

alternative storage in the Yucca Mountain Review Plan, NRC is inferring its expectation that a license application for a high-level waste repository at Yucca Mountain would cover alternate storage. The commenter noted the Yucca Mountain Review Plan is specific about assumed elements of the repository system, but does not describe such elements earlier in the review plan. The commenter suggested that the Yucca Mountain Review Plan be revised to include NRC expectations of the specific elements of the repository system that would be the subject of a license application.

Response. A review of DOE plans for alternate storage of waste is included within the Yucca Mountain Review Plan because these plans are specifically required by 10 CFR 63.21(c)(7), which requires that DOE's Safety Analysis Report include a description of plans for the alternate storage of the radioactive wastes should retrieval be necessary. Retrieved waste would need to be controlled in compliance with applicable regulations at the time of retrieval. Beyond requiring such plans, the regulations have no specific requirements on this subject. Accordingly, the three components of the related Review Method and Acceptance Criterion for reviewing plans for alternative storage of waste (*i.e.*, the physical location and boundary of the proposed alternate storage area are adequately defined; the proposed alternate storage area is sufficient to hold the waste; and the area is adequate to protect workers and the public during the transport of the waste to alternate storage) are sufficient.

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

4.3 Criticality

Issue: What equipment would be available for addressing criticality accidents?

Comment. One commenter asked what equipment would be available in a repository for high-level waste at Yucca Mountain to deal with criticality accidents.

Response. Pursuant to 10 CFR 63.112(e)(6), DOE must address the potential for criticality accidents during the preclosure period of operations. After any criticality risks have been established, NRC will evaluate whether equipment should be provided to deal with such accidents.

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

4.4 Preclosure Safety Analysis

Issue 1: Is the definition of probability associated with Category 2 event sequences adequate?

Comment. One commenter stated that the use of one chance in 10,000 over 300 years is illogical and non-conservative considering the trillions of curies that would be present in a high-level waste repository at Yucca Mountain. The commenter stated that if the criteria for excluding events from Category 2 are based on opinion and speculation, the information could be biased, erroneous, or misleading. The commenter stated that the criteria for Category 2 must be broadened to overcome these inadequacies and that NRC staff needs to be careful when excluding catastrophic events from Category 2.

Response. A licensing review for a high-level waste repository at Yucca Mountain will be conducted in an objective manner to determine whether information is accurate and regulatory standards are met. Error in analyses will be addressed in NRC staff's review of analysis, design, and operations.

The Commission addressed the Category 2 criteria in the "Statement of Considerations" for 10 CFR part 63 (66 FR 55741-55742, November 2, 2001) as follows.

The Commission agrees that the basis for determining the probability for design basis events and what initiating events should be considered in the safety analysis should be clarified. * * * the Commission has revised the rule for clarity as follows: (1) A new term "initiating event" is defined; (2) the present term "design basis event" is replaced with a new term "event sequence"; and (3) Section 63.102(f) is revised to clarify the scope of the preclosure safety analysis and the requirements for the inclusion or exclusion of specific, naturally-occurring, and human-induced hazards in the safety analysis.

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 are consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public).

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Within the context of the ISA (PSA), DOE is expected to identify the relevant initiating events and event sequences and estimate potential radiologic exposures. Part 63 provides flexibility to DOE in selecting an appropriate approach for estimating doses, including selection of pertinent exposure pathways and the degree of conservatism or realism to include in the analysis. DOE will need to defend and support whatever approach it selects for identifying initiating events and analyzing event sequences. In the selection of a particular approach, DOE will need to consider the uncertainties and

limitations associated with a particular method of analysis and data.

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 any associated uncertainty. These concepts underlie the "reasonable assurance" and "reasonable expectation" determinations that would be applied in reviewing the DOE license application. However, the Yucca Mountain Review Plan recognizes that, consistent with a risk-informed, performance-based approach, DOE has the flexibility to select an approach that could include reasonably conservative analyses.

The Commission addressed the issue of conservatism in the "Statement of Considerations" for 10 CFR part 63 (66 FR 55739-55740, November 2, 2001).

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, causes 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 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.

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