

The Yucca Mountain Review Plan facilitates a risk-informed, performance-based review and allows for flexibility in the level of detail required for this review. The Commission addressed the use of a risk-informed, performance-based review for a potential Yucca Mountain repository licensing proceeding in its "Statement of Considerations" for 10 CFR part 63 (66 FR 55732, 55736–55737, November 2, 2001) as follows.

In developing these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation ["Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities—Final Policy Statement" (60 FR 42622; August 16, 1995)]. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (*e.g.*, defense in depth), and performance history are used to: (1) Focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making.

Relevant defense-in-depth, safety margin, and performance history information from other facilities can be applied to a high-level waste repository. Many aspects of design and performance for nuclear facilities are analogous to those that would be used for a high-level waste repository. For example, there is extensive regulatory guidance on design and implementation of radiation health physics programs at nuclear facilities. Because this information would be used in review of a license application for a proposed repository at Yucca Mountain, the Yucca Mountain Review Plan references such regulatory guidance.

To clarify the risk-informed, performance-based review, the "Introduction" section of the draft Yucca Mountain Review Plan (now Appendix A) and the "Acceptance Review" section (now Appendix B) have been modified, as appropriate, to clarify the scope of NRC staff's licensing review.

**Issue 2:** Does the Yucca Mountain Review Plan assume that all licensing issues will be resolved and a license for a high-level waste repository at Yucca Mountain will be approved?

**Comment.** A commenter was concerned that the statement in the draft

Yucca Mountain Review Plan "Introduction" that NRC staff will resolve issues using its technical understanding implied that all issues will be resolved in favor of licensing.

**Response.** The language in the draft Yucca Mountain Review Plan "Introduction" was not intended to suggest that NRC staff had prejudged the acceptability of a license application for Yucca Mountain. A conclusion as to whether all licensing issues are resolved is premature. NRC staff must first conduct a detailed technical review of the license application and consider whether information in DOE's application satisfies regulatory requirements and demonstrates that public health and safety, and environment can be protected.

NRC staff revised the language in the Yucca Mountain Review Plan to clarify this point.

**Issue 3:** Does NRC have adequate authority to impose license conditions?

**Comment.** Two commenters expressed concern that NRC lacked authority to impose and enforce license conditions because the "Introduction" of the draft Yucca Mountain Review Plan states that an applicant must agree to any license conditions. The commenters are concerned that applicants can reject or negotiate license conditions with the party having the greater political power having the advantage. The commenters also expressed concern with the statement in the Yucca Mountain Review Plan "Introduction" that the Commission has no authority to compel an applicant to come forward with or prepare a different proposal.

**Response.** The language in the "Introduction" was intended to state that license conditions should be discussed with the licensee and imposed only as necessary to meet the reasonable assurance or reasonable expectation standard. It was not intended to suggest that the Commission lacks the authority to impose license conditions. In fact, 10 CFR 63.42 provides that the "Commission shall include any license 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 any license issued under 10 CFR part 63.

The Commission has authority to require regulatory compliance and protection of public health and safety and the environment. The Commission, however, cannot mandate that an applicant submit an application or adopt a specific design or analysis. The Commission has the authority to deny

an application, grant an application, or grant an application with conditions. Unless the Commission concludes that regulations will be complied with and a facility will be safely operated and material safely received and possessed, a license will not be granted.

The "Introduction" section of the Yucca Mountain Review Plan has been modified to clarify NRC's authority.

**Issue 4:** When will the Yucca Mountain Review Plan be finalized?

**Comment.** One commenter stated that NRC should consider and incorporate the comments received as soon as practicable after the close of the comment period on the Yucca Mountain Review Plan.

**Response.** Consistent with the comment and NRC's responsibility to provide guidance on a timely basis, this **Federal Register** notice indicates the availability of the Yucca Mountain Review Plan, NUREG-1804, Revision 2, Final Report, well in advance of the projected December 2004 DOE license application.

## 2 Acceptance Review

### 2.1 Acceptance Review Process

**Issue 1:** Will an acceptance review of a license application for a high-level waste repository at Yucca Mountain be adequate?

**Comment.** Commenters expressed concern about the statement in the "Acceptance Review" section of the draft Yucca Mountain Review Plan that NRC staff does not determine the technical adequacy of information during the acceptance review and the potential for NRC staff to accept biased and erroneous information and the need for NRC to determine the accuracy and adequacy of information.

**Response.** The purpose of the acceptance review is to determine whether the application can be docketed, that is, whether the application is complete and contains sufficient information to enable NRC staff to conduct its detailed licensing review. The acceptance review does not presuppose what that licensing decision will be and, therefore, does not evaluate the technical adequacy of the information. If the license application passes the acceptance review, the application would be docketed, and the detailed technical review would begin. During the detailed technical review, NRC staff would determine whether the submitted information is accurate and demonstrates that regulatory requirements are met. If the license application fails the acceptance review (for example, it is incomplete and lacks sufficient information to support the