### DEVELOPMENT OF A RISK-INFORMED AND PERFORMANCE-BASED REVIEW PLAN FOR A POTENTIAL REPOSITORY AT YUCCA MOUNTAIN

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#### ABSTRACT

The U.S. Nuclear Regulatory Commission is developing a risk-informed and performance-based review plan for licensing a potential geologic repository for high-level radioactive waste (HLW) at Yucca Mountain, Nevada. The Yucca Mountain Review Plan (YMRP) contains 3 major chapters for review of the Safety Analysis Report that would accompany a potential license application for the Yucca Mountain site from the U.S. Department of Energy (DOE): Preclosure Safety Evaluation; Postclosure Safety Evaluation; and Administrative and Programmatic Requirements Evaluation. For each review topic in these chapters, there are subsections that specify applicable regulatory requirements, areas of review, acceptance criteria, review methods, evaluation findings, and references. The risk-informed and performance-based approach taken in the YMRP encompasses a systematic evaluation of all related efforts, such as site characterization, experimental work, and design activities that DOE has conducted, documented, and used to support its safety case in a potential license application. Where appropriate, prescriptive criteria were eliminated, allowing DOE flexibility to utilize available resources in designing, constructing, operating, monitoring, and closing the potential repository safely. Revision 0 of the YMRP, containing the postclosure safety evaluation sections, is planned for completion by March 31, 2000. Revision 1 of the YMRP, containing all 3 major chapters, is planned for completion by September 30, 2000. NRC will seek public comments on Revision 1 of the YMRP. Revision 2 of the YMRP is planned for completion by September 30, 2001. Public comments received will be considered in Revision 2 along with any new technical information. As required by Congressional statute, NRC's implementing rule for a HLW geologic repository at the proposed Yucca Mountain site at 10 CFR Part 63 will be amended, if necessary, to be consistent with a final Yucca Mountain standard when it is issued by the U.S. Environmental Protection Agency. The YMRP will be modified, as necessary, to reflect any changes in the final 10 CFR Part 63.

#### **INTRODUCTION**

The U.S. Nuclear Regulatory Commission (NRC) staff is developing a review plan to evaluate a potential geologic repository license application for disposal of commercial spent fuel and high-level radioactive waste (HLW) at Yucca Mountain, Nevada. The Yucca Mountain Review Plan (YMRP) implements the proposed regulations at Part 63 of Title 10 of the Code of Federal Regulations, *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada* (1). 10 CFR Part 63 and the YMRP both incorporate NRC's risk-informed and performance-based (RIPB) regulatory approach (2). NRC also plans to use the YMRP to formulate its preliminary sufficiency comments on any Site Recommendation Considerations Report submitted by the U.S. Department of Energy (DOE) to the President in accordance with the requirements of the Nuclear Waste Policy Act of 1982, as amended (3).

#### BACKGROUND

The Energy Policy Act of 1992 (EnPA) (4) directed the U.S. Environmental Protection Agency (EPA) to contract with the National Academy of Sciences (NAS) to advise EPA on the appropriate technical basis for public health and safety standards governing a Yucca Mountain repository. On August 1, 1995, the NAS Committee issued its report, "Technical Bases for Yucca Mountain Standards." (5) In this report, the NAS recommended, among other items, that an individual protection standard, expressed as a limit on individual risk rather than dose, would provide a reasonable basis for protecting the health and safety of the general public. This approach was significantly different from that adopted by EPA for its disposal standards at 40 CFR Part 191 (6) (no longer applicable to Yucca Mountain, but used at the Waste Isolation Pilot Plant in New Mexico), as well as from that adopted by NRC for its existing generic regulations at 10 CFR Part 60 (7).

The EnPA also directed the EPA to issue final public health and safety standards for Yucca Mountain that "prescribe the maximum annual effective dose equivalent to individual members of the public" and that are "based upon and consistent with" the NAS findings and recommendations. In addition, the EnPA directs the NRC to modify its technical requirements and criteria to be consistent with the new EPA standards. Although EPA standards for Yucca Mountain have not been finalized, the NRC issued for public comment its proposed site-specific regulations for Yucca Mountain at 10 CFR Part 63 on February 22, 1999 (1). The NRC chose to develop its implementing regulations in parallel with development of the EPA standards because, under EnPA, NRC must carry out a rulemaking to modify its requirements for geologic repository disposal at the proposed Yucca Mountain site within a very short period of time following EPA publication of final standards for Yucca Mountain. The Commission believes that it is in the best interests of the national HLW disposal program to proceed with promulgation of its implementing regulations while recognizing that, when the EPA issues its final standards, NRC's regulations may need to be amended.

Another significant factor influencing the development of the regulatory framework for a potential repository at Yucca Mountain is that NRC is transitioning from a prescriptive and deterministic style of regulatory approach to one that is RIPB. Under the RIPB regulatory framework, insights obtained from quantitative risk assessments are considered together with the performance history and other qualitative factors to establish requirements that better focus licensee and regulatory attention on issues commensurate with their importance to public health and safety. The NRC's existing generic regulations at 10 CFR Part 60, promulgated about 15 years ago, were developed under the deterministic and prescriptive regulatory style. Consequently, when the NRC staff undertook to develop a site-specific regulatory strategy (i.e., 10 CFR Part 63 and the YMRP) for the proposed Yucca Mountain site, it did so with the understanding that the framework would be RIPB (8).

Issuing of proposed requirements for a potential repository at Yucca Mountain at 10 CFR Part 63 for public comments provided one of the bases for the development of the accompanying YMRP. As part of NRC staff's effort to streamline the HLW regulatory program, the YMRP will serve two purposes: (i) providing guidance to the staff on reviewing a potential Yucca Mountain license application; and (ii) providing guidance to the DOE on the format and content for a license application. This approach is unlike that associated with the generic regulations at 10 CFR Part 60, in which case both a draft Format and Content Regulatory Guide (9) and a draft review plan (10) were developed by the staff.

### FRAMEWORK

The NRC uses review plans to conduct its licensing reviews. NRC review plans are not the equivalent of regulations with which applicants must comply. Rather, they provide guidance to NRC staff on methods for conducting and documenting licensing reviews. Applicants are not required to follow the guidance provided in an NRC review plan. However, the review plan presents at least one approach for demonstrating compliance with applicable regulations that NRC will find acceptable. An applicant may demonstrate regulatory compliance using any other technique, so long as an appropriate and adequate rationale for that technique and its use are provided and the NRC can conclude with reasonable assurance that its regulations have been complied with. NRC review plans typically contain these subsections: applicable regulatory requirements, areas of review, acceptance criteria, review methods, evaluation findings, and references.

The "applicable regulatory requirements" provide the regulatory foundation for the acceptance criteria (ACs) and review methods (RMs) that will be used to conduct the licensing review. Linking the ACs and RMs to specific regulatory requirements ensures that license applicants will not be required to meet standards that are not supported by the governing regulations.

The "areas of review" identify topical areas and define the scope of the review that will be conducted. Having this scope in mind enables the reviewer to prepare for the review, including examining background material necessary to support the review.

The ACs define the standards that the reviewer is to use to determine whether the license applicant has complied with the regulations. By specifying the ACs in the review plan, the NRC staff defines the standards for

demonstrating compliance and, again, ensures that the licensing decision is made based on compliance with regulatory requirements.

The RMs provide the specific step-by-step procedures that the reviewer is to use to assess compliance with regulatory requirements. The RMs are often technically specific, but their level and complexity are determined by the specific regulatory requirements and, in the YMRP, by the significance of the topic to system performance. Therefore, in order for the RMs to not be unnecessarily prescriptive, it is essential that both 10 CFR Part 63 and the YMRP be developed using the RIPB approach.

The "evaluation findings" are statements that present the staff's conclusions regarding regulatory compliance. If the staff can find that all the individual regulatory requirements have been satisfied, then the NRC can grant a license. These evaluation findings will also be included in the safety evaluation report that the staff will prepare to document its licensing decision.

The "references" section of the review plan lists any references used in the development of the RMs. Often, review plans reference more detailed information on RMs rather than reproducing detailed technical procedures or specifications with the RMs.

The NRC staff has defined four principles that form the basis for the development of the YMRP:

- NRC is responsible for defending its licensing decision. DOE is responsible for ensuring that an adequate safety case is made in the Yucca Mountain license application.
- 10 CFR Part 63, a RIPB and site-specific rule, should be accompanied by a RIPB and site-specific review plan.
- The review plan should follow the total system approach laid out in the HLW regulatory strategy paper (8) and provide for an integrated review process.
- The review plan should incorporate the more than 15 years of knowledge gained about the Yucca Mountain site during the prelicensing period and avoid the imposition of unnecessarily prescriptive acceptance criteria for site characterization.

Using these principles, three major chapters were identified as necessary components for the review of a Safety Analysis Report (SAR) accompanying a potential HLW repository license application: (i) Repository Safety Prior to Permanent Closure; (ii) Repository Safety After Permanent Closure; and (iii) Administrative and Programmatic Requirements. These chapters, taken together with a General Information section, will provide for an evaluation of compliance with all regulatory requirements from the proposed 10 CFR Part 63 that are applicable to the DOE. Topics reviewed under the General Information section are: General Description; Proposed Schedule for Construction, Receipt, and Emplacement of Waste; Physical Protection Plan; Material Control and Accounting Program; and Description of Site Characterization Work. Figure 1 illustrates the organization of the YMRP. The approaches used in developing each of the three chapters for the review of a SAR vary somewhat. The preclosure and postclosure safety reviews will focus on whether the DOE has demonstrated that the corresponding performance objectives stated at 10 CFR Part 63 can be met with reasonable assurance. For both the preclosure and postclosure safety reviews, NRC staff is adopting a total system approach that takes advantage of (i) the knowledge of the site and design that has accumulated over the last decade; and (ii) the rapid growth in integrated safety analysis (ISA) and performance assessment (PA) capabilities, including the results of PA work by NRC and industry, and reviews of DOE's PAs for Yucca Mountain. This total system approach also ensures effective integration of the many technical disciplines required to review a potential license application for Yucca Mountain. In the YMRP, NRC staff plans to use existing standard guidance from other regulatory programs that is applicable to the construction and operation of a geologic repository for evaluating the administrative and programmatic aspects of a potential license application. Where feasible, the existing guidance will be modified to be consistent with the RIPB philosophy.



Figure 1. Organization of the Yucca Mountain Review Plan.

## PRECLOSURE SAFETY EVALUATION

The YMRP chapter for preclosure safety evaluation will include assessments of the adequacy of site characterization, repository design, construction, operation, monitoring, and closure. The proposed 10 CFR Part 63 specifies, as a performance objective for the repository preclosure period, that the radiation protection limits of 10 CFR Part 20 (11) be met under normal operations. The proposed rule also specifies additional performance objectives that require the DOE to factor event sequences into repository design. Rather than prescribing the design features, these performance objectives establish numerical guides in the form of allowable exposure limits for different categories of event sequences for design objectives that focus on protecting the public health and safety. Furthermore, the DOE is required to demonstrate that the final repository design will allow retrieval of waste packages up to 50 years after completion of emplacement and will accommodate implementation of a performance confirmation program.

The proposed rule specifies that compliance with the exposure limits be demonstrated through use of an integrated safety analysis (ISA). Accordingly, the preclosure safety portion of the YMRP focuses on ACs and RMs appropriate for reviewing an ISA and on evaluating whether the radiation protection limits will be met. The DOE will have flexibility in design details and methods, provided that the preclosure performance objectives are met. The foundation of the preclosure safety evaluation is, therefore, RIPB. It will be the DOE's responsibility to document an adequate repository design and to demonstrate compliance with the exposure limits specified in the regulatory requirements.

The preclosure chapter of the YMRP is expected to contain four major sections: (i) ISA; (ii) Plans for Retrieval and Alternate Storage of Radioactive Wastes; (iii) Program and Schedule for Design Resolution as it Pertains to

Preclosure Safety; and (iv) Performance Confirmation. The ISA section is based on the requirements for preclosure performance of the repository in the proposed 10 CFR Part 63 and contains review sections that correspond to the major elements of an acceptable ISA. Those sections are expected to include: Site and System Description; Identification of Hazards and Development of Event Sequences; Consequence Analyses; Identification of Major Structures, Systems, and Components Important to Safety and Controls; Design of Major Structures, Systems, and Components Important to Safety and Demonstration of Compliance with Performance Objectives.

### POSTCLOSURE SAFETY EVALUATION

The YMRP chapter evaluating performance of the repository during the postclosure period also incorporates a RIPB approach. The postclosure regulatory requirements in the proposed 10 CFR Part 63 have as their basis a demonstration that the peak average annual radiation exposure to an average member of the critical group not exceed a specific numerical value. This demonstration is to be made using a performance assessment (PA). The proposed 10 CFR Part 63 specifies a set of criteria that such a PA must satisfy. The proposed rule also specifies additional performance objectives that require the DOE to demonstrate (i) that the repository employs multiple barriers and safety does not unduly depend on any single barrier; and (ii) the resilience of the repository under an assumed human intrusion scenario. Furthermore, DOE is required to collect data as part of its performance confirmation program that will provide confidence to the expected system behavior demonstrated through the PA. Similar to the preclosure chapter, the postclosure chapter is being developed to contain ACs and RMs that are appropriate for reviewing a PA and for evaluating whether the DOE has demonstrated compliance with the postclosure performance objectives.

In its review of DOE's PA supporting a license application, NRC will evaluate key elements of the repository system to judge the effectiveness of the overall system in protecting the public health and safety. The staff has developed a systematic approach to reviewing DOE's PA as illustrated in Figure 2. The focal point of this review is the overall repository system, where the performance measure, as delineated in the proposed 10 CFR Part 63, is the peak average annual radiation exposure to an average

member of the critical group during the performance period of interest. To focus NRC's review effort, staff will evaluate the capabilities and characteristics of the three subsystems, namely, engineered system, geosphere, and biosphere, as shown in the middle tier of Figure 2, and their relative contribution to system performance. To facilitate this evaluation, each of these subsystems is further divided into discrete components. Recognizing that there are many different ways of dividing the overall system into smaller and analyzable components, this particular division is based primarily on the natural progression of radionuclide release and transport to a critical group at the proposed Yucca Mountain site. At the base of Figure 2 are the integrated subissues of the repository system that need to be abstracted into a PA. These integrated subissues, in general, are the integrated features, events, and processes that could influence system performance. The determination of which integrated subissues need to be examined is based on review of DOE's PAs, audit analyses performed by the NRC staff, and knowledge of the site characteristics and proposed design options. NRC's review will aim at (i) understanding the importance to performance of the various assumptions, models, and input data in DOE's PA; and (ii) ensuring that the degree of technical support for models and data abstractions is commensurate with their contribution to system performance.

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Figure 2. Components of Performance Assessment Review.

The postclosure chapter of the YMRP will contain three major sections: (i) Performance Assessment; (ii) Program and Schedule for Resolution of Issues for Structures, Systems, and Components and Engineered or Natural Barriers Important to Waste Isolation; and (iii) Performance Confirmation. The performance assessment section is based on the requirements for postclosure performance of the repository in the proposed 10 CFR Part 63 and contains review sections that correspond to the major components of an acceptable postclosure PA. Those sections are: System Description and Demonstration of Multiple Barriers; Scenario Analysis; Model Abstraction; and Demonstration of the Overall Performance Objective. The last section will also include an evaluation of DOE's analysis of repository performance in the event of limited human intrusion.

### ADMINISTRATIVE AND PROGRAMMATIC REQUIREMENTS EVALUATION

The approach to developing the administrative and programmatic chapter of the YMRP is somewhat different from that taken for the preclosure and postclosure safety chapters of the YMRP. The proposed regulations at 10 CFR Part 63 do not provide specific performance objectives for these areas, largely because they address procedural matters for which acceptable programs have long existed in other NRC regulatory programs. These administrative and programmatic items are also the underpinning of an acceptable demonstration of preclosure and postclosure safety. Accordingly, the staff will use regulatory guidance and review plans from these other programs as the foundation for this portion of the YMRP. This guidance will be modified, as necessary, to accommodate the specific characteristics of a HLW repository. Sections within this chapter are expected to include Quality Assurance; Records, Reports, Tests, and Inspections; Training and Certification of Personnel; Expert Elicitation; Plans for Startup Activities and Testing; Plans for Conduct of Normal Activities Including Maintenance, Surveillance, and Periodic Testing; Identification of Potential License Conditions; Emergency

Planning; Controls to Restrict Access and Regulate Land Use; and Uses of the Geologic Repository Operations Area for Purposes Other Than Disposal of Radioactive Wastes. SCHEDULE AND ACTIVITIES

Draft sections of the YMRP will be posted on the NRC website starting in early 2000. Revision 0 of the YMRP is currently planned for completion by March 31, 2000. Because the focus of NRC's HLW program has been on the postclosure period over the past several years, Revision 0 will contain only the postclosure sections. To facilitate stakeholder involvement, NRC is planning to hold public meetings and meetings with DOE after completion of Revision 0 of the YMRP. Revision 1 of the YMRP, currently planned for completion by September 30, 2000, will contain all three major chapters. NRC will seek public comment and conduct public meetings on Revision 1 of the YMRP, currently planned for completion by September 30, 2001, will consider public comments received and any new information and analysis results for the proposed Yucca Mountain site.

### CONCLUSION

As directed by the Commission, NRC is adopting a RIPB regulatory approach in its YMRP. For preclosure and postclosure safety evaluation, the YMRP focuses on risk- and performance-significant issues for a potential geologic repository. This approach encompasses a systematic evaluation of all related efforts, such as site characterization, experimental work, and design activities, that DOE has conducted, documented, and used to support its safety case in a potential license application for the Yucca Mountain site. Where appropriate, prescriptive criteria have been eliminated, allowing DOE flexibility to utilize available resources in designing, constructing, operating, monitoring, and closing the potential repository safely. This flexibility is particularly important given the long period of regulatory concern (10,000 years) and the uncertainties associated with the performance of the engineered and natural barriers during this time period. The development schedule for the YMRP was designed to maximize stakeholder involvement in the process and to ensure that NRC will have revisions of the YMRP in place prior to major milestones in the national HLW program. It should also be noted that, as required by Congressional statute, NRC's implementing rule at 10 CFR Part 63 for a HLW geologic repository at the proposed Yucca Mountain site will be amended, if necessary, to be consistent with a final Yucca Mountain Standard when it is issued by the EPA. Subsequently, the YMRP will be modified, as necessary, to be consistent with the requirements in the final 10 CFR Part 63.

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