

Issue 2: Does a DOE license application exist?

Comment. One commenter asked whether a DOE license application already existed.

Response. It is NRC's understanding that DOE had not yet prepared a license application.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 3: Will NRC hold DOE to appropriate standards in a licensing review?

Comment. One commenter asked whether NRC would hold DOE to the same standards that produced failures of high-level waste storage at other sites. Other commenters asked whether DOE's past research, organizational structure, and organizational culture would be considered in a licensing review for a high-level waste repository at Yucca Mountain.

Response. NRC has promulgated regulatory requirements for a high-level waste repository at 10 CFR part 63. These regulations require protection of public health and safety, and the environment. If DOE's license application demonstrates compliance with regulatory requirements at 10 CFR part 63, and applicable requirements in 10 CFR part 51, for high-level radioactive waste repository at Yucca Mountain, NRC staff would recommend issuance of a construction authorization or license to receive and possess waste, as appropriate.

DOE organization and qualifications are addressed in the following three sections of the draft Yucca Mountain Review Plan: (i) 4.5.3.1, "DOE Organizational Structure as it Pertains to Construction and Operation of Geologic Repository Operations Area"; (ii) 4.5.3.2, "Key Positions Assigned Responsibility for Safety and Operations of Geologic Repository Operations Area"; and (iii) 4.5.3.3, "Personnel Qualifications and Training Requirements." A licensing review using these sections of the Yucca Mountain Review Plan would support a conclusion as to whether DOE may receive a license for a high-level waste repository at Yucca Mountain.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 4: Will NRC regulations be rewritten to accommodate a Yucca Mountain license application?

Comment. One commenter asked whether NRC would change its regulations to accommodate a Yucca Mountain license application. One commenter asked whether performance bases are expected to change as waste is

processed and interred at a repository. Another commenter stated that NRC modified the standards for Yucca Mountain because DOE could not meet them.

Response. NRC regulations at 10 CFR part 63 were promulgated to specifically address an application for a potential repository at Yucca Mountain and were developed through a public rulemaking process. There are no plans to revise these regulations.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 5: What level of conservatism is appropriate in licensing a high-level waste repository at Yucca Mountain?

Comment. One commenter stated the statement in the draft Yucca Mountain Review Plan "Introduction" (now Appendix A) that NRC cannot require a different or additional proposal if the application satisfies applicable regulations to encourage an applicant to demonstrate compliance using non-conservative methods. The commenter noted that this approach is unacceptable for a repository with a disposal period of 10,000 years, and that the U.S. Department of Energy should be required to use the most conservative approach for demonstrating compliance.

Another commenter expressed the opposite concern that the very reliance on the use of "bounding values" is not consistent with a reasonable expectation compliance standard. The commenter noted that it may be necessary to use expert judgement in some cases and that the Yucca Mountain Review Plan should explicitly allow use of such judgement, or other accepted techniques, in certain circumstances. The commenter suggested that NRC staff adopt an "expected behavior approach" similar to that used by the commercial nuclear power industry, noting the similarities and differences in power reactor and repository licensing issues and acknowledging that the time and spatial scales for a repository limit the use of direct frequency data. To address this concern, the commenter suggested the use of natural analogue data, and the collection of data over longer time periods, to confirm models.

The same commenter suggested a dual modeling approach that uses the "expected behavior" model followed by application of conservative assumptions in areas where it might be difficult to accurately define the expected conditions. The intent would be that a conservative model would be used for the licensing decision, while the expected behavior model would be used to provide regulatory insight.

Response. NRC's regulations at 10 CFR part 63, are protective of health and safety and the environment. Therefore, ensuring compliance with them would protect health and safety and the environment and accomplish the mission of NRC.

Regulation of nuclear facilities requires realistic or reasonably conservative approaches that take into account importance to safety, technical complexity, and the degree and nature of associated uncertainty. These concepts underlie the "reasonable assurance" and "reasonable expectation" bases that would be applied in NRC staff's review of a license application for a high-level waste repository at Yucca Mountain.

The Commission addressed the issue of conservatism in the "Statements of Considerations" for 10 CFR part 63 (66 FR 55732, November 2, 2001). In "Statements of Considerations," the Commission stated, in part

Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process * * *. The Commission does not believe that NRC's use of "reasonable assurance," as a basis for judging compliance compels focus on extreme values (i.e., tails of distributions) for representing the performance of a Yucca Mountain repository. Further * * * if the Commission is called on to make a decision * * * the Commission will consider the full record before it. That record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) * * *. The Commission could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public.

The Commission is satisfied that a standard of "reasonable expectation" allows it the necessary flexibility to account for the inherently greater uncertainties in making long-term projections of a repository's performance. The Commission agrees with EPA and others that it is important to not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence * * *. The Commission expects that the required analyses of postclosure performance will focus on the full range of defensible and reasonable parameter distributions, and that they should not be constrained only to extreme physical situations and parameter values. For other determinations regarding compliance of the repository with preclosure objectives, the Commission will retain a standard of "reasonable assurance" consistent with its practice for other licensed operating facilities subject to active licensee oversight and control.