

Commission also adopted an EPA standard requiring DOE to calculate the peak dose of the reasonably maximally exposed individual that would occur after 10,000 years following disposal, but did not apply a regulatory standard to the results of this analysis. Instead, DOE is to include the results of the analyses and their bases in the environmental impact statement for YM as an indicator of long-term disposal system performance. *See* 10 CFR 63.341; *see also* 40 CFR 197.35. The Commission continues to believe, as articulated in the both the proposed and final regulations, that potential radiation exposures estimated at very long times into the future (e.g., 100,000 years and longer), such as those shown in the *National Geographic* graphic, are too speculative to provide meaningful information to make licensing decisions.

Need for Presentation of an Affirmative Safety Case

Petitioner believes that DOE must be required to present "an affirmative safety case" which demonstrates an understanding of repository performance. To ensure demonstration of an affirmative safety case, petitioner has proposed a new regulation (proposed § 63.21(c), *supra*) which is based on, but not identical to, recommendations made by the *Peer Review* with respect to DOE's TSPA-SR.¹² Although the *Peer Review* focused on DOE's TSPA-SR, it did make a few observations on NRC's proposed part 63:

The regulations require that a risk-informed approach should be adopted in demonstrating compliance with the dose limit, in recognition of the uncertainties inherent in making assessments over long time frames in the future. It is also required that the assessment should reveal an understanding of the relationship between the performance of the repository sub-systems and the total system performance. Nevertheless despite the prescriptive nature of the regulations, the [International] R[evue] T[eam] notes that the proposed licensing regulation 10 CFR 63 states that "consistent with a performance based philosophy, the Commission proposes to permit DOE the flexibility to select the approach for demonstrating this relationship that is most appropriate to its analysis."

The TSPA-SR methodology embodies a comprehensive computational framework for estimating possible doses to future generations using a complex systems-level model accounting for hundreds of features, events and processes and related parameter ranges. A key issue with this approach is the difficulty in understanding the meaning of the numerical results. In particular, it is often

difficult to understand how the system is likely to evolve and which process and parameters are the most important. *Peer Review* at 41.

In its review of the TSPA-SR, the IRT has observed a tendency for more focus to be given to the demonstration of numerical compliance with the proposed regulatory requirements than on developing and presenting an understanding of repository performance. Whilst it is completely understandable that the TSPA-SR should give due attention to demonstrating compliance with the prescribed dose limit, an in-depth understanding of the performance of the repository system is necessary to develop confidence in the overall design and safety of the repository and in the results of the assessment. In this regard, there is an emerging international consensus that building confidence in repository performance is of comparable importance to demonstrating compliance with criteria. *Thus it is recommended that in the future equal attention should be given to system understanding as to numerical compliance with regulatory criteria if the project proceeds to the licensing stage.*

Peer Review at 23–24 (emphasis in original).

Thus, the *Peer Review* acknowledged the importance of DOE presenting, in its TSPA, an in-depth understanding of the performance of the repository system and recognized that demonstration of safety is more than numerical compliance with the proposed regulatory requirements. As a matter of record, a similar concern was raised during the public comment period on the proposed regulation (*i.e.*, can performance assessment be relied on as the sole quantitative technique for evaluating compliance with the postclosure safety requirements). The Commission, in response to this concern, explained that the regulations contained a number of requirements directed at DOE's demonstrating an in-depth understanding of the repository system:

Although repository postclosure performance is evaluated with respect to a single performance measure for individual protection, the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the postclosure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain.

(66 FR 55746; November 2, 2001).

The current regulations require that DOE provide an adequate and appropriate understanding of the repository system as part of its compliance demonstration. For example, the requirements for the performance assessment, at 10 CFR 63.114, specify that DOE must account for uncertainty in representing the repository system (both in parameters and models); provide a technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment including the degradation, deterioration, or alteration processes of engineered and geologic barriers; and provide a technical basis for the models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs). Additionally, the requirements for multiple barriers, at 10 CFR 63.115, specify that DOE must identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; describe the capability of barriers identified as important to waste isolation actually to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers; and provide the technical basis for the description of the capability of barriers.

In summary, the current regulations require that DOE: demonstrate an adequate and appropriate understanding of the repository system, supported by technical and scientific information that includes a range of important technical concerns, such as the features, events, and processes that could affect the performance of the repository; provide an evaluation of how uncertainty in parameters and models affects the estimates of repository performance; and show the capabilities of the engineered and geologic barriers to isolate waste.

Petitioner had full opportunity during the extensive Part 63 rulemaking to suggest additional requirements for DOE's application to provide greater understanding of the repository system, and did so in its comments questioning the appropriateness of the Commission's proposal to establish risk-informed and performance based regulations which would not include the existing sub-system performance requirements of Part 60. The *Peer Review*, although published after NRC's issuance of the final rule, is based on information widely available during NRC's rulemaking proceeding (e.g., U.S. NRC

¹² The *Peer Review* expressed the view that the TSPA-SR could be improved with respect to developing a better understanding of the repository system: