

**THE U.S. NUCLEAR REGULATORY COMMISSION'S FINAL REGULATIONS
FOR DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES
IN A POTENTIAL GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN**

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ABSTRACT

On February 22, 1999, the U.S. Nuclear Regulatory Commission (NRC) proposed licensing criteria in a new, separate part of its regulations, at 10 CFR Part 63 (hereafter referred to as Part 63), for disposal of high-level radioactive waste (HLW) in a potential geologic repository at Yucca Mountain, Nevada (1). After publication of the proposed Part 63, the staff provided members of the public and other stakeholders multiple opportunities to discuss the proposed requirements. On June 13, 2001, the U.S. Environmental Protection Agency (EPA) issued final environmental standards for a potential geologic repository at Yucca Mountain, Nevada at 40 CFR Part 197 (2), as mandated by the Energy Policy Act of 1992 (EnPA)(3). The NRC has prepared its final regulations based on careful review and consideration of the public comments received on its proposed rule and the statutory direction for NRC to adopt technical criteria consistent with final EPA standards.

In setting forth these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for a Yucca Mountain facility that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. Risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used to: 1) focus attention on the most important activities, 2) establish objective criteria based upon risk insights for evaluating performance, 3) develop measurable or calculable parameters for monitoring system and licensee performance, and 4) focus on the results as the primary basis for regulatory decision making. Part 63 reflects the approach laid out for Yucca Mountain by EnPA and the final EPA standards. Specifically, EnPA defined an approach that requires the performance of a Yucca Mountain repository to comply with health-based standards, developed by EPA based on the recommendations of the National Academy of Sciences (NAS). The criteria address how a repository system at Yucca Mountain must perform and specify that the system must comprise both natural and engineered barriers. The final rule includes licensing procedures, and criteria

for public participation, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning.

INTRODUCTION

In 1992, Congress directed the EPA, at Section 801 of the EnPA, to contract with the NAS to advise EPA on the appropriate technical basis for public health and safety standards governing a potential repository at Yucca Mountain. On August 1, 1995, the NAS Committee on Technical Basis for Yucca Mountain Standards issued its report, "Technical Bases for Yucca Mountain Standards" (4). EPA issued its final standards applicable to Yucca Mountain in a new 40 CFR Part 197 on June 13, 2001. The NRC has prepared its final regulations based on careful review and consideration of the public comments received on its proposed rule and the statutory direction for NRC to adapt its technical criteria to be consistent with final EPA standards. The NRC published its final regulations in a new Part 63 on November 2, 2001. These regulations include criteria for long-term repository performance as well as licensing procedures, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning.

NAS RECOMMENDATIONS

The NAS Committee on Technical Basis for Yucca Mountain Standards issued its report, "Technical Bases for Yucca Mountain Standards," under the auspices of the National Research Council, which is jointly managed by the NAS and the National Academy of Engineering. The committee, consisting of 15 members representing engineering, geoscience, environmental, and risk disciplines, deliberated for more than 2 years, holding five public sessions in Las Vegas, Nevada, and Washington, DC, between May 1993 and April 1994.

Key conclusions and recommendations provided in the NAS report were:

- 1) 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. NAS declined to assign the appropriate level of risk, and stated that it views the determination of this level as a crucial policy judgment that should be addressed in a transparent rulemaking process. As a starting point in such a process, NAS suggested that consideration be given to risk levels comparable to an annual individual dose between 2 and 20 mrem/yr (0.02-0.2 mSv/yr).
- 2) For specifying the individual or individuals for whom the risk calculation is to be made, the NAS recommended that a critical-group approach should be used. The critical group concept is intended to ensure that no individual doses are unacceptably high, because the critical group represents the extreme of the dose distribution to the entire population. The critical group risk calculated for comparison with the risk limit established in the

standard, according to NAS, should be the mean of the risks to the members of a group whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of potential releases of radionuclides. For releases expected to occur in the far future, it will be necessary to define a hypothetical group of individuals by making assumptions about lifestyle, location, eating habits, and other factors. NAS concluded that it is not possible to predict on the basis of scientific analyses the societal factors necessary to define exposure scenarios, and that specification of such scenarios is a policy judgment best accomplished through a public rulemaking process. NAS cited the International Commission on Radiation Protection recommendation that present knowledge and cautious, but reasonable, assumptions be used in defining this group of individuals.

- 3) NAS recommended that compliance assessment should be conducted over a time frame that includes the period where greatest risk occurs. NAS found there to be no scientific basis for limiting the time period of an individual-risk standard, however, the NAS explicitly acknowledged that selection of a time period over which compliance should be evaluated necessarily involves both technical and policy considerations.
- 4) That it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years. Despite its conclusion that there exists no scientific basis for estimating the likelihood of human intrusion, NAS, nonetheless, asserts that "a collection of prescriptive requirements, including active institutional controls, record-keeping, and passive barriers and markers, would help to reduce the risk of human intrusion, at least in the near term."
- 5) In order to assess whether the repository's performance would be substantially degraded as a consequence of a postulated intrusion, NAS recommended the use of a "stylized intrusion scenario" to evaluate the consequences of an intrusion event. Consistent with its recommendation for the exposure scenarios, the NAS stated that specification of the intrusion scenario involved judgment and should be determined through a public rulemaking process. NAS recommended that the estimated risk from the stylized intrusion scenario be limited to the same risk limit applied to the undisturbed repository case "because a repository that is suitable for long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion."
- 6) NAS concluded that "because it is the performance of the total system in light of the risk-based standard that is crucial, imposing subsystem performance requirements might result in suboptimal design."

EPA STANDARDS

EPA published final standards for a potential geologic repository at Yucca Mountain, Nevada, at 40 CFR Part 197 on June 13, 2001. A brief summary of key aspects of the EPA's Standards is provided below.

Radiation Standards

The EPA specified radiation standards for the operational phase of repository development (i.e., the period of time during which waste is brought to the site and placed in the repository) and for permanent disposal (i.e., the period of time after permanent closure or sealing of the repository). The two phases are often referred to as the preclosure and postclosure phases. The preclosure or operational phase of the repository is limited by an annual individual dose limit of 0.15 mSv/year (15 mrem/year) for members of the public from normal operations at the repository.

The EPA standards specify three separate standards for the disposal or postclosure phase that address individual protection, human intrusion, and ground-water protection. The individual protection standard specifies that a reasonably maximally exposed individual (RMEI) shall receive no more than 0.15 mSv/year (15 mrem/year) from all exposure pathways (e.g., internal radiation exposures from ingestion of contaminated water, crops and animal products; external exposures from contamination on the ground). Consistent with the NAS recommendation that the standards define the characteristics of the exposure scenario, the EPA standards specify characteristics of the RMEI for estimating doses from potential releases from the repository. The standard specifies that the RMEI lives approximately 18 kilometers from the repository in the predominant direction of ground-water flow and withdraws water from the aquifer that contains the highest concentration of contamination; has a diet and living style representative of the people who now live in the Town of Amargosa Valley, Nevada; and drinks two liters of water daily. The radiation standard for human intrusion is also a dose limit of 0.15 mSv/year (15 mrem/year) for the RMEI, however, calculation of the consequences of human intrusion is constrained by specific assumptions. The circumstances of human intrusion assumes that exploratory drilling for ground water results in the intruders drilling directly through a waste package to the water table directly below the repository. The Department of Energy (DOE) is to determine the earliest time that an intrusion would occur, using current technology for drilling water wells, without recognition by the drillers that a waste package was penetrated. Finally, EPA specified separate standards for the protection of ground-water. The ground-water standards set concentration limits for certain Radionuclides (i.e., 5 pCi/l for radium 226 and 228, and 15 pCi/l for the combined alpha emitting radionuclides excluding radon and uranium) and a dose limit for other radionuclides (i.e., 0.04 mSv/yr (4 mrem/yr) to the whole body or any individual organ for beta and photon emitters). These postclosure standards apply over a 10,000 year compliance period. The EPA considered both policy and technical reasons in selecting this compliance period.

Performance Assessments

The performance assessment is a systematic analysis that identifies the features, events, and processes, FEPs, (i.e., specific conditions or attributes of the geologic setting; degradation, deterioration, or alteration processes of engineered barriers; and interactions between the natural

and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the potential radiological consequences. The DOE is required to show compliance with the postclosure performance objectives with a performance assessment. To ensure DOE uses meaningful and reasonable calculations, EPA specified certain limitations for the performance assessment to preclude boundless speculation. DOE's performance assessments are not to include consideration of "very unlikely" FEPs, which EPA defines to be those FEPs that have less than one chance in 10,000 of occurring within 10,000 years of disposal. In addition, EPA's standards direct NRC to exclude "unlikely" FEPs, or sequences of events and processes, from the required assessments for demonstrating compliance with the human intrusion and ground-water protection standards. EPA did not define unlikely FEPs in its standards, but, rather, left the specific probability of the unlikely FEPs for NRC to define. EPA's standards also specify criteria that pertain to the characteristics of a reference biosphere. The standards specify that the reference biosphere used in the performance assessments needs to be consistent with present conditions in the Yucca Mountain area and speculation on changes in society, human biology, or increases or decreases in human knowledge or technology should not be considered.

PUBLIC COMMENTS

On February 22, 1999, the Commission published a proposed rule for public comment that would establish licensing criteria for disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, Nevada (5). During the public comment period the Commission received more than 700 discrete comments enclosed in about 160 individual letters, as well as another 193 comments made at public meetings. The comments covered various technical topics (e.g., preclosure safety assessment, postclosure performance assessment, quality assurance, performance confirmation program) as well as programmatic topics (e.g., stringency of dose limits, separate requirements for protection of ground water, publication of NRC regulations before EPA issued final standards). The public comments provided a mixture of suggestions for changes to the proposed rule and support for approaches in the proposed rule. On the programmatic topics, many stakeholders from Nevada requested that NRC not publish regulations before EPA published final standards. These commenters preferred that NRC adopt the annual individual dose limit of 0.15 mSv/yr (15 mrem/yr) and separate requirements for protection of ground-water as proposed by the EPA (6). The NRC has honored these requests and issued its regulations accordingly, after EPA published its final standards. Various changes were made to the regulations to clarify the intended purpose. This paper discusses some of the regulatory clarifications below. For a complete discussion of the public comments and the associated changes, see the Supplementary Information accompanying the final rule (1).

NRC REGULATIONS

NRC published its final regulations for disposal of high-level radioactive wastes in a potential geologic repository at Yucca Mountain, Nevada on November 2, 2001. The regulations address the performance of the repository system in addition to addressing the licensing procedures, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning. The primary focus of the regulations is public health and safety. In particular, the regulations provide for safety evaluations, safety plans and procedures, and continued oversight of safety.

Safety Evaluations

Safety evaluations are required for compliance with both the preclosure and postclosure performance objectives. The NRC regulations contain specific requirements for the preclosure and postclosure safety analyses to ensure they consider an appropriate range of issues in sufficient detail to allow NRC to determine whether or not DOE has demonstrated compliance with the performance objectives.

The preclosure safety analysis is a systematic examination of the site; the design; and the potential hazards, initiating events and their resulting event sequences and potential radiological exposures to workers and the public. The regulations require the DOE to identify the event sequences that might lead to radiological exposures. An event sequence means a series of actions or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel. The regulations classify the event sequences by two broad categories called Category 1 and Category 2. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Consistent with EPA's final standards, Category 1 events sequences are limited to an annual individual dose of 0.15 mSv/year (15 mrem/year) for members of the public from normal operations at the repository. Other event sequences that have at least one chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences. The repository operations area is to be designed such that any Category 2 event sequence (i.e., those event sequences representing off-normal or accident conditions) will not result in an individual dose larger than 0.05 Sv (5 rem). The analysis of a specific Category 2 design basis event would include an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of individuals to radiation. An example design basis event is a postulated earthquake (the initiating event) which results in: 1) the failure of a crane lifting a spent fuel waste package inside a waste handling building, 2) damage to the building ventilation (filtration) system, 3) the drop and breach of the waste package, 4) damage to the spent fuel, 5) partitioning of a fraction of the radionuclide inventory to

the building atmosphere, 6) release of some radioactive material through the damaged ventilation (filtration) system, and 7) exposure of an individual (either a worker or a member of the public) to the released radioactive material.

A primary focus of the preclosure safety analysis is the identification of the structures, systems, and components relied on to limit or prevent potential event sequences or mitigate their consequences (i.e., important to safety). To ensure that DOE performs a comprehensive evaluation of safety for both workers and the public, the NRC regulations require that DOE address specific topics in its safety assessment. Among these are: means to limit concentration of radioactive material in air; means to limit the time needed to perform work near radioactive materials; means to control access to high radiation areas or airborne radioactivity areas; means to prevent and control criticality; radiation alarms that warn of significant increases of radiation levels, concentrations of radioactive material in air, and increased radioactivity in effluents; the ability of structures, systems, and components to perform their intended safety functions, assuming the event sequences occur; explosion and fire detection and suppression systems; means to provide reliable and timely emergency power to instruments, utility service systems, and operating systems important to safety if there is a loss of primary electric power; and means to inspect, test, and maintain structures, systems, and components important to safety to ensure their continued functioning and readiness.

The EPA final standards require that DOE show compliance with the postclosure performance objectives using a performance assessment subject to certain constraints (see previous discussion under EPA Standards). Evaluation of repository performance is complicated by uncertainties because of the first-of-a-kind nature of the repository and the very long time period for the analysis (i.e., 10,000 years). The NRC is confident that a scientifically credible performance assessment is the best basis on which NRC can make an informed, reasonable licensing decision. To ensure that DOE develops a sufficiently credible evaluation of postclosure performance, the NRC regulations require that: 1) uncertainties inherent in any performance assessment are thoroughly explained and analyzed or addressed; 2) DOE's performance assessment is tested (corroborated) to the extent practicable; and 3) there are added bases that provide confidence that the postclosure performance objectives will be met (i.e., multiple barriers). For example:

- 1) DOE is required to consider uncertainty in its representation of the repository (uncertainty and variability in parameter values must be taken into account) and the events that can happen during the compliance period (consideration of potentially disruptive events with a probability of occurrence as low as one chance in 10,000 of occurring over 10,000 years). Also, DOE must provide further assurances that uncertainty in the information (e.g., evaluation of site characterization data) used to develop the performance assessment has been evaluated by consideration of alternative conceptual models of features and processes that is consistent with available data and current scientific understanding. DOE must also supply its basis for including or excluding FEPs that significantly affect performance.

- 2) DOE is required to provide the technical basis for the models used in the performance assessment. Approaches for providing the technical basis would include comparisons of these models with information relevant to the conditions of geologic disposal and time periods of the assessment (e.g., results from detailed process-level models, field investigations, and natural analogs).
- 3) The geologic repository must include multiple barriers, consisting of both natural barriers and an engineered barrier system. The performance assessment makes use of models and parameters that represent the behavior of the natural features of the repository system (e.g., characteristics of the hydrology, geology, and chemistry of the natural setting of the repository) as well as its engineered components. Specific features that have a capability to significantly affect the amount of water that contacts waste or the movement radionuclides in the geosphere (e.g., waste package, radionuclide sorption capacity of specific hydrogeologic units) are important to isolation of waste and are termed "barriers." An important focus for the performance assessment is the identification of barriers relied on to isolate radioactive waste and characterization of each barrier's capabilities. Confidence that the postclosure performance objectives will be met is not solely a matter of quantitative comparison with the performance objectives. A requirement that multiple barriers make up the repository system ensures that repository performance is not wholly dependent on a single barrier. As a result, the system is more tolerant of failures and external challenges such as disruptive events.

Safety Plans and Procedures

Safety evaluations identify the types of situations or scenarios that might result in radiological exposures, however, requirements for safety plans and procedures are used to minimize the potential for radiological releases and to be prepared in the event of radiological releases occur. To minimize the potential for radiological releases, the regulations specify that DOE must provide programs for training of personnel, quality assurance, and performance confirmation.

The quality assurance program comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfactorily in service. The quality assurance program is applied to all structures, systems, and components important to safety (preclosure safety) and to design and characterization of barriers important to waste isolation (postclosure safety). Thus quality assurance requirements apply to a variety of activities such as: facility and equipment design and construction; facility operation and maintenance; inspecting; testing; analyses of samples and data; tests and experiments; and scientific studies.

Confidence in the safety of the repository can be increased further by a program of continued investigation of repository performance (i.e., performance confirmation program). The regulations provide for a performance confirmation program to confirm the assumptions, data, and analyses that led to the findings that permitted construction of the repository and subsequent

emplacement of the wastes. The general requirements for the performance confirmation program state that the program must provide data that indicate whether:

1) subsurface conditions encountered and changes in those conditions during construction and waste emplacement are within limits assumed in the licensing review; and 2) natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated. Thus, key geotechnical and design parameters, including any interactions between natural and engineered systems and components, will be monitored throughout site characterization, construction, emplacement, and operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives. Given the significant amount of time (e.g., tens of years) anticipated for construction and waste emplacement operations, it is likely that significant technical uncertainties will be resolved by performance confirmation, thereby providing greater assurance that the performance objectives will be met.

The regulations also contain certain requirements for DOE to be prepared for unexpected conditions. Specifically, the DOE is required to have plans to cope with radiological accidents (i.e., emergency planning) and for retrieval of waste. Emergency planning is intended to ensure that DOE is prepared to respond, both on site and off site, to accidents. The required Emergency Plan includes: identification of each type of accident, description of the means of mitigating the consequences of each type of accident; prompt notification of offsite response organizations; and adequate methods, systems, and equipment for assessing and monitoring actual or potential consequences of a radiological emergency condition. Additionally, DOE is required to design and plan the repository for a potential retrieval of the radioactive waste. Waste retrieval is intended to be an unusual event only to be undertaken to protect public health and safety. For example, if information became available during the performance confirmation program that indicated that public health and safety would not be protected, the radioactive waste could be retrieved from the repository.

Continued Safety Oversight

The regulations provide for continued oversight of the safety of the repository through requirements to help preserve knowledge of the repository for future generations. The regulations specify that DOE employ both active and passive means to regulate and prevent activities that could impair the long-term isolation of radioactive waste. These measures could include: construction of permanent markers to identify the site and repository; placement of records in the archives and land record systems of local, State and Federal government agencies to identify the location of the repository, boundaries of the site, and the nature and hazard of the waste; and a program for continued oversight to prevent any activity at the site that poses a risk of breaching the engineered barriers of the repository. Finally, the regulations require DOE to develop a program to provide long-term monitoring of the repository (i.e., after the repository has been closed).

CONCLUSION

EnPA directed federal agencies to develop new standards and regulations for HLW disposal at a potential repository at Yucca Mountain, Nevada. On February 22, 1999, the Commission published a proposed rule for public comment. Some stakeholders from Nevada requested the NRC to not publish final regulations before EPA published final standards and adopt the radiation limits of the final standards. The NRC honored these requests and issued its final regulations only after final EPA standards were published. In addition to adopting the radiation limits in EPA's final standards, Part 63 provides requirements to ensure: safety evaluations are comprehensive and technically supported; safety plans and procedures are adequate to cope with accidents and confirm repository performance; oversight of repository safety will continue into the future. These regulations establish a coherent body of risk-informed, performance-based criteria for a Yucca Mountain facility that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. Risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used to 1) focus attention on the most important activities, 2) establish objective criteria based upon risk insights for evaluating performance, 3) develop measurable or calculable parameters for monitoring system and licensee performance, and 4) focus on the results as the primary basis for regulatory decision making.

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