the wastes from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal.

(b) Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring.

(c) Disposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location.

(d) Disposal systems shall use different types of barriers to isolate the wastes from the accessible environment. Both engineered and natural barriers shall be included.

(e) Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. Resources to be considered shall include minerals, petroleum or natural gas, valuable geologic formations, and ground waters that are either irreplaceable because there is no reasonable alternative source of drinking water available for substantial populations or that are vital to the preservation of unique and sensitive ecosystems. Such places shall not be used for disposal of the wastes covered by this part unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future.

(f) Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal.

§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 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.

[58 FR 66414, Dec. 20, 1993]

§ 191.16 Alternative provisions for disposal.

The Administrator may, by rule, substitute for any of the provisions of subpart B alternative provisions chosen after:

(a) The alternative provisions have been proposed for public comment in the FEDERAL REGISTER together with information describing the costs, risks, and benefits of disposal in accordance with the alternative provisions and the reasons why compliance with the existing provisions of Subpart B appears inappropriate;

(b) A public comment period of at least 90 days has been completed, during which an opportunity for public hearings in affected areas of the country has been provided; and

(c) The public comments received have been fully considered in developing the final version of such alternative provisions.

[50 FR 38084, Sept. 19, 1985. Redesignated at 58 FR 66414, Dec. 20, 1993]

§ 191.17 Effective date.

The standards in this subpart shall be effective on November 18, 1985.

[50 FR 38084, Sept. 19, 1985; 50 FR 40003, Oct. 1, 1985. Redesignated at 58 FR 66414, Dec. 20, 1993]

Subpart C—Environmental Standards for Ground-Water Protection

SOURCE: 58 FR 66415, Dec. 20, 1993, unless otherwise noted.

§ 191.21 Applicability.

(a) This subpart applies to:

(1) Radiation doses received by members of the public as a result of activities subject to subpart B of this part; and

(2) Radioactive contamination of underground sources of drinking water in the accessible environment as a result of such activities.

(b) This subpart does not apply to:

(1) Disposal directly into the oceans or ocean sediments;

(2) Wastes disposed of before the effective date of this subpart; and

(3) The characterization, licensing, construction, operation, or closure of any site required to be characterized under section 113(a) of Public Law 97–425, 96 Stat. 2201.

§ 191.22 Definitions.

Unless otherwise indicated in this subpart, all terms have the same meaning as in subparts A and B of this part.

Public water system means a system for the provision to the public of piped water for human consumption, if such system has at least fifteen service connections or regularly serves at least twenty-five individuals. Such term includes:

(1) Any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system; and

(2) Any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system.

Total dissolved solids means the total dissolved (filterable) solids in water as determined by use of the method specified in 40 CFR part 136.

Underground source of drinking water means an aquifer or its portion which:

(1) Supplies any public water system; or

(2) Contains a sufficient quantity of ground water to supply a public water system; and

(i) Currently supplies drinking water for human consumption; or

(ii) Contains fewer than 10,000 milligrams of total dissolved solids per liter.

§ 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.

(b) [Reserved]

§ 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 (¼) mile 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.

§ 191.25 Compliance with other Federal regulations.

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

§ 191.26 Alternative provisions.

The Administrator may, by rule, substitute for any of the provisions of this subpart alternative provisions chosen after:

(a) The alternative provisions have been proposed for public comment in the FEDERAL REGISTER together with information describing the costs, risks, and benefits of disposal in accordance with the alternative provisions and the reasons why compliance with the existing provisions of this subpart appears inappropriate;

(b) A public comment period of at least 90 days has been completed, during which an opportunity for public hearings in affected areas of the country has been provided; and

(c) The public comments received have been fully considered in developing the final version of such alternative provisions.

§ 191.27 Effective date.

The standards in this subpart shall be effective on January 19, 1994.

APPENDIX A TO PART 191—TABLE FOR SUBPART B

TABLE 1—RELEASE LIMITS FOR CONTAINMENT REQUIREMENTS

[Cumulative releases to the accessible environment for 10,000 years after disposal]

Radionuclide	Release limit per 1,000 MTHM or other unit of waste (see notes) (curies)
Americium-241 or -243	100
Carbon-14	100
Cesium-135 or -137	1,000
Iodine-129	100
Neptunium-237	100
Plutonium-238, -239, -240, or -242	100
Radium-226	100
Strontium-90	1,000
Technetium-99	10,000
Thorium-230 or -232	10
Tin-126	1,000
Uranium-233, -234, -235, -236, or -238	100
Any other alpha-emitting radionuclide with a half-life greater than 20 years	100
Any other radionuclide with a half-life greater than 20 years that does not emit alpha particles	1,000

APPLICATION OF TABLE 1

NOTE 1: *Units of Waste*. The Release Limits in Table 1 apply to the amount of wastes in any one of the following:

(a) An amount of spent nuclear fuel containing 1,000 metric tons of heavy metal (MTHM) exposed to a burnup between 25,000 megawatt-days per metric ton of heavy metal (MWd/MTHM) and 40,000 MWd/MTHM;

(b) The high-level radioactive wastes generated from reprocessing each 1,000 MTHM exposed to a burnup between 25,000 MWd/MTHM and 40,000 MWd/MTHM;

(c) Each 100,000,000 curies of gamma or beta-emitting radionuclides with half-lives greater than 20 years but less than 100 years (for use as discussed in Note 5 or with materials that are identified by the Commission as high-level radioactive waste in accordance with part B of the definition of high-level waste in the NWPA);

(d) Each 1,000,000 curies of other radionuclides (*i.e.*, gamma or beta-emitters with half-lives greater than 100 years or any alpha-emitters with half-lives greater than 20 years) (for use as discussed in Note 5 or with materials that are identified by the

Commission as high-level radioactive waste in accordance with part B of the definition of high-level waste in the NWPA); or

(e) An amount of transuranic (TRU) wastes containing one million curies of alpha-emitting transuranic radionuclides with half-lives greater than 20 years.

NOTE 2: *Release Limits for Specific Disposal Systems.* To develop Release Limits for a particular disposal system, the quantities in Table 1 shall be adjusted for the amount of waste included in the disposal system compared to the various units of waste defined in Note 1. For example:

(a) If a particular disposal system contained the high-level wastes from 50,000 MTHM, the Release Limits for that system would be the quantities in Table 1 multiplied by 50 (50,000 MTHM divided by 1,000 MTHM).

(b) If a particular disposal system contained three million curies of alpha-emitting transuranic wastes, the Release Limits for that system would be the quantities in Table 1 multiplied by three (three million curies divided by one million curies).

(c) If a particular disposal system contained both the high-level wastes from 50,000 MTHM *and* 5 million curies of alpha-emitting transuranic wastes, the Release Limits for that system would be the quantities in Table 1 multiplied by 55:

$$\frac{50{,}000\,\text{MTHM}}{1{,}000\,\text{MTHM}} + \frac{5{,}000{,}000\,\text{curies TRU}}{1{,}000{,}000\,\text{curies TRU}} = 55$$

NOTE 3: *Adjustments for Reactor Fuels with Different Burnup.* For disposal systems containing reactor fuels (or the high-level wastes from reactor fuels) exposed to an average burnup of less than 25,000 MWd/MTHM or greater than 40,000 MWd/MTHM, the units of waste defined in (a) and (b) of Note 1 shall be adjusted. The unit shall be multiplied by the ratio of 30,000 MWd/MTHM divided by the fuel's actual average burnup, except that a value of 5,000 MWd/MTHM may be used when the average fuel burnup is below 5,000 MWd/MTHM and a value of 100,000 MWd/MTHM shall be used when the average fuel burnup is above 100,000 MWd/MTHM. This adjusted unit of waste shall then be used in determining the Release Limits for the disposal system.

For example, if a particular disposal system contained only high-level wastes with an average burnup of 3,000 MWd/MTHM, the unit of waste for that disposal system would be:

$$1{,}000\,\text{MTHM} \times \frac{(30{,}000)}{(5{,}000)} = 6{,}000\,\text{MTHM}$$

If that disposal system contained the high-level wastes from 60,000 MTHM (with an average burnup of 3,000 MWd/MTHM), then the Release Limits for that system would be the quantities in Table 1 multiplied by ten:

$$\frac{60{,}000\ \text{MTHM}}{6{,}000\ \text{MTHM}} = 10$$

which is the same as:

$$\frac{60{,}000\,\text{MTHM}}{1{,}000\,\text{MTHM}} \times \frac{(5{,}000\,\text{MWd/MTHM})}{(30{,}000\,\text{MWd/MTHM})} = 10$$

NOTE 4: *Treatment of Fractionated High-Level Wastes.* In some cases, a high-level waste stream from reprocessing spent nuclear fuel may have been (or will be) separated into two or more high-level waste components destined for different disposal systems. In such cases, the implementing agency may allocate the Release Limit multiplier (based upon the original MTHM and the average fuel burnup of the high-level waste stream) among the various disposal systems as it chooses, provided that the total Release Limit multiplier used for that waste stream at all of its disposal systems may not exceed the Release Limit multiplier that would be used if the entire waste stream were disposed of in one disposal system.

NOTE 5: *Treatment of Wastes with Poorly Known Burnups or Original MTHM.* In some cases, the records associated with particular high-level waste streams may not be adequate to accurately determine the original metric tons of heavy metal in the reactor fuel that created the waste, or to determine the average burnup that the fuel was exposed to. If the uncertainties are such that the original amount of heavy metal or the average fuel burnup for particular high-level waste streams cannot be quantified, the units of waste derived from (a) and (b) of Note 1 shall no longer be used. Instead, the units of waste defined in (c) and (d) of Note 1 shall be used for such high-level waste streams. If the uncertainties in such information allow a range of values to be associated with the original amount of heavy metal or the average fuel burnup, then the calculations described in previous Notes will be conducted using the values that result in the smallest Release Limits, except that the Release Limits need not be smaller than those that would be calculated using the units of waste defined in (c) and (d) of Note 1.

NOTE 6: *Uses of Release Limits to Determine Compliance with §191.13* Once release limits for a particular disposal system have been determined in accordance with Notes 1 through 5, these release limits shall be used to determine compliance with the requirements of §191.13 as follows. In cases where a mixture of radionuclides is projected to be released to the accessible environment, the limiting values shall be determined as follows: For each radionuclide in the mixture, determine the ratio between the cumulative release quantity projected over 10,000 years

and the limit for that radionuclide as determined from Table 1 and Notes 1 through 5. The sum of such ratios for all the radionuclides in the mixture may not exceed one with regard to §191.13(a)(1) and may not exceed ten with regard to §191.13(a)(2).

For example, if radionuclides A, B, and C are projected to be released in amounts Q_a, Q_b, and Q_c, and if the applicable Release Limits are RL_a, RL_b, and RL_c, then the cumulative releases over 10,000 years shall be limited so that the following relationship exists:

$$\frac{Q_a}{RL_a} + \frac{Q_b}{RL_b} + \frac{Q_c}{RL_c} \leq 1$$

[50 FR 38084, Sept. 19, 1985, as amended at 58 FR 66415, Dec. 20, 1993]

APPENDIX B TO PART 191—CALCULATION OF ANNUAL COMMITTED EFFECTIVE DOSE

I. Equivalent Dose

The calculation of the committed effective dose (CED) begins with the determination of the equivalent dose, H_T, to a tissue or organ, T, listed in Table B.2 below by using the equation:

$$H_T = \sum_R D_{T,R} \cdot w_R$$

where $D_{T,R}$ is the absorbed dose in rads (one gray, an SI unit, equals 100 rads) averaged over the tissue or organ, T, due to radiation type, R, and w_R is the radiation weighting factor which is given in Table B.1 below. The unit of equivalent dose is the rem (sievert, in SI units).

TABLE B.1—RADIATION WEIGHTING FACTORS, w_R [1]

Radiation type and energy range [2]	w_R value
Photons, all energies	1
Electrons and muons, all energies	1
Neutrons, energy <10 keV	5
10 keV to 100 keV	10
>100 keV to 2 MeV	20
>2 MeV to 20 MeV	10
>20 MeV	5
Protons, other than recoil protons, >2 MeV	5
Alpha particles, fission fragments, heavy nuclei	20

[1] All values relate to the radiation incident on the body or, for internal sources, emitted from the source.

[2] See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

II. Effective Dose

The next step is the calculation of the effective dose, E. The probability of occurrence of a stochastic effect in a tissue or organ is assumed to be proportional to the equivalent dose in the tissue or organ. The constant of proportionality differs for the various tissues of the body, but in assessing health detriment the total risk is required. This is taken into account using the tissue weighting factors, w_T in Table B.2, which represent the proportion of the stochastic risk resulting from irradiation of the tissue or organ to the total risk when the whole body is irradiated uniformly and H_T is the equivalent dose in the tissue or organ, T, in the equation:

$$E = \sum w_T \cdot H_T$$

TABLE B.2—TISSUE WEIGHTING FACTORS, w_T [1]

Tissue or organ	w_T value
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[2] 0.30

[1] The values are considered to be appropriate for protection for individuals of both sexes and all ages.

[2] For purposes of calculation, the remainder is comprised of the five tissues or organs not specifically listed in Table B.2 that receive the highest dose equivalents; a weighting factor of 0.06 is applied to each of them, including the various sections of the gastrointestinal tract which are treated as separate organs. This covers all tissues and organs except the hands and forearms, the feet and ankles, the skin and the lens of the eye. The excepted tissues and organs should be excluded from the computation of H_E.

III. Annual Committed Tissue or Organ Equivalent Dose

For internal irradiation from incorporated radionuclides, the total absorbed dose will be spread out in time, being gradually delivered as the radionuclide decays. The time distribution of the absorbed dose rate will vary with the radionuclide, its form, the mode of intake and the tissue within which it is incorporated. To take account of this distribution the quantity committed equivalent dose, $H_T(\tau)$ where is the integration time in years following an intake over any particular year, is used and is the integral over time of the equivalent dose rate in a particular tissue or organ that will be received by an individual following an intake of radioactive material into the body. The time period, τ, is taken as 50 years as an average time of exposure following intake:

$$H_T(\tau) = \int_{t_0}^{t_0+50} H_T(t)dt$$

for a single intake of activity at time t_0 where $H_T(t)$ is the relevant equivalent-dose rate in a tissue or organ at time t. For the purposes of this part, the previously mentioned single intake may be considered to be an annual intake.

IV. Annual Committed Effective Dose

If the committed equivalent doses to the individual tissues or organs resulting from an annual intake are multiplied by the appropriate weighting factors, w_T, and then summed, the result will be the annual committed effective dose, $E(\tau)$:

$$E(\tau) = \sum_T w_T \cdot H_T(\tau).$$

[58 FR 66415, Dec. 20, 1993]

APPENDIX C TO PART 191—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.]

The Agency believes that the implementing agencies must determine compliance with §§191.13, 191.15, and 191.16 of subpart B by evaluating long-term predictions of disposal system performance. Determining compliance with §191.13 will also involve predicting the likelihood of events and processes that may disturb the disposal system. In making these various predictions, it will be appropriate for the implementing agencies to make use of rather complex computational models, analytical theories, and prevalent expert judgment relevant to the numerical predictions. Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate; the implementing agencies may choose to supplement such predictions with qualitative judgments as well. Because the procedures for determining compliance with subpart B have not been formulated and tested yet, this appendix to the rule indicates the Agency's assumptions regarding certain issues that may arise when implementing §§191.13, 191.15, and 191.16. Most of this guidance applies to any type of disposal system for the wastes covered by this rule. However, several sections apply only to disposal in mined geologic repositories and would be inappropriate for other types of disposal systems.

Consideration of Total Disposal System. When predicting disposal system performance, the Agency assumes that reasonable projections of the protection expected from all of the engineered and natural barriers of a disposal system will be considered. Portions of the disposal system should not be disregarded, even if projected performance is uncertain, except for portions of the system that make negligible contributions to the overall isolation provided by the disposal system.

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 changed by such omissions.

Compliance with §191.13. The Agency assumes that, whenever practicable, the implementing agency will assemble all of the results of the performance assessments to determine compliance with §191.13 into a ''complementary cumulative distribution function'' that indicates the probability of exceeding various levels of cumulative release. When the uncertainties in parameters are considered in a performance assessment, the effects of the uncertainties considered can be incorporated into a single such distribution function for each disposal system considered. The Agency assumes that a disposal system can be considered to be in compliance with §191.13 if this single distribution function meets the requirements of §191.13(a).

Compliance with §§191.15 and 191.16. When the uncertainties in undisturbed performance of a disposal system are considered, the implementing agencies need not require that a very large percentage of the range of estimated radiation exposures or radionuclide concentrations fall below limits established in §§191.15 and 191.16, respectively. The Agency assumes that compliance can be determined based upon ''best estimate'' predictions (e.g., the mean or the median of the appropriate distribution, whichever is higher).

Institutional Controls. To comply with §191.14(a), the implementing agency will assume that none of the active institutional controls prevent or reduce radionuclide releases for more than 100 years after disposal. However, the Federal Government is committed to retaining ownership of all disposal sites for spent nuclear fuel and high-level and transuranic radioactive wastes and will establish appropriate markers and records, consistent with §191.14(c). The Agency assumes that, as long as such passive institutional controls endure and are understood, they: (1) Can be effective in deterring systematic or persistent exploitation of these

disposal sites; and (2) can reduce the likelihood of inadvertent, intermittent human intrusion to a degree to be determined by the implementing agency. However, the Agency believes that passive institutional controls can never be assumed to eliminate the chance of inadvertent and intermittent human intrusion into these disposal sites.

Consideration of Inadvertent Human Intrusion into Geologic Repositories. The most speculative potential disruptions of a mined geologic repository are those associated with inadvertent human intrusion. Some types of intrusion would have virtually no effect on a repository's containment of waste. On the other hand, it is possible to conceive of intrusions (involving widespread societal loss of knowledge regarding radioactive wastes) that could result in major disruptions that no reasonable repository selection or design precautions could alleviate. The Agency believes that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or use of passive controls (although passive institutional controls should not be assumed to completely rule out the possibility of intrusion). Therefore, inadvertent and intermittent intrusion by exploratory drilling for resources (other than any provided by the disposal system itself) can be the most severe intrusion scenario assumed by the implementing agencies. Furthermore, the implementing agencies can assume that passive institutional controls or the intruders' own exploratory procedures are adequate for the intruders to soon detect, or be warned of, the incompatibility of the area with their activities.

Frequency and Severity of Inadvertent Human Intrusion into Geologic Repositories. The implementing agencies should consider the effects of each particular disposal system's site, design, and passive institutional controls in judging the likelihood and consequences of such inadvertent exploratory drilling. However, the Agency assumes that the likelihood of such inadvertent and intermittent drilling need not be taken to be greater than 30 boreholes per square kilometer of repository area per 10,000 years for geologic repositories in proximity to sedimentary rock formations, or more than 3 boreholes per square kilometer per 10,000 years for repositories in other geologic formations. Furthermore, the Agency assumes that the consequences of such inadvertent drilling need not be assumed to be more severe than: (1) Direct release to the land surface of all the ground water in the repository horizon that would promptly flow through the newly created borehole to the surface due to natural lithostatic pressure—or (if pumping would be required to raise water to the surface) release of 200 cubic meters of ground water pumped to the surface if that much water is readily available to be pumped; and (2) creation of a ground water flow path with a permeability typical of a borehole filled by the soil or gravel that would normally settle into an open hole over time—not the permeability of a carefully sealed borehole.

[50 FR 38084, Sept. 19, 1985. Redesignated and amended at 58 FR 66415, Dec. 20, 1993]

PART 192—HEALTH AND ENVIRONMENTAL PROTECTION STANDARDS FOR URANIUM AND THORIUM MILL TAILINGS

Subpart A—Standards for the Control of Residual Radioactive Materials from Inactive Uranium Processing Sites

Sec.

Subpart B—Standards for Cleanup of Land and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites

Subpart C—Implementation

Subpart D—Standards for Management of Uranium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended

Subpart E—Standards for Management of Thorium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended

AUTHORITY: Sec. 275 of the Atomic Energy Act of 1954, 42 U.S.C. 2022, as added by the Uranium Mill Tailings Radiation Control Act of 1978, Pub. L. 95–604, as amended.

SOURCE: 48 FR 602, Jan. 5, 1983, unless otherwise noted.

Subpart A—Standards for the Control of Residual Radioactive Materials from Inactive Uranium Processing Sites

§ 192.00 Applicability.

This subpart applies to the control of residual radioactive material at designated processing or depository sites under section 108 of the Uranium Mill Tailings Radiation Control Act of 1978 (henceforth designated ''the Act''), and to restoration of such sites following any use of subsurface minerals under section 104(h) of the Act.

(2) Other wastes (which the Secretary determines to be radioactive) at a processing site which relate to such processing, including any residual stock of unprocessed ores or low-grade materials.

(b) *Remedial* action means any action performed under section 108 of the Act.

(c) *Control* means any remedial action intended to stabilize, inhibit future misuse of, or reduce emissions or effluents from residual radioactive materials.

(d) *Disposal site* means the region within the smallest perimeter of residual radioactive material (excluding cover materials) following completion of control

§ 192.01 Definitions.

(a) *Residual radioactive material* means:

(1) Waste (which the Secretary determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores; and activities.

(e) *Depository site* means a site (other than a processing site) selected under Section 104(b) or 105(b) of the Act.

(f) *Curie* (Ci) means the amount of radioactive material that produces 37 billion nuclear transformation per second. One picocurie (pCi) = 10^{-12} Ci.

(g) *Act* means the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

(h) *Administrator* means the Administrator of the Environmental Protection Agency.

(i) *Secretary* means the Secretary of Energy.

(j) *Commission* means the Nuclear Regulatory Commission.

(k) *Indian tribe* means any tribe, band, clan, group, pueblo, or community of Indians recognized as eligible for services provided by the Secretary of the Interior to Indians.

(l) *Processing site* means:

(1) Any site, including the mill, designated by the Secretary under Section 102(a)(1) of the Act; and

(2) Any other real property or improvement thereon which is in the vicinity of such site, and is determined by the Secretary, in consultation with the Commission, to be contaminated with residual radioactive materials derived from such site.

(m) *Tailings* means the remaining portion of a metal-bearing ore after some or all of such metal, such as uranium, has been extracted.

(n) *Disposal period* means the period of time beginning March 7, 1983 and ending with the completion of all subpart A requirements specified under a plan for remedial action except those specified in § 192.03 and § 192.04.

(o) *Plan for remedial action* means a written plan (or plans) for disposal and cleanup of residual radioactive materials associated with a processing site that incorporates the results of site characterization studies, environmental assessments or impact statements, and engineering assessments so as to satisfy the requirements of subparts A and B of this part. The plan(s) shall be developed in accordance with the provisions of Section 108(a) of the Act with the concurrence of the Commission and in consultation, as appropriate, with the Indian Tribe and the Secretary of Interior.

(p) *Post-disposal period* means the period of time beginning immediately after the disposal period and ending at

termination of the monitoring period established under § 192.03.

(q) *Groundwater* means water below the ground surface in a zone of saturation.

(r) *Underground source of drinking water* means an aquifer or its portion:

(1)(i) Which supplies any public water system as defined in § 141.2 of this chapter; or

(ii) Which contains a sufficient quantity of groundwater to supply a public water system; and

(A) Currently supplies drinking water for human consumption; or

(B) Contains fewer than 10,000 mg/l total dissolved solids; and

(2) Which is not an exempted aquifer as defined in § 144.7 of this chapter.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2865, Jan. 11, 1995]

§ 192.02 Standards.

Control of residual radioactive materials and their listed constituents shall be designed[1] to:

(a) Be effective for up to one thousand years, to the extent reasonably achievable, and, in any case, for at least 200 years, and,

(b) Provide reasonable assurance that releases of radon-222 from residual radioactive material to the atmosphere will not:

(1) Exceed an average[2] release rate of 20 picocuries per square meter per second, or

(2) Increase the annual average concentration of radon-222 in air at or above any location outside the disposal site by more than one-half picocurie per liter.

(c) Provide reasonable assurance of conformance with the following groundwater protection provisions:

(1) The Secretary shall, on a site-specific basis, determine which of the constituents listed in Appendix I to Part 192 are present in or reasonably derived from residual radioactive materials and shall establish a monitoring program adequate to determine background levels of each such constituent in groundwater at each disposal site.

(2) The Secretary shall comply with conditions specified in a plan for remedial action which includes engineering specifications for a system of disposal designed to ensure that constituents identified under paragraph (c)(1) of this section entering the groundwater from a depository site (or a processing site, if residual radioactive materials are retained on the site) will not exceed the concentration limits established under paragraph (c)(3) of this section (or the supplemental standards established under § 192.22) in the uppermost aquifer underlying the site beyond the point of compliance established under paragraph (c)(4) of this section.

(3) Concentration limits:

(i) Concentration limits shall be determined in the groundwater for listed constituents identified under paragraph (c)(1) of this section. The concentration of a listed constituent in groundwater must not exceed:

(A) The background level of that constituent in the groundwater; or

(B) For any of the constituents listed in Table 1 to subpart A, the respective value given in that Table if the background level of the constituent is below the value given in the Table; or

(C) An alternate concentration limit established pursuant to paragraph (c)(3)(ii) of this section.

(ii)(A) The Secretary may apply an alternate concentration limit if, after considering remedial or corrective actions to achieve the levels specified in paragraphs (c)(3)(i)(A) and (B) of this section, he has determined that the constituent will not pose a substantial present or potential hazard to human health and the environment as long as the alternate concentration limit is not exceeded, and the Commission has concurred.

(B) In considering the present or potential hazard to human health and the

[1] Because the standard applies to design, monitoring after disposal is not required to demonstrate compliance with respect to § 192.02(a) and (b).

[2] This average shall apply over the entire surface of the disposal site and over at least a one-year period. Radon will come from both residual radioactive materials and from materials covering them. Radon emissions from the covering materials should be estimated as part of developing a remedial action plan for each site. The standard, however, applies only to emissions from residual radioactive materials to the atmosphere.

environment of alternate concentration limits, the following factors shall be considered:

(*1*) Potential adverse effects on groundwater quality, considering:

(*i*) The physical and chemical characteristics of constituents in the residual radioactive material at the site, including their potential for migration;

(*ii*) The hydrogeological characteristics of the site and surrounding land;

(*iii*) The quantity of groundwater and the direction of groundwater flow;

(*iv*) The proximity and withdrawal rates of groundwater users;

(*v*) The current and future uses of groundwater in the region surrounding the site;

(*vi*) The existing quality of groundwater, including other sources of contamination and their cumulative impact on the groundwater quality;

(*vii*) The potential for health risks caused by human exposure to constituents;

(*viii*) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to constituents;

(*ix*) The persistence and permanence of the potential adverse effects;

(*x*) The presence of underground sources of drinking water and exempted aquifers identified under §144.7 of this chapter; and

(*2*) Potential adverse effects on hydraulically-connected surface-water quality, considering:

(*i*) The volume and physical and chemical characteristics of the residual radioactive material at the site;

(*ii*) The hydrogeological characteristics of the site and surrounding land;

(*iii*) The quantity and quality of groundwater, and the direction of groundwater flow;

(*iv*) The patterns of rainfall in the region;

(*v*) The proximity of the site to surface waters;

(*vi*) The current and future uses of surface waters in the region surrounding the site and any water quality standards established for those surface waters;

(*vii*) The existing quality of surface water, including other sources of contamination and their cumulative impact on surface water quality;

(*viii*) The potential for health risks caused by human exposure to constituents;

(*ix*) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to constituents; and

(*x*) The persistence and permanence of the potential adverse effects.

(4) Point of compliance: The point of compliance is the location at which the groundwater concentration limits of paragraph (c)(3) of this section apply. The point of compliance is the intersection of a vertical plane with the uppermost aquifer underlying the site, located at the hydraulically downgradient limit of the disposal area plus the area taken up by any liner, dike, or other barrier designed to contain the residual radioactive material.

(d) Each site on which disposal occurs shall be designed and stabilized in a manner that minimizes the need for future maintenance.

[60 FR 2865, Jan. 11, 1995]

§192.03 Monitoring.

A groundwater monitoring plan shall be implemented, to be carried out over a period of time commencing upon completion of remedial actions taken to comply with the standards in §192.02, and of a duration which is adequate to demonstrate that future performance of the system of disposal can reasonably be expected to be in accordance with the design requirements of §192.02(c). This plan and the length of the monitoring period shall be modified to incorporate any corrective actions required under §192.04 or §192.12(c).

[60 FR 2866, Jan. 11, 1995]

§192.04 Corrective action.

If the groundwater concentration limits established for disposal sites under provisions of §192.02(c) are found or projected to be exceeded, a corrective action program shall be placed into operation as soon as is practicable, and in no event later than eighteen (18) months after a finding of exceedance. This corrective action program will restore the performance of the system of disposal to the original concentration limits established under

§ 192.02(c)(3), to the extent reasonably achievable, and, in any case, as a minimum shall:

(a) Conform with the groundwater provisions of § 192.02(c)(3), and

(b) Clean up groundwater in conformance with subpart B, modified as appropriate to apply to the disposal site.

[60 FR 2866, Jan. 11, 1995]

TABLE 1 TO SUBPART A OF PART 192—MAXIMUM CONCENTRATION OF CONSTITUENTS FOR GROUNDWATER PROTECTION

Constituent concentration [1]	Maximum
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chromium	0.05
Lead	0.05
Mercury	0.002
Selenium	0.01
Silver	0.05
Nitrate (as N)	10.
Molybdenum	0.1
Combined radium-226 and radium-228	5 pCi/liter
Combined uranium-234 and uranium-238 [2].	30 pCi/liter
Gross alpha-particle activity (excluding radon and uranium).	15 pCi/liter
Endrin (1,2,3,4,10,10-hexachloro-6,7-exposy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo,endo-5,8-dimethanonaphthalene).	0.0002
Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma insomer).	0.004
Methoxychlor (1,1,1-trichloro-2,2′-bis(p-methoxyphenylethane)).	0.1
Toxaphene (C_{10} H_{10} Cl_6, technical chlorinated camphene, 67–69 percent chlorine).	0.005
2,4-D (2,4-dichlorophenoxyacetic acid)	0.1
2,4,5-TP Silvex (2,4,5-trichlorophenoxypropionic acid).	0.01

[1] Milligrams per liter, unless stated otherwise.

[2] Where secular equilibrium obtains, this criterion will be satisfied by a concentration of 0.044 milligrams per liter (0.044 mg/l). For conditions of other than secular equilibrium, a corresponding value may be derived and applied, based on the measured site-specific ratio of the two isotopes of uranium.

[60 FR 2866, Jan. 11, 1995]

Subpart B—Standards for Cleanup of Land and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites

§ 192.10 Applicability.

This subpart applies to land and buildings that are part of any processing site designated by the Secretary of Energy under section 102 of the Act. section 101 of the Act, states, in part, that ''processing site'' means—

(a) Any site, including the mill, containing residual radioactive materials at which all or substantially all of the uranium was produced for sale to any Federal agency prior to January 1, 1971, under a contract with any Federal agency, except in the case of a site at or near Slick Rock, Colorado, unless—

(1) Such site was owned or controlled as of Januray 1, 1978, or is thereafter owned or controlled, by any Federal agency, or

(2) A license (issued by the (Nuclear Regulatory) Commission or its predecessor agency under the Atomic Energy Act of 1954 or by a State as permitted under section 274 of such Act) for the production at site of any uranium or thorium product derived from ores is in effect on January 1, 1978, or is issued or renewed after such date; and

(b) Any other real property or improvement thereon which—

(1) Is in the vicinity of such site, and

(2) Is determined by the Secretary, in consultation with the Commission, to be contaminated with residual radioactive materials derived from such site.

§ 192.11 Definitions.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as defined in subpart A.

(b) *Land* means any surface or subsurface land that is not part of a disposal site and is not covered by an occupiable building.

(c) *Working Level* (WL) means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts.

(d) *Soil* means all unconsolidated materials normally found on or near the surface of the earth including, but not limited to, silts, clays, sands, gravel, and small rocks.

(e) *Limited use groundwater* means groundwater that is not a current or potential source of drinking water because (1) the concentration of total dissolved solids is in excess of 10,000 mg/l,

or (2) widespread, ambient contamination not due to activities involving residual radioactive materials from a designated processing site exists that cannot be cleaned up using treatment methods reasonably employed in public water systems, or (3) the quantity of water reasonably available for sustained continuous use is less than 150 gallons per day. The parameters for determining the quantity of water reasonably available shall be determined by the Secretary with the concurrence of the Commission.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2866, Jan. 11, 1995]

§ 192.12 Standards.

Remedial actions shall be conducted so as to provide reasonable assurance that, *as a result of residual radioactive materials from any designated processing site:*

(a) The concentration of radium-226 in land averaged over any area of 100 square meters shall not exceed the background level by more than—

(1) 5 pCi/g, averaged over the first 15 cm of soil below the surface, and

(2) 15 pCi/g, averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(b) In any occupied or habitable building—

(1) The objective of remedial action shall be, and reasonable effort shall be made to achieve, an annual average (or equivalent) radon decay product concentration (including background) not to exceed 0.02 WL. In any case, the radon decay product concentration (including background) shall not exceed 0.03 WL, and

(2) The level of gamma radiation shall not exceed the background level by more than 20 microroentgens per hour.

(c) The Secretary shall comply with conditions specified in a plan for remedial action which provides that contamination of groundwater by listed constituents from residual radioactive material at any designated processing site (§ 192.01(1)) shall be brought into compliance as promptly as is reasonably achievable with the provisions of § 192.02(c)(3) or any supplemental standards established under § 192.22. For the purposes of this subpart:

(1) A monitoring program shall be carried out that is adequate to define backgroundwater quality and the areal extent and magnitude of groundwater contamination by listed constituents from residual radioactive materials (§ 192.02(c)(1)) and to monitor compliance with this subpart. The Secretary shall determine which of the constituents listed in Appendix I to part 192 are present in or could reasonably be derived from residual radioactive material at the site, and concentration limits shall be established in accordance with § 192.02(c)(3).

(2) (i) If the Secretary determines that sole reliance on active remedial procedures is not appropriate and that cleanup of the groundwater can be more reasonably accomplished in full or in part through natural flushing, then the period for remedial procedures may be extended. Such an extended period may extend to a term not to exceed 100 years if:

(A) The concentration limits established under this subpart are projected to be satisfied at the end of this extended period,

(B) Institutional control, having a high degree of permanence and which will effectively protect public health and the environment and satisfy beneficial uses of groundwater during the extended period and which is enforceable by the administrative or judicial branches of government entities, is instituted and maintained, as part of the remedial action, at the processing site and wherever contamination by listed constituents from residual radioactive materials is found in groundwater, or is projected to be found, and

(C) The groundwater is not currently and is not now projected to become a source for a public water system subject to provisions of the Safe Drinking Water Act during the extended period.

(ii) Remedial actions on groundwater conducted under this subpart may occur before or after actions under Section 104(f)(2) of the Act are initiated.

(3) Compliance with this subpart shall be demonstrated through the monitoring program established under paragraph (c)(1) of this section at those locations not beneath a disposal site

and its cover where groundwater contains listed constituents from residual radioactive material.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2867, Jan. 11, 1995]

Subpart C—Implementation

§ 192.20 Guidance for implementation.

Section 108 of the Act requires the Secretary of Energy to select and perform remedial actions with the concurrence of the Nuclear Regulatory Commission and the full participation of any State that pays part of the cost, and in consultation, as appropriate, with affected Indian Tribes and the Secretary of the Interior. These parties, in their respective roles under section 108, are referred to hereafter as ''the implementing agencies.'' The implementing agencies shall establish methods and procedures to provide ''reasonable assurance'' that the provisions of Subparts A and B are satisfied. This should be done as appropriate through use of analytic models and site-specific analyses, in the case of Subpart A, and for Subpart B through measurements performed within the accuracy of currently available types of field and laboratory instruments in conjunction with reasonable survey and sampling procedures. These methods and procedures may be varied to suit conditions at specific sites. In particular:

(a)(1) The purpose of Subpart A is to provide for long-term stabilization and isolation in order to inhibit misuse and spreading of residual radioactive materials, control releases of radon to air, and protect water. Subpart A may be implemented through analysis of the physical properties of the site and the control system and projection of the effects of natural processes over time. Events and processes that could significantly affect the average radon release rate from the entire disposal site should be considered. Phenomena that are localized or temporary, such as local cracking or burrowing of rodents, need to be taken into account only if their cumulative effect would be significant in determining compliance with the standard. Computational models, theories, and prevalent expert judgment may be used to decide that a control system design will satisfy the standard. The numerical range provided in the standard for the longevity of the effectiveness of the control of residual radioactive materials allows for consideration of the various factors affecting the longevity of control and stabilization methods and their costs. These factors have different levels of predictability and may vary for the different sites.

(2) Protection of water should be considered on a case-specific basis, drawing on hydrological and geochemical surveys and all other relevant data. The hydrologic and geologic assessment to be conducted at each site should include a monitoring program sufficient to establish background groundwater quality through one or more upgradient or other appropriately located wells. The groundwater monitoring list in Appendix IX of part 264 of this chapter (plus the additional constituents in Table A of this paragraph) may be used for screening purposes in place of Appendix I of part 192 in the monitoring program. New depository sites for tailings that contain water at greater than the level of ''specific retention'' should use aliner or equivalent. In considering design objectives for groundwater protection, the implementing agencies should give priority to concentration levels in the order listed under §192.02(c)(3)(i). When considering the potential for health risks caused by human exposure to known or suspected carcinogens, alternate concentration limits pursuant to paragraph 192.02(c)(3)(ii) should be established at concentration levels which represent an excess lifetime risk, at a point of exposure, to an average individual no greater than between 10^{-4} and 10^{-6}.

TABLE A TO § 192.20(a)(2)—ADDITIONAL LISTED CONSTITUENTS

Nitrate (as N)
Molybdenum
Combined radium-226 and radium-228
Combined uranium-234 and uranium-238
Gross alpha-particle activity (excluding radon and uranium)

(3) The plan for remedial action, concurred in by the Commission, will specify how applicable requirements of subpart A are to be satisfied. The plan

should include the schedule and steps necessary to complete disposal operations at the site. It should include an estimate of the inventory of wastes to be disposed of in the pile and their listed constituents and address any need to eliminate free liquids; stabilization of the wastes to a bearing capacity sufficient to support the final cover; and the design and engineering specifications for a cover to manage the migration of liquids through the stabilized pile, function without maintenance, promote drainage and minimize erosion or abrasion of the cover, and accommodate settling and subsidence so that cover integrity is maintained. Evaluation of proposed designs to conform to subpart A should be based on realistic technical judgments and include use of available empirical information. The consideration of possible failure modes and related corrective actions should be limited to reasonable failure assumptions, with a demonstration that the disposal design is generally amenable to a range of corrective actions.

(4) The groundwater monitoring list in Appendix IX of part 264 of this chapter (plus the additional constituents in Table A in paragraph (a)(2) of this section) may be used for screening purposes in place of Appendix I of part 192 in monitoring programs. The monitoring plan required under §192.03 should be designed to include verification of site-specific assumptions used to project the performance of the disposal system. Prevention of contamination of groundwater may be assessed by indirect methods, such as measuring the migration of moisture in the various components of the cover, the tailings, and the area between the tailings and the nearest aquifer, as well as by direct monitoring of groundwater. In the case of vicinity properties (§192.01(l)(2)), such assessments may not be necessary, as determined by the Secretary, with the concurrence of the Commission, considering such factors as local geology and the amount of contamination present. Temporary excursions from applicable limits of groundwater concentrations that are attributable to a disposal operation itself shall not constitute a basis for considering corrective action under §192.04 during the disposal period, unless the disposal operation is suspended prior to completion for other than seasonal reasons.

(b)(1) Compliance with §192.12(a) and (b) of subpart B, to the extent practical, should be demonstrated through radiation surveys. Such surveys may, if appropriate, be restricted to locations likely to contain residual radioactive materials. These surveys should be designed to provide for compliance averaged over limited areas rather than point-by-point compliance with the standards. In most cases, measurement of gamma radiation exposure rates above and below the land surface can be used to show compliance with §192.12(a). Protocols for making such measurements should be based on realistic radium distributions near the surface rather than extremes rarely encountered.

(2) In §192.12(a), ''background level'' refers to the native radium concentration in soil. Since this may not be determinable in the presence of contamination by residual radioactive materials, a surrogate ''background level'' may be established by simple direct or indirect (e.g., gamma radiation) measurements performed nearby but outside of the contaminated location.

(3) Compliance with §192.12(b) may be demonstrated by methods that the Department of Energy has approved for use under Pub. L. 92–314 (10 CFR part 712), or by other methods that the implementing agencies determine are adequate. Residual radioactive materials should be removed from buildings exceeding 0.03 WL so that future replacement buildings will not pose a hazard [unless removal is not practical—see §192.21(c)]. However, sealants, filtration, and ventilation devices may provide reasonable assurance of reductions from 0.03 WL to below 0.02 WL. In unusual cases, indoor radiation may exceed the levels specified in §192.12(b) due to sources other than residual radioactive materials. Remedial actions are not required in order to comply with the standard when there is reasonable assurance that residual radioactive materials are not the cause of such an excess.

(4) The plan(s) for remedial action will specify how applicable requirements of subpart B would be satisfied. The plan should include the schedule and steps necessary to complete the cleanup of groundwater at the site. It should document the extent of contamination due to releases prior to final disposal, including the identification and location of listed constituents and the rate and direction of movement of contaminated groundwater, based upon the monitoring carried out under §192.12(c)(1). In addition, the assessment should consider future plume movement, including an evaluation of such processes as attenuation and dilution and future contamination from beneath a disposal site. Monitoring for assessment and compliance purposes should be sufficient to establish the extent and magnitude of contamination, with reasonable assurance, through use of a carefully chosen minimal number of sampling locations. The location and number of monitoring wells, the frequency and duration of monitoring, and the selection of indicator analytes for long-term groundwater monitoring, and, more generally, the design and operation of the monitoring system, will depend on the potential for risk to receptors and upon other factors, including characteristics of the subsurface environment, such as velocity of groundwater flow, contaminant retardation, time of groundwater or contaminant transit to receptors, results of statistical evaluations of data trends, and modeling of the dynamics of the groundwater system. All of these factors should be incorporated into the design of a site-specific monitoring program that will achieve the purpose of the regulations in this subpart in the most cost-effective manner. In the case of vicinity properties (§192.01(l)(2)), such assessments will usually not be necessary. The Secretary, with the concurrence of the Commission, may consider such factors as local geology and amount of contamination present in determining criteria to decide when such assessments are needed. In cases where §192.12(c)(2) is invoked, the plan should include a monitoring program sufficient to verify projections of plume movement and attenuation periodically during the extended cleanup period. Finally, the plan should specify details of the method to be used for cleanup of groundwater.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2867, Jan. 11, 1995]

§192.21 Criteria for applying supplemental standards.

Unless otherwise indicated in this subpart, all terms shall have the same meaning as defined in Title I of the Act or in subparts A and B. The implementing agencies may (and in the case of paragraph (h) of this section shall) apply standards under §192.22 in lieu of the standards of subparts A or B if they determine that any of the following circumstances exists:

(a) Remedial actions required to satisfy subpart A or B would pose a clear and present risk of injury to workers or to members of the public, notwithstanding reasonable measures to avoid or reduce risk.

(b) Remedial actions to satisfy the cleanup standards for land, §192.12(a), and groundwater, §192.12(c), or the acquisition of minimum materials required for control to satisfy §§192.02(b) and (c), would, notwithstanding reasonable measures to limit damage, directly produce health and environmental harm that is clearly excessive compared to the health and environmental benefits, now or in the future. A clear excess of health and environmental harm is harm that is long-term, manifest, and grossly disproportionate to health and environmental benefits that may reasonably be anticipated.

(c) The estimated cost of remedial action to satisfy §192.12(a) at a ''vicinity'' site (described under section 101(6)(B) of the Act) is unreasonably high relative to the long-term benefits, and the residual radioactive materials do not pose a clear present or future hazard. The likelihood that buildings will be erected or that people will spend long periods of time at such a vicinity site should be considered in evaluating this hazard. Remedial action will generally not be necessary where residual radioactive materials have been placed semi-permanently in a location where site-specific factors limit their hazard and from which they are costly or difficult to remove, or

where only minor quantities of residual radioactive materials are involved. Examples are residual radioactive materials under hard surface public roads and sidewalks, around public sewer lines, or in fence post foundations. Supplemental standards should not be applied at such sites, however, if individuals are likely to be exposed for long periods of time to radiation from such materials at levels above those that would prevail under §192.12(a).

(d) The cost of a remedial action for cleanup of a building under §192.12(b) is clearly unreasonably high relative to the benefits. Factors that should be included in this judgment are the anticipated period of occupancy, the incremental radiation level that would be affected by the remedial action, the residual useful lifetime of the building, the potential for future construction at the site, and the applicability of less costly remedial methods than removal of residual radioactive materials.

(e) There is no known remedial action.

(f) The restoration of groundwater quality at any designated processing site under §192.12(c) is technically impracticable from an engineering perspective.

(g) The groundwater meets the criteria of §192.11(e).

(h) Radionuclides other than radium-226 and its decay products are present in sufficient quantity and concentration to constitute a significant radiation hazard from residual radioactive materials.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2868, Jan. 11, 1995]

§ 192.22 Supplemental standards.

Federal agencies implementing subparts A and B may in lieu thereof proceed pursuant to this section with respect to generic or individual situations meeting the eligibility requirements of §192.21.

(a) When one or more of the criteria of §192.21(a) through (g) applies, the Secretary shall select and perform that alternative remedial action that comes as close to meeting the otherwise applicable standard under §192.02(c)(3) as is reasonably achievable.

(b) When §192.21(h) applies, remedial actions shall reduce other residual radioactivity to levels that are as low as is reasonably achievable and conform to the standards of subparts A and B to the maximum extent practicable.

(c) The implementing agencies may make general determinations concerning remedial actions under this section that will apply to all locations with specified characteristics, or they may make a determination for a specific location. When remedial actions are proposed under this section for a specific location, the Department of Energy shall inform any private owners and occupants of the affected location and solicit their comments. The Department of Energy shall provide any such comments to the other implementing agencies. The Department of Energy shall also periodically inform the Environmental Protection Agency of both general and individual determinations under the provisions of this section.

(d) When §192.21(b), (f), or (g) apply, implementing agencies shall apply any remedial actions for the restoration of contamination of groundwater by residual radioactive materials that is required to assure, at a minimum, protection of human health and the environment. In addition, when §192.21(g) applies, supplemental standards shall ensure that current and reasonably projected uses of the affected groundwater are preserved.

[48 FR 602, Jan. 5, 1983, as amended at 60 FR 2868, Jan. 11, 1995]

§ 192.23 Effective date.

Subparts A, B, and C shall be effective March 7, 1983.

Subpart D—Standards for Management of Uranium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended

SOURCE: 48 FR 45946, Oct. 7, 1983, unless otherwise noted.

§ 192.30 Applicability.

This subpart applies to the management of uranium byproduct materials under section 84 of the Atomic Energy Act of 1954 (henceforth designated ''the

Act''), as amended, during and following processing of uranium ores, and to restoration of disposal sites following any use of such sites under section 83(b)(1)(B) of the Act.

§ 192.31 Definitions and cross-references.

References in this subpart to other parts of the Code of Federal Regulations are to those parts as codified on January 1, 1983.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as in Title II of the Uranium Mill Tailings Rediation Control Act of 1978, subparts A and B of this part, or parts 190, 260, 261, and 264 of this chapter. For the purposes of this subpart, the terms ''waste,'' ''hazardous waste,'' and related terms, as used in parts 260, 261, and 264 of this chapter shall apply to byproduct material.

(b) *Uranium byproduct material* means the tailings or wastes produced by the extraction or concentration of uranium from any ore processed primarily for its source material content. Ore bodies depleted by uranium solution extraction operations and which remain underground do not constitute ''byproduct material'' for the purpose of this subpart.

(c) *Control* means any action to stabilize, inhibit future misuse of, or reduce emissions or effluents from uranium byproduct materials.

(d) *Licensed site* means the area contained within the boundary of a location under the control of persons generating or storing uranium byproduct materials under a license issued pursuant to section 84 of the Act. For purposes of this subpart, ''licensed site'' is equivalent to ''regulated unit'' in subpart F of part 264 of this chapter.

(e) *Disposal site* means a site selected pursuant to section 83 of the Act.

(f) *Disposal area* means the region within the perimeter of an impoundment or pile containing uranium by product materials to which the postclosure requirements of §192.32(b)(1) of this subpart apply.

(g) *Regulatory agency* means the U.S. Nuclear Regulatory Commission.

(h) *Closure period* means the period of time beginning with the cessation, with respect to a waste impoundment, of uranium ore processing operations and ending with completion of requirements specified under a closure plan.

(i) *Closure plan* means the plan required under §264.112 of this chapter.

(j) *Existing portion* means that land surface area of an existing surface impoundment on which significant quantities of uranium byproduct materials have been placed prior to promulgation of this standard.

(k) *As expeditiously as practicable considering technological feasibility* means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of available technology; the need for consistency with mandatory requirements of other regulatory programs; and factors beyond the control of the licensee. The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term ''available technology.''

(l) *Permanent Radon Barrier* means the final radon barrier constructed to achieve compliance with, including attainment of, the limit on releases of radon-222 in §192.32(b)(1)(ii).

(m) *Available technology* means technologies and methods for emplacing a permanent radon barrier on uranium mill tailings piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry or one that is reasonably analogous, (such as, by way of illustration only, unreasonable overtime, staffing or transportation requirements, etc., considering normal practice in the industry; laser fusion, of soils, etc.), provided there is reasonable progress toward emplacement of a permanent radon barrier. To determine grossly excessive costs, the relevant baseline against which cost increases shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's tailings closure plan, but costs beyond such estimates shall not automatically be considered grossly excessive.

(n) *Tailings Closure Plan (Radon)* means the Nuclear Regulatory Commission or Agreement State approved plan detailing activities to accomplish timely emplacement of a permanent

radon barrier. A tailings closure plan shall include a schedule for key radon closure milestone activities such as wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and emplacement of a permanent radon barrier constructed to achieve compliance with the 20 pCi/m^2-s flux standard as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee).

(o) *Factors beyond the control of the licensee* means factors proximately causing delay in meeting the schedule in the applicable license for timely emplacement of the permanent radon barrier notwithstanding the good faith efforts of the licensee to achieve compliance. These factors may include, but are not limited to, physical conditions at the site; inclement weather or climatic conditions; an act of God; an act of war; a judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance; labor disturbances; any modifications, cessation or delay ordered by state, Federal or local agencies; delays beyond the time reasonably required in obtaining necessary governmental permits, licenses, approvals or consent for activities described in the tailings closure plan (radon) proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the tailings closure plan by NRC or the affected Agreement State; and an act or omission of any third party over whom the licensee has no control.

(p) *Operational* means that a uranium mill tailings pile or impoundment is being used for the continued placement of uranium byproduct material or is in standby status for such placement. A tailings pile or impoundment is operational from the day that uranium byproduct material is first placed in the pile or impoundment until the day final closure begins.

(q) *Milestone* means an enforceable date by which action, or the occurrence of an event, is required for purposes of achieving compliance with the 20 pCi/m^2−s flux standard.

[48 FR 45946, Oct. 7, 1983, as amended at 58 FR 60355, Nov. 15, 1993]

§ 192.32 Standards.

(a) *Standards for application during processing operations and prior to the end of the closure period.* (1) Surface impoundments (except for an existing portion) subject to this subpart must be designed, constructed, and installed in such manner as to conform to the requirements of § 264.221 of this chapter, except that at sites where the annual precipitation falling on the impoundment and any drainage area contributing surface runoff to the impoundment is less than the annual evaporation from the impoundment, the requirements of § 264.228(a)(2)(iii)(E) referenced in § 264.221 do not apply.

(2) Uranium byproduct materials shall be managed so as to conform to the ground water protection standard in § 264.92 of this chapter, except that for the purposes of this subpart:

(i) To the list of hazardous constituents referenced in § 264.93 of this chapter are added the chemical elements molybdenum and uranium,

(ii) To the concentration limits provided in Table 1 of § 264.94 of this chapter are added the radioactivity limits in Table A of this subpart,

(iii) Detection monitoring programs required under § 264.98 to establish the standards required under § 264.92 shall be completed within one (1) year of promulgation,

(iv) The regulatory agency may establish alternate concentration limits (to be satisfied at the point of compliance specified under § 264.95) under the criteria of § 264.94(b), provided that, after considering practicable corrective actions, these limits are as low as reasonably achievable, and that, in any case, the standards of § 264.94(a) are satisfied at all points at a greater distance than 500 meters from the edge of the disposal area and/or outside the site boundary, and

(v) The functions and responsibilities designated in Part 264 of this chapter as those of the ''Regional Administrator'' with respect to ''facility permits'' shall be carried out by the regulatory agency, except that exemptions of hazardous constituents under §264.93 (b) and (c) of this chapter and alternate concentration limits established under §264.94 (b) and (c) of this chapter (except as otherwise provided in §192.32(a)(2)(iv)) shall not be effective until EPA has concurred therein.

(3)(i) Uranium mill tailings piles or impoundments that are nonoperational and subject to a license by the Nuclear Regulatory Commission or an Agreement State shall limit releases of radon-222 by emplacing a permanent radon barrier. This permanent radon barrier shall be constructed as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee) after the pile or impoundment ceases to be operational. Such control shall be carried out in accordance with a written tailings closure plan (radon) to be incorporated by the Nuclear Regulatory Commission or Agreement State into individual site licenses.

(ii) The Nuclear Regulatory Commission or Agreement State may approve a licensee's request to extend the time for performance of milestones if, after providing an opportunity for public participation, the Nuclear Regulatory Commission or Agreement State finds that compliance with the 20 pCi/m^2-s flux standard has been demonstrated using a method approved by the NRC, in the manner required in 192.32(a)(4)(i). Only under these circumstances and during the period of the extension must compliance with the 20 pCi/m^2-s flux standard be demonstrated each year.

(iii) The Nuclear Regulatory Commission or Agreement State may extend the final compliance date for emplacement of the permanent radon barrier, or relevant milestone, based upon cost if the new date is established after a finding by the Nuclear Regulatory Commission or Agreement State, after providing an opportunity for public participation, that the licensee is making good faith efforts to emplace a permanent radon barrier; the delay is consistent with the definition of ''available technology'' in §192.31(m); and the delay will not result in radon releases that are determined to result in significant incremental risk to the public health.

(iv) The Nuclear Regulatory Commission or Agreement State may, in response to a request from a licensee, authorize by license or license amendment a portion of the site to remain accessible during the closure process to accept uranium byproduct material as defined in section 11(e)(2) of the Atomic Energy Act, 42 U.S.C. 2014(e)(2), or to accept materials similar to the physical, chemical and radiological characteristics of the in situ uranium mill tailings and associated wastes, from other sources. No such authorization may be used as a means for delaying or otherwise impeding emplacement of the permanent radon barrier over the remainder of the pile or impoundment in a manner that will achieve compliance with the 20 pCi/m^2-s flux standard, averaged over the entire pile or impoundment.

(v) The Nuclear Regulatory Commission or Agreement State may, in response to a request from a licensee, authorize by license or license amendment a portion of a pile or impoundment to remain accessible after emplacement of a permanent radon barrier to accept uranium byproduct material as defined in section 11(e)(2) of the Atomic Energy Act, 42 U.S.C. 2014(e)(2), if compliance with the 20 pCi/m^2-s flux standard of §192.32(b)(1)(ii) is demonstrated by the licensee's monitoring conducted in a manner consistent with §192.32(a)(4)(i). Such authorization may be provided only if the Nuclear Regulatory Commission or Agreement State makes a finding, constituting final agency action and after providing an opportunity for public participation, that the site will continue to achieve the 20 pCi/m2−s flux standard when averaged over the entire impoundment.

(4)(i) Upon emplacement of the permanent radon barrier pursuant to 40 CFR 192.32(a)(3), the licensee shall conduct appropriate monitoring and analysis of the radon-222 releases to demonstrate that the design of the permanent radon barrier is effective in limiting releases of radon-222 to a level

not exceeding 20 pCi/m^2−s as required by 40 CFR 192.32(b)(1)(ii). This monitoring shall be conducted using the procedures described in 40 CFR part 61, Appendix B, Method 115, or any other measurement method proposed by a licensee that the Nuclear Regulatory Commission or Agreement State approves as being at least as effective as EPA Method 115 in demonstrating the effectiveness of the permanent radon barrier in achieving compliance with the 20 pCi/m^2−s flux standard.

(ii) When phased emplacement of the permanent radon barrier is included in the applicable tailings closure plan (radon), then radon flux monitoring required under §192.32(a)(4)(i) shall be conducted, however the licensee shall be allowed to conduct such monitoring for each portion of the pile or impoundment on which the radon barrier has been emplaced by conducting flux monitoring on the closed portion.

(5) Uranium byproduct materials shall be managed so as to conform to the provisions of:

(i) Part 190 of this chapter, ''Environmental Radiation Protection Standards for Nuclear Power Operations'' and

(ii) Part 440 of this chapter, ''Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, Subpart C, Uranium, Radium, and Vanadium Ores Subcategory.''

(6) The regulatory agency, in conformity with Federal Radiation Protection Guidance (FR, May 18, 1960, pgs. 4402–4403), shall make every effort to maintain radiation doses from radon emissions from surface impoundments of uranium byproduct materials as far below the Federal Radiation Protection Guides as is practicable at each licensed site.

(b) *Standards for application after the closure period.* At the end of the closure period:

(1) Disposal areas shall each comply with the closure performance standard in §264.111 of this chapter with respect to nonradiological hazards and shall be designed[1] to provide reasonable assurance of control of radiological hazards to

(i) Be effective for one thousand years, to the extent reasonably achievable, and, in any case, for at least 200 years, and,

(ii) Limit releases of radon-222 from uranium byproduct materials to the atmosphere so as to not exceed an average[2] release rate of 20 picocuries per square meter per second (pCi/m2s).

(2) The requirements of §192.32(b)(1) shall not apply to any portion of a licensed and/or disposal site which contains a concentration of radium-226 in land, averaged over areas of 100 square meters, which, as a result of uranium byproduct material, does not exceed the background level by more than:

(i) 5 picocuries per gram (pCi/g), averaged over the first 15 centimeters (cm) below the surface, and

(ii) 15 pCi/g, averaged over 15 cm thick layers more than 15 cm below the surface.

[48 FR 45946, Oct. 7, 1983, as amended at 58 FR 60355, Nov. 15, 1993]

§192.33 Corrective action programs.

If the ground water standards established under provisions of §192.32(a)(2) are exceeded at any licensed site, a corrective action program as specified in §264.100 of this chapter shall be put into operation as soon as is practicable, and in no event later than eighteen (18) months after a finding of exceedance.

§192.34 Effective date.

Subpart D shall be effective December 6, 1983.

TABLE A TO SUBPART D OF PART 192

	pCi/liter
Combined radium-226 and radium-228	5

[1] The standard applies to design with a monitoring requirement as specified in §192.32(a)(4).

[2] This average shall apply to the entire surface of each disposal area over periods of at least one year, but short compared to 100 years. Radon will come from both uranium byproduct materials and from covering materials. Radon emissions from covering materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only to emissions from uranium byproduct materials to the atmosphere.

	pCi/liter
Gross alpha-particle activity (excluding radon and uranium)	15

Subpart E—Standards for Management of Thorium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended

SOURCE: 48 FR 45947, Oct. 7, 1983, unless otherwise noted.

§ 192.40 Applicability.

This subpart applies to the management of thorium byproduct materials under section 84 of the Atomic Energy Act of 1954, as amended, during and following processing of thorium ores, and to restoration of disposal sites following any use of such sites under section 83(b)(1)(B) of the Act.

§ 192.41 Provisions.

Except as otherwise noted in §192.41(e), the provisions of subpart D of this part, including §§192.31, 192.32, and 192.33, shall apply to thorium byproduct material and:

(a) Provisions applicable to the element uranium shall also apply to the element thorium;

(b) Provisions applicable to radon-222 shall also apply to radon-220; and

(c) Provisions applicable to radium-226 shall also apply to radium-228.

(d) Operations covered under §192.32(a) shall be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

(e) The provisions of §192.32(a) (3) and (4) do not apply to the management of thorium byproduct material.

[48 FR 45946, Oct. 7, 1983, as amended at 58 FR 60356, Nov. 15, 1993]

§ 192.42 Substitute provisions.

The regulatory agency may, with the concurrence of EPA, substitute for any provisions of §192.41 of this subpart alternative provisions it deems more practical that will provide at least an equivalent level of protection for human health and the environment.

§ 192.43 Effective date.

Subpart E shall be effective December 6, 1983.

APPENDIX I TO PART 192—LISTED CONSTITUENTS

Acetonitrile
Acetophenone (Ethanone, 1-phenyl)
2-Acetylaminofluorene (Acetamide, N-9H-fluoren-2-yl-)
Acetyl chloride
1-Acetyl-2-thiourea (Acetamide, N-(aminothioxymethyl)-)
Acrolein (2-Propenal)
Acrylamide (2-Propenamide)
Acrylonitrile (2-Propenenitrile)
Aflatoxins
Aldicarb (Propenal, 2-methyl-2-(methylthio)-,O-[(methylamino)carbonyl]oxime
Aldrin (1,4:5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro(1α,4α,4aβ,5α,8α,8αβ)-)
Allyl alcohol (2-Propen-1-ol)
Allyl chloride (1-Propane,3-chloro)
Aluminum phosphide
4-Aminobiphenyl ([1,1′-Biphenyl]-4-amine)
5-(Aminomethyl)-3-isoxazolol (3(2H)-Isoxazolone,5-(aminomethyl)-)
4-Aminopyridine (4-Pyridineamine)
Amitrole (lH-1,2,4-Triazol-3-amine)
Ammonium vanadate (Vanadic acid, ammonium salt)
Aniline (Benzenamine)
Antimony and compounds, N.O.S.[1]
Aramite (Sulfurous acid, 2-chloroethyl 2-[4-(1,1-dimethylethyl)phenoxy]-1-methylethyl ester)
Arsenic and compounds, N.O.S.
Arsenic acid (Arsenic acid H_3 AsO_4)
Arsenic pentoxide (Arsenic oxide As_2 O_5)
Auramine (Benzamine, 4,4′-carbonimidoylbis[N,N-dimethyl-])
Azaserine (L-Serine, diazoacetate (ester))
Barium and compounds, N.O.S.
Barium cyanide
Benz[c]acridine (3,4-Benzacridine)
Benz[a]anthracene (1,2-Benzanthracene)
Benzal chloride (Benzene, dichloromethyl-)
Benzene (Cyclohexatriene)
Benzenearsonic acid (Arsenic acid, phenyl-)
Benzidine ([1,1′-Biphenyl]-4,4′-diamine)
Benzo[b]fluoranthene (Benz[e]acephananthrylene)

[1]The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this appendix.

Benzo[j]fluoranthene
Benzo[k]fluoranthene
Benzo[a]pyrene
p-Benzoquinone (2,5-Cyclohexadiene-1,4-dione)
Benzotrichloride (Benzene, (trichloro-methyl)-)
Benzyl chloride (Benzene, (chloromethyl)-)
Beryllium and compounds, N.O.S.
Bromoacetone (2-Propanone, 1-bromo-)
Bromoform (Methane, tribromo-)
4-Bromophenyl phenyl ether (Benzene, 1-bromo-4-phenoxy-)
Brucine (Strychnidin-10-one, 2,3-dimeth-oxy-)
Butyl benzyl phthalate (1,2-Benzenedicarbozylic acid, butyl phenylmethyl ester)
Cacodylic acid (Arsinic acid, dimethyl)
Cadmium and compounds, N.O.S.
Calcium chromate (Chromic acid H_2 CrO_4, calcium salt)
Calcium cyanide ($Ca(CN)_2$)
Carbon disulfide
Carbon oxyfluoride (Carbonic difluoride)
Carbon tetrachloride (Methane, tetrachloro-)
Chloral (Acetaldehyde, trichloro-)
Chlorambucil (Benzenebutanoic acid, 4-[bis(2-chloroethyl)amino]-)
Chlordane (4,7-Methano-1H-indene,1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-)
Chlorinated benzenes, N.O.S.
Chlorinated ethane, N.O.S.
Chlorinated fluorocarbons, N.O.S.
Chlorinated naphthalene, N.O.S.
Chlorinated phenol, N.O.S.
Chlornaphazin (Naphthalenamine, N,N′-bis(2-chlorethyl)-)
Chloroacetaldehyde (Acetaldehyde, chloro-)
Chloroalkyl ethers, N.O.S.
p-Chloroaniline (Benzenamine, 4-chloro-)
Chlorobenzene (Benzene, chloro-)
Chlorobenzilate (Benzeneacetic acid, 4-chloro-α-(4-chlorophenyl)-α-hydroxy-, ethyl ester)
p-Chloro-m-cresol (Phenol, 4-chloro-3-methyl)
2-Chloroethyl vinyl ether (Ethene, (2-chloroethoxy)-)
Chloroform (Methane, trichloro-)
Chloromethyl methyl ether (Methane, chloromethoxy-)
β-Chloronapthalene (Naphthalene, 2-chloro-)
o-Chlorophenol (Phenol, 2-chloro-)
1-(o-Chlorophenyl)thiourea (Thiourea, (2-chlorophenyl-))
3-Chloropropionitrile (Propanenitrile, 3-chloro-)
Chromium and compounds, N.O.S.
Chrysene
Citrus red No. 2 (2-Naphthalenol, 1-[(2,5-dimethoxyphenyl)azo]-)
Coal tar creosote
Copper cyanide (CuCN)
Creosote
Cresol (Chresylic acid) (Phenol, methyl-)
Crotonaldehyde (2-Butenal)
Cyanides (soluble salts and complexes), N.O.S.
Cyanogen (Ethanedinitrile)
Cyanogen bromide ((CN)Br)
Cyanogen chloride ((CN)Cl)
Cycasin (beta-D-Glucopyranoside, (methyl-ONN-azoxy)methyl)
2-Cyclohexyl-4,6-dinitrophenol (Phenol, 2-cyclohexyl-4,6-dinitro-)
Cyclophosphamide (2H-1,3,2-Oxazaphosphorin-2-amine,N,N-bis(2-chloroethyl) tetrahydro-,2-oxide)
2,4-D and salts and esters (Acetic acid, (2,4-dichlorophenoxy)-)
Daunomycin (5,12-Naphthacenedione,8-acetyl-10-[(3-amino-2,3,6-trideoxy-α-Llyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-,(8S-cis))
DDD (Benzene, 1,1′-(2,2-dichloroethylidene)bis[4-chloro-)
DDE (Benzene, 1,1-(dichloroethylidene)bis[4-chloro-)
DDT (Benzene, 1,1′-(2,2,2-trichloroethlyidene)bis[4-chloro-)
Diallate (Carbomothioic acid, bis(1-methylethyl)-,S-(2,3-dichloro-2-propenyl) ester)
Dibenz[a,h]acridine
Dibenz[a,j]acridine
Dibenz[a,h]anthracene
7H-Dibenzo[c,g]carbazole
Dibenzo[a,e]pyrene (Naphtho[1,2,4,5-def)crysene)
Dibenzo[a,h]pyrene (Dibenzo[b,def]crysene)
Dibenzo[a,i]pyrene (Benzo[rst]pentaphene)
1,2-Dibromo-3-chloropropane (Propane, 1,2-dibromo-3-chloro-)
Dibutylphthalate (1,2-Benzenedicarboxylic acid, dibutyl ester)
o-Dichlorobenzene (Benzene, 1,2-dichloro-)
m-Dichlorobenzene (Benzene, 1,3-dichloro-)
p-Dichlorobenzene (Benzene, 1,4-dichloro-)
Dichlorobenzene, N.O.S. (Benzene; dichloro-, N.O.S.)
3,3′-Dichlorobenzidine ([1,1′-Biphenyl]-4,4′-diamine, 3,3′-dichloro-)
1,4-Dichloro-2-butene (2-Butene, 1,4-dichloro-)
Dichlorodifluoromethane (Methane, dichlorodifluoro-)
Dichloroethylene, N.O.S.
1,1-Dichloroethylene (Ethene, 1,1-dichloro-)
1,2-Dichloroethylene (Ethene, 1,2-dichloro-,(E)-)
Dichloroethyl ether (Ethane, 1,1′-oxybis[2-chloro-)
Dichloroisopropyl ether (Propane, 2,2′-oxybis[2-chloro-)
Dichloromethoxy ethane (Ethane, 1,1′-[methylenebis(oxy)bis[2-chloro-)
Dichloromethyl ether (Methane, oxybis[chloro-)
2,4-Dichlorophenol (Phenol, 2,4-dichloro-)
2,6-Dichlorophenol (Phenol, 2,6-dichloro-)
Dichlorophenylarsine (Arsinous dichloride, phenyl-)

Dichloropropane, N.O.S. (Propane, dichloro-,)
Dichloropropanol, N.O.S. (Propanol, dichloro-,)
Dichloropropene; N.O.S. (1-Propane, dichloro-,)
1,3-Dichloropropene (1-Propene, 1,3-dichloro-)
Dieldrin (2,7:3,6-Dimethanonaphth[2,3-b]oxirene,3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a,octahydro-,(1aα,2β,2aα,3β,6β,6aα,7β,7aα)-)
1,2:3,4-Diepoxybutane (2,2′-Bioxirane)
Diethylarsine (Arsine, diethyl-)
1,4 Diethylene oxide (1,4-Dioxane)
Diethylhexyl phthalate (1,2-Benzenedicarboxlyic acid, bis(2-ethylhexl) ester)
N,N-Diethylhydrazine (Hydrazine, 1,2-diethyl)
O,O-Diethyl S-methyl dithiophosphate (Phosphorodithioic acid, O,O-diethyl S-methyl ester)
Diethyl-p-nitrophenyl phosphate (Phosphoric acid, diethyl 4-nitrophenyl ester)
Diethyl phthalate (1,2-Benzenedicarboxylic acid, diethyl ester)
O,O-Diethyl O-pyrazinyl phosphorothioate (Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester)
Diethylstilbesterol (Phenol, 4,4′-(1,2-diethyl-1,2-ethenediyl)bis-,(E)-)
Dihydrosafrole (1,3-Benxodioxole, 5-propyl-)
Diisopropylfluorophosphate (DFP) (Phosphorofluoridic acid, bis(1-methyl ethyl) ester)
Dimethoate (Phosphorodithioic acid, O,O-dimethyl S-[2-(methylamino) 2-oxoethyl] ester)
3,3′-Dimethoxybenzidine ([1,1′-Biphenyl]-4,4′-diamine, 3,3′-dimethoxy-)
p-Dimethylaminoazobenzene (Benzenamine, N,N-dimethyl-4-(phenylazo)-)
7,12-Dimethylbenz[a]anthracene (Benz[a]anthracene, 7,12-dimethyl-)
3,3′-Dimethylbenzidine ([1,1′-Biphenyl]-4,4′-diamine, 3,3′-dimethyl-)
Dimethylcarbamoyl chloride (carbamic chloride, dimethyl-)
1,1-Dimethylhydrazine (Hydrazine, 1,1-dimethyl-)
1,2-Dimethylhydrazine (Hydrazine, 1,2-dimethyl-)
α,α-Dimethylphenethylamine (Benzeneethanamine, α,α-dimethyl-)
2,4-Dimethylphenol (Phenol, 2,4-dimethyl-)
Dimethylphthalate (1,2-Benzenedicarboxylic acid, dimethyl ester)
Dimethyl sulfate (Sulfuric acid, dimethyl ester)
Dinitrobenzene, N.O.S. (Benzene, dinitro-)
4,6-Dinitro-o-cresol and salts (Phenol, 2-methyl-4,6-dinitro-)
2,4-Dinitrophenol (Phenol, 2,4-dinitro-)
2,4-Dinitrotoluene (Benzene, 1-methyl-2,4-dinitro-)
2,6-Dinitrotoluene (Benzene, 2-methyl-1,3-dinitro-)
Dinoseb (Phenol, 2-(1-methylpropyl)-4,6-dinitro-)
Di-n-octyl phthalate (1,2-Benzenedicarboxylic acid, dioctyl ester)
1,4-Dioxane (1,4-Diethyleneoxide)
Diphenylamine (Benzenamine, N-phenyl-)
1,2-Diphenylhydrazine (Hydrazine, 1,2-diphenyl-)
Di-n-propylnitrosamine (1-Propanamine,N-nitroso-N-propyl-)
Disulfoton (Phosphorodithioic acid, O,O-diethyl S-[2-(ethylthio)ethyl] ester)
Dithiobiuret (Thioimidodicarbonic diamide $[(H_2 N)C(S)]_2 NH$)
Endosulfan (6,9,Methano-2,4,3-benzodioxathiepin,6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9ahexahydro,3-oxide)
Endothall (7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid)
Endrin and metabolites (2,7:3,6-Dimethanonaphth[2,3-b]oxirene,3,4,5,6,9,9-hexachloro1a,2,2a,3,6,6a,7,7a-octahydro,(1aα,2β,2aβ,3α,6α,6aβ,7β,7aα)-)
Epichlorohydrin (Oxirane, (chloromethyl)-)
Epinephrine (1,2-Benzenediol,4-[1-hydroxy-2-(methylamino)ethyl]-,(R)-,)
Ethyl carbamate (urethane) (Carbamic acid, ethyl ester)
Ethyl cyanide (propanenitrile)
Ethylenebisdithiocarbamic acid, salts and esters (Carbamodithioic acid, 1,2-Ethanediylbis-)
Ethylene dibromide (1,2-Dibromoethane)
Ethylene dichloride (1,2-Dichloroethane)
Ethylene glycol monoethyl ether (Ethanol, 2-ethoxy-)
Ethyleneimine (Aziridine)
Ethylene oxide (Oxirane)
Ethylenethiourea (2-Imidazolidinethione)
Ethylidene dichloride (Ethane, 1,1-Dichloro-)
Ethyl methacrylate (2-Propenoic acid, 2-methyl-, ethyl ester)
Ethylmethane sulfonate (Methanesulfonic acid, ethyl ester)
Famphur (Phosphorothioic acid, O-[4-[(dimethylamino)sulphonyl]phenyl] O,O-dimethyl ester)
Fluoranthene
Fluorine
Fluoroacetamide (Acetamide, 2-fluoro-)
Fluoroacetic acid, sodium salt (Acetic acid, fluoro-, sodium salt)
Formaldehyde (Methylene oxide)
Formic acid (Methanoic acid)
Glycidylaldehyde (Oxiranecarboxyaldehyde)
Halomethane, N.O.S.
Heptachlor (4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-)
Heptachlor epoxide (α, β, and γ isomers) (2,5-Methano-2H-indeno[1,2-b]-oxirene, 2,3,4,5,6,7,7-heptachloro-1a,1b,5,5a,6,6a-hexahydro-,(1aα,1bβ,2α,5α,5aβ,6β,6aα)-)
Hexachlorobenzene (Benzene, hexachloro-)
Hexachlorobutadiene (1,3-Butadiene, 1,1,2,3,4,4-hexachloro-)

Hexachlorocyclopentadiene (1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-)
Hexachlorodibenzofurans
Heptachlorodibenzo-p-dioxins
Hexachloroethane (Ethane, hexachloro-)
Hexachlorophene (phenol, 2,2′-Methylenebis[3,4,6-trichloro-)
Hexachloropropene (1-Propene, 1,1,2,3,3,3-hexachloro-)
Hexaethyl tetraphosphate (Tetraphosphoric acid, hexaethyl ester)
Hydrazine
Hydrocyanic acid
Hydrofluoric acid
Hydrogen sulfide (H_2 S)
Indeno(1,2,3-cd)pyrene
Isobutyl alcohol (1-Propanol, 2-methyl-)
Isodrin (1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro, (1α,4α,4aβ,5β,8β,8aβ)-)
Isosafrole (1,3-Benzodioxole, 5-(1-propenyl)-)
Kepone (1,3,4-Metheno-2H-cyclobuta[cd]pentalen-2-one, 1,1a,3,3a,4,5,5,5a,5b,6-decachlorooctahydro-)
Lasiocarpine (2-Butenoic acid, 2-methyl-,7-[[2,3-dihydroxy-2-(1-methoxyethyl)-3-methyl-1-oxobutoxy]methyl]-2,3,5,7a-tetrahydro-1H-pyrrolizin-l-yl ester)
Lead and compounds, N.O.S.
Lead acetate (Acetic acid, lead(2 +) salt)
Lead phosphate (Phosphoric acid, lead(2 +) salt(2:3))
Lead subacetate (Lead, bis(acetato-O)tetrahydroxytri-)
Lindane (Clohexane, 1,2,3,4,5,6-hexachloro-, (1α,2α,3β,4α,5α,6β)-)
Maleic anhydride (2,5-Furandione)
Maleic hydrazide (3,6-Pyridazinedione, 1,2-dihydro-)
Malononitrile (Propanedinitrile)
Melphalan (L-Phenylalanine, 4-[bis(2-chloroethyl)aminol]-)
Mercury and compounds, N.O.S.
Mercury fulminate (Fulminic acid, mercury(2 +) salt)
Methacrylonitrile (2-Propenenitrile, 2-methyl-)
Methapyrilene (1,2-Ethanediamine, N,N-dimethyl-N′-2-pyridinyl-N′-(2-thienylmethyl)-)
Metholmyl (Ethamidothioic acid, N-[[(methylamino)carbonyl]oxy]thio-, methyl ester)
Methoxychlor (Benzene, 1,1′-(2,2,2-trichloroethylidene)bis[4-methoxy-)
Methyl bromide (Methane, bromo-)
Methyl chloride (Methane, chloro-)
Methyl chlorocarbonate (Carbonchloridic acid, methyl ester)
Methyl chloroform (Ethane, 1,1,1-trichloro-)
3-Methylcholanthrene (Benz[j]aceanthrylene, 1,2-dihydro-3-methyl-)
4,4′-Methylenebis(2-chloroaniline) (Benzenamine, 4,4′-methylenebis(2-chloro-)
Methylene bromide (Methane, dibromo-)
Methylene chloride (Methane, dichloro-)
Methyl ethyl ketone (MEK) (2-Butanone)
Methyl ethyl ketone peroxide (2-Butanone, peroxide)
Methyl hydrazine (Hydrazine, methyl-)
Methyl iodide (Methane, iodo-)
Methyl isocyanate (Methane, isocyanato-)
2-Methyllactonitrile (Propanenitrile, 2-hydroxy-2-methyl-)
Methyl methacrylate (2-Propenoic acid, 2-methyl-, methyl ester)
Methyl methanesulfonate (Methanesulfonic acid, methyl ester)
Methyl parathion (Phosphorothioic acid, O,O-dimethyl O-(4-nitrophenyl) ester)
Methylthiouracil (4(1H)Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-)
Mitomycin C (Azirino[2′,3′:3,4]pyrrolo[1,2-a]indole-4,7-dione,6-amino-8-[[(aminocarbonyl) oxy]methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methy-, [1aS-(1aα,8β,8aα,8bα)]-)
MNNG (Guanidine, N-methyl-N′-nitro-N-nitroso-)
Mustard gas (Ethane, 1,1′-thiobis[2-chloro-)
Naphthalene
1,4-Naphthoquinone (1,4-Naphthalenedione)
α-Naphthalenamine (1-Naphthylamine)
β-Naphthalenamine (2-Naphthylamine)
α-Naphthylthiourea (Thiourea, 1-naphthalenyl-)
Nickel and compounds, N.O.S.
Nickel carbonyl ($Ni(CO)_4$ (T-4)-)
Nickel cyanide ($Ni(CN)_2$)
Nicotine and salts (Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-)
Nitric oxide (Nitrogen oxide NO)
p-Nitroaniline (Benzenamine, 4-nitro-)
Nitrobenzene (Benzene, nitro-)
Nitrogen dioxide (Nitrogen oxide NO_2)
Nitrogen mustard, and hydrochloride salt (Ethanamine, 2-chloro-N-(2-chloroethyl)-N-methyl-)
Nitrogen mustard N-oxide and hydrochloride salt (Ethanamine, 2chloro-N-(2-chloroethyl)N-methyl-, N-oxide)
Nitroglycerin (1,2,3-Propanetriol, trinitrate)
p-Nitrophenol (Phenol, 4-nitro-)
2-Nitropropane (Propane, 2-nitro-)
Nitrosamines, N.O.S.
N-Nitrosodi-n-butylamine (l-Butanamine, N-butyl-N-nitroso-)
N-Nitrosodiethanolamine (Ethanol, 2,2′-(nitrosoimino)bis-)
N-Nitrosodiethylamine (Ethanamine, N-ethyl-N-nitroso-1)
N-Nitrosodimethylamine (Methanamine, N-methyl-N-nitroso-)
N-Nitroso-N-ethylurea (Urea, N-ethyl-N-nitroso-)
N-Nitrosomethylethylamine (Ethanamine, N-methyl-N-nitroso-)
N-Nitroso-N-methylurea (Urea, N-methyl-N-nitroso-)
N-Nitroso-N-methylurethane (Carbamic acid, methylnitroso-, ethyl ester)
N-Nitrosomethylvinylamine (Vinylamine, N-methyl-N-nitroso-)

N-Nitrosomorpholine (Morpholine, 4-nitroso-)
N-Nitrosonornicotine (Pyridine, 3-(1-nitroso-2-pyrrolidinyl)-, (S)-)
N-Nitrosopiperidine (Piperidine, 1-nitroso-)
Nitrosopyrrolidine (Pyrrolidine, 1-nitroso-)
N-Nitrososarcosine (Glycine, N-methyl-N-nitroso-)
5-Nitro-o-toluidine (Benzenamine, 2-methyl-5-nitro-)
Octamethylpyrophosphoramide (Diphosphoramide, octamethyl-)
Osmium tetroxide (Osmium oxide OsO_4, (T-4)-)
Paraldehyde (1,3,5-Trioxane, 2,4,6-trimethyl-)
Parathion (Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester)
Pentachlorobenzene (Benzene, pentachloro-)
Pentachlorodibenzo-p-dioxins
Pentachlorodibenzofurans
Pentachloroethane (Ethane, pentachloro-)
Pentachloronitrobenzene (PCNB) (Benzene, pentachloronitro-)
Pentachlorophenol (Phenol, pentachloro-)
Phenacetin (Acetamide, N-(4-ethoxyphenyl)-)
Phenol
Phenylenediamine (Benzenediamine)
Phenylmercury acetate (Mercury, (acetato-O)phenyl-)
Phenylthiourea (Thiourea, phenyl-)
Phosgene (Carbonic dichloride)
Phosphine
Phorate (Phosphorodithioic acid, O,O-diethyl S-[(ethylthiomethyl] ester)
Phthalic acid esters, N.O.S.
Phthalic anhydride (1,3-isobenzofurandione)
2-Picoline (Pyridine, 2-methyl-)
Polychlorinated biphenyls, N.O.S.
Potassium cyanide (K(CN))
Potassium silver cyanide (Argentate(l-), bis(cyano-C)-, potassium)
Pronamide (Benzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)-)
1,3-Propane sultone (1,2-Oxathiolane, 2,2-dioxide)
n-Propylamine (1-Propanamine)
Propargyl alcohol (2-Propyn-1-ol)
Propylene dichloride (Propane, 1,2-dichloro-)
1,2-Propylenimine (Aziridine, 2-methyl-)
Propylthiouracil (4(1H)-Pyrimidinone, 2,3-dihydro-6-propyl-2-thioxo-)
Pyridine
Reserpinen (Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-[(3,4,5-trimethoxybenzoyl)oxy]-smethyl ester, (3β,16 β,17α,18β,20α)-)
Resorcinol (1,3-Benzenediol)
Saccharin and salts (1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide)
Safrole (1,3-Benzodioxole, 5-(2-propenyl)-)
Selenium and compounds, N.O.S.
Selenium dioxide (Selenious acid)
Selenium sulfide (SeS_2)
Selenourea
Silver and compounds, N.O.S.
Silver cyanide (Silver cyanide Ag(CN))
Silvex (Propanoic acid, 2-(2,4,5-trichlorophenoxy)-)
Sodium cyanide (Sodium cyanide Na(CN))
Streptozotocin (D-Glucose, 2-deoxy-2-[[methylnitrosoamino)carbonyl]amino]-)
Strychnine and salts (Strychnidin-10-one)
TCDD (Dibenzo[b,e][1,4]dioxin, 2,3,7,8-tetrachloro-)
1,2,4,5-Tetrachlorobenzene (Benzene, 1,2,4,5-tetrachloro-)
Tetrachlorodibenzo-p-dioxins
Tetrachlorodibenxofurans
Tetrachloroethane, N.O.S. (Ethane, tetrachloro-, N.O.S.)
1,1,1,2-Tetrachloroethane (Ethane, 1,1,1,2-tetrachloro-)
1,1,2,2-Tetrachloroethane (Ethane, 1,1,2,2-tetrachloro-)
Tetrachloroethylene (Ethene, tetrachloro-)
2,3,4,6-Tetrachlorophenol (Phenol, 2,3,4,6-tetrachloro-)
Tetraethyldithiopyrophosphate (Thiodiphosphoric acid, tetraethyl ester)
Tetraethyl lead (Plumbane, tetraethyl-)
Tetraethyl pyrophosphate (Diphosphoric acid, tetraethyl ester)
Tetranitromethane (Methane, tetranitro-)
Thallium and compounds, N.O.S.
Thallic oxide (Thallium oxide $Tl_2 O_3$)
Thallium (I) acetate (Acetic acid, thallium (1 +) salt)
Thallium (I) carbonate (Carbonic acid, dithallium (1 +) salt)
Thallium (I) chloride (Thallium chloride TlCl)
Thallium (I) nitrate (Nitric acid, thallium (1 +) salt)
Thallium selenite (Selenius acid, dithallium (1 +) salt)
Thallium (I) sulfate (Sulfuric acid, thallium (1 +) salt)
Thioacetamide (Ethanethioamide)
3,Thiofanox (2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-[(methylamino)carbonyl] oxime)
Thiomethanol (Methanethiol)
Thiophenol (Benzenethiol)
Thiosemicarbazide (Hydrazinecarbothioamide)
Thiourea
Thiram (Thioperoxydicarbonic diamide [(H_2 N)C(S)]2S_2, tetramethyl-)
Toluene (Benzene, methyl-)
Toluenediamine (Benzenediamine, ar-methyl-)
Toluene-2,4-diamine (1,3-Benzenediamine, 4-methyl-)
Toluene-2,6-diamine (1,3-Benzenediamine, 2-methyl-)
Toluene-3,4-diamine (1,2-Benzenediamine, 4-methyl-)
Toluene diisocyanate (Benzene, 1,3-diisocyanatomethyl-)
o-Toluidine (Benzenamine, 2-methyl-)
o-Toluidine hydrochloride (Benzenamine, 2-methyl-, hydrochloride)
p-Toluidine (Benzenamine, 4-methyl-)

Toxaphene
1,2,4-Trichlorobenzene (Benzene, 1,2,4-trichloro-)
1,1,2-Trichloroethane (Ethane, 1,1,2-trichloro-)
Trichloroethylene (Ethene,trichloro-)
Trichloromethanethiol (Methanethiol, trichloro-)
Trichloromonofluoromethane (Methane, trichlorofluoro-)
2,4,5-Trichlorophenol (Phenol, 2,4,5-trichloro-)
2,4,6-Trichlorophenol (Phenol, 2,4,6-trichloro-)
2,4,5-T (Acetic acid, 2,4,5- trichloro-phenoxy-)
Trichloropropane, N.O.S.
1,2,3-Trichloropropane (Propane, 1,2,3-trichloro-)
O,O,O-Triethyl phosphorothioate (Phosphorothioic acid, O,O,O-triethyl ester)
Trinitrobenzene (Benzene, 1,3,5-trinitro-)
Tris(1-aziridinyl)phosphine sulfide (Aziridine, 1,1′,1″phosphinothioylidyne-tris-))
Tris(2,3-dibromopropyl) phosphate (1-Propanol, 2,3-dibromo-, phosphate (3:1))
Trypan blue (2,7-Naphthalendisulfonic acid, 3,3′-[(3,3′-dimethyl[1,1′-biphenyl]-4,4′-diyl)bis(azo)]bis(5-amino-4-hydroxy-, tetrasodium salt)
Uracil mustard (2,4-(1H,3H)-Pyrimidinedione, 5-[bis(2-chloroethyl)amino]-)
Vanadium pentoxide (Vanadium oxide $V_2 O_5$)
Vinyl chloride (Ethene, chloro-)
Wayfarin (2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenlybutyl)-)
Zinc cyanide ($Zn(CN)_2$)
Zinc phosphide ($Zn_3 P_2$)

[60 FR 2868, Jan. 11, 1995]

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

Subpart A—General Provisions

Sec.

Subpart B—Compliance Certification and Re-certification Applications

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GENERAL REQUIREMENTS

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Subpart D—Public Participation

COMPLIANCE WITH THE 40 CFR PART 191 DISPOSAL REGULATIONS AND THE 40 CFR PART 194 COMPLIANCE CRITERIA

AUTHORITY: Pub. L. 102–579, 106 Stat. 4777, as amended by Pub. L. 104–201,110 Stat. 2422; Reorganization Plan No. 3 of 1970, 35 FR 15623, Oct. 6, 1970, 5 U.S.C. app. 1; Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011–2296 and 10101–10270.

SOURCE: 61 FR 5235, Feb. 9, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 194.1 Purpose, scope, and applicability.

This part specifies criteria for the certification or any re-certification, or subsequent actions relating to the terms or conditions of certification of the Department of Energy's Waste Isolation Pilot Plant's compliance with the disposal regulations found at part 191 of this chapter and pursuant to section 8(d)(1) and section 8(f), respectively, of the WIPP LWA. The compliance certification application submitted pursuant to section 8(d)(1) of the WIPP LWA and any compliance re-certification application submitted pursuant to section 8(f) of the WIPP LWA shall comply with the requirements of this part.

§ 194.2 Definitions.

Unless otherwise indicated in this part, all terms have the same meaning as in part 191 of this chapter.

Acceptable knowledge means any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste, conducted prior to or separate from the waste certification process authorized by EPA's Certification Decision, to show compliance with Condition 3 of the certification decision (appendix A of this part).

Administrator's authorized representative means the director in charge of radiation programs at the Agency.

Certification means any action taken by the Administrator pursuant to section 8(d)(1) of the WIPP LWA.

Compliance application(s) means the compliance certification application submitted to the Administrator pursuant to section 8(d)(1) of the WIPP LWA or any compliance re-certification applications submitted to the Administrator pursuant to section 8(f) of the WIPP LWA.

Compliance assessment(s) means the analysis conducted to determine compliance with §191.15, and part 191, subpart C of this chapter.

Delaware Basin means those surface and subsurface features which lie inside the boundary formed to the north, east and west of the disposal system by the innermost edge of the Capitan Reef, and formed, to the south, by a straight line drawn from the southeastern point of the Davis Mountains to the most southwestern point of the Glass Mountains.

Deep drilling means those drilling events in the Delaware Basin that reach or exceed a depth of 2,150 feet below the surface relative to where such drilling occurred.

Department means the United States Department of Energy.

Disposal regulations means part 191, subparts B and C of this chapter.

Management systems review means the qualitative assessment of a data collection operation or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate to ensure that the type and quality of data needed are obtained.

Minor alternative provision means an alternative provision to the Compliance Criteria that only clarifies an existing regulatory provision, or does not substantively alter the existing regulatory requirements.

Modification means action(s) taken by the Administrator that alters the terms or conditions of certification pursuant to section 8(d)(1) of the WIPP LWA. Modification of any certification shall comply with this part and part 191 of this chapter.

Population of CCDFs means all possible complementary, cumulative distribution functions (CCDFs) that can be generated from all disposal system parameter values used in performance assessments.

Population of estimates means all possible estimates of radiation doses and radionuclide concentrations that can be generated from all disposal system

parameter values used in compliance assessments.

Quality assurance means those planned and systematic actions necessary to provide adequate confidence that the disposal system will comply with the disposal regulations set forth in part 191 of this chapter. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

Re-certification means any action taken by the Administrator pursuant to section 8(f) of the WIPP LWA.

Regulatory time frame means the time period beginning at disposal and ending 10,000 years after disposal.

Revocation means any action taken by the Administrator to terminate the certification pursuant to section 8(d)(1) of the WIPP LWA.

Secretary means the Secretary of Energy.

Shallow drilling means those drilling events in the Delaware Basin that do not reach a depth of 2,150 feet below the surface relative to where such drilling occurred.

Suspension means any action taken by the Administrator to withdraw, for a limited period of time, the certification pursuant to section 8(d)(1) of the WIPP LWA.

Waste means the radioactive waste, radioactive material and coincidental material subject to the requirements of part 191 of this chapter.

Waste characteristic means a property of the waste that has an impact on the containment of waste in the disposal system.

Waste component means an ingredient of the total inventory of the waste that influences a waste characteristic.

WIPP means the Waste Isolation Pilot Plant, as authorized pursuant to section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Pub. L. 96–164; 93 Stat. 1259, 1265).

WIPP LWA means the Waste Isolation Pilot Plant Land Withdrawal Act of 1992 (Pub.L. 102–579, 106 Stat. 4777).

[61 FR 5235, Feb. 9, 1996, as amended at 63 FR 27404, May 18, 1998; 69 FR 42580, July 16, 2004]

§ 194.3 Communications.

(a) Compliance application(s) shall be:

(1) Addressed to the Administrator; and

(2) Signed by the Secretary.

(b) Communications and reports concerning the criteria in this part shall be:

(1) Addressed to the Administrator or the Administrator's authorized representative; and

(2) Signed by the Secretary or the Secretary's authorized representative.

§ 194.4 Conditions of compliance certification.

(a) Any certification of compliance issued pursuant to section 8(d)(1) of the WIPP LWA may include such conditions as the Administrator finds necessary to support such certification.

(b) Whether stated therein or not, the following conditions shall apply in any such certification:

(1) The certification shall be subject to modification, suspension or revocation by the Administrator. Any suspension of the certification shall be done at the discretion of the Administrator. Any modification or revocation of the certification shall be done by rule pursuant to 5 U.S.C. 553. If the Administrator revokes the certification, the Department shall retrieve, as soon as practicable and to the extent practicable, any waste emplaced in the disposal system.

(2) Any time after the Administrator issues a certification, the Administrator or the Administrator's authorized representative may submit a written request to the Department for information to enable the Administrator to determine whether the certification should be modified, suspended or revoked. Unless otherwise specified by the Administrator or the Administrator's authorized representative, the Department shall submit such information to the Administrator or the Administrator's authorized representative

within 30 calendar days of receipt of the request.

(3) Any time after the Administrator issues a certification, the Department shall report any planned or unplanned changes in activities or conditions pertaining to the disposal system that differ significantly from the most recent compliance application.

(i) The Department shall inform the Administrator, in writing, prior to making such a planned change in activity or disposal system condition.

(ii) In the event of an unplanned change in activity or condition, the Department shall immediately cease emplacement of waste in the disposal system if the Department determines that one or more of the following conditions is true:

(A) The containment requirements established pursuant to §191.13 of this chapter have been or are expected to be exceeded;

(B) Releases from already-emplaced waste lead to committed effective doses that are or are expected to be in excess of those established pursuant to §191.15 of this chapter. For purposes of this paragraph (b)(3)(ii)(B), emissions from operations covered pursuant to part 191, subpart A of this chapter are not included; or

(C) Releases have caused or are expected to cause concentrations of radionuclides or estimated doses due to radionuclides in underground sources of drinking water in the accessible environment to exceed the limits established pursuant to part 191, subpart C of this chapter.

(iii) If the Department determines that a condition described in paragraph (b)(3)(ii) of this section has occurred or is expected to occur, the Department shall notify the Administrator, in writing, within 24 hours of the determination. Such notification shall, to the extent practicable, include the following information:

(A) Identification of the location and environmental media of the release or the expected release;

(B) Identification of the type and quantity of waste (in activity in curies of each radionuclide) released or expected to be released;

(C) Time and date of the release or the estimated time of the expected release;

(D) Assessment of the hazard posed by the release or the expected release; and

(E) Additional information requested by the Administrator or the Administrator's authorized representative.

(iv) The Department may resume emplacement of waste in the disposal system upon written notification that the suspension has been lifted by the Administrator.

(v) If the Department discovers a condition or activity that differs significantly from what is indicated in the most recent compliance application, but does not involve conditions or activities listed in paragraph (b)(3)(ii) of this section, then the difference shall be reported, in writing, to the Administrator within 10 calendar days of its discovery.

(vi) Following receipt of notification, the Administrator will notify the Secretary in writing whether any condition or activity reported pursuant to paragraph (b)(3) this section:

(A) Does not comply with the terms of the certification; and, if it does not comply,

(B) Whether the compliance certification must be modified, suspended or revoked. The Administrator or the Administrator's authorized representative may request additional information before determining whether modification, suspension or revocation of the compliance certification is required.

(4) Not later than six months after the Administrator issues a certification, and at least annually thereafter, the Department shall report to the Administrator, in writing, any changes in conditions or activities pertaining to the disposal system that were not required to be reported by paragraph (b)(3) of this section and that differ from information contained in the most recent compliance application.

§194.5 Publications incorporated by reference.

(a) The following publications are incorporated into this part by reference:

(1) U.S. Nuclear Regulatory Commission, NUREG–1297 ''Peer Review for

High-Level Nuclear Waste Repositories,'' published February 1988; incorporation by reference (IBR) approved for §§ 194.22, 194.23 and 194.27.

(2) American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard, NQA–1–1989 edition, ''Quality Assurance Program Requirements for Nuclear Facilities;'' IBR approved for § 194.22.

(3) ASME NQA–2a–1990 addenda, part 2.7, to ASME NQA–2–1989 edition ''Quality Assurance Requirements for Nuclear Facility Applications;'' IBR approved for § 194.22 and § 194.23.

(4) ASME NQA–3–1989 edition, ''Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories'' (excluding section 2.1 (b) and (c)); IBR approved for § 194.22.

(b) The publications listed in paragraph (a) of this section were approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected or obtained from the Air Docket, Docket No. A–92–56, room M1500 (LE131), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, or copies may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* or copies may be obtained from the following addresses:

(1) For ASME standards, contact American Society of Mechanical Engineers, 22 Law Drive, P.O. Box 2900, Fairfield, NJ 07007–2900, phone 1–800–843–2763.

(2) For Nuclear Regulatory Commission documents, contact Division of Information Support Services, Distribution Service, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or contact National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, phone 703–487–4650.

[61 FR 5235, Feb. 9, 1996, as amended at 65 FR 47325, Aug. 2, 2000; 69 FR 18803, Apr. 9, 2004]

§ 194.6 Alternative provisions.

The Administrator may, by rule pursuant to 5 U.S.C. 553, substitute for any of the provisions of this part alternative provisions, or minor alternative provisions, in accordance with the following procedures:

(a) Alternative provisions may be substituted after:

(1) Alternative provisions have been proposed for public comment in the FEDERAL REGISTER together with information describing how the alternative provisions comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the costs, risks and benefits of compliance in accordance with the alternative provisions;

(2) A public comment period of at least 120 days has been completed and public hearings have been held in New Mexico;

(3) The public comments received have been fully considered; and

(4) A notice of final rulemaking is published in the FEDERAL REGISTER.

(b) Minor alternative provisions may be substituted after:

(1) The minor alternative provisions have been proposed for public comment in the FEDERAL REGISTER together with information describing how they comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the benefit of compliance in accordance with the minor alternative provision;

(2) A public comment period of at least 30 days has been completed for the minor alternative provisions and the public comments received have been fully considered;

(3) A notice of final rulemaking is published in the FEDERAL REGISTER for the minor alternative provisions.

[69 FR 42581, July 16, 2004]

§ 194.7 Effective date.

The criteria in this part shall be effective on April 9, 1996. The incorporation by reference of certain publications listed in the criteria is approved by the Director of the Federal Register as of April 9, 1996.

§ 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.

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.

(b) A description of the design of the disposal system including:

(1) Information on materials of construction including, but not limited to: Geologic media, structural materials, engineered barriers, general arrangement, and approximate dimensions; and

(2) Computer codes and standards that have been applied to the design and construction of the disposal system.

(c) Results of assessments conducted pursuant to this part.

(d) A description of input parameters associated with assessments conducted pursuant to this part and the basis for selecting those input parameters.

(e) Documentation of measures taken to meet the assurance requirements of this part.

(f) A description of waste acceptance criteria and actions taken to assure adherence to such criteria.

(g) A description of background radiation in air, soil and water in the vicinity of the disposal system and the procedures employed to determine such radiation.

(h) One or more topographic map(s) of the vicinity of the disposal system. The contour interval shall be sufficient to show clearly the pattern of surface water flow in the vicinity of the disposal system. The map(s) shall include standard map notations and symbols, and, in addition, shall show boundaries of the controlled area and the location of any active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system.

(i) A description of past and current climatologic and meteorologic conditions in the vicinity of the disposal 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 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 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;

(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.

(2) That all waste components influencing the waste characteristics identified in paragraph (b)(1) of this section have been identified and assessed for their impact on disposal system performance. The components to be analyzed shall include, but shall not be limited to: metals; cellulosics; chelating agents; water and other liquids; and activity in curies of each isotope of the radionuclides present.

(3) Any decision to exclude consideration of any waste characteristic or waste component because such characteristic or component is not expected to significantly influence the containment of the waste in the disposal system.

(c) For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (*i.e.*, margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:

(1) Demonstrate that, for the total inventory of waste proposed for disposal in the disposal system, WIPP complies with the numeric requirements of §194.34 and §194.55 for the upper or lower limits (including the associated uncertainties), as appropriate, for each waste component identified in paragraph (b)(2) of this section, and for the plausible combinations of upper and lower limits of such waste components that would result in the greatest estimated release.

(2) Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section.

(3) Provide information that demonstrates that the use of acceptable knowledge to quantify components in waste for disposal conforms with the

quality assurance requirements of §194.22.

(4) Provide information which demonstrates that a system of controls has been and will continue to be implemented 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 paragraph (c) of this section. The system of controls shall include, but shall not be limited to: Measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation.

(5) Identify and describe such controls delineated in paragraph (c)(4) of this section and confirm that they are applied in accordance with the quality assurance requirements found in §194.22.

(d) The Department shall include a waste loading scheme in any compliance application, or else performance assessments conducted pursuant to §194.32 and compliance assessments conducted pursuant to §194.54 shall assume random placement of waste in the disposal system.

(e) Waste may be emplaced in the disposal system only if the emplaced components of such waste will not cause:

(1) The total quantity of waste in the disposal system to exceed the upper limiting value, including the associated uncertainty, described in the introductory text to paragraph (c) of this section; or

(2) The total quantity of waste that will have been emplaced in the disposal system, prior to closure, to fall below the lower limiting value, including the associated uncertainty, described in the introductory text to paragraph (c) of this section.

(f) Waste emplacement shall conform to the assumed waste loading conditions, if any, used in performance assessments conducted pursuant to §194.32 and compliance assessments conducted pursuant to §194.54.

(g) The Department shall demonstrate in any compliance application that the total inventory of waste emplaced in the disposal system complies with the limitations on transuranic waste disposal described in the WIPP LWA.

(h) The Administrator will use inspections and records reviews, such as audits, to verify compliance with this section.

[61 FR 5235, Feb. 9, 1996, as amended at 69 FR 42583, July 16, 2004]

§194.25 Future state assumptions.

(a) Unless otherwise specified in this part or in the disposal regulations, performance assessments and compliance assessments conducted pursuant the provisions of this part to demonstrate compliance with §191.13, §191.15 and part 191, subpart C shall assume that characteristics of the future remain what they are at the time the compliance application is prepared, provided that such characteristics are not related to hydrogeologic, geologic or climatic conditions.

(b) In considering future states pursuant to this section, the Department shall document in any compliance application, to the extent practicable, effects of potential future hydrogeologic, geologic and climatic conditions on the disposal system over the regulatory time frame. Such documentation shall be part of the activities undertaken pursuant to §194.14, Content of compliance certification application; §194.32, Scope of performance assessments; and §194.54, Scope of compliance assessments.

(1) In considering the effects of hydrogeologic conditions on the disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to hydrogeologic conditions.

(2) In considering the effects of geologic conditions on the disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to geologic conditions, including, but not limited to: Dissolution; near surface geomorphic features and processes; and related subsidence in the geologic units of the disposal system.

(3) In considering the effects of climatic conditions on the disposal system, the Department shall document in

any compliance application, to the extent practicable, the effects of potential changes to future climate cycles of increased precipitation (as compared to present conditions).

§ 194.26 Expert judgment.

(a) Expert judgment, by an individual expert or panel of experts, may be used to support any compliance application, provided that expert judgment does not substitute for information that could reasonably be obtained through data collection or experimentation.

(b) Any compliance application shall:

(1) Identify any expert judgments used to support the application and shall identify experts (by name and employer) involved in any expert judgment elicitation processes used to support the application.

(2) Describe the process of eliciting expert judgment, and document the results of expert judgment elicitation processes and the reasoning behind those results. Documentation of interviews used to elicit judgments from experts, the questions or issues presented for elicitation of expert judgment, background information provided to experts, and deliberations and formal interactions among experts shall be provided. The opinions of all experts involved in each elicitation process shall be provided whether the opinions are used to support compliance applications or not.

(3) Provide documentation that the following restrictions and guidelines have been applied to any selection of individuals used to elicit expert judgments:

(i) Individuals who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment were not selected; and

(ii) Individuals who maintain, at any organizational level, a supervisory role or who are supervised by those who will utilize the judgment were not selected.

(4) Provide information which demonstrates that:

(i) The expertise of any individual involved in expert judgment elicitation comports with the level of knowledge required by the questions or issues presented to that individual; and

(ii) The expertise of any expert panel, as a whole, involved in expert judgment elicitation comports with the level and variety of knowledge required by the questions or issues presented to that panel.

(5) Explain the relationship among the information and issues presented to experts prior to the elicitation process, the elicited judgment of any expert panel or individual, and the purpose for which the expert judgment is being used in compliance applications(s).

(6) Provide documentation that the initial purpose for which expert judgment was intended, as presented to the expert panel, is consistent with the purpose for which this judgment was used in compliance application(s).

(7) Provide documentation that the following restrictions and guidelines have been applied in eliciting expert judgment:

(i) At least five individuals shall be used in any expert elicitation process, unless there is a lack or unavailability of experts and a documented rationale is provided that explains why fewer than five individuals were selected.

(ii) At least two-thirds of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors, unless the Department can demonstrate and document that there is a lack or unavailability of qualified independent experts. If so demonstrated, at least one-third of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors.

(c) The public shall be afforded a reasonable opportunity to present its scientific and technical views to expert panels as input to any expert elicitation process.

§ 194.27 Peer review.

(a) Any compliance application shall include documentation of peer review that has been conducted, in a manner required by this section, for:

(1) Conceptual models selected and developed by the Department;

(2) Waste characterization analyses as required in § 194.24(b); and

(3) Engineered barrier evaluation as required in §194.44.

(b) Peer review processes required in paragraph (a) of this section, and conducted subsequent to the promulgation of this part, shall be 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.)

(c) Any compliance application shall:

(1) Include information that demonstrates that peer review processes required in paragraph (a) of this section, and conducted prior to the implementation of the promulgation of this part, were conducted in accordance with an alternate process substantially equivalent in effect to NUREG–1297 and approved by the Administrator or the Administrator's authorized representative; and

(2) Document any peer review processes conducted in addition to those required pursuant to paragraph (a) of this section. Such documentation shall include formal requests, from the Department to outside review groups or individuals, to review or comment on any information used to support compliance applications, and the responses from such groups or individuals.

CONTAINMENT REQUIREMENTS

§194.31 Application of release limits.

The release limits shall be calculated according to part 191, appendix A of this chapter, using the total activity, in curies, that will exist in the disposal system at the time of disposal.

§194.32 Scope of performance assessments.

(a) Performance assessments shall consider natural processes and events, mining, deep drilling, and shallow drilling that may affect the disposal system during the regulatory time frame.

(b) Assessments of mining effects may be limited to changes in the hydraulic conductivity of the hydrogeologic units of the disposal system from excavation mining for natural resources. Mining shall be assumed to occur with a one in 100 probability in each century of the regulatory time frame. Performance assessments shall assume that mineral deposits of those resources, similar in quality and type to those resources currently extracted from the Delaware Basin, will be completely removed from the controlled area during the century in which such mining is randomly calculated to occur. Complete removal of such mineral resources shall be assumed to occur only once during the regulatory time frame.

(c) Performance assessments shall include an analysis of the effects on the disposal system of any activities that occur in the vicinity of the disposal system prior to disposal and are expected to occur in the vicinity of the disposal system soon after disposal. Such activities shall include, but shall not be limited to, existing boreholes and the development of any existing leases that can be reasonably expected to be developed in the near future, including boreholes and leases that may be used for fluid injection activities.

(d) Performance assessments need not consider processes and events that have less than one chance in 10,000 of occurring over 10,000 years.

(e) Any compliance application(s) shall include information which:

(1) Identifies all potential processes, events or sequences and combinations of processes and events that may occur during the regulatory time frame and may affect the disposal system;

(2) Identifies the processes, events or sequences and combinations of processes and events included in performance assessments; and

(3) Documents why any processes, events or sequences and combinations of processes and events identified pursuant to paragraph (e)(1) of this section were not included in performance assessment results provided in any compliance application.

§194.33 Consideration of drilling events in performance assessments.

(a) Performance assessments shall examine deep drilling and shallow drilling that may potentially affect the disposal system during the regulatory time frame.

(b) The following assumptions and process shall be used in assessing the likelihood and consequences of drilling

events, and the results of such process shall be documented in any compliance application:

(1) Inadvertent and intermittent intrusion by drilling for resources (other than those resources provided by the waste in the disposal system or engineered barriers designed to isolate such waste) is the most severe human intrusion scenario.

(2) In performance assessments, drilling events shall be assumed to occur in the Delaware Basin at random intervals in time and space during the regulatory time frame.

(3) The frequency of deep drilling shall be calculated in the following manner:

(i) Identify deep drilling that has occurred for each resource in the Delaware Basin over the past 100 years prior to the time at which a compliance application is prepared.

(ii) The total rate of deep drilling shall be the sum of the rates of deep drilling for each resource.

(4) The frequency of shallow drilling shall be calculated in the following manner:

(i) Identify shallow drilling that has occurred for each resource in the Delaware Basin over the past 100 years prior to the time at which a compliance application is prepared.

(ii) The total rate of shallow drilling shall be the sum of the rates of shallow drilling for each resource.

(iii) In considering the historical rate of all shallow drilling, the Department may, if justified, consider only the historical rate of shallow drilling for resources of similar type and quality to those in the controlled area.

(c) Performance assessments shall document that in analyzing the consequences of drilling events, the Department assumed that:

(1) Future drilling practices and technology will remain consistent with practices in the Delaware Basin at the time a compliance application is prepared. Such future drilling practices shall include, but shall not be limited to: The types and amounts of drilling fluids; borehole depths, diameters, and seals; and the fraction of such boreholes that are sealed by humans; and

(2) Natural processes will degrade or otherwise affect the capability of boreholes to transmit fluids over the regulatory time frame.

(d) With respect to future drilling events, performance assessments need not analyze the effects of techniques used for resource recovery subsequent to the drilling of the borehole.

§ 194.34 Results of performance assessments.

(a) The results of performance assessments shall be assembled into ''complementary, cumulative distribution functions'' (CCDFs) that represent the probability of exceeding various levels of cumulative release caused by all significant processes and events.

(b) Probability distributions for uncertain disposal system parameter values used in performance assessments shall be developed and documented in any compliance application.

(c) Computational techniques, which draw random samples from across the entire range of the probability distributions developed pursuant to paragraph (b) of this section, shall be used in generating CCDFs and shall be documented in any compliance application.

(d) The number of CCDFs generated shall be large enough such that, at cumulative releases of 1 and 10, the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability. Values of cumulative release shall be calculated according to Note 6 of Table 1, appendix A of part 191 of this chapter.

(e) Any compliance application shall display the full range of CCDFs generated.

(f) Any compliance application shall provide information which demonstrates that there is at least a 95 percent level of statistical confidence that the mean of the population of CCDFs meets the containment requirements of §191.13 of this chapter.

ASSURANCE REQUIREMENTS

§ 194.41 Active institutional controls.

(a) Any compliance application shall include detailed descriptions of proposed active institutional controls, the controls' location, and the period of

time the controls are proposed to remain active. Assumptions pertaining to active institutional controls and their effectiveness in terms of preventing or reducing radionuclide releases shall be supported by such descriptions.

(b) Performance assessments shall not consider any contributions from active institutional controls for more than 100 years after disposal.

§ 194.42 Monitoring.

(a) The Department shall conduct an analysis of the effects of disposal system parameters on the containment of waste in the disposal system and shall include the results of such analysis in any compliance application. The results of the analysis shall be used in developing plans for pre-closure and post-closure monitoring required pursuant to paragraphs (c) and (d) of this section. The disposal system parameters analyzed shall include, at a minimum:

(1) Properties of backfilled material, including porosity, permeability, and degree of compaction and reconsolidation;

(2) Stresses and extent of deformation of the surrounding roof, walls, and floor of the waste disposal room;

(3) Initiation or displacement of major brittle deformation features in the roof or surrounding rock;

(4) Ground water flow and other effects of human intrusion in the vicinity of the disposal system;

(5) Brine quantity, flux, composition, and spatial distribution;

(6) Gas quantity and composition; and

(7) Temperature distribution.

(b) For all disposal system parameters analyzed pursuant to paragraph (a) of this section, any compliance application shall document and substantiate the decision not to monitor a particular disposal system parameter because that parameter is considered to be insignificant to the containment of waste in the disposal system or to the verification of predictions about the future performance of the disposal system.

(c) Pre-closure monitoring. To the extent practicable, pre-closure monitoring shall be conducted of significant disposal system parameter(s) as identified by the analysis conducted pursuant to paragraph (a) of this section. A disposal system parameter shall be considered significant if it affects the system's ability to contain waste or the ability to verify predictions about the future performance of the disposal system. Such monitoring shall begin as soon as practicable; however, in no case shall waste be emplaced in the disposal system prior to the implementation of pre-closure monitoring. Pre-closure monitoring shall end at the time at which the shafts of the disposal system are backfilled and sealed.

(d) Post-closure monitoring. The disposal system shall, to the extent practicable, be monitored as soon as practicable after the shafts of the disposal system are backfilled and sealed to detect substantial and detrimental deviations from expected performance and shall end when the Department can demonstrate to the satisfaction of the Administrator that there are no significant concerns to be addressed by further monitoring. Post-closure monitoring shall be complementary to monitoring required pursuant to applicable federal hazardous waste regulations at parts 264, 265, 268, and 270 of this chapter and shall be conducted with techniques that do not jeopardize the containment of waste in the disposal system.

(e) Any compliance application shall include detailed pre-closure and post-closure monitoring plans for monitoring the performance of the disposal system. At a minimum, such plans shall:

(1) Identify the parameters that will be monitored and how baseline values will be determined;

(2) Indicate how each parameter will be used to evaluate any deviations from the expected performance of the disposal system; and

(3) Discuss the length of time over which each parameter will be monitored to detect deviations from expected performance.

§ 194.43 Passive institutional controls.

(a) Any compliance application shall include detailed descriptions of the

measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system. Such measures shall include:

(1) Identification of the controlled area by markers that have been designed and will be fabricated and emplaced to be as permanent as practicable;

(2) Placement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that would likely be consulted by individuals in search of unexploited resources. Such records shall identify:

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

(ii) The design of the disposal system;

(iii) The nature and hazard of the waste;

(iv) Geologic, geochemical, hydrologic, and other site data pertinent to the containment of waste in the disposal system, or the location of such information; and

(v) The results of tests, experiments, and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and other tests, experiments, or analyses pertinent to the containment of waste in the disposal system, or the location of such information.

(3) Other passive institutional controls practicable to indicate the dangers of the waste and its location.

(b) Any compliance application shall include the period of time passive institutional controls are expected to endure and be understood.

(c) The Administrator may allow the Department to assume passive institutional control credit, in the form of reduced likelihood of human intrusion, if the Department demonstrates in the compliance application that such credit is justified because the passive institutional controls are expected to endure and be understood by potential intruders for the time period approved by the Administrator. Such credit, or a smaller credit as determined by the Administrator, cannot be used for more than several hundred years and may decrease over time. In no case, however, shall passive institutional controls be assumed to eliminate the likelihood of human intrusion entirely.

§ 194.44 Engineered barriers.

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

(b) In selecting any engineered barrier(s) for the disposal system, the Department shall evaluate the benefit and detriment of engineered barrier alternatives, including but not limited to: Cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, grout and bentonite backfill, melting of metals, alternative configurations of waste placements in the disposal system, and alternative disposal system dimensions. The results of this evaluation shall be included in any compliance application and shall be used to justify the selection and rejection of each engineered barrier evaluated.

(c)(1) In conducting the evaluation of engineered barrier alternatives, the following shall be considered, to the extent practicable:

(i) The ability of the engineered barrier to prevent or substantially delay the movement of water or waste toward the accessible environment;

(ii) The impact on worker exposure to radiation both during and after incorporation of engineered barriers;

(iii) The increased ease or difficulty of removing the waste from the disposal system;

(iv) The increased or reduced risk of transporting the waste to the disposal system;

(v) The increased or reduced uncertainty in compliance assessment;

(vi) Public comments requesting specific engineered barriers;

(vii) The increased or reduced total system costs;

(viii) The impact, if any, on other waste disposal programs from the incorporation of engineered barriers (e.g., the extent to which the incorporation of engineered barriers affects the volume of waste);

(ix) The effects on mitigating the consequences of human intrusion.

(2) If, after consideration of one or more of the factors in paragraph (c)(1)

of this section, the Department concludes that an engineered barrier considered within the scope of the evaluation should be rejected without evaluating the remaining factors in paragraph (c)(1) of this section, then any compliance application shall provide a justification for this rejection explaining why the evaluation of the remaining factors would not alter the conclusion.

(d) In considering the ability of engineered barriers to prevent or substantially delay the movement of water or radionuclides toward the accessible environment, the benefit and detriment of engineered barriers for existing waste already packaged, existing waste not yet packaged, existing waste in need of re-packaging, and to-be-generated waste shall be considered separately and described.

(e) The evaluation described in paragraphs (b), (c) and (d) of this section shall consider engineered barriers alone and in combination.

§ 194.45 Consideration of the presence of resources.

Any compliance application shall include information that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of the disposal system being disturbed as a result of the presence of those resources. If performance assessments predict that the disposal system meets the containment requirements of §191.13 of this chapter, then the Agency will assume that the requirements of this section and §191.14(e) of this chapter have been fulfilled.

§ 194.46 Removal of waste.

Any compliance application shall include documentation which demonstrates that removal of waste from the disposal system is feasible for a reasonable period of time after disposal. Such documentation shall include an analysis of the technological feasibility of mining the sealed disposal system, given technology levels at the time a compliance application is prepared.

INDIVIDUAL AND GROUND-WATER PROTECTION REQUIREMENTS

§ 194.51 Consideration of protected individual.

Compliance assessments that analyze compliance with §191.15 of this chapter shall assume that an individual resides at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system.

§ 194.52 Consideration of exposure pathways.

In compliance assessments that analyze compliance with §191.15 of this chapter, all potential exposure pathways from the disposal system to individuals shall be considered. Compliance assessments with part 191, subpart C and §191.15 of this chapter shall assume that individuals consume 2 liters per day of drinking water from any underground source of drinking water in the accessible environment.

§ 194.53 Consideration of underground sources of drinking water.

In compliance assessments that analyze compliance with part 191, subpart C of this chapter, all underground sources of drinking water in the accessible environment that are expected to be affected by the disposal system over the regulatory time frame shall be considered. In determining whether underground sources of drinking water are expected to be affected by the disposal system, underground interconnections among bodies of surface water, ground water, and underground sources of drinking water shall be considered.

§ 194.54 Scope of compliance assessments.

(a) Any compliance application shall contain compliance assessments required pursuant to this part. Compliance assessments shall include information which:

(1) Identifies potential processes, events, or sequences of processes and events that may occur over the regulatory time frame;

(2) Identifies the processes, events, or sequences of processes and events included in compliance assessment results provided in any compliance application; and

(3) Documents why any processes, events, or sequences of processes and events identified pursuant to paragraph (a)(1) of this section were not included in compliance assessment results provided in any compliance application.

(b) Compliance assessments of undisturbed performance shall include the effects on the disposal system of:

(1) Existing boreholes in the vicinity of the disposal system, with attention to the pathways they provide for migration of radionuclides from the site; and

(2) Any activities that occur in the vicinity of the disposal system prior to or soon after disposal. Such activities shall include, but shall not be limited to: Existing boreholes and the development of any existing leases that can be reasonably expected to be developed in the near future, including boreholes and leases that may be used for fluid injection activities.

§ 194.55 Results of compliance assessments.

(a) Compliance assessments shall consider and document uncertainty in the performance of the disposal system.

(b) Probability distributions for uncertain disposal system parameter values used in compliance assessments shall be developed and documented in any compliance application.

(c) Computational techniques which draw random samples from across the entire range of values of each probability distribution developed pursuant to paragraph (b) of this section shall be used to generate a range of:

(1) Estimated committed effective doses received from all pathways pursuant to § 194.51 and § 194.52;

(2) Estimated radionuclide concentrations in USDWs pursuant to § 194.53; and

(3) Estimated dose equivalent received from USDWs pursuant to § 194.52 and § 194.53.

(d) The number of estimates generated pursuant to paragraph (c) of this section shall be large enough such that the maximum estimates of doses and concentrations generated exceed the 99th percentile of the population of estimates with at least a 0.95 probability.

(e) Any compliance application shall display:

(1) The full range of estimated radiation doses; and

(2) The full range of estimated radionuclide concentrations.

(f) Any compliance application shall document that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the requirements of § 191.15 and part 191, subpart C of this chapter, respectively.

Subpart D—Public Participation

§ 194.61 Advance notice of proposed rulemaking for certification.

(a) Upon receipt of a compliance application submitted pursuant to section 8(d)(1) of the WIPP LWA and § 194.11, the Agency will publish in the FEDERAL REGISTER an Advance Notice of Proposed Rulemaking announcing that a compliance application has been received, soliciting comment on such application, and announcing the Agency's intent to conduct a rulemaking to certify whether the WIPP facility will comply with the disposal regulations.

(b) A copy of the compliance application will be made available for inspection in Agency dockets established pursuant to § 194.67.

(c) The notice will provide a public comment period of 120 days.

(d) A public hearing concerning the notice will be held if a written request is received by the Administrator or the Administrator's authorized representative within 30 calendar days of the date of publication pursuant to paragraph (a) of this section.

(e) Any comments received on the notice will be made available for inspection in the dockets established pursuant to § 194.67.

(f) Any comments received on the notice will be provided to the Department and the Department may submit to the Agency written responses to the comments.

§ 194.62 Notice of proposed rulemaking for certification.

(a) The Administrator will publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER announcing the Administrator's proposed decision, pursuant to section 8(d)(1) of the WIPP LWA, whether to issue a certification that the WIPP facility will comply with the disposal regulations and soliciting comment on the proposal.

(b) The notice will provide a public comment period of at least 120 days.

(c) The notice will announce public hearings in New Mexico.

(d) Any comments received on the notice will be made available for inspection in the dockets established pursuant to § 194.67.

§ 194.63 Final rule for certification.

(a) The Administrator will publish a Final Rule in the FEDERAL REGISTER announcing the Administrator's decision, pursuant to section 8(d)(1) of the WIPP LWA, whether to issue a certification that the WIPP facility will comply with the disposal regulations.

(b) A document summarizing significant comments and issues arising from comments received on the Notice of Proposed Rulemaking, as well as the Administrator's response to such significant comments and issues, will be prepared and will be made available for inspection in the dockets established pursuant to § 194.67.

§ 194.64 Documentation of continued compliance.

(a) Upon receipt of documentation of continued compliance with the disposal regulations pursuant to section 8(f) of the WIPP LWA and § 194.11, the Administrator will publish a notice in the FEDERAL REGISTER announcing that such documentation has been received, soliciting comment on such documentation, and announcing the Administrator's intent to determine whether or not the WIPP facility continues to be in compliance with the disposal regulations.

(b) Copies of documentation of continued compliance received by the Administrator will be made available for inspection in the dockets established pursuant to § 194.67.

(c) The notice will provide a public comment period of at least 30 days after publication pursuant to paragraph (a) of this section.

(d) Any comments received on such notice will be made available for public inspection in the dockets established pursuant to § 194.67.

(e) Upon completion of review of the documentation of continued compliance with the disposal regulations, the Administrator will publish a notice in the FEDERAL REGISTER announcing the Administrator's decision whether or not to re-certify the WIPP facility.

§ 194.65 Notice of proposed rulemaking for modification or revocation.

(a) If the Administrator determines that any changes in activities or conditions pertaining to the disposal system depart significantly from the most recent compliance application, the Agency will publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER announcing the Administrator's proposed decision on modification or revocation, and soliciting comment on the proposal.

(b) Any comments received on the notice will be made available for inspection in the dockets established pursuant to § 194.67.

§ 194.66 Final rule for modification or revocation.

(a) The Administrator will publish a Final Rule in the FEDERAL REGISTER announcing the Administrator's decision on modification or revocation.

(b) A document summarizing significant comments and issues arising from comments received on the Notice of Proposed Rulemaking as well as the Administrator's response to such significant comments and issues will be prepared and will be made available for inspection in the dockets established pursuant to § 194.67.

§ 194.67 Dockets.

The Agency will establish and maintain dockets in the State of New Mexico and Washington, DC. The dockets will consist of all relevant, significant information received from outside parties and all significant information

considered by the Administrator in certifying whether the WIPP facility will comply with the disposal regulations, in certifying whether or not the WIPP facility continues to be in compliance with the disposal regulations, and in determining whether compliance certification should be modified, suspended or revoked.

APPENDIX A TO PART 194—CERTIFICATION OF THE WASTE ISOLATION PILOT PLANT'S COMPLIANCE WITH THE 40 CFR PART 191 DISPOSAL REGULATIONS AND THE 40 CFR PART 194 COMPLIANCE CRITERIA

In accordance with the provisions of the WIPP Compliance Criteria of this part, the Agency finds that the Waste Isolation Pilot Plant (''WIPP'') will comply with the radioactive waste disposal regulations at part 191, subparts B and C, of this chapter. Therefore, pursuant to Section 8(d)(2) of the WIPP Land Withdrawal Act (''WIPP LWA''), as amended, the Administrator certifies that the WIPP facility will comply with the disposal regulations. In accordance with the Agency's authority under §194.4(a), the certification of compliance is subject to the following conditions:

Condition 1: §194.14(b), Disposal system design, panel closure system. The Department shall close filled waste panels in a manner that has been specifically approved by the Agency. DOE must inform EPA of any modification to the approved panel closure design pursuant to §194.4(b)(3)(i), and provide any supporting information required by §194.14, *Content of compliance certification application*. The Administrator or Administrator's authorized representative will determine whether the change differs significantly from the design included in the most recent compliance certification, and whether the planned change would require modification of the compliance criteria. The EPA's approval of a panel closure change request requires that performance assessment calculations adequately represent the waste panel closure design, and that those calculations demonstrate the WIPP's compliance with the release standards set by 40 CFR part 191, Subpart B in accordance with §194.34, *Results of performance assessments*.

Condition 2: §194.22: Quality Assurance. The Secretary shall not allow any waste generator site other than the Los Alamos National Laboratory to ship waste for disposal at the WIPP until the Agency determines that the site has established and executed a quality assurance program, in accordance with §§194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5) for waste characterization activities and assumptions. The Agency will determine compliance of site-specific quality assurance programs at waste generator sites using the process set forth in §194.8.

Condition 3: §194.24: Waste Characterization. The Secretary may allow shipment for disposal at the WIPP of legacy debris waste at the Los Alamos National Laboratory (''LANL'') that can be characterized using the systems and processes inspected by the Agency and documented in Docket A–93–02, Item II–I–70. The Secretary shall not allow shipment of any waste from any additional LANL waste stream(s) or from any waste generator site other than LANL for disposal at the WIPP until the Agency has approved the processes for characterizing those waste streams for shipment using the process set forth in §194.8.

Condition 4: §194.43, Passive institutional controls.

(a) Not later than the final recertification application submitted prior to closure of the disposal system, the Department shall provide, to the Administrator or the Administrator's authorized representative:

(1) a schedule for implementing passive institutional controls that has been revised to show that markers will be fabricated and emplaced, and other measures will be implemented, as soon as possible following closure of the WIPP. Such schedule should describe how testing of any aspect of the conceptual design will be completed prior to or soon after closure, and what changes to the design of passive institutional controls may be expected to result from such testing.

(2) documentation showing that the granite pieces for the proposed monuments and information rooms described in Docket A–93–02, Item II–G–1, and supplementary information may be: quarried (cut and removed from the ground) without cracking due to tensile stresses from handling or isostatic rebound; engraved on the scale required by the design; transported to the site, given the weight and dimensions of the granite pieces and the capacity of existing rail cars and rail lines; loaded, unloaded, and erected without cracking based on the capacity of available equipment; and successfully joined.

(3) documentation showing that archives and record centers will accept the documents identified and will maintain them in the manner identified in Docket A–93–02, Item II–G–1.

(4) documentation showing that proposed recipients of WIPP information other than archives and record centers will accept the information and make use of it in the manner indicated by the Department in Docket A–93–02, Item II–G–1 and supplementary information.

(b) Upon receipt of the information required under paragraph (a) of this condition, the Agency will place such documentation in

the public dockets identified in §194.67. The Agency will determine if a modification to the compliance certification in effect is necessary. Any such modification will be conducted in accordance with the requirements at §§194.65 and 194.66.

[63 FR 27405, May 18, 1998, as amended at 79 FR 60756, Oct. 8, 2014]

PART 195—RADON PROFICIENCY PROGRAMS

Subpart A—General Provisions

Sec.

Subpart B—Fees

AUTHORITY: 15 U.S.C. 2665.

SOURCE: 59 FR 13175, Mar. 18, 1994, unless otherwise noted.

Subpart A—General Provisions

§ 195.1 Purpose and applicability.

(a) *Purpose*. The purpose of this part is to establish and collect the fees from applicants and participants required by section 305 of the Toxic Substances Control Act, U.S.C. 2665 to defray the cost to EPA for operating the following programs: The National Radon Measurement Proficiency (RMP) Program, the individual proficiency component of the RMP Program, and the National Radon Contractor Proficiency (RCP) Program.

(b) *Applicability*. This part applies to all applicants and participants in the following EPA programs: The National Radon Measurement Proficiency Program, the individual proficiency component of the RMP Program, and the National Radon Contractor Proficiency Program.

§ 195.2 Definitions.

Definitions in 15 U.S.C. 2602 and 2662 apply to this part unless otherwise specified in this section. In addition, the following definitions apply:

Acceptance date means the date on which EPA enters the application into the data system.

Accepted application refers to an application that has been entered into the data system.

Applicant means an individual or organization that submits an application to the RMP program, including the individual proficiency component of the RMP program, or the RCP program. An applicant to the RMP program must submit a separate application for each location from which it provides radon measurement services. After the application is accepted by EPA, the applicant becomes a ''participant'' in the proficiency programs.

Application means the documents submitted to EPA by applicants to the RMP and RCP programs which request participation in a program.

Device/measurement device means a unit, component, or system designed to measure radon gas or radon decay products.

EPA means the U.S. Environmental Protection Agency.

Individual proficiency/RMP exam means the exam which evaluates individuals who provide radon measurement services in a residential environment.

Listed participant in an individual or organization who has met all the requirements for listing in the RMP and RCP programs.

Measurement method is a means of measuring radon gas or radon decay products encompassing similar measurement devices, sampling techniques, or analysis procedures.

Organization is any individual, sole proprietorship, partnership, business, company, corporation, college or university, government agency (includes Federal, State and local government entities), laboratory, or institution.

Participant is an individual or organization engaged in radon measurement and/or mitigation activities or in offering radon measurement and/or mitigation services to consumers and others, whose proficiency program application EPA has accepted.

Primary measurement services (primary) refers to radon measurement services using a specific device which services include the capability to read and/or analyze the results generated from the device.

Radon Contractor Proficiency (RCP) program refers to EPA's program to evaluate radon mitigation contractors and the contractor's ability to communicate information to the public.

Radon Measurement Proficiency (RMP) program refers to EPA's program to evaluate organizations and individuals offering measurement services to consumers. It provides a means for organizations to demonstrate their proficiency in measuring radon and its decay products in indoor air.

Radon mitigation contractor means a contractor who provides radon mitigation services to the public.

Secondary radon measurement services (secondary) refers to radon measurement services that do not include the reading or the ability to analyze the results of the measurement devices used. These services may include placement and retrieval of devices, reporting results, and/or consultation with consumers.

Subpart B—Fees

§ 195.20 Fee payments.

(a) *Fee Amounts.* Applicants to and participants in the RMP and RCP programs shall pay fees according to the following fee schedule:

(1) *Organizations Listed for or Seeking Listing for Primary Measurement Services in the RMP Program.* (i) In order to remain a listed participant, each organization that is listed for primary measurement services in the RMP program on the effective date of this section shall pay an annual fee of $390 for each device.

(ii) Each organization seeking listing for primary measurement services that submits an initial application after the effective date of this section shall pay an annual fee of $390 per device. This fee will be prorated quarterly, based on the acceptance date of an organization's application.

(iii) Organizations that have or are seeking a listing for secondary measurement services for their primary devices will not be required to pay the additional $50 fee applicable to secondary organizations.

(2) *Organizations Listed for or Seeking Listing for Secondary Measurement Services in the RMP Program.* (i) In order to remain a listed participant, each organization that is listed for secondary measurement services in the RMP program on the effective date of this section shall pay an annual fee of $50 for each business location listed.

(ii) Each organization seeking listing for secondary measurement services that submits an initial application after the effective date of this section shall pay an annual fee of $50 for each business location listed. This fee will be prorated quarterly, based on the acceptance date of an organization's application.

(iii) Primary organizations that have or are seeking secondary listings for methods other than those for which they are listed as a primary, are subject to the fees.

(3) *Individual Proficiency Component of the RMP Program.* (i) In order to remain a listed participant, each individual listed in the RMP individual proficiency program on the effective date of this section shall pay an annual fee of $105.

(ii) Each individual who submits an initial application after the effective date of this section shall pay an annual fee of $105. This fee will be prorated quarterly, based on the acceptance date of an individual's application.

(iii) Individuals who have or are seeking listing status as an RMP primary or secondary organization are subject to the applicable fees under paragraphs (a)(1) and (2) of this section.

(4) *RCP Program.* (i)(A) In order to remain a listed participant, each individual listed in the RCP program on the effective date of this section shall pay an annual fee of $210.

(B) Each individual who is not a listed participant in the RCP program on the effective date of this section and submits an initial application after the effective date of this section shall pay an annual fee of $210. This fee will be prorated quarterly, based on the acceptance date of an individual's application.

(ii) An organization or individual who is not a listed participant in EPA's radon proficiency programs on the effective date of this section and/or whose proficiency program application has not yet been accepted by EPA becomes subject to the fees described

above once its application has been accepted by EPA. Fees for such organizations or individuals will be prorated quarterly, based on the acceptance date of the application. To remain listed, each participant in the RMP or RCP programs, whether individual or organization, shall submit the appropriate annual fee to EPA each year.

(b) *Exemptions.* State and local governments are exempted from these fees under section 305(e)(2) of TSCA, 15 U.S.C. 2665.

(c) *Determination of Fees.* (1) Participants listed in the RMP and RCP programs on the effective date of this section will be sent, by EPA, a payment invoice with its fee calculation at least 30 days before the payment is due. Fees will be assessed based on the current information in EPA's proficiency data bases. Participants who intend to pay the invoiced fee amount must send their payment to EPA following the procedures in the invoice. Organizations or individuals who wish to notify EPA of any errors or corrections they wish to make to their listing status must do so by following the instructions on the payment invoice. Corrected payment invoices for both the RMP Program and the RCP Program shall be sent to: Radon Proficiency Programs User Fees, c/o Sanford Cohen and Associates, Inc. (SC&A), 1418 I–85 Parkway, Montgomery, Alabama, 36106. EPA will review the corrections noted on the payment invoice, adjust the payment invoice amount (as appropriate) and issue a new invoice. Participants must pay the amount in the corrected payment invoice within 30 days of the date listed on the corrected invoice.

(2) If the appropriate fee or a revised payment invoice for an individual or organization participating in the RMP or RCP program has not been received by EPA on or before the payment due date, EPA will send, by certified mail, notice that the individual or organization will be delisted from the proficiency program unless he/she pays the fee within 30 days of this second certified notification. If payment still has not been received by EPA after 30 days of the second certified notification, the organization's or individual's listing shall be removed from the proficiency program.

(3) New or initial applicants to the RMP or RCP programs will be assessed a fee at the time of their initial application. EPA will send a payment invoice to the new applicant upon acceptance of the initial application. The applicant will be given at least 30 days from the date on the payment invoice to remit payment. The fee assessed will be prorated quarterly, based on the acceptance date of the application. If the appropriate fee has not been received by EPA by the payment due date, the application will be placed in an inactive file with no further action taken by EPA.

(d) *Payment Procedures.* Each remittance to EPA under this section shall be in United States currency and shall be paid by certified check, personal or business check, or money order made payable to the order of the ''U.S. ENVIRONMENTAL PROTECTION AGENCY'' and sent to: U.S. EPA, Washington Financial Management Center, Radon Proficiency Program User Fees (IRAA), P.O. Box 952491, St. Louis, Missouri, 63195–2491. The fee payment shall include the original copy of the EPA payment invoice. Collection of fees will begin in the calendar year beginning January 1, 1995. Specific guidance on how and when fees must be paid can be found in How to Pay Your Radon Proficiency Programs User Fees, U.S. EPA/Office of Radiation and Indoor Air. Copies of this document can be obtained by contacting the RIS at (334) 272–2797 or by FAX at (334) 260–9051.

(e) *Adjustment of Fees.* (1) EPA shall collect 100 percent of its operating costs associated with its radon proficiency programs by calendar year 1998. As necessary, EPA shall adjust the fees established by this subpart each year over the next four years to collect the following percentages of program costs:

Year 1	Year 2	Year 3	Year 4	Year 5
30%	47.5%	65%	82.5%	100%

Actual fees for each fiscal year will be calculated based on program costs and participation rates. New fee schedules will be published in the FEDERAL REGISTER as a technical amendment final

rule to this part to become effective 30 days or more after publication.

(2) EPA will use a three-step process to adjust the fees annually. First, EPA will estimate the costs of providing each of the proficiency programs for the upcoming year. EPA will account for future additional fixed costs (e.g., updating examinations) and increases/decreases in variable costs due to inflation and other factors. In order to calculate increases/decreases in costs due to inflation, EPA may use one of the three following indices: the Federal General Schedule (GS) pay scale, the Consumer Price Index (CPI), and/or a component of the CPI, such as services. Second, EPA will estimate the number of participants for each program. At a minimum, these participation rates will be based on past and current program participation rates. Third, EPA shall calculate the per capita costs that individuals and organizations should pay to enable it to recover its fixed and variable costs each year for each program. EPA shall also consider potential industry impacts as it adjusts to levels to ultimately achieve full cost recovery over the period of five years.

[60 FR 41816, Aug. 14, 1995]

§ 195.30 Failure to remit fee.

EPA will not process an application or continue a participant's listing in the National Radon Measurement Proficiency program, individual proficiency component of the RMP program, or the National Radon Contractor Proficiency program until the appropriate remittance provided in §195.20(a) has been received by EPA. Failure by a currently EPA-listed organization or individual to remit the required fees in a timely manner will result in the loss of that organization's or individual's listing status as specified in §195.20(c).

PART 197—PUBLIC HEALTH AND ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR YUCCA MOUNTAIN, NEVADA

Subpart A—Public Health and Environmental Standards for Storage

Sec.

Subpart B—Public Health and Environmental Standards for Disposal

AUTHORITY: Sec. 801, Pub. L. 102–486, 106 Stat. 2921, 42 U.S.C. 10141 n.

SOURCE: 66 FR 32132, June 13, 2001, unless otherwise noted.

Subpart A—Public Health and Environmental Standards for Storage

§ 197.1 What does subpart A cover?

This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site.

§ 197.2 What definitions apply in subpart A?

Annual committed effective dose equivalent means the effective dose equivalent received by an individual in one year from radiation sources external to the individual plus the committed effective dose equivalent.

Committed effective dose equivalent means the effective dose equivalent received over a period of time (e.g., 30 years,), as determined by NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides.

DOE means the Department of Energy.

Effective dose equivalent means the sum of the products of the dose equivalent received by specified tissues following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. Annual committed effective dose equivalents shall be calculated using weighting factors in appendix A of this part, unless otherwise directed by NRC in accordance with the introduction to appendix A of this part.

EPA means the Environmental Protection Agency.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

High-level radioactive waste means:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and

(2) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

Member of the public means anyone who is not a radiation worker for purposes of worker protection.

NRC means the Nuclear Regulatory Commission.

Radioactive material means matter composed of or containing radionuclides subject to the Atomic Energy Act of 1954, as amended (42 U.S.C. 2014 *et seq.*). Radioactive material includes, but is not limited to, high-level radioactive waste and spent nuclear fuel.

Spent nuclear fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

Storage means retention (and any associated activity, operation, or process necessary to carry out successful retention) of radioactive material with the intent or capability to readily access or retrieve such material.

Yucca Mountain repository means the excavated portion of the facility constructed underground within the Yucca Mountain site.

Yucca Mountain site means:

(1) The site recommended by the Secretary of DOE to the President under section 112(b)(1)(B) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10132(b)(1)(B)) on May 27, 1986; or

(2) The area under the control of DOE for the use of Yucca Mountain activities at the time of licensing, if the site designated under the Nuclear Waste Policy Act is amended by Congress prior to the time of licensing.

[66 FR 32132, June 13, 2001, as amended at 73 FR 61287, Oct. 15, 2008]

§ 197.3 How is subpart A implemented?

The NRC implements this subpart A. The DOE must demonstrate to NRC that normal operations at the Yucca Mountain site will and do occur in compliance with this subpart before NRC may grant or continue a license for DOE to receive and possess radioactive material within the Yucca Mountain site.

§ 197.4 What standard must DOE meet?

The DOE must ensure that no member of the public in the general environment receives more than an annual committed effective dose equivalent of

150 microsieverts (15 millirems) from the combination of:

(a) Management and storage (as defined in 40 CFR 191.2) of radioactive material that:

(1) Is subject to 40 CFR 191.3(a); and

(2) Occurs outside of the Yucca Mountain repository but within the Yucca Mountain site; and

(b) Storage (as defined in §197.2) of radioactive material inside the Yucca Mountain repository.

§ 197.5 When will this part take effect?

The standards in this part take effect on July 13, 2001.

Subpart B—Public Health and Environmental Standards for Disposal

§ 197.11 What does subpart B cover?

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE.

§ 197.12 What definitions apply in subpart B?

All definitions in subpart A of this part and the following:

Accessible environment means any point outside of the controlled area, including:

(1) The atmosphere (including the atmosphere above the surface area of the controlled area);

(2) Land surfaces;

(3) Surface waters;

(4) Oceans; and

(5) The lithosphere.

Aquifer means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

Barrier means any material, structure, or feature that, for a period to be determined by NRC, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

Controlled area means:

(1) The surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(a) South than 36°40′13.6661″ north latitude, in the predominant direction of ground water flow; and

(b) Than five kilometers from the repository footprint in any other direction; and

(2) The subsurface underlying the surface area.

Disposal means the emplacement of radioactive material into the Yucca Mountain disposal system with the intent of isolating it for as long as reasonably possible and with no intent of recovery, whether or not the design of the disposal system permits the ready recovery of the material. Disposal of radioactive material in the Yucca Mountain disposal system begins when all of the ramps and other openings into the Yucca Mountain repository are sealed.

Ground water means water that is below the land surface and in a saturated zone.

Human intrusion means breaching of any portion of the Yucca Mountain disposal system, within the repository footprint, by any human activity.

Passive institutional controls means:

(1) Markers, as permanent as practicable, placed on the Earth's surface;

(2) Public records and archives;

(3) Government ownership and regulations regarding land or resource use; and

(4) Other reasonable methods of preserving knowledge about the location, design, and contents of the Yucca Mountain disposal system.

Peak dose means the highest annual committed effective dose equivalent projected to be received by the reasonably maximally exposed individual.

Performance assessment means an analysis that:

(1) Identifies the features, events, processes, (except human intrusion), and sequences of events and processes

(except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates the annual committed effective dose equivalent incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

Period of geologic stability means the time during which the variability of geologic characteristics and their future behavior in and around the Yucca Mountain site can be bounded, that is, they can be projected within a reasonable range of possibilities. This period is defined to end at 1 million years after disposal.

Plume of contamination means that volume of ground water in the predominant direction of ground water flow that contains radioactive contamination from releases from the Yucca Mountain repository. It does not include releases from any other potential sources on or near the Nevada Test Site.

Repository footprint means the outline of the outermost locations of where the waste is emplaced in the Yucca Mountain repository.

Slice of the plume means a cross-section of the plume of contamination with sufficient thickness parallel to the prevalent direction of flow of the plume that it contains the representative volume.

Total dissolved solids means the total dissolved (filterable) solids in water as determined by use of the method specified in 40 CFR part 136.

Undisturbed performance means that human intrusion or the occurrence of unlikely natural features, events, and processes do not disturb the disposal system.

Undisturbed Yucca Mountain disposal system means that the Yucca Mountain disposal system is not affected by human intrusion.

Waste means any radioactive material emplaced for disposal into the Yucca Mountain repository.

Well-capture zone means the volume from which a well pumping at a defined rate is withdrawing water from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval.

Yucca Mountain disposal system means the combination of underground engineered and natural barriers within the controlled area that prevents or substantially reduces releases from the waste.

[66 FR 32132, June 13, 2001, as amended at 73 FR 61287, Oct. 15, 2008]

§ 197.13 How is Subpart B implemented?

The NRC implements this subpart B. The DOE must demonstrate to NRC that there is a reasonable expectation of compliance with this subpart before NRC may issue a license.

(a) The NRC will determine compliance, based upon the arithmetic mean of the projected doses from DOE's performance assessments for the period within 1 million years after disposal, with:

(1) Sections 197.20(a)(1) and 197.20(a)(2) of this subpart; and

(2) Sections 197.25(b)(1), 197.25(b)(2), and 197.30 of this subpart, if performance assessment is used to demonstrate compliance with either or both of these sections.

(b) [Reserved]

[73 FR 61287, Oct. 15, 2008]

§ 197.14 What is a reasonable expectation?

Reasonable expectation means that NRC is satisfied that compliance will be achieved based upon the full record before it. Characteristics of reasonable expectation include that it:

(a) Requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance;

(b) Accounts for the inherently greater uncertainties in making long-term

projections of the performance of the Yucca Mountain disposal system;

(c) Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence; and

(d) Focuses performance assessments and analyses upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 197.15 How must DOE take into account the changes that will occur during the period of geologic stability?

The DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at the time of license application submission to NRC. However, DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions of the changes in these factors that could affect the Yucca Mountain disposal system during the period of geologic stability, consistent with the requirements for performance assessments specified at § 197.36.

[73 FR 61287, Oct. 15, 2008]

INDIVIDUAL-PROTECTION STANDARD

§ 197.20 What standard must DOE meet?

(a) The DOE must demonstrate, using performance assessment, that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than the following annual committed effective dose equivalent from releases from the undisturbed Yucca Mountain disposal system:

(1) 150 microsieverts (15 millirems) for 10,000 years following disposal; and

(2) 1 millisievert (100 millirems) after 10,000 years, but within the period of geologic stability.

(b) The DOE's performance assessment must include all potential pathways of radionuclide transport and exposure.

[73 FR 61287, Oct. 15, 2008]

§ 197.21 Who is the reasonably maximally exposed individual?

The reasonably maximally exposed individual is a hypothetical person who meets the following criteria:

(a) Lives in the accessible environment above the highest concentration of radionuclides in the plume of contamination;

(b) Has a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada. The DOE must use projections based upon surveys of the people residing in the Town of Amargosa Valley, Nevada, to determine their current diets and living styles and use the mean values of these factors in the assessments conducted for §§ 197.20 and 197.25; and

(c) Drinks 2 liters of water per day from wells drilled into the ground water at the location specified in paragraph (a) of this section.

HUMAN-INTRUSION STANDARD

§ 197.25 What standard must DOE meet?

(a) The DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion (see § 197.26) could occur without recognition by the drillers.

(b) The DOE must demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual will receive an annual committed effective dose equivalent, as a result of the human intrusion, of no more than:

(1) 150 microsieverts (15 millirems) for 10,000 years following disposal; and

(2) 1 millisievert (100 millirems) after 10,000 years, but within the period of geologic stability.

(c) The analysis must include all potential environmental pathways of radionuclide transport and exposure.

[73 FR 61288, Oct. 15, 2008]

§ 197.26 What are the circumstances of the human intrusion?

For the purposes of the analysis of human intrusion, DOE must make the following assumptions:

(a) There is a single human intrusion as a result of exploratory drilling for ground water;

(b) The intruders drill a borehole directly through a degraded waste package into the uppermost aquifer underlying the Yucca Mountain repository;

(c) The drillers use the common techniques and practices that are currently employed in exploratory drilling for ground water in the region surrounding Yucca Mountain;

(d) Careful sealing of the borehole does not occur, instead natural degradation processes gradually modify the borehole;

(e) Only releases of radionuclides that occur as a result of the intrusion and that are transported through the resulting borehole to the saturated zone are projected; and

(f) No releases are included which are caused by unlikely natural processes and events.

GROUND WATER PROTECTION STANDARDS

§ 197.30 What standards must DOE meet?

The DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of undisturbed performance after disposal, releases of radionuclides from waste in the Yucca Mountain disposal system into the accessible environment will not cause the level of radioactivity in the representative volume of ground water to exceed the limits in the following Table 1:

TABLE 1—LIMITS ON RADIONUCLIDES IN THE REPRESENTATIVE VOLUME

Radionuclide or type of radiation emitted	Limit	Is natural background included?
Combined radium-226 and radium-228	5 picocuries per liter	Yes.
Gross alpha activity (including radium-226 but excluding radon and uranium).	15 picocuries per liter	Yes.
Combined beta and photon emitting radionuclides	40 microsieverts (4 millirem) per year to the whole body or any organ, based on drinking 2 liters of water per day from the representative volume.	No.

§ 197.31 What is a representative volume?

(a) It is the volume of ground water that would be withdrawn annually from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water to supply a given water demand. The DOE must project the concentration of radionuclides released from the Yucca Mountain disposal system that will be in the representative volume. The DOE must then use the projected concentrations to demonstrate a reasonable expectation to NRC that the Yucca Mountain disposal system complies with §197.30. The DOE must make the following assumptions concerning the representative volume:

(1) It includes the highest concentration level in the plume of contamination in the accessible environment;

(2) Its position and dimensions in the aquifer are determined using average hydrologic characteristics which have cautious, but reasonable, values representative of the aquifers along the radionuclide migration path from the Yucca Mountain repository to the accessible environment as determined by site characterization; and

(3) It contains 3,000 acre-feet of water (about 3,714,450,000 liters or 977,486,000 gallons).

(b) The DOE must use one of two alternative methods for determining the dimensions of the representative volume. The DOE must propose its chosen method, and any underlying assumptions, to NRC for approval.

(1) The DOE may calculate the dimensions as a well-capture zone. If DOE uses this approach, it must assume that the:

(i) Water supply well(s) has (have) characteristics consistent with public water supply wells in the Town of Amargosa Valley, Nevada, for example,

well-bore size and length of the screened intervals;

(ii) Screened interval(s) include(s) the highest concentration in the plume of contamination in the accessible environment; and

(iii) Pumping rates and the placement of the well(s) must be set to produce an annual withdrawal equal to the representative volume and to tap the highest concentration within the plume of contamination.

(2) The DOE may calculate the dimensions as a slice of the plume. If DOE uses this approach, it must:

(i) Propose to NRC, for its approval, where the location of the edge of the plume of contamination occurs. For example, the place where the concentration of radionuclides reaches 0.1% of the level of the highest concentration in the accessible environment;

(ii) Assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(iii) Assume that the volume of ground water contained within the slice of the plume equals the representative volume.

ADDITIONAL PROVISIONS

§ 197.35 [Reserved]

§ 197.36 Are there limits on what DOE must consider in the performance assessments?

(a) Yes, there are limits on what DOE must consider in the performance assessments.

(1) The DOE's performance assessments conducted to show compliance with §§ 197.20(a)(1), 197.25(b)(1), and 197.30 shall not include consideration of very unlikely features, events, or processes, i.e., those that are estimated to have less than one chance in 100,000,000 per year of occurring. Features, events, and processes with a higher chance of occurring shall be considered for use in performance assessments conducted to show compliance with §§ 197.20(a)(1), 197.25(b)(1), and 197.30, except as stipulated in paragraph (b) of this section. In addition, unless otherwise specified in these standards or NRC regulations, DOE's performance assessments need not evaluate the impacts resulting from features, events, and processes or sequences of events and processes with a higher chance of occurring if the results of the performance assessments would not be changed significantly in the initial 10,000-year period after disposal.

(2) The same features, events, and processes identified in paragraph (a)(1) of this section shall be used in performance assessments conducted to show compliance with §§ 197.20(a)(2) and 197.25(b)(2), with additional considerations as stipulated in paragraph (c) of this section.

(b) For performance assessments conducted to show compliance with §§ 197.25(b) and 197.30, DOE's performance assessments shall exclude unlikely features, events, or processes, or sequences of events and processes. The DOE should use the specific probability of the unlikely features, events, and processes as specified by NRC.

(c) For performance assessments conducted to show compliance with §§ 197.20(a)(2) and 197.25(b)(2), DOE's performance assessments shall project the continued effects of the features, events, and processes included in paragraph (a) of this section beyond the 10,000-year post-disposal period through the period of geologic stability. The DOE must evaluate all of the features, events, or processes included in paragraph (a) of this section, and also:

(1) The DOE must assess the effects of seismic and igneous scenarios, subject to the probability limits in paragraph (a) of this section for very unlikely features, events, and processes. Performance assessments conducted to show compliance with § 197.25(b)(2) are also subject to the probability limits for unlikely features, events, and processes as specified by NRC.

(i) The seismic analysis may be limited to the effects caused by damage to the drifts in the repository, failure of the waste packages, and changes in the elevation of the water table under Yucca Mountain. NRC may determine the magnitude of the water table rise and its significance on the results of the performance assessment, or NRC may require DOE to demonstrate the magnitude of the water table rise and its significance in the license application. If NRC determines that the increased elevation of the water table does not significantly affect the results

of the performance assessment, NRC may choose to not require its consideration in the performance assessment.

(ii) The igneous analysis may be limited to the effects of a volcanic event directly intersecting the repository. The igneous event may be limited to that causing damage to the waste packages directly, causing releases of radionuclides to the biosphere, atmosphere, or ground water.

(2) The DOE must assess the effects of climate change. The climate change analysis may be limited to the effects of increased water flow through the repository as a result of climate change, and the resulting transport and release of radionuclides to the accessible environment. The nature and degree of climate change may be represented by constant climate conditions. The analysis may commence at 10,000 years after disposal and shall extend through the period of geologic stability. The NRC shall specify in regulation the values to be used to represent climate change, such as temperature, precipitation, or infiltration rate of water.

(3) The DOE must assess the effects of general corrosion on engineered barriers. The DOE may use a constant representative corrosion rate throughout the period of geologic stability or a distribution of corrosion rates correlated to other repository parameters.

[73 FR 61288, Oct. 15, 2008]

§ 197.37 Can EPA amend this rule?

Yes. We can amend this rule by conducting another notice-and-comment rulemaking. Such a rulemaking must include a public comment period. Also, we may hold one or more public hearings, if we receive a written request to do so.

§ 197.38 Are the Individual Protection and Ground Water Protection Standards Severable?

Yes. The individual protection and ground water protection standards are severable.

APPENDIX A TO PART 197—CALCULATION OF ANNUAL COMMITTED EFFECTIVE DOSE EQUIVALENT

Unless otherwise directed by NRC, DOE shall use the radiation weighting factors and tissue weighting factors in this Appendix to calculate the internal component of the annual committed effective dose equivalent for compliance with §§197.20 and 197.25 of this part. NRC may allow DOE to use updated factors issued after the effective date of this regulation. Any such factors shall have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance in order to be considered generally accepted and eligible for this use. Further, they must be compatible with the effective dose equivalent dose calculation methodology established in ICRP 26 and 30, and continued in ICRP 60 and 72, and incorporated in this appendix.

I. EQUIVALENT DOSE

The calculation of the committed effective dose equivalent (CEDE) begins with the determination of the equivalent dose, H_T, to a tissue or organ, T, listed in Table A.2 below by using the equation:

$$\underline{H}_T = \sum_R \underline{D}_{T,R} \cdot \underline{w}_R$$

where $D_{T,R}$ is the absorbed dose in rads (one gray, an SI unit, equals 100 rads) averaged over the tissue or organ, T, due to radiation type, R, and w_R is the radiation weighting factor which is given in Table A.1 below. The unit of equivalent dose is the rem (sievert, in SI units).

TABLE A.1—RADIATION WEIGHTING FACTORS, w_R[1]

Radiation type and energy range[2]	w_R value
Photons, all energies	1
Electrons and muons, all energies	1
Neutrons, energy	
<10 keV	5
10 keV to 100 keV	10
>100 keV to 2 MeV	20
>2 MeV to 20 MeV	10
>20 MeV	5
Protons, other than recoil protons, >2 MeV	5
Alpha particles, fission fragments, heavy nuclei	20

[1] All values relate to the radiation incident on the body or, for internal sources, emitted from the source.

[2] See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

II. EFFECTIVE DOSE EQUIVALENT

The next step is the calculation of the *effective dose equivalent*, E. The probability of occurrence of a stochastic effect in a tissue or organ is assumed to be proportional to the equivalent dose in the tissue or organ. The

constant of proportionality differs for the various tissues of the body, but in assessing health detriment the total risk is required. This is taken into account using the tissue weighting factors, w_T in Table A.2, which represent the proportion of the stochastic risk resulting from irradiation of the tissue or organ to the total risk when the whole body is irradiated uniformly and H_T is the equivalent dose in the tissue or organ, T, in the equation:

$$E = \sum \underline{w}_T \cdot \underline{H}_T.$$

TABLE A.2—TISSUE WEIGHTING FACTORS, w_T

Tissue or organ	w_T value
Gonads	0.20
Bone marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Esophagus	0.05
Thyroid	0.05
Skin	0.01
Bone surface	0.01
Remainder	[a] [b] 0.05

[a] Remainder is composed of the following tissues: adrenals, brain, extrathoracic airways, small intestine, kidneys, muscle, pancreas, spleen, thymus, and uterus.

[b] The value 0.05 is applied to the mass-weighted average dose to the Remainder tissues group, except when the following "splitting rule" applies: If a tissue of Remainder receives a dose in excess of that received by any of the 12 tissues for which weighting factors are specified, a weighting factor of 0.025 (half of Remainder) is applied to that tissue or organ and 0.025 to the mass-averaged committed equivalent dose equivalent in the rest of the Remainder tissues.

III. ANNUAL COMMITTED TISSUE OR ORGAN EQUIVALENT DOSE

For internal irradiation from incorporated radionuclides, the total absorbed dose will be spread out in time, being gradually delivered as the radionuclide decays. The time distribution of the absorbed dose rate will vary with the radionuclide, its form, the mode of intake and the tissue within which it is incorporated. To take account of this distribution the quantity *committed equivalent dose*, $H_T(\tau)$ where τ is the integration time in years following an intake over any particular year, is used and is the integral over time of the equivalent dose rate in a particular tissue or organ that will be received by an individual following an intake of radioactive material into the body:

$$H_T(\tau) = \int_{t_0}^{t_0 + \tau} H_T(t)\, dt$$

for a single intake of activity at time t_0 where $H_T(\tau)$ is the relevant equivalent-dose rate in a tissue or organ at time t. For the purposes of this rule, the previously mentioned single intake may be considered to be an annual intake.

IV. INTERNAL COMPONENT OF THE ANNUAL COMMITTED EFFECTIVE DOSE EQUIVALENT

If the annual committed equivalent doses to the individual tissues or organs resulting from an annual intake are multiplied by the appropriate weighting factors, w_T, from table A.2, and then summed, the result will be the internal component of the *annual committed effective dose equivalent* $E(\tau)$:

$$E(\tau) = \sum_T w_T \cdot H_T(\tau).$$

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