

Comment. One commenter asked that the meanings of the terms reasonable assurance and reasonable expectation be clarified. The commenter stated that, as used in the draft Yucca Mountain Review Plan, these terms seem to mean approximately the same thing. The commenter argued that this was not the intent of NRC when it promulgated 10 CFR part 63.

The commenter agreed that use of reasonable assurance as a measure of compliance for preclosure safety was appropriate and consistent with NRC regulation of other nuclear facilities. However, the commenter opined that reasonable expectation implies a different standard that recognizes the inherent uncertainties in predicting repository performance far into the future. The differences include the need for realistic, rather than bounding, modeling approaches, and for taking into account the stepwise nature of repository licensing. According to the commenter, a reasonable expectation standard should allow for considerable information to be added after a license is initially granted, but before repository closure. The commenter argued that reasonable expectation should allow gaps in understanding to exist at the time a license is initially granted, provided adequate efforts to address these gaps are implemented.

The commenter added that the U.S. Environmental Protection Agency defined reasonable expectation in 40 CFR part 197 with the intent that it be explicitly different from reasonable assurance and allowed NRC the flexibility to determine how the term would be applied. Since the Yucca Mountain Review Plan is the key NRC implementation guidance, the distinction between reasonable assurance and reasonable expectation should be clear in the Review Plan.

Response. The Commission addressed its adoption and use of the reasonable expectation and reasonable assurance regulatory compliance standards in its "Statement of Considerations" for 10 CFR part 63 (66 FR 55739–55740, November 2, 2001) where it stated:

Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process. It is the Commission's responsibility to determine whether DOE has or has not demonstrated compliance. 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 DOE is authorized to file a license application, and if the Commission is called on to make a decision, irrespective of the term used, 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) contained in Subparts E, K, and L. 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. To avoid any misunderstanding and to achieve consistency with final EPA standards, the Commission has decided to adopt EPA's preferred criterion of "reasonable expectation" for purposes of judging compliance with the postclosure performance objectives. 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. By adopting what EPA has characterized as a more flexible standard of "reasonable expectation" for determining compliance with postclosure performance objectives, the Commission hopes to make clear its expectations. 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.

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As stated previously, in order to avoid further misunderstanding of its intent, the Commission will adopt EPA's preferred standard of "reasonable expectation" for purposes of judging compliance with the numerical postclosure performance objectives. However, the Commission wants to make clear that its proposed use of "reasonable assurance" as a basis for judging compliance was not intended to imply a requirement for more stringent analyses (e.g., use of extreme values for important parameters) or for comparison with a potentially more stringent statistical criteria (e.g., use of the 95th percentile of the distribution of the estimate of dose).

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

11 Other Comments

11.1 Codes and Standards

Issue: Should the Yucca Mountain Review Plan identify specific codes and standards to be used by the applicant?

Comment. One commenter stated that the draft Yucca Mountain Review Plan refers to codes and standards that are not compatible with the risks from a geologic repository. The commenter recommended that the Yucca Mountain Review Plan be revised to clarify that the applicant has the flexibility to use codes, standards, and methodologies it demonstrates to be applicable. Another commenter noted that some referenced codes and standards were outdated.

Commenters identified locations in the draft Yucca Mountain Review Plan related to their concerns.

Response. The risk-informed, performance-based regulations at 10 CFR part 63 give the applicant the responsibility to select codes, standards, and methodologies; demonstrate that they are appropriate for use with a geologic repository for high-level waste; and then use them appropriately. When specific codes, standards, or methodologies were listed in the Yucca Mountain Review Plan, they were included only as examples or to indicate the kinds of approaches that have been successfully used in other licensing programs.

The Yucca Mountain Review Plan has been revised to clarify that references to specific codes, standards, methodologies, or outdated codes have been deleted.

11.2 General Comments on the License Application and the Licensing Process

Issue 1: Will NRC ignore mistakes in a DOE license application?

Comment. Two commenters asked whether NRC would ignore mistakes in DOE's license application and how the Commission would address major problems in DOE's work. One commenter also stated that NRC must have the power to reject a license application.

Response. A DOE license application must demonstrate compliance with applicable regulations. Editorial mistakes that prevent NRC from understanding the compliance demonstration may have to be corrected. Technical mistakes could even invalidate a DOE analysis to demonstrate compliance. The nature, extent, and effects of mistakes in a license application would be considered in the NRC review.

NRC has the statutory authority as well as the responsibility to reject a license application if the applicant fails to show that applicable regulatory requirements are satisfied.

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