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 ground water, 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 locations 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 ground-water 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) *Ground-water protection.* Separate ground-water protection standards are designed to protect the ground water resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of ground water 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 ground-water 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,