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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 activities 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.

(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

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§ 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.

(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;