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fluidized bed dryers; thin film evaporators; extruders, evaporators; and Compactors); the suitability of volume reduction equipment to the circumstances (specific activity considerations, actual volume reduction factors, generation of secondary wastes, equipment contamination, effluent releases, worker exposure, and equipment availability); and the administrative controls which could be applied, in making a determination whether waste to be delivered for disposal under this part has been reduced in volume to the maximum extent practicable using available technology.

§ 62.26 Criteria for designating a disposal facility.

(a) The Commission shall designate an appropriate non-Federal or regional disposal facility if an affirmative determination is made pursuant to §§ 62.21, 62.23, or 62.24 of this part.

(b) The Commission will exclude a disposal facility from consideration if:

(1) The low-level radioactive wastes of the generator do not meet the criteria established by the license agreement or the license agreement of the facility; or

(2) The disposal facility is in excess of its approved capacity; or

(3) Granting emergency access would delay the closing of the disposal facility pursuant to plans established before the receipt of the request for emergency access; or

(4) The volume of waste requiring emergency access exceeds 20 percent of the total volume of low-level radioactive waste accepted for disposal at the facility during the previous calendar year.

(c) If, after applying the exclusionary criteria in paragraph (b) of this section, more than one disposal facility is identified as appropriate for designation, the Commission will then consider additional factors in designating a facility or facilities including—

(1) Type of waste and its characteristics,

(2) Previous disposal practices,

(3) Transportation

(4) Radiological effects,

(5) Site capability for handling waste,

(6) The volume of emergency access waste previously accepted by each site

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both for the particular year and overall, and

(7) Any other considerations deemed appropriate by the Commission.

(d) The Commission, in making its designation, will also consider any information submitted by the operating non-Federal or regional LLW disposal sites, or any information submitted by the public in response to a FEDERAL REGISTER notice requesting comment, as provided in paragraph (b) of § 62.11 of this part.

Subpart D—Termination of Emergency Access

§ 62.31 Termination of emergency access.

(a) The Commission may terminate a grant of emergency access when emergency access is no longer necessary to eliminate an immediate threat to public health and safety or the common defense and security.

(b) The Commission may terminate a grant of emergency access if an applicant has provided inaccurate information in its application for emergency access or if the applicant has failed to comply with this part or any conditions set by the Commission pursuant to this part.

PART 63—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

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AUTHORITY: Atomic Energy Act of 1954, secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 223, 234 (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 42 U.S.C. 2021a; National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 114, 117, 121 (42 U.S.C. 10134, 10137, 10141); 44 U.S.C. 3504 note.

SOURCE: 66 FR 55792, Nov. 2, 2001, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 63 appear at 81 FR 86909, Dec. 2, 2016.

Subpart A—General Provisions

§ 63.1 Purpose and scope.

This part prescribes rules governing the licensing (including issuance of a construction authorization) of the U.S. Department of Energy to receive and possess source, special nuclear, and by-product material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992. As provided in 10 CFR 60.1, the regulations in part 60 of this chapter do not apply to any activity licensed under another part of this chapter. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor,

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components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 63.11.

[69 FR 2280, Jan. 14, 2004]

§ 63.2 Definitions.

As used in this part:

Affected Indian Tribe means any Indian Tribe within whose reservation boundaries a repository for high-level radioactive waste or spent fuel is proposed to be located; or whose Federally-defined possessory or usage rights to other lands outside of the reservation's boundaries arising out of Congressionally-ratified treaties or other Federal law may be substantially and adversely affected by the location of the facility if the Secretary of the Interior finds, on the petition of the appropriate governmental officials of the Tribe, that the effects are both substantial and adverse to the Tribe.

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.

Commencement of construction means clearing of land, surface or subsurface excavation, or other substantial action that would adversely affect the environment of a site. It does not include changes desirable for the temporary use of the land for public recreational uses, site characterization activities, other preconstruction monitoring and investigation necessary to establish background information related to the suitability of the Yucca Mountain site or to the protection of environmental values, or procurement or manufacture

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of components of the geologic repository operations area.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Containment means the confinement of radioactive waste within a designated boundary.

Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be constraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include:

- (1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

- (2) Estimates of severe external human-induced events to be used for deriving design bases, that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Director means the Director of the Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Disposal means the emplacement of radioactive waste in a geologic repository with the intent of leaving it there permanently.

DOE means the U.S. Department of Energy or its duly authorized representatives.

Engineered barrier system means the waste packages, including engineered components and systems other than the waste package (e.g., drip shields), and the underground facility.

Event sequence means a series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area

that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least one chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences.

Geologic repository means a system that is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the engineered barrier system and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic repository operations area means a high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted.

Geologic setting means the geologic, hydrologic, and geochemical systems of the region in which a geologic repository is or may be located.

High-level radioactive waste or *HLW* 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;

- (2) Irradiated reactor fuel; and

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

HLW facility means a facility subject to the licensing and related regulatory authority of the Commission pursuant

to sections 202(3) and 202(4) of the Energy Reorganization Act of 1974 (88 Stat. 1244).¹

Host rock means the geologic medium in which the waste is emplaced.

Important to safety, with reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in radiological exposures exceeding the values specified at § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide a reasonable expectation that high-level waste can be disposed of without exceeding the requirements of § 63.113(b) and (c).

Initiating event means a natural or human induced event that causes an event sequence.

Isolation means inhibiting the transport of radioactive material to:

(1) The location of the reasonably maximally exposed individual so that radiological exposures will not exceed the requirements of § 63.113(b); and

(2) The accessible environment so that releases of radionuclides into the accessible environment will not exceed the requirements of § 63.113(c).

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 dose 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.

Performance confirmation means the program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in subpart E of this part.

Permanent closure means final backfilling of the underground facility, if appropriate, and the sealing of shafts, ramps, and boreholes.

Preclosure safety analysis means a systematic examination of the site; the design; and the potential hazards, initiating events and event sequences and their consequences (e.g., radiological exposures to workers and the public). The analysis identifies structures, systems, and components important to safety.

Public Document Room means the place at One White Flint North, 11555 Rockville Pike, Room O-1F13, Rockville, MD, at which records of the Commission will ordinarily be made available for public inspection and any other place, the location of which has been published in the FEDERAL REGISTER, at which public records of the Commission pertaining to a geologic repository at the Yucca Mountain site are made available for public inspection.

Publicly Available Records System (PARS) Library means the electronic library generated by the NRC's Agency-wide Documents Access and Management System (ADAMS) to provide access to public documents. PARS has full text documents which can be

¹These are DOE "facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such Act (the Atomic Energy Act)" and "Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by (DOE), which are not used for, or are part of, research and development activities."

searched using specific fields and parameters. The public can search, download, print, create reports, and order documents online. The PARS Library contains publicly available documents created or received by NRC since November 1, 1999, as well as some older documents that the NRC has retrofit into the collection. PARS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

Radioactive waste or *waste* means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reasonably maximally exposed individual means the hypothetical person meeting the criteria specified at § 63.312.

Reference biosphere means the description of the environment inhabited by the reasonably maximally exposed individual. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of permanently removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means that part of the earth's crust beneath the regional water table in which statistically all voids, large and small, are filled with water under pressure greater than atmospheric.

Site means that area surrounding the geologic repository operations area for which DOE exercises authority over its use in accordance with the provisions of this part.

Site characterization means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and

the surrounding region to the extent necessary, relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository.

Total effective dose equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Underground facility means the underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts, and boreholes, including their seals).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Unsaturated zone means the zone between the land surface and the regional water table. Generally, fluid pressure in this zone is less than atmospheric pressure, and some of the voids may contain air or other gases at atmospheric pressure. Beneath flooded areas or in perched water bodies, the fluid pressure locally may be greater than atmospheric.

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

Waste package means the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

Water table means that surface in a groundwater body, separating the unsaturated zone from the saturated zone, at which the water pressure is atmospheric.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003; 74 FR 10828, Mar. 13, 2009]

§ 63.3 License required.

(a) DOE may not receive nor possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site except as authorized by a license issued by the Commission under this part.

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(b) DOE may not begin construction of a geologic repository operations area at the Yucca Mountain site unless it has filed an application with the Commission and has obtained construction authorization as provided in this part. Failure to comply with this requirement is grounds for denial of a license.

§ 63.4 Communications and records.

(a) Except as otherwise specified, in this part or in subpart J of part 2 of this chapter, all communications and reports concerning the regulations in this part and applications filed under them should be sent to the NRC as follows:

(1) By mail addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001;

(2) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; ATTN: Document Control Desk; Director, Office of Nuclear Material Safety and Safeguards; or,

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media

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with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003; 74 FR 62683, Dec. 1, 2009; 80 FR 74981, Dec. 1, 2015]

§ 63.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel is binding on the Commission.

EFFECTIVE DATE NOTE: At 90 FR 55632, Dec. 3, 2025, § 63.5 was amended, effective January 8, 2026.

§ 63.6 Exemptions.

The Commission may, upon application by DOE, any interested person, or upon its own initiative, grant an exemption from the requirements of this part if it determines that the exemption is authorized by law, does not endanger life nor property nor the common defense and security, and is otherwise in the public interest.

§ 63.7 License not required for certain preliminary activities.

The requirement for a license set forth in § 63.3(a) is not applicable to the extent that DOE receives and possesses source, special nuclear, and byproduct material at a geologic repository at the Yucca Mountain site:

(a) For purposes of site characterization; or

(b) For use, during site characterization or construction, as components of radiographic, radiation monitoring, or similar equipment or instrumentation.

§ 63.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction

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Act (44 U.S.C. 3501, *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0199.

(b) The approved information collection requirements contained in this Part appear in §§ 63.6, 63.47, 63.62, 63.63, and 63.65.

(c) In § 63.47, IAEA Design Information Questionnaire forms IAEA Design Information Questionnaire forms are approved under control number 3150-0056, and DOC/NRC Forms AP-1, AP-A, and associated forms are approved under control numbers 0694-0135.

[66 FR 55792, Nov. 2, 2001, as amended at 73 FR 78606, Dec. 23, 2008; 85 FR 65663, Oct. 16, 2020]IAEA Design Information Questionnaire forms

§ 63.9 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant, against an employee, for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission, or his or her employer, information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those aforementioned statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section, or under these requirements, if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section;

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section does not apply to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license;

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant; or

(3) Other enforcement action.

(d) Actions taken by an employer, or others, that adversely affect an employee, may be predicated on non-discriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by non-prohibited considerations.

(e)(1) Each licensee and each applicant for a license shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, via email to Forms.Resource@nrc.gov, or by visiting the NRC's online library at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision that would prohibit, restrict, or otherwise discourage an employee from participating in a protected activity as defined in paragraph (a)(1) of this section, including, but not limited to, providing information to NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003; 72 FR 63974, Nov. 14, 2007; 73 FR 30459, May 28, 2008; 79 FR 66605, Nov. 10, 2014]

§ 63.10 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee, or information required by statute, or required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) The applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, within 2 working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the Commission by other reporting or updating requirements.

§ 63.11 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to NRC, a licensee, an applicant, or a licensee's or

applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Subpart B—Licenses

PREAPPLICATION REVIEW

§ 63.15 Site characterization.

(a) DOE shall conduct a program of site characterization with respect to the Yucca Mountain site before it submits an application for a license to be issued under this part.

(b) DOE shall conduct the investigations to obtain the required information in a manner that limits adverse effects on the long-term performance of the geologic repository at Yucca Mountain to the extent practical.

§ 63.16 Review of site characterization activities.²

(a) If DOE's planned site characterization activities include onsite testing with radioactive material, including radioactive tracers, the Commission shall determine whether the proposed use of such radioactive material is necessary to provide data for the preparation of the environmental reports re-

quired by law and for an application to be submitted under § 63.22.

(b) During the conduct of site characterization activities at the Yucca Mountain site, DOE shall report the nature and extent of the activities, the information that has been developed, and the progress of waste form and waste package research and development to the Commission not less than once every 6 months. The semiannual reports must include the results of site characterization studies, the identification of new issues, plans for additional studies to resolve new issues, elimination of planned studies no longer necessary, identification of decision points reached, and modifications to schedules, where appropriate. DOE shall also report its progress in developing the design of a geologic repository operations area appropriate for the area being characterized, noting when key design parameters or features that depend on the results of site characterization will be established. Other topics related to site characterization must also be covered if requested by the Director.

(c) During the conduct of site characterization activities at the Yucca Mountain site, NRC staff shall be permitted to visit and inspect the locations at which such activities are carried out and to observe excavations, borings, and in situ tests, as they are done.

(d) The Director may comment at any time in writing to DOE, expressing current views on any aspect of site characterization or performance assessment at the Yucca Mountain site. In particular, the Director shall comment whenever he or she determines that there are substantial grounds for making recommendations or stating objections to DOE's site characterization program. The Director shall invite public comment on any comments that the Director makes to DOE on review of the DOE semiannual reports or on any other comments that the Director makes to DOE on site characterization and performance assessment by placing the comments in a public forum to allow the public to comment on them after the Director's comments are sent to DOE.

²In addition to the review of site characterization activities specified in this section, the Commission contemplates an ongoing review of other information on site investigation and site characterization, to allow early identification of potential licensing issues for timely resolution at the staff level.

(e) The Director shall transmit copies of all comments to DOE made by the Director under this section to the Governor and legislature of the State of Nevada and to the governing body of any affected Indian Tribe.

(f) The NRC shall place all correspondence between DOE and NRC resulting from the requirements of this section, including the reports described in paragraph (b) of this section, in the Publicly Available Records System (PARS) Library.

(g) The activities described in paragraphs (a) through (f) of this section constitute informal conference between a prospective applicant and the NRC staff, as described in § 2.101(a)(1) of this chapter, and are not part of a proceeding under the Atomic Energy Act of 1954, as amended. Accordingly, the issuance of the Director's comments made under this section does not constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board, other presiding officers, or the Director, in any such proceeding.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003]

LICENSE APPLICATION

§ 63.21 Content of application.

(a) An application consists of general information and a Safety Analysis Report. An environmental impact statement must be prepared in accordance with the Nuclear Waste Policy Act of 1982, as amended, and must accompany the application. Any Restricted Data or National Security Information must be separated from unclassified information. The application must be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) The general information must include:

(1) A general description of the proposed geologic repository at the Yucca Mountain site, identifying the location of the geologic repository operations area, the general character of the proposed activities, and the basis for the exercise of the Commission's licensing authority.

(2) Proposed schedules for construction, receipt of waste, and emplacement of wastes at the proposed geologic repository operations area.

(3) A description of the detailed security measures for physical protection of high-level radioactive waste in accordance with § 73.51 of this chapter. This plan must include the design for physical protection, the licensee's safeguards contingency plan, and security organization personnel training and qualification plan. The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with such requirements.

(4) A description of the material control and accounting program to meet the requirements of § 63.78.

(5) A description of work conducted to characterize the Yucca Mountain site.

(c) The Safety Analysis Report must include:

(1) A description of the Yucca Mountain site, with appropriate attention to those features, events, and processes of the site that might affect design of the geologic repository operations area and performance of the geologic repository. The description of the site must include information regarding features, events, and processes outside of the site to the extent the information is relevant and material to safety or performance of the geologic repository. The information referred to in this paragraph must include:

(i) The location of the geologic repository operations area with respect to the boundary of the site;

(ii) Information regarding the geology, hydrology, and geochemistry of the site, including geomechanical properties and conditions of the host rock;

(iii) Information regarding surface water hydrology, climatology, and meteorology of the site; and

(iv) Information regarding the location of the reasonably maximally exposed individual, and regarding local human behaviors and characteristics, as needed to support selection of conceptual models and parameters used for the reference biosphere and reasonably maximally exposed individual.

(2) Information relative to materials of construction of the geologic repository operations area (including geologic media, general arrangement, and approximate dimensions), and codes and standards that DOE proposes to apply to the design and construction of the geologic repository operations area.

(3) A description and discussion of the design of the various components of the geologic repository operations area and the engineered barrier system including:

(i) Dimensions, material properties, specifications, analytical and design methods used along with any applicable codes and standards;

(ii) The design criteria used and their relationships to the preclosure and postclosure performance objectives specified at § 63.111(b), § 63.113(b), and § 63.113(c); and

(iii) The design bases and their relation to the design criteria.

(4) A description of the kind, amount, and specifications of the radioactive material proposed to be received and possessed at the geologic repository operations area at the Yucca Mountain site.

(5) A preclosure safety analysis of the geologic repository operations area, for the period before permanent closure, to ensure compliance with § 63.111(a), as required by § 63.111(c). For the purposes of this analysis, it is assumed that operations at the geologic repository operations area will be carried out at the maximum capacity and rate of receipt of radioactive waste stated in the application.

(6) A description of the program for control and monitoring of radioactive effluents and occupational radiological exposures to maintain such effluents and exposures in accordance with the requirements of § 63.111.

(7) A description of plans for retrieval and alternate storage of the radioactive wastes, should retrieval be necessary.

(8) A description of design considerations that are intended to facilitate permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(9) An assessment to determine the degree to which those features, events,

and processes of the site that are expected to materially affect compliance with § 63.113—whether beneficial or potentially adverse to performance of the geologic repository—have been characterized, and the extent to which they affect waste isolation. Investigations must extend from the surface to a depth sufficient to determine principal pathways for radionuclide migration from the underground facility. Specific features, events, and processes of the geologic setting must be investigated outside of the site if they affect performance of the geologic repository.

(10) An assessment of the anticipated response of the geomechanical, hydrogeologic, and geochemical systems to the range of design thermal loadings under consideration, given the pattern of fractures and other discontinuities and the heat transfer properties of the rock mass and water.

(11) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure, as required by § 63.113(b).

(12) An assessment of the ability of the proposed geologic repository to limit releases of radionuclides into the accessible environment as required by § 63.113(c).

(13) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure in the event of human intrusion into the engineered barrier system as required by § 63.113(d).

(14) An evaluation of the natural features of the geologic setting and design features of the engineered barrier system that are considered barriers important to waste isolation as required by § 63.115.

(15) An explanation of measures used to support the models used to provide the information required in paragraphs (c)(9) through (c)(14) of this section. Analyses and models that will be used to assess performance of the geologic repository must be supported by using an appropriate combination of such methods as field tests, in situ tests,

laboratory tests that are representative of field conditions, monitoring data, and natural analog studies.

(16) An identification of those structures, systems, and components of the geologic repository, both surface and subsurface, that require research and development to confirm the adequacy of design. For structures, systems, and components important to safety and for the engineered and natural barriers important to waste isolation, DOE shall provide a detailed description of the programs designed to resolve safety questions, including a schedule indicating when these questions would be resolved.

(17) A description of the performance confirmation program that meets the requirements of subpart F of this part.

(18) An identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of license specifications. Special attention must be given to those items that may significantly influence the final design.

(19) An explanation of how expert elicitation was used.

(20) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation. The description of the quality assurance program must include a discussion of how the applicable requirements of § 63.142 will be satisfied.

(21) A description of the plan for responding to, and recovering from, radiological emergencies that may occur at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities, as required by § 63.161.

(22) The following information concerning activities at the geologic repository operations area:

(i) The organizational structure of DOE as it pertains to construction and operation of the geologic repository operations area, including a description of any delegations of authority and assignments of responsibilities, whether in the form of regulations, administrative directives, contract provisions, or otherwise.

(ii) Identification of key positions that are assigned responsibility for safety at and operation of the geologic repository operations area.

(iii) Personnel qualifications and training requirements.

(iv) Plans for startup activities and startup testing.

(v) Plans for conduct of normal activities, including maintenance, surveillance, and periodic testing of structures, systems, and components of the geologic repository operations area.

(vi) Plans for permanent closure and plans for the decontamination or decontamination and dismantlement of surface facilities.

(vii) Plans for any uses of the geologic repository operations area at the Yucca Mountain site for purposes other than disposal of radioactive wastes, with an analysis of the effects, if any, that such uses may have on the operation of the structures, systems, and components important to safety and the engineered and natural barriers important to waste isolation.

(23) A description of the program to be used to maintain the records described in §§ 63.71 and 63.72.

(24) A description of the controls that DOE will apply to restrict access and to regulate land use at the Yucca Mountain site and adjacent areas, including a conceptual design of monuments that would be used to identify the site after permanent closure.

(d) The applicant for a license to receive and possess source, special nuclear, and byproduct material at a geologic repository at Yucca Mountain, Nevada, shall protect Safeguards Information in accordance with the requirements in § 73.21, and the requirements in § 73.22, or § 73.23 of this chapter, as applicable, and shall protect classified information in accordance with the requirements of parts 25 and 95 of this chapter, as applicable.

[66 FR 55792, Nov. 2, 2001, as amended at 73 FR 63572, Oct. 24, 2008]

§ 63.22 Filing and distribution of application.

(a) An application for a construction authorization for a high-level radioactive waste repository at a geologic repository operations area at Yucca

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Mountain, and an application for a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site that has been characterized, any amendments to the application, and an accompanying environmental impact statement and any supplements, must be signed by the Secretary of Energy or the Secretary's authorized representative and must be filed with the Director in triplicate on paper and optical storage media.

(b) DOE shall submit 30 additional copies, on paper and optical storage media, of each portion of the application and any amendments, and each environmental impact statement and any supplements. DOE shall maintain the capability to generate additional copies for distribution in accordance with written instructions from the Director or the Director's designee.

(c) On notification of the appointment of an Atomic Safety and Licensing Board, DOE shall update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement must be served in the same manner.

(d) When an application, and any amendment to it is filed, copies on paper and optical storage media must be made available in appropriate locations near the proposed geologic repository operations areas at the Yucca Mountain site for inspection by the public. These copies must be updated as amendments to the application are made. The environmental impact statement and any supplements to it must be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, must be produced at any public hearing held by the Commission on the application for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it

may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of these documents submitted as required by this part.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003; 69 FR 2280, Jan. 14, 2004]

§ 63.23 Elimination of repetition.

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, if the references are clear and specific and copies of the information incorporated are made available to the public locations near the site of the proposed geologic repository, as specified in § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

(a) The application must be as complete as possible in light of the information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license—

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction;

(2) Conformance of construction of structures, systems, and components with the design;

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

CONSTRUCTION AUTHORIZATION

§ 63.31 Construction authorization.

On review and consideration of an application and environmental impact statement submitted under this part, the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site if it determines:

(a) *Safety.* (1) That there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received and possessed in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public; and (2) That there is reasonable expectation that the materials can be disposed of without unreasonable risk to the health and safety of the public.

(3) In arriving at these determinations, the Commission shall consider whether—

(i) DOE has described the proposed geologic repository as specified at § 63.21;

(ii) The site and design comply with the performance objectives and requirements contained in subpart E of this part;

(iii) DOE's quality assurance program complies with the requirements of subpart G of this part;

(iv) DOE's personnel training program complies with the criteria contained in subpart H of this part;

(v) DOE's emergency plan complies with the criteria contained in subpart I of this part; and

(vi) DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate.

(b) *Common defense and security.* That there is reasonable assurance that the activities proposed in the application will not be inimical to the common defense and security.

(c) *Environmental.* That, after weighing the environmental, economic, technical, and other benefits against environmental costs, and considering available alternatives, the action called for is the issuance of the construction authorization, with any appropriate conditions to protect environmental values.

§ 63.32 Conditions of construction authorization.

(a) In a construction authorization for a geologic repository operations area at the Yucca Mountain site, the Commission shall include any conditions it considers necessary to protect the health and safety of the public, the common defense and security, or environmental values.

(b) The Commission shall incorporate provisions in the construction authorization requiring DOE to furnish periodic or special reports regarding:

(1) Progress of construction;

(2) Any data about the site, obtained during construction, that are not within the predicted limits on which the facility design was based;

(3) Any deficiencies, in design and construction, that, if uncorrected, could adversely affect safety at any future time; and

(4) Results of research and development programs being conducted to resolve safety questions.

(c) The construction authorization for a geologic repository operations area at the Yucca Mountain site will include restrictions on subsequent changes to the features of the geologic repository and the procedures authorized. The restrictions that may be imposed under this paragraph can include measures to prevent adverse effects on the geologic setting as well as measures related to the design and construction of the geologic repository operations area. These restrictions will fall into three categories of descending importance to public health and safety, as follows:

(1) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission;

(ii) 30 days notice of opportunity for a prior hearing; and

(iii) Prior Commission approval;

(2) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission; and

(ii) Prior Commission approval; and

(3) Those features and procedures that may not be changed without 60 days notice to the Commission. Features and procedures falling in this paragraph section may not be changed

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without prior Commission approval if the Commission, after having received the required notice, so orders.

(d) A construction authorization must be subject to the limitation that a license to receive and possess source, special nuclear, or byproduct material at the Yucca Mountain site geologic repository operations area may not be issued by the Commission until;

(1) DOE has updated its application, as specified at § 63.24; and

(2) The Commission has made the findings stated in § 63.41.

§ 63.33 Amendment of construction authorization.

(a) An application for amendment of a construction authorization must be filed with the Commission that fully describes any desired changes and follows, as far as applicable, the content requirements prescribed in § 63.21.

(b) In determining whether an amendment of a construction authorization will be approved, the Commission will be guided by the considerations that govern the issuance of the initial construction authorization, to the extent applicable.

LICENSE ISSUANCE AND AMENDMENT

§ 63.41 Standards for issuance of a license.

A license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site may be issued by the Commission on finding that—

(a) Construction of the geologic repository operations area has been substantially completed in conformity with the application as amended, the provisions of the Atomic Energy Act, and the rules and regulations of the Commission. Construction may be considered substantially complete for the purposes of this paragraph if the construction of—

(1) Surface and interconnecting structures, systems, and components; and

(2) Any underground storage space required for initial operation, are substantially complete.

(b) The activities to be conducted at the geologic repository operations area

will be in conformity with the application as amended, the provisions of the Atomic Energy Act and the Energy Reorganization Act, and the rules and regulations of the Commission.

(c) The issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public.

(d) Adequate protective measures can and will be taken in the event of a radiological emergency at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(e) All applicable requirements of part 51 of this chapter have been satisfied.

§ 63.42 Conditions of license.

(a) The Commission shall include any conditions, including license specifications, it considers necessary to protect the health and safety of the public, the common defense and security, and environmental values in a license issued under this part.

(b) Whether stated in the license or not, the following are considered to be conditions in every license issued:

(1) The license is subject to revocation, suspension, modification, or amendment for cause, as provided by the Atomic Energy Act and the Commission's regulations.

(2) DOE shall, at any time while the license is in effect, on written request of the Commission, submit written statements to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

(3) The license is subject to the provisions of the Atomic Energy Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to or by reason of rules, regulations, and orders issued in accordance with the terms of the Atomic Energy Act.

(c) Each license includes the provisions set forth in section 183 b-d, inclusive, of the Atomic Energy Act, whether or not these provisions are expressly set forth in the license.

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(d) A license issued under this part includes the provisions set forth in section 114(d) of the Nuclear Waste Policy Act, as amended, defining the quantity of solidified high-level radioactive waste and spent nuclear fuel, until such time as a second repository is in operation, whether or not these provisions are expressly set forth in the license.

(e) The licensee (Department of Energy) shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in § 73.21, and the requirements in § 73.22, or § 73.23 of this chapter, as applicable, and shall protect classified information in accordance with the requirements of parts 25 and 95 of this chapter, as applicable.

[66 FR 55792, Nov. 2, 2001, as amended at 73 FR 63572, Oct. 24, 2008]

§ 63.43 License specification.

(a) A license issued under this part includes license conditions derived from the analyses and evaluations included in the application, including amendments made before a license is issued, together with any additional conditions the Commission finds appropriate.

(b) License conditions include items in the following categories:

(1) Restrictions as to the physical and chemical form and radioisotopic content of radioactive waste.

(2) Restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging.

(3) Restrictions as to the amount of waste permitted per unit volume of storage space, considering the physical characteristics of both the waste and the host rock.

(4) Requirements relating to test, calibration, or inspection, to assure that the foregoing restrictions are observed.

(5) Controls to be applied to restrict access and to avoid disturbance to the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113.

(6) Administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure that activi-

ties at the facility are conducted in a safe manner and in conformity with the other license specifications.

§ 63.44 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the geologic repository operations area design or procedures that affects a design function, event sequence, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the Safety Analysis Report (SAR) (as updated) used in establishing the preclosure safety analyses or performance assessment* means:

(i) Changing any of the elements of the method described in the SAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the SAR to another method unless that method has been approved by NRC for the intended application, addition or removal.

(3) *Safety Analysis Report (SAR) (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as updated in accordance with § 63.24.

(4) *Geologic repository operations area as described in the SAR (as updated)* means:

(i) The structures, systems, and components important to safety or barriers important to waste isolation that are described in the SAR (as updated); and

(ii) The design and performance requirements for such structures, systems, and components described in the SAR (as updated).

(5) *Procedures as described in the SAR (as updated)* means those procedures that contain information described in the SAR (as updated) such as how structures, systems, and components important to safety, or important to waste isolation, are operated or controlled.

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(6) *Tests or experiments not described in the SAR (as updated)* means any condition where the geologic repository operations area or any of its structures, systems, and components important to safety, or important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the SAR (as updated); or

(ii) Inconsistent with the analyses or descriptions in the SAR (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the SAR (as updated), make changes in the procedures as described in the SAR (as updated), and conduct tests or experiments not described in the SAR (as updated), without obtaining either an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, if:

(i) A change in the conditions incorporated in the construction authorization or license is not required; and

(ii) The change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section.

(2) DOE shall obtain an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, before implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the frequency of occurrence of an event sequence previously evaluated in the SAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an event sequence previously evaluated in the SAR (as updated);

(iv) Result in more than a minimal increase in the consequences of malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(v) Create the possibility for an event sequence, or of a pathway for release of radionuclides, of a different type than

any evaluated previously in the SAR (as updated);

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety, or important to waste isolation, with a different result than any evaluated previously in the SAR (as updated);

(vii) Result in a departure from a method of evaluation described in the SAR (as updated) used in establishing the preclosure safety analysis or the performance assessment.

(3) In implementing this paragraph, the SAR (as updated) is considered to include SAR changes resulting from evaluations performed pursuant to this section and from safety analyses performed under § 63.33 or § 63.45, as applicable, after the last Safety Analysis Report was updated under § 63.24.

(4) The provisions in this section do not apply to changes to the geologic repository operations area or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(c)(1) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site, of changes in procedures, and of tests and experiments made under paragraph (b) of this section. These records must include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require an amendment of construction authorization or license amendment under paragraph (b) of this section.

(2) No less frequently than every 24 months, DOE shall prepare a report containing a brief description of such changes, tests, and experiments, including a summary of the evaluation of each. These written reports must be sent to the NRC using an appropriate method listed in § 63.4; addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-001; and DOE shall furnish the report to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter. Any report submitted under this paragraph must be made a part of the public record of the licensing proceedings.

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(d) Changes to the quality assurance program description required by § 63.21(c)(20) must be processed in accordance with § 63.144.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003]

§ 63.45 Amendment of license.

(a) An application for amendment of a license may be filed with the Commission fully describing the changes desired and following as far as applicable the format prescribed for license applications.

(b) In determining whether an amendment of a license will be approved, the Commission will be guided by the considerations that govern the issuance of the initial license, to the extent applicable.

§ 63.46 Particular activities requiring license amendment.

(a) Unless expressly authorized in the license, a license amendment is required for any of the following activities:

(1) Any action that would make emplaced high-level radioactive waste irretrievable or that would substantially increase the difficulty of retrieving the emplaced waste;

(2) Dismantling of structures;

(3) Removal or reduction of controls applied to restrict access to or avoid disturbance of the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113;

(4) Destruction or disposal of records required to be maintained under the provisions of this part;

(5) Any substantial change to the design or operating procedures from that specified in the license, except as authorized in § 63.44; and

(6) Permanent closure.

(b) An application for an amendment must be filed, and will be reviewed, as specified in § 63.45.

US/IAEA SAFEGUARDS AGREEMENT

§ 63.47 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a construction authorization or license and each recipient of a construction

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authorization or a license shall submit facility information, as described in § 75.10 of this chapter, on IAEA Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;

(b) As required by the Additional Protocol, applicants and licensees specified in paragraph (a) of this section shall submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms;

(c) Shall permit verification thereof by the International Atomic Energy Agency (IAEA) and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in Part 75 of this chapter.

[73 FR 78606, Dec. 23, 2008, as amended at 85 FR 65663, Oct. 16, 2020]

PERMANENT CLOSURE

§ 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission must consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required by subpart F, and pertinent to compliance with § 63.113.

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed—such as land use controls, construction of monuments, and preservation of records—to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, these measures must include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed,

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fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders—such records to identify the location of the geologic repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, drip shields, waste packages, interactions between natural and engineered systems, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of permanent closure, DOE shall also supplement its environmental impact statement and submit this statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site,

DOE may apply for an amendment to terminate the license.

(b) The application must be filed and will be reviewed in accordance with the provisions of § 63.45 and this section.

(c) A license may be terminated only when the Commission finds with respect to the geologic repository:

(1) That the final disposition of radioactive wastes has been made in conformance with DOE's plan, as amended and approved as part of the license.

(2) That the final state of the geologic repository operations area conforms to DOE's plans for permanent closure and DOE's plans for the decontamination or decontamination and dismantlement of surface facilities, as amended and approved as part of the license.

(3) That the termination of the license is authorized by law, including sections 57, 62, and 81 of the Atomic Energy Act, as amended.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

§ 63.61 Provision of information.

(a) The Director shall provide the Governor and the Nevada State legislature, affected units of local government, and the governing body of any affected Indian Tribe, with timely and complete information regarding determinations or plans made by the Commission with respect to the Yucca Mountain site. Information must be provided concerning the site characterization, siting, development, design, licensing, construction, operation, regulation, permanent closure, or decontamination and dismantlement of surface facilities of the geologic repository operations area at the site.

(b) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to the document, that entity or its counsel is included on a service list prepared under part 2 of this chapter.

(c) The NRC shall place communications by the Director under this section in the Publicly Available Records

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System (PARS) Library and furnish copies to DOE.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003]

§ 63.62 Site review.

(a) The Director shall make the NRC staff available to consult with representatives of the State of Nevada, affected units of local government, and affected Indian Tribes regarding the status of site characterization at the Yucca Mountain site.

(b) Requests for consultation must be made in writing to the Director.

(c) Consultation under this section may include:

(1) Keeping the parties informed of the Director's views on the progress of site characterization.

(2) Review of applicable NRC regulations, licensing procedures, schedules, and opportunities for State, affected units of local government, and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State, affected units of local government, and Tribal participation in license reviews.

§ 63.63 Participation in license reviews.

(a) The State, affected units of local government, and affected Indian Tribes may participate in license reviews as provided in subpart J of part 2 of this chapter.

(b) In addition, a State, or an affected unit of local government, or an affected Indian Tribe may submit a proposal to the Director to facilitate its participation in the review of the license application. The proposal may be submitted at any time and must contain a description and schedule of how the State, or affected unit of local government, or affected Indian Tribe wishes to participate in the review, or what services or activities the State, or affected unit of local government, or affected Indian Tribe wishes the NRC to carry out, and how the services or activities proposed to be carried out by the NRC would contribute to this participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as es-

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tablishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State, or affected unit of local government, or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State, or affected unit of local government, or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described in paragraph (c) of this section, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State, or affected unit of local government, or affected Indian Tribe may bear;

(2) The proposed activities—

(i) Will enhance communications between NRC and the State, or affected unit of local government, or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director shall advise the State, or affected unit of local government, or affected Indian Tribe whether its proposal has been accepted or denied. If all or any part of a proposal is denied, the Director shall state the reason for the denial.

(f) The NRC shall place all proposals submitted under this section, and responses to them, in the Publicly Available Records System (PARS) Library.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58816, Oct. 10, 2003]

§ 63.64 Notice to State.

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide the notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

§ 63.65 Representation.

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature of Nevada), for an affected unit of local government, or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in this capacity.

Subpart D—Records, Reports, Tests, and Inspections**§ 63.71 Records and reports.**

(a) DOE shall maintain records and make reports in connection with the licensed activity that are required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site must contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

§ 63.72 Construction records.

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

(b) The records required under paragraph (a) of this section must include at least the following—

(1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;

(2) A description of the materials encountered;

(3) Geologic maps and geologic cross-sections;

(4) Locations and amount of seepage;

(5) Details of equipment, methods, progress, and sequence of work;

(6) Construction problems;

(7) Anomalous conditions encountered;

(8) Instrument locations, readings, and analysis;

(9) Location and description of structural support systems;

(10) Location and description of dewatering systems;

(11) Details, methods of emplacement, and location of seals used; and

(12) Facility design records (e.g., design specifications and “as built” drawings).

§ 63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design, and construction of the geologic repository operations area that, were it to remain uncorrected, could—

(1) Adversely affect safety at any future time;

(2) Represent a significant deviation from the design criteria and design basis stated in the design application; or

(3) Represent a deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) DOE shall implement a program for evaluating and reporting deviations and failures to comply, to identify defects and failures to comply associated with substantial safety hazards, based on the applicable requirements in 10 CFR 50.55(e) as it applies to the construction authorization and design of the geologic repository operations area at the Yucca Mountain site.

(c) DOE shall implement a program of reporting specific events and conditions that is the same as that specified in 10 CFR 72.75.

(d) The requisite notification must be as specified in the applicable regulation. By an appropriate method listed in § 63.4 of this chapter, written reports must be submitted to NRC addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-001; and to the NRC onsite representative. DOE shall also furnish the

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report to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58815, Oct. 10, 2003]

§ 63.74 Tests.

(a) DOE shall perform, or permit the Commission to perform, those tests the Commission considers appropriate or necessary for the administration of the regulations in this part. This may include tests of—

- (1) Radioactive waste,
- (2) The geologic repository, including portions of the geologic setting and the structures, systems, and components constructed or placed therein,
- (3) Radiation detection and monitoring instruments, and
- (4) Other equipment and devices used in connection with the receipt, handling, or storage of radioactive waste.

(b) The tests required under this section must include a performance confirmation program carried out in accordance with subpart F of this part.

§ 63.75 Inspections.

(a) DOE shall allow the Commission to inspect the premises of the geologic repository operations area at the Yucca Mountain site and adjacent areas to which DOE has rights of access.

(b) DOE shall make available to the Commission for inspection, on reasonable notice, records kept by DOE pertaining to activities under this part.

(c)(1) DOE shall, on requests by the Director, Office of Nuclear Material Safety and Safeguards, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air-conditioning, light, electrical outlets, and janitorial services must be furnished by DOE. The office must be convenient to and have full access to the facility and must provide the inspector both visual and acoustic privacy.

(2) The space provided must be adequate to accommodate two full-time inspectors, and other transient NRC personnel and will be generally commensurate with other office facilities at the Yucca Mountain site geologic repository operations area. A space of 250 square feet either within the geologic

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repository operations area's office complex or in an office trailer or other onsite space at the geologic repository operations area is suggested as a guide. For locations at which activities are carried out under licenses issued under other parts of this chapter, additional space may be requested to accommodate additional full-time inspectors. The office space provided is subject to the approval of the Director, Office of Nuclear Material Safety and Safeguards. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) DOE shall afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors identified by the Regional Administrator as likely to inspect the Yucca Mountain facility, immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

§ 63.78 Material control and accounting records and reports.

DOE shall implement a program of material control and accounting (and accidental criticality reporting) that is the same as that specified in §§ 72.72, 72.74, 72.76, and 72.78 of this chapter.

Subpart E—Technical Criteria

§ 63.101 Purpose and nature of findings.

(a)(1) Subpart B prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives for postclosure performance of the geologic repository and other criteria that, if satisfied, support a finding of no unreasonable risk. Postclosure performance objectives for the geologic repository include a requirement to limit radiological exposures to the reasonably maximally exposed individual, a

requirement to limit releases of radionuclides to the accessible environment to protect groundwater, and a requirement to limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion (see § 63.113(b), (c), and (d), respectively).

(2) Although the postclosure performance objectives specified at § 63.113 are generally stated in unqualified terms, it is not expected that complete assurance that the requirements will be met can be presented. A reasonable expectation, on the basis of the record before the Commission, that the postclosure performance objectives will be met, is the general standard required. Proof that the geologic repository will conform with the objectives for postclosure performance is not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable expectation, making allowance for the time period, hazards, and uncertainties involved, that the outcome will conform with the objectives for postclosure performance for the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Compliance demonstrations should not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. The performance assessments and analyses should focus upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values. Further, in reaching a determination of reasonable expectation, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

(b) Subpart B lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. Prior to closure, § 63.31(a)(1) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and stored in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. After permanent closure, § 63.31(a)(2) requires the Commission to consider whether there is a reasonable expectation the site and design comply with the postclosure performance objectives. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to paragraph (a)(2) of § 63.31.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency, the definitions in § 63.2 prevail.

(a) *The HLW facility at the Yucca Mountain site.* NRC exercises licensing and related regulatory authority over those facilities described in section 202 (3) and (4) of the Energy Reorganization Act of 1974, including the site at Yucca Mountain, as designated by the Energy Policy Act of 1992.

(b) *The geologic repository operations area.* (1) These regulations deal with the exercise of authority with respect to a particular class of HLW facility—namely, a geologic repository operations area at Yucca Mountain.

(2) *A geologic repository operations area* consists of those surface and subsurface areas of the site that are part of a geologic repository where radioactive waste handling activities are conducted. The underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts and boreholes, including their seals), are designated the *underground facility*.

(3) The exercise of Commission authority requires that the geologic repository operations area be used for storage (which includes disposal) of *high-level radioactive wastes* (HLW).

(4) HLW includes irradiated reactor fuel as well as reprocessing wastes. However, if DOE proposes to use the geologic repository operations area for storage of radioactive waste other than HLW, the storage of this radioactive waste is subject to the requirements of this part.

(c) *Stages in the licensing process.* There are several stages in the licensing process. The *site characterization* stage, when the performance confirmation program is started, begins before submission of a license application, and may result in consequences requiring evaluation in the license review. The construction stage would follow after the issuance of a construction authorization. A period of operations follows the Commission's issuance of a license. The period of operations includes the time during which *emplacement* of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are *retrievable*; and *permanent closure*, which includes sealing openings to the repository. Permanent closure represents the end of the performance confirmation program; final backfilling of the underground facility, if appropriate; and the sealing of shafts, ramps, and boreholes.

(d) *Areas related to isolation.* Although the activities subject to regulation under this part are those to be carried out at the geologic repository operations area, the licensing process also considers characteristics of adjacent areas that are defined in other ways. There must be an area surrounding the geologic repository operations area, that could include either a portion or all of the site, within which DOE shall exercise specified controls to prevent adverse human actions after permanent closure. There is an area, designated the geologic setting, which includes the geologic, hydrologic, and geochemical systems of the region in which the site and geologic repository operations area are located. The geologic repository operations area, plus the portion of the geologic setting that provides isolation of the radioactive

waste, make up the geologic repository.

(e) *Performance objectives through permanent closure.* Before permanent closure, the geologic repository operations area is required to limit radiation levels and radiological exposures, in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, as specified at § 63.111(a).

(f) *Preclosure safety analysis.* Section 63.111 includes performance objectives for the geologic repository operations area for the period before permanent closure and decontamination or permanent closure, decontamination, and dismantlement of surface facilities. The preclosure safety analysis is a systematic examination of the site; the design; and the potential hazards, initiating events and their resulting event sequences and potential radiological exposures to workers and the public. Initiating events are to be considered for inclusion in the preclosure safety analysis for determining event sequences only if they are reasonable (*i.e.*, based on the characteristics of the geologic setting and the human environment, and consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public). The analysis identifies structures, systems, and components important to safety.

(g) *Performance objectives after permanent closure.* After permanent closure, the geologic repository is required to:

(1) Limit radiological exposures to the reasonably maximally exposed individual, as specified at § 63.113(b);

(2) Limit releases of radionuclides to the accessible environment to protect groundwater, as specified at § 63.113(c); and

(3) Limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion, as specified at § 63.113(d).

(h) *Multiple barriers.* Section 63.113(a) requires that the geologic repository include multiple barriers, both natural and engineered. Geologic disposal of HLW is predicated on the expectation that one or more aspects of the geologic setting will be capable of contributing to the isolation of radioactive waste and thus be a barrier important

to waste isolation. Although there is an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. In addition, there are uncertainties in the isolation capability and performance of engineered barriers. Although the composition and configuration of engineered structures (barriers) can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic and natural analogs, there is a limited experience base for the performance of complex, engineered structures over periods longer than a few hundred years, considering the uncertainty in characterizing and modeling individual barriers. These uncertainties are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system is required in addition to the natural barriers provided by the geologic setting. The performance assessment provides an evaluation of the repository performance based on credible models and parameters including the consideration of uncertainty in the behavior of the repository system. Thus the performance assessment results reflect the capability of each of the barriers to cope with a variety of challenges (e.g., combinations of parameters leading to less favorable performance for individual barriers and combinations of barriers). A description of each barrier's capability (e.g., retardation of radionuclides in the saturated zone, waste package lifetime, matrix diffusion in the unsaturated zone), as reflected in the performance assessment, provides an understanding of how the natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository. The Commission believes that this understanding can increase confidence that the postclosure performance objectives specified at §63.113(b) and (c) will be achieved and that DOE's design includes a system of multiple barriers.

(i) *Reference biosphere and reasonably maximally exposed individual.* The performance assessment will estimate the amount of radioactive material released to water or air at various loca-

tions and times in the future. To estimate the potential for future human exposures resulting from release of radioactive material from a geologic repository at Yucca Mountain, it is necessary to make certain assumptions about the location and characteristics of the reasonably maximally exposed individual. The environment inhabited by the reasonably maximally exposed individual, along with associated human exposure pathways and parameters, make up the reference biosphere, as described in §63.305. The reasonably maximally exposed individual, as a hypothetical person living in a community with characteristics of the Town of Amargosa Valley, is a representative person using water with average concentrations of radionuclides as described at §63.312. The reasonably maximally exposed individual is selected to represent those persons in the vicinity of Yucca Mountain who are reasonably expected to receive the greatest exposure to radioactive material released from a geologic repository at Yucca Mountain. Characteristics of the reference biosphere and the reasonably maximally exposed individual are to be based on current human behavior and biospheric conditions in the region, as described in §63.305 and §63.312.

(j) *Performance assessment.* Demonstrating compliance with the postclosure performance objective specified at §63.113(b) requires a performance assessment to quantitatively estimate radiological exposures to the reasonably maximally exposed individual at any time during the compliance period. The performance assessment is a systematic analysis that identifies the features, events, and processes (*i.e.*, specific conditions or attributes of the geologic setting, degradation, deterioration, or alteration processes of engineered barriers, and interactions between the natural and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the radiological exposures to the reasonably maximally exposed individual. The features, events, and processes considered in the performance assessment should represent

a wide range of both beneficial and potentially adverse effects on performance (e.g., beneficial effects of radionuclide sorption; potentially adverse effects of fracture flow or a criticality event). Those features, events, and processes expected to materially affect compliance with § 63.113(b) or be potentially adverse to performance are included, while events (event classes or scenario classes) that are very unlikely (less than one chance in 10,000 over 10,000 years) can be excluded from the analysis. An event class consists of all possible specific initiating events that are caused by a common natural process (e.g., the event class for seismicity includes the range of credible earthquakes for the Yucca Mountain site). Radiological exposures to the reasonably maximally exposed individual are estimated using the selected features, events, and processes, and incorporating the probability that the estimated exposures will occur. Additionally, performance assessment methods are appropriate for use in demonstrating compliance with the postclosure performance objectives for groundwater protection and human intrusion, and are subject to the requirements for performance assessments specified at § 63.114 and applicable criteria in Subpart L (e.g., criteria for evaluating compliance with groundwater protection and individual protection standards).

(k) *Institutional controls.* Active and passive institutional controls will be maintained over the Yucca Mountain site, and are expected to reduce significantly, but not eliminate, the potential for human activity that could inadvertently cause or accelerate the release of radioactive material. However, because it is not possible to make scientifically sound forecasts of the long-term reliability of institutional controls, it is not appropriate to include consideration of human intrusion into a fully risk-based performance assessment for purposes of evaluating the ability of the geologic repository to achieve the performance objective at § 63.113(b). Hence, human intrusion is addressed in a stylized manner as described in paragraph (l) of this section.

(l) *Human intrusion.* In contrast to events unrelated to human activity,

the probability and characteristics of human intrusion occurring many hundreds or thousands of years into the future cannot be estimated by examining either the historic or geologic record. Rather than speculating on the nature and probability of future intrusion, it is more useful to assess how resilient the geologic repository would be against a human intrusion event. Although the consequences of an assumed intrusion event would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of human intrusion specified at §§ 63.321, 63.322 and 63.342 of subpart L of this part.

(m) *Performance confirmation.* A performance confirmation program will be conducted to evaluate the adequacy of assumptions, data, and analyses that led to the findings that permitted construction of the repository and subsequent emplacement of the wastes. Key geotechnical and design parameters, including any interactions between natural and engineered systems and components, will be monitored throughout site characterization, construction, emplacement, and operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified at § 63.113(b) and (c).

(n) *Groundwater protection.* Separate groundwater protection standards are designed to protect the groundwater resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of groundwater concentrations in the representative volume of water. Depending on the radionuclide, the estimated concentrations must either be below a specified concentration or result in an annual, drinking water dose to the whole body or any organ of no greater than 0.04 mSv (4 mrem). Although the estimation of radionuclide concentrations in the representative volume would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of groundwater protection specified at §§ 63.331, 63.332 and 63.342 of subpart L of this part.

(o) *Implementation of TEDE.* When external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The radiation and organ or tissue weighting factors in Appendix A of 40 CFR part 197 are to be used to calculate TEDE. After the effective date of this regulation, the Commission may allow DOE to use updated factors, which have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance. Additionally, as scientific models and methodologies for estimating doses are updated, DOE may use the most current and appropriate (e.g., those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation.

[66 FR 55792, Nov. 2, 2001, as amended at 74 FR 10828, Mar. 13, 2009]

PRECLOSURE PERFORMANCE OBJECTIVES

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) *Protection against radiation exposures and releases of radioactive material.*

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual TEDE (hereafter referred to as “dose”) to any real member of the public located beyond the boundary of the site may not exceed the preclosure standard specified at § 63.204.

(b) *Numerical guides for design objectives.* (1) The geologic repository operations area must be designed so that, taking into consideration Category 1

event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area must be designed so that, taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site will receive, as a result of the single Category 2 event sequence, the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysis.* A preclosure safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 must be performed. This analysis must demonstrate that:

(1) The requirements of § 63.111(a) will be met; and

(2) The design meets the requirements of § 63.111(b).

(d) *Performance confirmation.* The geologic repository operations area must be designed so as to permit implementation of a performance confirmation program that meets the requirements of subpart F of this part.

(e) *Retrievability of waste.* (1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the geologic repository operations area must be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at

any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the Commission. This different time period may be established on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

(2) This requirement may not preclude decisions by the Commission to allow backfilling part, or all of, or permanent closure of the geologic repository operations area, before the end of the period of design for retrievability.

(3) For purposes of paragraph (e) of this section, a reasonable schedule for retrieval is one that would permit retrieval in about the same time as that required to construct the geologic repository operations area and emplace waste.

PRECLOSURE SAFETY ANALYSIS

§63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

The preclosure safety analysis of the geologic repository operations area must include:

(a) A general description of the structures, systems, components, equipment, and process activities at the geologic repository operations area;

(b) An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential event sequences;

(c) Data pertaining to the Yucca Mountain site, and the surrounding region to the extent necessary, used to identify naturally occurring and human-induced hazards at the geologic repository operations area;

(d) The technical basis for either inclusion or exclusion of specific, naturally occurring and human-induced hazards in the safety analysis;

(e) An analysis of the performance of the structures, systems, and components to identify those that are important to safety. This analysis identifies and describes the controls that are relied on to limit or prevent potential event sequences or mitigate their consequences. This analysis also identifies measures taken to ensure the avail-

ability of safety systems. The analysis required in this paragraph must include, but not necessarily be limited to, consideration of—

(1) Means to limit concentration of radioactive material in air;

(2) Means to limit the time required to perform work in the vicinity of radioactive materials;

(3) Suitable shielding;

(4) Means to monitor and control the dispersal of radioactive contamination;

(5) Means to control access to high radiation areas or airborne radioactivity areas;

(6) Means to prevent and control criticality;

(7) Radiation alarm system to warn of significant increases of radiation levels, concentrations of radioactive material in air, and increased radioactivity in effluents;

(8) Ability of structures, systems, and components to perform their intended safety functions, assuming the occurrence of event sequences;

(9) Explosion and fire detection systems and appropriate suppression systems;

(10) Means to control radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency;

(11) Means to provide reliable and timely emergency power to instruments, utility service systems, and operating systems important to safety if there is a loss of primary electric power;

(12) Means to provide redundant systems necessary to maintain, with adequate capacity, the ability of utility services important to safety; and

(13) Means to inspect, test, and maintain structures, systems, and components important to safety, as necessary, to ensure their continued functioning and readiness.

(f) A description and discussion of the design, both surface and subsurface, of the geologic repository operations area, including—

(1) The relationship between design criteria and the requirements specified at §63.111(a) and (b); and

(2) The design bases and their relation to the design criteria.

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POSTCLOSURE PERFORMANCE OBJECTIVES

§ 63.113 Performance objectives for the geologic repository after permanent closure.

(a) The geologic repository must include multiple barriers, consisting of both natural barriers and an engineered barrier system.

(b) The engineered barrier system must be designed so that, working in combination with natural barriers, radiological exposures to the reasonably maximally exposed individual are within the limits specified at § 63.311 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of Subpart L of this part.

(c) The engineered barrier system must be designed so that, working in combination with natural barriers, releases of radionuclides into the accessible environment are within the limits specified at § 63.331 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart and §§ 63.303, 63.332 and 63.342 of subpart L of this part.

(d) The ability of the geologic repository to limit radiological exposures to the reasonably maximally exposed individual, in the event of human intrusion into the engineered barrier system, must be demonstrated through an analysis that meets the requirements at §§ 63.321 and 63.322 of subpart L of this part. Estimating radiological exposures to the reasonably maximally exposed individual requires a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of subpart L of this part.

POSTCLOSURE PERFORMANCE ASSESSMENT

§ 63.114 Requirements for performance assessment.

(a) Any performance assessment used to demonstrate compliance with § 63.113 for 10,000 years after disposal must:

(1) Include data related to the geology, hydrology, and geochemistry (in-

cluding disruptive processes and events) of the Yucca Mountain site, and the surrounding region to the extent necessary, and information on the design of the engineered barrier system used to define, for 10,000 years after disposal, parameters and conceptual models used in the assessment.

(2) Account for uncertainties and variabilities in parameter values, for 10,000 years after disposal, and provide for the technical basis for parameter ranges, probability distributions, or bounding values used in the performance assessment.

(3) Consider alternative conceptual models of features and processes, for 10,000 years after disposal, that are consistent with available data and current scientific understanding and evaluate the effects that alternative conceptual models have on the performance of the geologic repository.

(4) Consider only features, events, and processes consistent with the limits on performance assessment specified at § 63.342.

(5) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, for 10,000 years after disposal, would be significantly changed by their omission.

(6) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, for 10,000 years after disposal, would be significantly changed by their omission.

(7) Provide the technical basis for models used to represent the 10,000

years after disposal in the performance assessment, such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

(b) The performance assessment methods used to satisfy the requirements of paragraph (a) of this section are considered sufficient for the performance assessment for the period of time after 10,000 years and through the period of geologic stability.

[74 FR 10823, Mar. 13, 2009]

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

(a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers.

(c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste. The technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessments used to demonstrate compliance with § 63.113(b) and (c).

LAND OWNERSHIP AND CONTROL

§ 63.121 Requirements for ownership and control of interests in land.

(a) *Ownership of land.* (1) The geologic repository operations area must be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use.

(2) These lands must be held free and clear of all encumbrances, if significant, such as:

- (i) Rights arising under the general mining laws;
- (ii) Easements for right-of-way; and
- (iii) All other rights arising under lease, rights of entry, deed, patent,

mortgage, appropriation, prescription, or otherwise.

(b) *Additional controls for permanent closure.* Appropriate controls must be established outside of the geologic repository operations area. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

(c) *Additional controls through permanent closure.* Appropriate controls must be established outside the geologic repository operations area. DOE shall exercise any jurisdiction or control of activities necessary to ensure the requirements at § 63.111(a) and (b) are met. Control includes the authority to exclude members of the public, if necessary.

(d) *Water rights.* (1) DOE shall also have obtained such water rights as may be needed to accomplish the purpose of the geologic repository operations area.

(2) Water rights are included in the additional controls to be established under paragraph (b) of this section.

Subpart F—Performance Confirmation Program

§ 63.131 General requirements.

(a) The performance confirmation program must provide data that indicate, where practicable, whether:

(1) Actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review; and

(2) Natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated.

(b) The program must have been started during site characterization, and it will continue until permanent closure.

(c) The program must include in situ monitoring, laboratory and field testing, and in situ experiments, as may be appropriate to provide the data required by paragraph (a) of this section.

(d) The program must be implemented so that:

(1) It does not adversely affect the ability of the geologic and engineered elements of the geologic repository to meet the performance objectives.

(2) It provides baseline information and analysis of that information on those parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operational activities.

(3) It monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository.

§ 63.132 Confirmation of geotechnical and design parameters.

(a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping must be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of design changes needed to accommodate actual field conditions encountered.

(b) Subsurface conditions must be monitored and evaluated against design assumptions.

(c) Specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components, must be identified in the performance confirmation plan.

(d) These measurements and observations must be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods must be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In situ monitoring of the thermomechanical response of the un-

derground facility must be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

§ 63.133 Design testing.

(a) During the early or developmental stages of construction, a program for testing of engineered systems and components used in the design, such as, for example, borehole and shaft seals, backfill, and drip shields, as well as the thermal interaction effects of the waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

(b) The testing must be initiated as early as practicable.

(c) If backfill is included in the repository design, a test must be conducted to evaluate the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Tests must be conducted to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

(d) The waste package monitoring program must continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance 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.

§ 63.142 Quality assurance criteria.

(a) *Introduction and Applicability.* DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied. DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation

and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) *Organization.* DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components.

(2) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

(3) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations

where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must have direct access to the levels of management as may be necessary to perform this function.

(c) *Quality assurance program.* DOE shall establish a quality assurance program that complies with the requirements of this subpart at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout facility life in accordance with those policies, procedures, or instructions.

(1) DOE shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.

(2) Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

(3) The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary

to assure that suitable proficiency is achieved and maintained.

(4) DOE shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

(d) *Design control.* (1) DOE shall establish measures to assure that applicable regulatory requirements and the design basis, as defined in § 63.2 and as specified in the license application, for those structures, systems, and components to which this subpart applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are important to waste isolation and important to safety functions of the structures, systems and components.

(2) DOE shall establish measures to identify and control design interfaces and for coordination among participating design organizations. These measures must include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(i) The design control measures must provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process must be performed by individuals or groups other than those who performed the original design. These individuals may be from the same organization. If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design

control measures must be applied to items such as: criticality physics, stress, thermal, hydraulic, and preclosure and postclosure analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests.

(ii) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

(e) *Procurement document control.* DOE shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this section.

(f) *Instructions, procedures, and drawings.* Activities affecting quality must be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(g) *Document control.* DOE shall establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same orga-

nizations that performed the original review and approval unless the applicant designates another responsible organization.

(h) *Control of purchased material, equipment, and services.* DOE shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

(1) These measures must include appropriate provisions for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(2) Documentary evidence that material and equipment conform to the procurement requirements must be available at the high-level waste repository site before the material and equipment are installed or used. This documentary evidence must be retained at the high-level waste repository site and be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

(3) The effectiveness of the control of quality by contractors and subcontractors must be assessed by the licensee or applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

(i) *Identification and control of materials, parts, and components.* Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.

(j) *Control of special processes.* DOE shall establish measures to assure that special processes, including welding,

heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(k) *Inspection.* DOE shall establish and execute a program for inspection of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(1) *Test control.* DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components important to safety will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

(m) *Control of measuring and test equipment.* DOE shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(n) *Handling, storage, and shipping.* DOE shall establish measures to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

(o) *Inspection, test, and operating status.* DOE shall establish measures to indicate the status of inspections and tests performed on individual items of the high-level waste repository by markings such as stamps, tags, labels, routing cards, or other suitable means. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of structures, systems, and components of the high-level waste repository, such as by tagging valves and switches, to prevent inadvertent operation.

(p) *Nonconforming materials, parts, or components.* DOE shall establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions

adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

§ 63.144 Quality assurance program change.

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows:

(a) DOE may change a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted every 24 months, in accordance with paragraph (b)(1) of this section. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC which is more recent than the quality assurance standard in DOE's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost

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and schedule when opposed to safety considerations.

(b) DOE shall submit changes made to the NRC-accepted Safety Analysis Report quality assurance program description that do reduce the commitments to the NRC and receive NRC approval prior to implementation, as follows:

(1) By an appropriate method listed in § 63.4 of this chapter, the signed document must be submitted to the Nuclear Regulatory Commission, addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site or facility.

(2) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to describe how the requirements of § 63.142 will be satisfied and continues to satisfy the criteria of § 63.142 and the Safety Analysis Report quality assurance program description previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) DOE shall maintain records of quality assurance program changes that do reduce commitments.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58816, Oct. 10, 2003]

Subpart H—Training and Certification of Personnel

§ 63.151 General requirements.

Operations of systems and components that have been identified as important to safety in the Safety Analysis Report and in the license must be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who

direct operations that are important to safety must also be certified in such operations.

§ 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

§ 63.153 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety may not be such as might cause operational errors that could endanger the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accommodate the conditions.

Subpart I—Emergency Planning Criteria

§ 63.161 Emergency plan for the geologic repository operations area through permanent closure.

DOE shall develop and be prepared to implement a plan to cope with radiological accidents that may occur at the geologic repository operations area, at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities. The emergency plan must be based on the criteria of § 72.32(b) of this chapter.

Subpart J—Violations

§ 63.171 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil

penalty imposed under section 234 of the Atomic Energy Act:

- (1) For violations of—
 - (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;
 - (ii) Section 206 of the Energy Reorganization Act;
 - (iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;
 - (iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.
- (2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 63.172 Criminal penalties.

- (a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in this part 63 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.
- (b) The regulations in this part 63 that are not issued under sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 63.1, 63.2, 63.5, 63.6, 63.7, 63.8, 63.15, 63.16, 63.21, 63.22, 63.23, 63.24, 63.31, 63.32, 63.33, 63.41, 63.42, 63.43, 63.45, 63.46, 63.51, 63.52, 63.61, 63.62, 63.63, 63.64, 63.65, 63.101, 63.102, 63.111, 63.112, 63.113, 63.114, 63.115, 63.121, 63.131, 63.132, 63.133, 63.134, 63.141, 63.142, 63.143, 63.153, 63.161, 63.171, 63.172, 63.201, 63.202, 63.203, 63.204, 63.301, 63.302, 63.303, 63.304, 63.305, 63.311, 63.312, 63.321, 63.322, 63.331, 63.332, 63.341, and 63.342.

Subpart K—Preclosure Public Health and Environmental Standards

§ 63.201 Purpose and scope.

This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site. For the purposes of demonstrating compliance with this subpart, to the extent there may be

any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.202 Definitions for Subpart K.

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

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

Radioactive material means matter composed of or containing radionuclides subject to the Atomic Energy Act of 1954, as amended (42 U.S.C. sec. 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.

§ 63.203 Implementation of Subpart K.

DOE must demonstrate that normal operations at the Yucca Mountain site will and do occur in compliance with this subpart before the Commission grants or continues a license for DOE to receive and possess radioactive material within the Yucca Mountain site.

§ 63.204 Preclosure standard.

DOE must ensure that no member of the public in the general environment receives more than an annual dose of 0.15 mSv (15 mrem) 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 § 63.202) of radioactive material inside the Yucca Mountain repository.

Subpart L—Postclosure Public Health and Environmental Standards

§ 63.301 Purpose and scope.

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE. For the purposes of demonstrating compliance with this subpart, to the extent that there may be any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this part, including definitions, the requirements in this subpart shall take precedence.

§ 63.302 Definitions for Subpart L.

All definitions in subpart K 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 groundwater to a well or spring.

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:

- (i) South than 36°40'13.6661" North latitude, in the predominant direction of groundwater flow; and

- (ii) 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.

Groundwater 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 dose projected to be received by the reasonably maximally exposed individual.

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 groundwater in the predominant direction of groundwater flow that contains radioactive contamination from releases from the Yucca Mountain repository. It does not include releases from any other potential

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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 55792, Nov. 2, 2001, as amended at 74 FR 10829, Mar. 13, 2009]

§ 63.303 Implementation of Subpart L.

(a) Compliance is 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 63.311(a)(1) and 63.311(a)(2); and

(2) Sections 63.321(b)(1), 63.321(b)(2), and 63.331, if performance assessment is used to demonstrate compliance with either or both of these sections.

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(b) [Reserved]

[74 FR 10829, Mar. 13, 2009]

§ 63.304 Reasonable expectation.

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

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

(2) Accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system;

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

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

§ 63.305 Required characteristics of the reference biosphere.

(a) Features, events, and processes that describe the reference biosphere must be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(b) 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 submission of the license application.

(c) 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 § 63.342.

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(d) Biosphere pathways must be consistent with arid or semi-arid conditions.

[66 FR 55792, Nov. 2, 2001, as amended at 74 FR 10829, Mar. 13, 2009]

POSTCLOSURE INDIVIDUAL PROTECTION STANDARD

§ 63.311 Individual protection standard after permanent closure.

(a) 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 dose from releases from the undisturbed Yucca Mountain disposal system:

(1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and

(2) 1.0 mSv (100 mrem) after 10,000 years, but within the period of geologic stability.

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

[74 FR 10829, Mar. 13, 2009]

§ 63.312 Required characteristics of 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. 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 §§ 63.311 and 63.321;

(c) Uses well water with average concentrations of radionuclides based on an annual water demand of 3000 acre-feet;

(d) Drinks 2 liters of water per day from wells drilled into the groundwater at the location specified in paragraph (a) of this section; and

(e) Is an adult with metabolic and physiological considerations consistent with present knowledge of adults.

HUMAN INTRUSION STANDARD

§ 63.321 Individual protection standard for human intrusion.

(a) DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion (see § 63.322) could occur without recognition by the drillers.

(b) DOE must demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives, as a result of the human intrusion, no more than the following annual dose:

(1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and

(2) 1.0 mSv (100 mrem) after 10,000 years, but within the period of geologic stability.

(c) DOE's analysis must include all potential environmental pathways of radionuclide transport and exposure, subject to the requirements of § 63.322.

[74 FR 10829, Mar. 13, 2009]

§ 63.322 Human intrusion scenario.

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 groundwater;

(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 groundwater in the region surrounding Yucca Mountain;

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

(e) No particulate waste material falls into the borehole;

(f) The exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports

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radionuclides by way of the borehole to the saturated zone); and

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

GROUNDWATER PROTECTION STANDARDS

§ 63.331 Separate standards for protection of groundwater.

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 groundwater 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	0.04 mSv (4 mrem) per year to the whole body or any organ, based on drinking 2 liters of water per day from the representative volume.	No.

§ 63.332 Representative volume.

(a) The representative volume is the volume of groundwater 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. DOE must project the concentration of radionuclides released from the Yucca Mountain disposal system that will be in the representative volume. DOE must use the projected concentrations to demonstrate a reasonable expectation that the Yucca Mountain disposal system complies with § 63.331. 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) 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) 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) DOE may calculate the dimensions as a slice of the plume. If DOE uses this approach, it must:

(i) Propose, for 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 groundwater contained within the slice of the plume equals the representative volume.

ADDITIONAL PROVISIONS

§ 63.342 Limits on performance assessments.

(a) DOE's performance assessments conducted to show compliance with §§ 63.311(a)(1), 63.321(b)(1), and 63.331 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. In addition, DOE's performance assessments need not evaluate the impacts resulting from any 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.

(b) For performance assessments conducted to show compliance with §§ 63.321(b)(1) and 63.331, DOE's performance assessments shall exclude the unlikely features, events, and processes, *i.e.*, those that are estimated to have less than one chance in 100,000 per year of occurring and at least one chance in 100,000,000 per year of occurring.

(c) For performance assessments conducted to show compliance with §§ 63.311(a)(2) and 63.321(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. DOE must evaluate all of the features, events, or processes included in paragraph (a) of this section, and also:

(1) DOE must assess the effects of seismic and igneous activity scenarios, subject to the probability limits in paragraph (a) of this section for very unlikely features, events, and processes, or sequences of events and processes. Performance assessments conducted to show compliance with § 63.321(b)(2) are also subject to the probability limits in paragraph (b) of this section for unlikely features,

events, and processes, or sequences of events and processes.

(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 (*i.e.*, the magnitude of the water table rise under Yucca Mountain).

(ii) The igneous activity 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 groundwater.

(2) 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-in-time climate conditions. The analysis may commence at 10,000 years after disposal and shall extend through the period of geologic stability. The constant-in-time values to be used to represent climate change are to be the spatial average of the deep percolation rate within the area bounded by the repository footprint. The constant-in-time deep percolation rates to be used to represent climate change shall be based on a lognormal distribution with an arithmetic mean of 41 mm/year (1.6 in./year) and a standard deviation of 33 mm/year (1.3 in./year). The lognormal distribution is to be truncated so that the deep percolation rates vary between 10 and 100 mm/year (0.39 and 3.9 in./year).

(3) DOE must assess the effects of general corrosion on engineered barriers. 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.

[74 FR 10829, Mar. 13, 2009]

§ 63.343 Severability of individual protection and groundwater protection standards.

The individual protection and groundwater protection standards are severable.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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