POLICY ISSUE
(Notation Vote)

December 24, 1997 SECY-97-300

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROPOSED STRATEGY FOR DEVELOPMENT OF REGULATIONS GOVERNING DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A PROPOSED REPOSITORY AT YUCCA MOUNTAIN, NEVADA

PURPOSE:

To inform the Commission of a proposed strategy for development of regulations for disposal of high-level radioactive wastes (HLW) in a proposed geologic repository at Yucca Mountain (YM), Nevada; seek Commission guidance on an appropriate approach for implementing that strategy; and obtain Commission approval to develop a corresponding rulemaking plan.

BACKGROUND:

The Commission has directed the staff to pursue the development of site-specific, performance-based regulations for YM to implement forthcoming Environmental Protection Agency (EPA) standards. In a March 17, 1997, Staff Requirements Memorandum, the Commission endorsed its earlier views on Direction-setting Issue 6. Those views indicated that the staff was to seek Commission approval for this rulemaking before initiating significant work on a "new Part 60." As stated above, the staff proposes a strategy for carrying out this directive.

Existing U.S. Nuclear Regulatory Commission regulations at 10 CFR Part 60, initially issued in 1983, contain generic criteria governing the licensing of the Department of Energy (DOE) to receive and possess source, special nuclear, and byproduct material at a geologic repository that is sited, constructed, and operated in accordance with the Nuclear Waste Policy Act of 1982

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To be made publicly available when the final SRM is made available.

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(NWPA-Public Law 97-425). The NWPA required NRC to develop technical criteria, for HLW disposal, that: provide for a system of multiple barriers; include restrictions on retrievability; and are not inconsistent with environmental standards promulgated by EPA pursuant to NWPA. NRC promulgated its Part 60 regulations assuming that EPA would issue standards limiting cumulative radionuclide releases from a geologic repository.

In 1985, some 2 years after Part 60 was published, EPA issued final standards at 40 CFR Part 191, which contained not only cumulative release limits, but also provided additional criteria (*i.e.*, for individual and ground-water protection) that had not been included in EPA's rulemaking proposal. In 1986, NRC proposed "conforming amendments" to incorporate the EPA standards into NRC's regulations (51 FR 22288, June 19, 1986). The proposed amendments were withdrawn in 1987 when EPA's standards were vacated by the U.S. Court of Appeals. Also, in 1987, Congress amended NWPA, redirecting the national waste program to focus exclusively on the characterization of the YM site as a potential geologic repository.

In the Energy Policy Act of 1992 (EnPA — Public Law 102-486), Congress directed EPA (at Section 801) to contract with the National Academy of Sciences (NAS) to advise EPA on the appropriate technical basis for public health and safety standards governing the YM repository. On August 1, 1995, the Committee on Technical Bases for Yucca Mountain Standards, of the National Research Council, issued its report, "Technical Bases for Yucca Mountain Standards." Important differences exist among NAS' recommendations, prior EPA standards for HLW, and NRC's existing regulations at Part 60. Attachment 1 contains a summary of the principal NAS recommendations, compared with prior NRC positions that were presented to the NAS Committee in May 1993 (a draft of this summary was provided to the Commission on August 1, 1995).

Within 1 year of receiving the NAS report, EPA was obligated, under EnPA, to issue final public health and safety standards that are "based upon and consistent" with the NAS findings and recommendations (*i.e.*, by August 1, 1996). According to EnPA, EPA's new health-based disposal standards "... shall be the only such standards applicable to the Yucca Mountain site." EPA has yet to publish a proposal for new YM standards. After establishment of final EPA standards, NRC must modify its technical requirements and criteria under section 121(b) of the NWPA (*i.e.*, Part 60) to be consistent with the new EPA standards, and also to implement certain assumptions that are specified in the EnPA, with regard to the effectiveness of post-closure oversight of the repository to the extent consistent with the NAS report. NRC has 1 year to make these modifications.[1]

To issue final regulations within the short time allotted by EnPA, NRC's rulemaking development must be undertaken in parallel with development of EPA's new standards for YM. With this in mind, members of the Division of Waste Management (DWM) staff met frequently with EPA's technical staff for more than a year after publication of the NAS report. In the course of these interactions, DWM staff shared preliminary results of performance assessment (PA) calculations

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[1]In addition to the EnPA, Congress continues to contemplate further legislation that, if enacted, could affect the regulation of HLW disposal at YM (*e.g.*, S.104, passed by the Senate on April 15, 1997, and H.R. 1270, passed by the House on October 30, 1997). The Commission has testified that these bills contain the elements of an integrated HLW management system necessary for the protection of the public health and safety.

relevant to dose-based performance measures as they were being carried out by DWM staff and the Center for Nuclear Waste Regulatory Analyses. During these meetings, DWM took the opportunity to bring specific implementation concerns to the attention of the EPA staff.

DISCUSSION:

NRC's generic regulations at Part 60 contain general, administrative, technical, and quality assurance requirements. Technical requirements include performance objectives as well as siting and design criteria for pre-closure operations and for long-term, post-closure performance of a repository. In 1996, the Commission updated its generic requirements at Part 60 for activities conducted at a geologic repository operations area before permanent closure (61 FR 64267, December 4, 1996). These changes sought, in part, to clarify the relationship of pre-closure design and operating criteria to the pre-closure performance objective for radiation protection and to achieve greater consistency with the Commission's licensing requirements for independent storage of spent fuel and HLW at 10 CFR Part 72.

During the 14 years after Part 60 was promulgated, there has been considerable evolutic NRC and elsewhere, in the capability of PA methods and computer codes for compliance demonstration, as well as in the development of methods to quantify and propagate uncertainty. Experience with these techniques, together with substantially more information about YM and legislative redirection, has altered the technical assumptions and estimated behavior of post-closure repository performance that formed the basis for the existing Part 60 criteria. These changes call into question the utility of these generic criteria for evaluating conditions at YM that were not envisioned when the criteria were established and suggest that alternatives to the generic criteria in Part 60 need to be considered for YM to avoid the imposition of unnecessary or potentially ambiguous requirements.

As it prepares to develop a proposal for rulemaking, the staff seeks to identify simpler, more straightforward, easy-to-implement requirements, for post-closure performance of a repository at YM, that are risk-informed and unambiguously performance-based. To draft such requirements, staff intends to bring to bear the insights acquired from international guidelines for regulation of HLW disposal, NRC and DOE PAs, the results of systematic analyses of the existing regulations, advances in the incorporation of uncertainty in risk-informed decision-making, and a large amount of site-specific information, all of which have become available since Part 60 was developed.

Before embarking on formal rulemaking, the staff solicits Commission approval of a general overall strategy (described in more detail in Attachment 2) that staff intends to use to develop a formal rulemaking plan. Additional background information supporting staff's development of this strategy is provided in Attachment 3, which discusses, in some depth, NRC's consideration of multiple barriers to provide "defense-in-depth" for the regulation of HLW disposal. Key elements of the staff's strategy can be summarized as follows:

1. Adopt, as much as possible, definitions, administrative, preclosure, retrievability, and quality assurance portions of Part 60, with minor revisions for purposes of clarity and simplification.

2. Establish compliance with forthcoming EPA standards, limiting individual dose (or risk) to the average member of a critical group, as the single overall measure of post-closure system performance.

3. Specify reference biosphere assumptions and define the characteristics and location of the critical group appropriate for YM.

4. Specify an intrusion scenario to be used to evaluate the consequences of an assumed human intrusion event.

5. Require demonstration that post-closure performance is achieved using a system of multiple barriers, but place no quantitative requirements on the performance of individual repository subsystems or their components.

6. Instead, require that DOE demonstrate the contributions of multiple barriers, and their respective uncertainties, to the achievement of the post-closure performance objective, by providing the results of intermediate calculations within DOE's analysis of system performance. The transparency afforded by these calculations will inform decision-makers about the key contributors to system-level performance.

7. Evaluate only those site attributes and design features that are directly relevant to a YM site, as part of the YM-specific performance evaluation (as illustrated in the accompanying figure); and eliminate, as much as possible, unnecessary, generic siting and post-closure design criteria that are not appropriate for assessing performance of a YM site.

8. Consistent with Commission policy, make no provision, at this time, for the implementation of additional criteria for protection of ground water.

Staff has evaluated two approaches for implementing this strategy, as follows:

Alternative 1:

The Commission could direct staff to draft a new, separate part of the regulations that would apply only to YM, leaving Part 60 as written.

PRO: a. Allows the Commission to specify concise, site-specific, criteria, for YM, that are consistent with current assumptions, with site-specific information and PA experience, and with forthcoming dose or risk standards.

b. Is the most direct means to establish a coherent body of risk-informed, performance-based criteria for YM, consistent with the Commission's philosophy of risk-informed, performance-based regulation.

c. Generic requirements remain intact and in place, if needed, for sites other than YM, although their application may be difficult.

d. Is more likely to permit NRC to comply with timeframe mandated by EnPA if rulemaking development is in' .ed immediately.

CON: a. Regulatory uncertainties identified in Part 60 may need to be addressed in the future if other sites are considered for licensing.

b. Retaining Part 60, unmodified, might pose some additional litigative risk, if the new criteria for YM are perceived to be less stringent than generic criteria that remain in force, and which still could be applied, at least in principle, to another site.

Alternative 2:

The Commission could direct staff to revise Part 60 to apply only to YM, thereby eliminating any generic regulations.

PRO: a. Allows the Commission to replace existing regulations with site-specific criteria, for YM, that are consistent with current assumptions, with site-specific information and PA experience, and with forthcoming dose or risk standards.

b. Would remove, from NRC regulations, generic criteria that were developed assuming different EPA standards, and outdated understanding of repository performance.

CON: a. May necessitate the development, later, of additional site-specific criteria for sites other than YM.

b. May prove more time-consuming, if staff finds it necessary to justify deletion of each criterion in Part 60, separately, as irrelevant or unnecessary for YM.

c. Could be interpreted as going beyond statutory direction; EnPA does not explicitly direct NRC either to retain or to eliminate *generic* requirements; EnPA only directs NRC to modify its requirements to be consistent with EPA's YM standards.

Staff also considered two additional alternatives: creation of a new Part for YM while simultaneously updating Part 60, or updating Part 60 in such a way as to include a site-specific Subpart for YM. Both were dismissed as too resource-intensive, given the absence of any foreseeable need for revised generic criteria governing deep geologic disposal of HLW. Should such a need arise, and staff resources become available, the staff will propose, for Commission approval, an approach to update Part 60 for other potential repository sites.

Consideration also was given to deferring regulatory development until EPA standards for YM are in place, or until new legislation is enacted. The advantage here would be avoidance of unnecessary resource expenditure, should EPA promulgate (or Congress prescribe), standards that are significantly different from those anticipated by DWM staff. This was dismissed, however, because such deferral would make it impossible for NRC to issue final implementing regulations within 1 year, as specified by EnPA. Also, DOE has indicated that NRC regulations will be needed by July of 1999, for the national program to proceed without further delay.

Irrespective of the level of protection, or who, ultimately, sets the standards for YM, NRC will still need to develop a technical basis and regulatory approach for implementing dose- or risk-based standards for YM. Furthermore, in the face of a national need and the absence of EPA standards, the staff believes NRC has an obligation to make public how it would implement dose- or risk-based standards at YM.

A preliminary timetable has been developed for implementation of either Alternative 1 or 2 (Attachment 4). The Commission should note, however, that the preliminary estimates offered therein are dependent on specified assumptions regarding the progress of EPA's rulemaking. Significant delays, beyond the milestones projected, could delay publication of implementing NRC regulations.

RECOMMENDATIONS: That the Commission:

1. Approve the staff's proposed general strategy for developing site-specific regulations, for YM, to implement forthcoming EPA standards while deferring the updating of Part 60 generic requirements to a later date;

2. Approve Alternative 1, directing the staff to implement its proposed strategy by drafting a new, separate part of the regulations that would apply solely to the proposed YM repository; and

3. Approve staff preparation of a formal rulemaking plan implementing Alternative 1.

COORDINATION:

OGC has reviewed this paper and has no legal objections to its issuance. There are no resource, information management, or information technology impacts expected as a result of implementing this strategy.

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Executive Director
for Operations

Attachments:
1. 8/1/95 preliminary NRC observations and positions, re: NAS recommendations--a comparison
2. Conceptual Approach for developing YM regulations
3. NRC consideration of multiple barriers to provide defense-in-depth for HLW regulation
4. Preliminary timetable for developing YM regulations

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by c.o.b. Monday, January 12, 1998. Commission staff office comments, if any should be submitted to the Commissioners NLT Monday, January 5, 1998, with an information copy to SECY. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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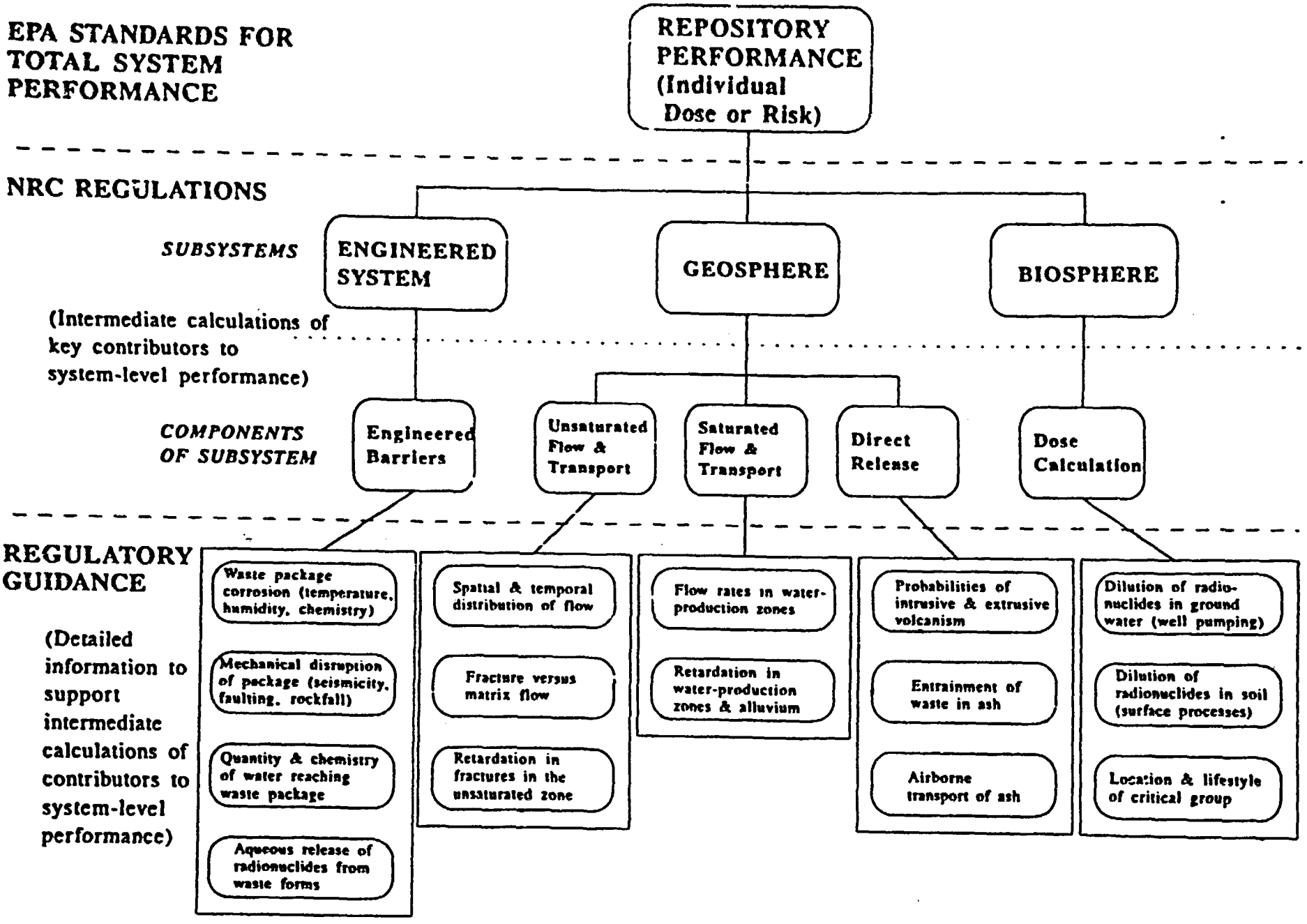

Proposed framework for NRC regulations for Yucca Mountain.

NATIONAL ACADEMY OF SCIENCES REPORT ON TECHNICAL BASES FOR YUCCA MOUNTAIN STANDARDS

PRELIMINARY NUCLEAR REGULATORY COMMISSION OBSERVATIONS AND POSITIONS--A COMPARISON

August 1, 1995

BACKGROUND

The Energy Policy Act of 1992 (EnPA) requires the Environmental Protection Agency (EPA) to promulgate environmental standards for the Yucca Mountain site based on, and consistent with, findings and recommendations of the National Academy of Sciences (NAS), on the technical bases for such standards. Within 1 year of receiving the NAS findings, EPA is directed to develop individual dose standards. After EPA promulgation of environmental standards for Yucca Mountain, the U.S. Nuclear Regulatory Commission has 1 year to modify its technical criteria, at 10 CFR Part 60, for consistency.

A Committee of 15 members representing engineering, geoscience, environmental, and risk disciplines deliberated since May 1993, holding five public sessions in Las Vegas, Nevada, and Washington, D.C.

NRC, EPA, and the Department of Energy (DOE) participated through their liaisons to the Committee, providing recommendations and technical support throughout the deliberations. NRC presented formal recommendations, based on prior Commission positions, to the Committee in May 1993.

At a minimum, under the EnPA, the NAS was required to provide recommendations on reasonable standards that address the following:

(a) Whether health-based standards, based on doses to individual members of the public, from releases to the accessible environment, will provide a reasonable standard;

(b) Whether a system of post-closure oversight, based on active institutional controls, can be effective in preventing unreasonable risk of breaching engineered or geologic barriers and in preventing an increase in individual doses above allowable limits; and

(c) Whether it is possible to make scientifically supportable predictions of the probability that repository barriers will be breached as a result of human intrusion, over a 10,000-year period.

NAS' MAJOR FINDINGS AND RECOMMENDATIONS

NAS' findings and recommendations, as reported by the Committee, are summarized below. (Also noted, as appropriate, are brief descriptions of positions taken by the staff, as they were presented to the NAS Committee in May 1993.)

1. The standard should specify a limit on risk, rather than dose, to the individual. The Committee explicitly recommended against a quantitative release limit. The Committee does not recommend the appropriate level of risk, but views its determination as a crucial policy call that should be addressed in a transparent rulemaking process. The Committee recommends that, for consistency with other radiation protection standards, EPA should consider, as a starting point, risk levels comparable to International Commission on Radiological Protection (ICRP) recommended dose limits (100 mrem/yr (1 mSv/yr) maximum individual dose from all sources, with 10-30 mrem/yr (0.1-0.3 mSv/yr) allocated for high-level waste disposal).

2. The critical group approach, as specified by the ICRP, modified for individual risk, should be used.

   Prior NRC position: With respect to 1 and 2, above, NRC endorsed the value of including radiation protection for individuals as part of the standard and encouraged its application in a reasonable manner using a critical group approach. However, for ease of implementation, the staff expressed a preference for a derived standard (*i.e.*, in the form of a release limit). The staff indicated that a fundamental standard, based on dose or risk, would be acceptable, provided that it could be implemented using a reference biosphere.

3. Compliance assessment should be conducted over a timeframe that includes the period where greatest risk occurs. There is no scientific basis for selection of an arbitrary compliance period, such as the 10,000 years currently specified by EPA under 40 CFR Part 191.

   Prior NRC position: Inconsistent with the staff position taken in May 1993. Although acknowledging that significant risks from a repository may well extend beyond 10,000 years, the staff supported the 10,000-year cut-off to facilitate implementation. The staff suggested that potential releases occurring after the regulatory period should be estimated by DOE and disclosed as part of the Environmental Impact Statement.

4. An individual risk standard would provide adequate protection of the public health and safety provided that policy makers and the public accept that very low doses of radiation pose negligible risk to the collective population. The Committee acknowledged that this is a policy call and suggested that EPA address this matter explicitly. In recommending that EPA address the issue explicitly, it suggested that the risk equivalent of 1 mrem/yr (0.01 mSv/yr) individual dose, as recommended by the National Council on Radiation Protection and Measurements, could serve as a suitable starting point for a determination of negligible individual risk.

Prior NRC position: The staff took no position with respect to the definition of a negligible risk level in the context of the NAS study.

5. Physical and Geologic processes are sufficiently quantifiable and the associated uncertainties sufficiently boundable such that performance can be assessed over the timeframe during which the geological system is relatively stable. Included in the body of the NAS report is guidance relevant to the probabilistic treatment of rare geologic events.

   Prior NRC position: Staff expressed concern with regard to long-term predictions of the probabilities of rare geologic events and encouraged the Committee to address them, along with human intrusion, when considering whether it is possible to make scientifically supportable predictions.

6. It is not possible to predict societal factors required for exposure scenarios. Specification of appropriate scenarios is a policy judgment best accomplished through rulemaking.

   Prior NRC position: Generally consistent with prior NRC position. Any dose or risk-based standard should be implemented using a "static" or "reference" biosphere. Staff indicated that it would object to any fundamental standard that permitted unlimited speculation about future human locations, lifestyles, and societal conditions.

7. It is not reasonable to assume that post-closure oversight, based on active institutional controls, will be effective to prevent breach of repository barriers or prevent radiation exposure in excess of allowable limits.

8. It is not possible to make scientifically supportable predictions of the probability that barriers will be breached as a result of human intrusion over 10,000 years.

   Prior NRC position: Both 7 and 8 are generally consistent with existing NRC regulations [as were in place on August 1,1995] that do not assume that active controls are effective for more than 100 years. The staff expressed its view that this continues to be a prudent assumption, but that passive controls are likely to persist and be effective in deterring (but not preventing) future human intrusion.

9. Human intrusion should not be included in a probabilistic performance assessment. Instead, a consequence analysis of an assumed, stylized intrusion scenario should be required and the resulting risk should not exceed the limit adopted for undisturbed performance.

   Prior NRC position: Staff made no recommendation to the NAS Committee on the merits of separate treatment of human intrusion.

10. There is no scientific basis for incorporating an "as low as is reasonably achievable (ALARA)" requirement into the EPA standard or implementing NRC regulations.

Prior NRC position: Consistent with staff objections to inclusion of broad-based ALARA requirement as speculative and unworkable.

11. In modifying its Part 60 regulations, NRC should not reinstate quantitative subsystem performance criteria. Only overall system performance is crucial and the imposition of quantitative limits of the performance of specific subsystems could result in suboptimal design.

12. Quantitative, technology-based release standards for near-term performance are of no importance for long-term compliance. Their value for additional assurance is a policy judgment and may be considered by EPA as such.

Prior NRC position: With respect to 11 and 12, above, the staff did not address the subsystem performance criteria in 10 CFR Part 60.113 in its May 1993 positions.

identified at the bottom of the accompanying figure would replace the evaluation of the generic "potentially adverse conditions," "favorable conditions" (10 CFR 60.122), and most post-closure design[6] requirements currently in Part 60. The purpose of this change, and one of its simplifying benefits, is the clear tie between key processes included in overall system performance, which is the basis for the compliance demonstration, and the intermediate calculations of subsystem and subsystem component performance. For example, rather than having to perform a separate evaluation of the presence or absence of a potentially adverse site condition (*e.g.*, structural deformation or faulting) and the effects on regional ground-water flow, generally, any such site attribute or condition would be considered only as fully integrated performance-based input to the overall dose calculation (by calculating the number of waste packages expected to fail as a result of focused flow from faults in the context of the key process, "waste package corrosion," as shown in the aforementioned figure). Similarly, prescriptive, post-closure design requirements such as those at 10 CFR 60.134 (a) for the design of seals of shafts and boreholes would not be included, *per se*, in the site-specific implementing rule. Rather, DOE, would be required to consider the advantage or disadvantages of seals, and their design, solely in the context of their impact on overall performance (*i.e.*, "Spatial and Temporal Distribution of Flow" into the repository). Decisions on whether, and what type of, seals are necessary, would be based upon the contribution that seals make to the performance of the Unsaturated Zone Flow and Transport component of the system.

Because it is expected that the detailed information identified at this lowest tier of the staff's hierarchical approach may change as a result of additional site characterization, iterative assessments of repository performance, and the results of performance confirmation, it is considered unsuitable for incorporation into an implementing rule. Consequently, the identification of the material key to demonstrating compliance in a license application will be provided as regulatory guidance, in the SRP, that will accompany the site-specific regulations. Changes to the key processes resulting from the pre-licensing and performance confirmation data collection and assessment activities will be incorporated in subsequent revisions to the SRP. This conceptual approach optimizes transparency and information for the decision-maker while ensuring consistency among the regulatory requirements, the SRP, that will guide staff's review of a license application, and staff's methodology for assessing repository performance and its significance for protecting public health and safety.

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[6]Post-closure design cannot be separated entirely from pre-closure design in that pre-closure design features may have some impact on post-closure performance. As a result, pre-closure design features represent a starting point for analysis of post-closure design features that may contribute to, or detract from, repository performance.

CONCEPTUAL APPROACH FOR DEVELOPING SITE-SPECIFIC REGULATIONS FOR HLW DISPOSAL AT YUCCA MOUNTAIN, NEVADA

INTRODUCTION

The staff is proposing a strategy for the development of risk-informed, performance-based regulations that will implement forthcoming Environmental Protection Agency (EPA) standards for a proposed geologic repository at Yucca Mountain (YM), Nevada. The EPA standards will be promulgated pursuant to the Energy Policy Act of 1992 (EnPA) and are expected to be based on and consistent with the findings and recommendations of the National Academy of Sciences (NAS). The principal objective of the legislative direction in Section 801 of EnPA, the NAS report, and the forthcoming EPA standards is the creation of new, site-specific criteria for evaluating the performance of the YM repository after final closure. Thus, the strategy presented here focuses on the key post-closure considerations attendant to the development of site-specific Nuclear Regulatory Commission regulations for the proposed repository at YM. As much as possible, in developing these regulations, the staff expects to adopt the definitions, administrative, pre-closure,[1] retrievability, and quality assurance portions of generic NRC regulations at 10 CFR Part 60, with only minor revisions for purposes of clarity and simplicity.

Since 1987, the staff and the Center for Nuclear Waste Regulatory Analyses have applied the principles of systems engineering to integrate and streamline the implementation of the NRC high-level waste (HLW) regulatory program. Results of systematic regulatory analysis (SRA), in conjunction with iterative performance assessment, have been useful in uncovering regulatory, institutional, and technical uncertainties in the existing HLW disposal regulations at Part 60.[2] Insights acquired from the use of these techniques have contributed to the identification of the 10 key technical issues (KTIs) that form the basis for NRC's refocused HLW regulatory program, as discussed in SECY-96-120, "Nuclear Regulatory Commission's Refocused Prelicensing High-level Waste Repository Program." The staff intends to apply lessons learned from the application of SRA when developing new regulations to implement forthcoming EPA standards for a proposed repository at YM. Specifically, the staff seeks to develop risk-informed regulations, for YM, that are understandable and unambiguous; that state clear and specific objectives directly related to the protection of health and safety; and that afford flexibility to both the applicant and the regulator, regarding how they are to be achieved. Staff

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[1]In 1996, the Commission updated its generic requirements at Part 60 for activities conducted at a geologic repository operations area before permanent closure (61 FR 64267, December 4, 1996). These changes sought, in part, to clarify the relationship of pre-closure design and operating criteria to the pre-closure performance objective for radiation protection and to achieve greater consistency with the Commission's licensing requirements for independent storage of spent fuel and HLW at 10 CFR Part 72.

[2]See, for example, SECY-89-339," Regulatory Strategy for the High-Level Waste Repository Program: Description of Uncertainties Being Addressed by the U.S. Nuclear Regulatory Commission Staff," October 31, 1989.

intends that all interrelationships between specific regulatory requirements will be transparent, and that in demonstrating compliance, it will be possible to make allowance for advances in technology.

In developing flexible regulations for YM, the staff will need to apply the Commission's philosophy of "risk-informed, performance-based regulation" in a manner appropriate to the post-closure performance of a geologic repository system -- a system with physical characteristics, failure mechanisms, and operating lifetime that differ significantly from other NRC-regulated facilities such as nuclear power reactors.

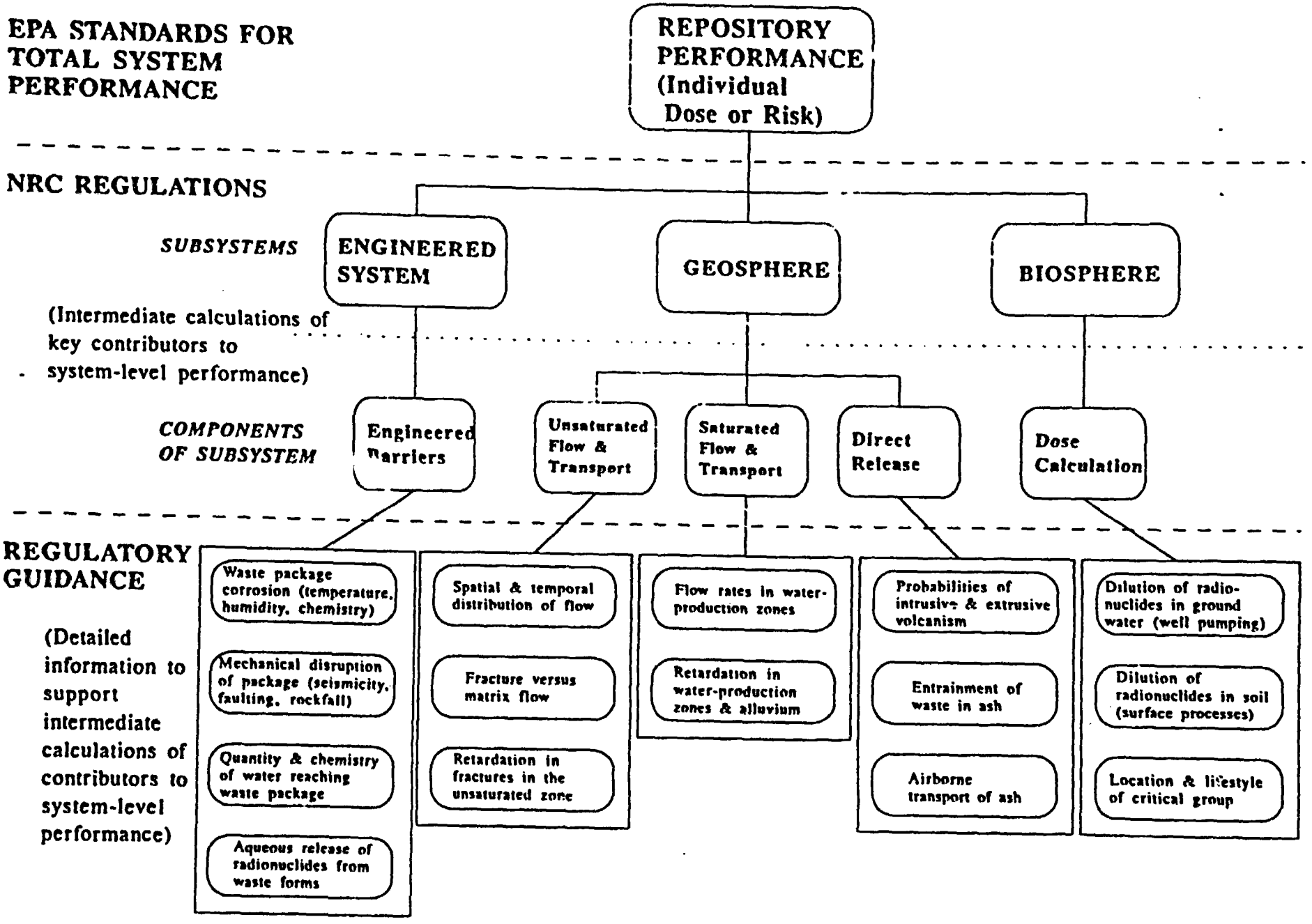
The staff is proposing not to undertake, at this time, the simultaneous updating of the generic aspects of Part 60 that are applicable to potential repository sites other than YM. Updating the generic requirements and criteria in Part 60 would be more resource-intensive than developing new criteria specifically for a repository at the YM site. Further, at present, there is no foreseeable need for updated generic requirements and criteria because, among other things, no site other than YM is undergoing characterization as a HLW repository. Should the need for an updated Part 60 arise, and as staff resources become available, staff would propose an approach, for Commission approval, to update the generic aspects of Part 60 to address any significant inconsistencies between the YM criteria and the generic aspects of Part 60.

CONCEPTUAL APPROACH

Because forthcoming EPA standards for YM are expected to limit the maximum annual dose or risk to the average member of the critical group at YM, certain assumptions about the nature of the future biosphere and the characteristics and location of a critical group appropriate for YM, will be needed to reasonably bound considerations for, and preclude unlimited speculation during, licensing. In addition, the NAS recommended the adoption, in regulation, of a stylized calculation to evaluate the impact of human intrusion on the resiliency of a repository. Accordingly, NRC regulations will need to specify an intrusion scenario that will be used to evaluate the consequences of an assumed human intrusion event at YM.

In developing a strategy for defining new, site-specific regulations for post-closure performance, staff has applied knowledge of the YM site obtained through reviews of site characterization activities over the past years and knowledge of the performance of the repository system gained through reviews of the Department of Energy's (DOE's) past performance assessments of YM, as well as its own independent performance assessments. Drawing on this knowledge and experience, the staff has constructed a conceptual approach that will enable the development of implementing regulations that are: (1) risk-informed and performance-based; (2) easy to implement; (3) consistent with Commission policy on defense-in-depth; and (4) directly related to YM-specific performance assessments. Additional detail is provided below.

For simplicity, the staff's approach is displayed in hierarchical form, comprising three tiers (as illustrated in the accompanying figure). The first two tiers represent topical areas to be addressed directly in the implementing regulations, themselves, and the third, or lowest tier, defines the character and scope of corresponding regulatory guidance that will be prepared as



Proposed framework for NRC regulations for Yucca Mountain.

a standard review plan (SRP).[3] The uppermost tier represents the singular, overall performance objective for the repository system, an individual dose or risk standard, as specified by EPA. This is in contrast to requirements of Part 60, which contain -- in addition to an overall system performance objective (10 CFR 60.112) -- separate quantitative criteria for individual subsystems (10 CFR 60.113). In the proposed strategy, all post-closure requirements (and associated regulatory guidance) will focus on assessing the ability of the YM repository system to meet the individual dose or risk standard identified as the sole performance objective.[4]

The second tier of the staff's approach identifies the subsystems of the repository system (Engineered System, Geosphere, and the Biosphere) and their respective components. There is general agreement among those involved in the HLW program that quantitative estimation of the performance of these subsystems and their respective components is necessary to transparently illustrate their contributions to overall system performance. Such estimates will also inform the decision-maker about the applicant's approach to implementing the Commission's defense-in-depth, multi-barrier philosophy as a means to enhance confidence in regulatory decisions.

In Part 60, the system of multiple barriers was codified by requiring demonstration of compliance with numerical limits for the performance of the engineered and natural barriers, that were selected in the absence of any direct relationship to the overall performance objective. By contrast, the staff's conceptual approach would not incorporate the existing subsystem performance objectives in Part 60 but would, instead, implement the multiple-barrier philosophy by requiring the applicant to provide the results of intermediate calculations that illustrate the relative contribution of individual barriers to overall performance. In demonstrating compliance with the overall system performance objective, DOE would need to present the results of these intermediate calculations, along with their associated uncertainties, thereby demonstrating the effectiveness of key subsystems and increasing the transparency of the overall analysis. In addition to implementing the multiple-barrier approach, this information could serve to support a conclusion that there exists reasonable assurance that the "bottom line," individual-dose calculation resulting from DOE's performance assessment (i.e., expected dose to the average member of the critical group), is a technically sound, supportable estimate of repository performance.

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[3]It must be recognized that the repository system is not a linear system as depicted in the aforementioned figure. Multiple interactions and interdependencies operate between the components and key processes identified. Although not depicted in the diagram, for ease of communication, these interactions and interdependencies will be addressed in full as a part of the SRP.

[4]Consistent with Commission policy that a separate ground-water protection standard is unnecessary to protect public health and safety (See, for example, "Staff Requirements -- SECY-97-046A - Final Rule on Radiological Criteria for License Termination," Memorandum from John C. Hoyle to L. Joseph Callan, May 21, 1997), the staff approach makes no provision, at this time, to implement additional standards for ground water. However, should it become necessary to implement separate ground-water protection standards, the approach depicted in the accompanying figure could be modified accordingly.

These intermediate outputs from the overall performance calculation for the repository system would be directly related to the calculation of the individual dose (or risk) compliance measure; would not be separate, nor additional calculations beyond those that would be expected as part of a competent total system performance assessment; and would not be assigned numerical targets or limits. Interme·"ate calculations that might be appropriate for this purpose might include: 1) the distribution of release rates, as a function of time, of radionuclides from the engineered barrier system; 2) the distribution of release rates, as a function of time, of radionuclides to the water table below YM; and 3) radionuclide concentration, as a function of time, in soil or ground water, used by the critical group. As stated above, these intermediate outputs from the performance assessment calculation, supplied as a part of the documentation supporting the license application, would serve to demonstrate that a multiple-barrier approach was indeed achieved, and would build confidence that the dose expected to accrue to the average member of the critical group, as asserted in the license application, is a reasonable estimation of the performance of the repository system.

The staff is attempting to expand and modify the basic concepts of importance analyses derived from system reliability assessments and traditionally applied to reactors and other systems described by binary states. Unlike operating facilities, such as reactors, which contain active components (*e.g.*, valves and pumps), that are described as either functioning or failing (*i.e.*, their performance is modeled as binary) components of the repository system are passive, and tend to behave largely in a continuous, rather than in a discrete, manner. If successfully applied to the repository system, such "importance measures" are anticipated to provide valuable insights into the effectiveness of multiple barriers and their contribution to the achievement of overall repository performance.

The third and bottom tier of the hierarchy portrayed in the aforementioned figure identifies key processes that could significantly affect repository performance, and signifies the fundamental data and process-level analyses needed as input to demonstrate the contribution of the various components of the repository system. The key processes were derived from the 10 KTIs that are the current basis of the staff's HLW regulatory program. They were identified through staff experience resulting from the review and evaluation of the results of site characterization at YM, SRA of existing regulations, and past independent assessments of repository performance.[5] One output of these independent assessments of repository performance is estimates of risk. In generating these risk estimates, the input parameters for those processes that could affect repository performance are sampled probabilistically, and the consequences of the various scenarios are weighted by their respective probabilities. This risk information can then be used in estimating the relative importance of the various processes and scenarios under consideration. In this way, the staff is implementing a risk-informed approach to identify the key processes that need to be considered, to provide insights on the performance of individual barriers, and to estimate the overall system performance.

These key, YM-specific, processes are designed to substitute for the generic siting and design criteria in the existing Part 60 requirements. Specifically, consideration of the key processes

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[5]Through its pre-licensing interactions with DOE and its ongoing sensitivity studies, the staff expects to continue to reevaluate and update the key processes, as needed, to reflect the results of new information and new interpretations of existing information.

identified at the bottom of the accompanying figure would replace the evaluation of the generic "potentially adverse conditions," "favorable conditions" (10 CFR 60.122), and most post-closure design[6] requirements currently in Part 60. The purpose of this change, and one of its simplifying benefits, is the clear tie between key processes included in overall system performance, which is the basis for the compliance demonstration, and the intermediate calculations of subsystem and subsystem component performance. For example, rather than having to perform a separate evaluation of the presence or absence of a potentially adverse site condition (*e.g.*, structural deformation or faulting) and the effects on regional ground-water flow, generally, any such site attribute or condition would be considered only as fully integrated performance-based input to the overall dose calculation (by calculating the number of waste packages expected to fail as a result of focused flow from faults in the context of the key process, "waste package corrosion," as shown in the aforementioned figure). Similarly, prescriptive, post-closure design requirements such as those at 10 CFR 60.123 (a) for the design of seals of shafts and boreholes would not be included, *per se*, in the site-specific implementing rule. Rather, DOE, would be required to consider the advantage or disadvantages of seals, and their design, solely in the context of their impact on overall performance (*i.e.*, "Spatial and Temporal Distribution of Flow" into the repository). Decisions on whether, and what type of, seals are necessary, would be based upon the contribution that seals make to the performance of the Unsaturated Zone Flow and Transport component of the system.

Because it is expected that the detailed information identified at this lowest tier of the staff's hierarchical approach may change as a result of additional site characterization, iterative assessments of repository performance, and the results of performance confirmation, it is considered unsuitable for incorporation into an implementing rule. Consequently, the identification of the material key to demonstrating compliance in a license application will be provided as regulatory guidance, in the SRP, that will accompany the site-specific regulations. Changes to the key processes resulting from the pre-licensing and performance confirmation data collection and assessment activities will be incorporated in subsequent revisions to the SRP. This conceptual approach optimizes transparency and information for the decision-maker while ensuring consistency among the regulatory requirements, the SRP, that will guide staff's review of a license application, and staff's methodology for assessing repository performance and its significance for protecting public health and safety.

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[6]Post-closure design cannot be separated entirely from pre-closure design in that pre-closure design features may have some impact on post-closure performance. As a result, pre-closure design features represent a starting point for analysis of post-closure design features that may contribute to, or detract from, repository performance.

DISCUSSION OF NRC CONSIDERATION OF THE USE OF MULTIPLE BARRIERS AS A MEANS TO PROVIDE "DEFENSE-IN-DEPTH" FOR THE REGULATION OF HLW DISPOSAL

INTRODUCTION

The Nuclear Regulatory Commission has applied the concept of defense-in-depth broadly throughout its regulations to ensure safety of its licensed facilities through requirements for multiple, independent barriers, and, where possible, redundant safety systems and barriers. The defense-in-depth principle has served as a cornerstone of NRC's deterministic regulatory framework for nuclear reactors, and it provides an important tool for making regulatory decisions with regard to complex facilities, in the face of large uncertainties. Traditionally, the reliance on independence and redundancy of barriers has been used to provide assurance of safety when reliable, quantitative assessments of barrier reliability are unavailable. Because defense-in-depth is applied, generally speaking, without direct consideration of the relative likelihood of specific threats to barrier integrity, the approach is inherently conservative.

The development of NRC regulations for geologic disposal in 1983 represented a unique application of the defense-in-depth philosophy to a first-of-a-kind type of facility. While waste is being emplaced, and before a geologic repository is closed, its operation is readily amenable to regulation in much the same manner as any other NRC -licensed facility. Regulatory criteria for pre-closure operations contained in 10 CFR Part 60, in fact, reflect the defense-in-depth approach commonly used in other parts of NRC regulations, in that safety is ensured for the operating repository by the use of conservatism and diversity of design, application of comprehensive quality assurance and radiation safety programs and procedures, and the maintenance of appropriate emergency plans. Application of defense-in-depth principles for regulation of repository performance, for long time periods following closure, must account for the difference between a geologic repository and an operating facility with active safety systems and the potential for active control and intervention. A closed repository is essentially a passive system, and assessment of its safety over long timeframes is best evaluated through consideration of the relative likelihood of threats to its integrity and performance. Although it is relatively easy to identify multiple, diverse barriers that comprise the engineered and geologic systems, the performance of any of these systems and their respective subsystems cannot be considered either truly independent or totally redundant.

The Nuclear Waste Policy Act of 1982 (NWPA), (hereafter the Act), as amended, directed the Commission to develop technical requirements and criteria for high-level waste (HLW) repositories that provide for a system of multiple barriers and which are not inconsistent with generally applicable U.S. Environmental Protection Agency (EPA) standards for HLW disposal. The Act also mandated that the technical criteria developed by the Commission "...shall provide for the use of a system of multiple barriers in the design of the repository." Although the law demands that NRC require a system of multiple barriers, the issue of how the performance of those barriers should be assessed, consistent with the Commission's policy of defense-in-depth, has been a major issue throughout the development, promulgation, and implementation of the Part 60 regulations.

MULTIPLE BARRIERS AND THE NEED TO COMPENSATE FOR UNCERTAINTY

Well before NWPA was enacted, the Commission had considered the appropriate bases for establishing regulations for HLW disposal. In developing proposed technical criteria for Part 60, the Commission placed primary emphasis on the need to compensate for the large uncertainty that is inherent in the assessment of the long-term performance of HLW disposal systems. In an Advance Notice for Proposed Rulemaking (NRC, 1980), the Commission discussed its approach to deciding which barriers should be considered as part of the repository system. The Commission expressed its view, then, that the state-of-the-art in the earth sciences was such that all the uncertainties related to predicting long-term performance of a repository could not be resolved through consideration of the geologic setting, alone.

It should be noted that during the late 1970s and early 1980s, when the Commission was considering the development of proposed regulatory criteria, quantitative techniques for assessing repository performance were in their infancy. In documents supporting Commission consideration of a proposed rule, the NRC staff noted that:

> In principle, uncertainties in the numerical models, uncertainties in characterization of the site and engineered elements, and uncertainties in basic physical processes can be estimated and bounded. Therefore, it might be possible to account for them directly in determining whether the EPA standard will be met. ***However, a direct accounting of uncertainties has not been done in any modeling to date*** (emphasis added) (NRC 1981a).

This lack of experience with, and confidence in, the quantitative methods for addressing uncertainty weighed heavily as the staff, and eventually the Commission, considered options for formulating HLW regulations. In presenting alternatives for Commission consideration, the staff noted that:

> Compensation for uncertainty that would otherwise confound adequate demonstration of compliance with the EPA standard is an essential part of the NRC staff's regulatory approach. Because any licensing proceeding will involve the question of adequately demonstrating compliance with an EPA standard, ***the NRC staff has placed primary emphasis on selecting approaches to facilitate resolution of this issue*** [emphasis added] (*ibid.*).

The staff documented its evaluation of three potential approaches for developing technical criteria at Part 60 for regulating geologic disposal (*ibid.*):

1. Prescribe a single overall performance standard that must be met by the system, in this case, compliance with the EPA standards;

2. Prescribe minimum performance standards for each of the major system elements (as they were envisioned at the time) as well as requiring the overall system to comply with the EPA standards; or

3. Prescribe detailed, numerical criteria for critical engineering attributes of the system in addition to requiring the overall system to comply with the EPA standards.

The first alternative, frequently referred to as the "systems approach," had as a principal advantage the fact that regulation would be through a single figure of merit, that of overall system performance, leaving maximum flexibility for determining the extent and focus of site characterization, and for the designer to make trade-offs among components of the system. Staff noted, at the time, that this approach could include a requirement that the system design incorporate multiple barriers to compensate for uncertainty in overall system performance. It was believed, at the time, however, that compensation for uncertainties in assessing the system's overall performance could only be achieved, it was felt, by introducing conservatism. Intentional addition of conservatism, either by making the measure of performance unduly stringent or by using worst-case, bounding assumptions in the evaluation, were argued to be impractical from a regulatory point of view.

The second alternative was thought to have two advantages over the systems approach, if the barriers were chosen judiciously. It was argued that barriers could be prescribed which act "independently," and that performance measures for these "independent" barriers could be selected that would reduce calculational uncertainty. Identification of such subsystem performance measures was expected to be helpful input to U.S. Department of Energy's (DOE's) design process, without being overly restrictive.

The final approach of specifying numerical criteria for certain engineering attributes of the system (*e.g.*, peak canister wall temperature), was viewed as having two advantages, in that it would provide clear guidance to the designers, and would allow the criteria to be selected "...to compensate directly for uncertainty" through the introduction of acceptable levels of conservatism. Of the three approaches considered, this was the most prescriptive, and most restrictive of design flexibility, with the regulator assuming the role of designer. Furthermore, it was recognized that NRC would have to define such criteria on the basis of limited, existing knowledge, without benefit of future research and development, and the information that would be acquired during site characterization. Although it was not acknowledged at the time, it is now clear that the latter was also true of the second alternative.

The Commission issued a proposed rule for Part 60 on July 8, 1981, (NRC,1981b), wherein public comment was requested on the first two of the three approaches discussed above. The Commission dismissed the third as overly restrictive of design flexibility. In the notice of proposed rulemaking, the Commission expressed its preference for Alternative 2, stating that "...while [the approach] limits the repository designer's flexibility, it is clear that meeting these minimum design goals would substantially enhance the Commission's confidence that the final EPA standard will be met." To implement Alternative 2, the Commission proposed numerical performance criteria for:

1. the length of time all radionuclides should be contained in the waste packages;
2. the rate of subsequent releases from the engineered system; and
3. the pre-emplacement ground-water travel time to the accessible environment.

In the Proposed Rule, the Commission discussed the respective roles for the engineered and natural systems. With respect to the engineered barriers, the Commission expressed its intent to exploit the ability to design engineered features to meet specific performance objectives as a means of reducing some of the uncertainties in the calculations of overall repository performance. Because the thermal disturbance of the area near the emplaced wastes was believed to add significantly to the uncertainties in the calculation of the transport of the radionuclides through the geologic environment, technical criteria for the engineered systems were intended to compensate for uncertainty by controlling the timing and rate of radionuclide release, thereby, limiting the source term. By requiring containment during the period when the thermal conditions around the waste packages are most severe, the Commission expected, at the time, that evaluation of repository performance would be greatly simplified. Once the engineered barriers begin to degrade, their function then should be to control the release of radionuclides from the underground facility to the geologic setting, which ultimately must provide the longer-term isolation of the wastes from the environment.

The vast majority of comments received on the proposed approaches favored the first alternative, or "systems approach." Although the value of multiple barriers for providing defense-in depth was widely acknowledged, the approach favored by the Commission to ensure their contribution to performance was severely criticized. Many commenters noted that the values specified in the proposed rule had not been shown to be either necessary or sufficient to meet any particular standard, and, as a result, the Commission had failed to demonstrate any logical connection between performance of individual subsystems and overall performance. Prescription of specified numerical values for barrier performance was further criticized as being, at best, premature, absent either proposed or final EPA standards,[1] and, at worst, arbitrary and unduly restrictive of the applicant's flexibility to design the barriers to meet conditions at a specific site. Even some commenters supportive of Alternative 2 suggested greater flexibility in application of the quantitative criteria, or selection of criteria more directly tied to the overall performance objective (NRC, 1983a).

The force of these arguments notwithstanding, in publishing its final rule, the Commission elected to retain the proposed approach, stating that "...in simply adopting the EPA standard as the sole measure of performance, it [the Commission] would have failed to convey in any meaningful way the degree of confidence which it expects must be achieved in order for it to be able to make the required licensing decisions" and, further that "...The Commission firmly believes that the performance of the engineered and natural barriers must each make a definite contribution in order for the Commission to be able to conclude that the EPA standard will be met (NRC, 1983b)."

In support of the Final Rule, the Commission examined how particular values for the performance of the proposed barriers would assist in concluding that the EPA standard had been met, given an assumed set of anticipated processes and events. Final EPA standards had not yet been promulgated, so analyses were conducted based on NRC staff assumptions

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[1]EPA proposed "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-level, and Transuranic Radioactive Wastes" on December 29, 1982 (47 FR 58195).

regarding the final standards. These analyses, based on a simplified modeling study for a hypothetical repository located in a variety of ***saturated*** (emphasis added) geologic media, are documented at NRC, 1983a. For many, but by no means all, of the cases examined, compliance with the proposed subsystem performance objectives did increase the probability of meeting the assumed EPA standard. The staff was not able to demonstrate, however, that compliance with the subsystem criteria was sufficient to meet the assumed EPA standard, nor that compliance with the assumed EPA standard would suffice to assure compliance with the subsystem criteria. For the cases analyzed, however, the staff asserted that the analyses "...demonstrate that compliance with 10 CFR Part 60 can substantially increase confidence that the assumed EPA standard will be met."

Lastly, in order to address concerns that quantitative subsystem performance criteria may unduly restrict the applicant's flexibility, the Commission modified the proposed rule to explicitly recognize the potential need to adjust the subsystem objectives to account for unique features of a specific site or design. This flexibility was provided in the Final Rule at 10 CFR 60.113 (b) which states that:

> On a case-by-case basis, the Commission may approve or specify some other radionuclide release rate, designed containment period or pre-emplacement groundwater travel time, provided that the overall system performance objective, as it relates to anticipated processes and events, is satisfied. Among the factors that the Commission may take into account are–
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> (1) Any generally applicable environmental standard for radioactivity established by the Environmental Protection Agency;
> (2) The age and nature of the waste and the design of the underground facility, particularly as these factors bear upon the time during which the thermal pulse is dominated by the decay heat from the fission products;
> (3) The geochemical characteristics of the host rock, surrounding strata and groundwater; and
> (4) Particular sources of uncertainty in predicting the performance of the geologic repository.

CALLS FOR NRC RECONSIDERATION OF SUBSYSTEM REQUIREMENTS

For many years after their promulgation, the Part 60 regulations, and the subsystem criteria in 10 CFR 60.113, in particular, have been criticized as overly prescriptive, lacking a sound technical basis, and unclear in their wording. In addition to DOE and representatives of the nuclear industry, critics have included the National Academy of Sciences (NAS) Board on Radioactive Waste Management, former Commissioner James R. Curtiss, and the Nuclear Waste Technical Review Board (NWTRB).

In a 1983 report (NAS, 1983), the Waste Isolation Systems Panel of the NAS Board on Radioactive Waste Management found that NRC's proposed numerical criteria "...are of questionable importance to long-term safety and are proposed without a technically valid basis." The panel took particular exception to the release rate criterion, stating that: "...it is both

unnecessary and unrealistic for the NRC staff to prescribe a single fractional dissolution rate that must apply to essentially all of the 1,000-year inventory of radionuclides...NRC's across-the-board specification of a release rate limit of 10^{-5}/yr for all radionuclides...is not only unnecessary but it is also likely impossible to achieve."

In July of 1990, the NAS Board on Radioactive Waste Management issued a report entitled "Rethinking High-Level Waste Disposal (NAS, 1990)." The Board concluded that the existing approach had resulted in the U.S. program's lack of satisfactory progress because of the regulatory requirements (*i.e.*, the EPA's 40 CFR Part 191 and NRC's Part 60) and program implementation. Among other things, the Board called on NRC to reconsider its detailed licensing requirements and to provide greater flexibility. In a symposium held later that year on the Board's report (NAS,1992), James Curtiss, then NRC Commissioner, was the invited keynote speaker. In his remarks, Commissioner Curtiss highlighted the fact that NRC had been unable to identify a clear and unambiguous approach to implementing the EPA standards, in large measure attributable to the lack of a "technical nexus" between the EPA's standards and NRC's quantitative requirements. Curtiss decried this lack of a clear link between the two as creating, in effect, two legally distinct licensing standards, and further, called on NRC to restructure its technical criteria. Curtiss also questioned, as a practical matter, whether any future Commission would be able to implement the flexibility intended by 10 CFR 60.113 (b) during the actual licensing process (Curtiss, 1990).

Pursuant to the Energy Policy Act of 1992, the NAS Committee on Technical Bases for Yucca Mountain Standards issued a report (NAS, 1995) that found, among other things, that the physical and geologic process relevant to a Yucca Mountain (YM) repository: "...are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance [of a repository] can be assessed over timeframes during which the geological system is relatively stable or varies in a boundable manner."

As described earlier, it was lack of confidence in the ability to quantify overall performance and adequately bound uncertainty that factored prominently in NRC's decision to include quantitative subsystem requirements in the Part 60 regulations. The NAS strongly recommended against implementation of multiple barriers through the use of subsystem performance requirements. The Committee 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 repository design."

In a 1993 briefing before the Commission, NWTRB recommended that NRC should permit trade-offs between engineered barriers and natural barriers, and that the Commission should consider revisions to Part 60 that would provide for less prescriptive, more flexible implementation of the EPA standards (NWTRB, 1993). More recently, the NWTRB (NWTRB, 1996) expressed its general views on the regulatory framework for geologic disposal at YM:

> The current EPA health and safety standard, and the NRC and DOE regulations, were overly detailed and enacted too early in the process of searching for a permanent repository site. Scientific and technical knowledge, particularly when applied to a first-of-a-kind undertaking, takes time to evolve. In retrospect, the wiser

course may have been to collect that knowledge and use it in developing a regulatory framework. In the absence of that approach, the Board believes that the NAS report and current scientific and technical understanding of the conditions at the YM site should provide a basis for revising safety standards and regulations.

Most recently, in a letter of October 31, 1997, NRC's Advisory Committee on Nuclear Waste (ACNW) stated that it "...does not endorse the establishment of rule-based subsystem requirements as exist in 10 CFR Part 60." The ACNW explained, further, that:

> Current thinking, which is supported by much experience and empirical evidence in both probabilistic performance assessment and site characterization is that performance-based regulations are much more efficient and effective in protecting health, safety, and the environment than are "command-and-control" approaches. Focusing on quantitative subsystem requirements for the proposed repository at YM would run counter to this thinking because it potentially could force a design that would increase overall risk even though all subsystem requirements were met.

The ACNW also asserts that "...an overall performance-based regulation in the context of a risk-based standard is a superior tool for promoting safety relative to imposed subsystem requirements."

In closing, ACNW points out, however, that:

> The primacy of an overall performance-based regulation does not imply that DOE, as the license applicant for Yucca Mountain, would not have to demonstrate convincingly to the NRC that both the geologic system and multiple aspects of the engineered system were effective in providing waste isolation capacity. The NRC should insist that the applicant's PA [performance assessment] clearly and quantitatively indicates how each barrier contributes to meeting the overall safety objective. This information should provide the basis for an informed decision on the license application (ACNW, 1997).

LIMITATIONS OF THE 10 CFR 60.113 SUBSYSTEM CRITERIA

It is clear, from a review of the regulatory history, that much of the basis for the staff's initial recommendation of the numerical values for the subsystem criteria was generic judgment with regard to what was feasible. For example, the release rate criterion of 10^{-5}/yr was recommended based primarily on staff consideration of typical leach rates of a range of synthetic glass waste forms that were then under consideration by DOE. Because the stated goal was to compensate for uncertainty, as discussed above, there is no direct link between the quantitative criteria and the level or dose or risk reduction achieved by their application. Furthermore, these judgments with regard to technological achievability in the selection of

specific numerical criteria were made on the basis of technical assumptions that are now out-of-date, or inappropriate for an unsaturated site, such as YM.[2]

When the Part 60 subsystem criteria were selected, they were intended to be separate, "independent," easily-determined measures of subsystem performance that would require technology that was readily available. Extensive experience with site-specific performance assessment has shown them to be none of these. For example, because container performance, release rate, and ground-water travel time will be derived from the same general data and knowledge base as the total system performance assessment (TSPA), they are subject to most of the same uncertainties. However, additional models and data will need to be developed beyond those necessary for TSPA to support demonstration of compliance with the existing subsystem criteria. Furthermore, waste package performance and release rate are both a function of available water; therefore, it is arguable whether the existing (or any other) subsystem measures can provide truly independent assurance of total system performance.

The wording of the individual subsystem requirements, and disagreements with regard to the intended meaning of terms such as "substantially complete" containment, "fastest path of likely radionuclide travel," and "disturbed zone" have also given rise to considerable regulatory uncertainty. For example, although the meaning of the term "substantially complete" containment has yet to be resolved, the NRC staff was compelled to clarify a related matter by issuing Staff Position SP 60-001 in 1990. The staff position was issued to clarify the meaning of the wording at 10 CFR 60.113 (a)(1)(ii)(A), which states that "Containment of HLW within the waste packages will be substantially complete for a period to be determined by the Commission ...provided, that such period shall be not less than 300 years nor more than 1,000 years after permanent closure. ." Because the phrase "...not less than 300 years nor more than 1000 years" was being taken out of context and the nature of the requirement misrepresented, the staff found it necessary to make clear that the requirement represented a minimum performance requirement, and should not be viewed as a cap on waste package lifetime or a limitation on the credit that can be taken in engineered barrier system or overall system performance assessment if the waste package is designed to provide containment in excess of 1000 years.

CURRENT VIEWS OF THE NRC STAFF ON REQUIREMENTS FOR MULTIPLE BARRIERS

The staff continues to believe that a multiplicity of barriers must each make a definite contribution to the achievement of the overall safety objective for a repository at YM, to find, with reasonable assurance, that the safety objective is achieved. To ensure defense-in-depth, the performance of individual barriers, along with the associated uncertainties, must be demonstrated, for the staff to recommend to the Commission that there exists reasonable

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[2]When the Commission proposed amendments to Part 60, in 1984, that would include specific criteria for the unsaturated zone (NRC, 1984), the Commission acknowledged that it may be more appropriate to specify a parameter, other than ground-water travel time, on which performance should be evaluated for a geologic setting in the unsaturated zone. Despite comments supporting an alternative approach, the Commission elected, in the final rule, to retain the ground-water travel time criterion, at the same time highlighting its flexibility, under 10 CFR 60.113(b), to prescribe alternate criteria to a particular geologic setting "...when such an action is deemed appropriate" (NRC, 1985).

assurance that the EPA standards have been met. That being said, however, the staff now believes that risk-informed, performance-based regulation of geologic disposal is unnecessarily complicated by the imposition of quantitative subsystem requirements.

The staff agrees, consistent with the 1995 NAS finding cited above, that more than 15 years of performance assessment experience (see Bonano, *et al.*, 1989; Electric Power Research Institute, 1990, 1992, and 1996; NRC, 1992, 1995, and 1997; Sandia National Laboratories, 1992; Pacific Northwest Laboratory 1993; and DOE, 1995) have provided significantly greater confidence in the technical ability to assess overall repository performance and to address and quantify the corresponding uncertainty, than existed when Part 60 was promulgated. As a result, the staff sees no need for additional quantitative requirements beyond compliance with the overall performance goal. Furthermore, the staff is now persuaded that additional quantitative criteria for repository subsystems needlessly limit the flexibility of the applicant in achieving compliance with the overall performance goal. The staff sees no public health and safety benefit of requiring the applicant to develop separate analytical approaches, and collect additional information beyond that which is necessary to demonstrate compliance with the overall safety objective.

As a procedural matter, staff also agrees with former Commissioner Curtiss that development and application of alternative criteria, as provided under 10 CFR 60.113 (b), would be extraordinarily difficult and disruptive to implement late in the licensing process.

The staff believes that it is possible to establish a regulatory approach that can include the evaluation of barrier performance, without specifying numerical goals, in the context of the overall performance assessment for YM. Such an approach would require the applicant to provide greater transparency in its analyses of overall performance, and associated uncertainty, but would not require compliance with additional, *de facto* standards unrelated to the EPA standards. To implement such an approach, the staff is exploring alternative approaches for displaying subsystem performance through the use of importance analyses. Staff believes that as a part of its overall performance assessment, DOE should be able to supply the results of intermediate calculations that are directly related to the calculation of overall repository performance, and which can provide insight on the relative contribution of multiple barriers, and their respective uncertainties, to the achievement of that performance.

It may be appropriate to consider how the recommendation in this paper, to depart from the use of subsystem performance criteria in HLW regulation, relates to the ongoing consideration of a subsystem performance goal in reactor regulation (*e.g.*, core-damage frequency).[3] Both represent possible approaches to the implementation of risk-informed, performance-based regulation appropriate to different facilities.

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[3]The Commission staff has recently provided a discussion to the Commission on a number of policy issues, including the possible elevation of core damage frequency to a fundamental safety goal (SECY-97-208, "Elevation of the Core Damage Frequency Objective to a Fundamental Commission Safety Goal," September 12, 1997). The Commission has agreed with the staff's recommendation to defer the decision on this issue until the staff has gathered more information and has finalized guidance on risk-informed, performance-based approaches for regulation of nuclear power reactors (Staff Requirements Memorandum–SECY-97-208, October 16, 1997).

Differences in the physical behavior and characteristics of these two physical systems, the repository and the reactor, suggest the need for different treatment of subsystem performance goals in the two cases. The reactor is a single, coherent system, compared to the repository, which is a large dispersed system comprised of many similar components. Core damage, if it occurs, is a significant threat to the reactor's safety systems and produces, in and of itself, an intolerable hazard. On the other hand, a repository has a large physical extent [~5 km^2 (2 mi^2)], so that a severe failure or disruption is unlikely to affect the entire system, in a potentially catastrophic fashion. For example, current analyses of volcanic disruption (within the footprint of the repository) suggest that it is likely that only a small fraction of the emplaced inventory of waste packages would contribute to the source term arising from such a disruption. Because the repository is so physically large, the radioactive hazard is dispersed and it is difficult to envision a credible condition causing a catastrophic threat. The reactor is designed to contain its radioactive core, completely, over a lifetime of about 40 years; in contrast, the repository is intended to provide for the gradual and dispersed release of emplaced radionuclides over a very long time period, say 10,000 years. Many of the components of the repository (*e.g.*, the waste package, the saturated zone hydrology) are expected to behave continuously, rather than work or fail in a binary fashion. For example, the waste package is expected to go from a state of complete integrity and total containment of the waste, to a state of gradual failure, which progressively worsens to allow more waste to enter the geosphere over a prolonged time period. In this context of gradual failure, it is difficult to define a state equivalent to a reactor core damage, much less use it productively in a regulatory context. Recognizing these differences in the systems regulated (potential for a catastrophic failure, mission time, nature of component, and subsystem failure), the Division of Waste Management staff has proposed eliminating subsystem performance requirements for the repository.

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DEVELOPMENT OF HIGH LEVEL WASTE (HLW) DISPOSAL REGULATIONS FOR YUCCA MOUNTAIN (YM)
- PRELIMINARY SCHEDULE -

Fiscal Year 1998

Strategy for revising HLW regulations (Commission Paper)	10/97 (in concurrence)
Commission approves strategy for YM regulations	1/98
Draft Rulemaking Plan	1/98 (in concurrence)
Environmental Protection Agency (EPA) Publishes Draft Standards for YM	2/98 (Staff Assumption)
Rulemaking Plan	2/98 (to Commission)
Commission approves rulemaking plan	3/98
EPA Comment period closes	4/98 (Staff Assumption)
Draft Comments on Proposed EPA Standards (Commission Paper)	3/98 (to Commission) 4/98 (to EPA)
Draft Requirements for Reference Biosphere & Critical Group	3/98 (Internal Division Review)
Complete Draft Postclosure Requirements	4/98 (Internal Division Review)
Complete Draft Preclosure and Administrative Requirements	5/98 (Internal Division Review)
Meet with Advisory Committee on Nuclear Waste (ACNW) on Draft Requirements	6/98
EPA Issues Final Standard for YM	7/98 (Staff Assumption)

Attachment 4

PRELIMINARY SCHEDULE (CONT.)

Staff Analyses of Final EPA Standards (Commission Paper)	8/98
Draft Proposed Regulations (Commission Paper)	7/98 (In Concurrence) 8/98 (Meet with ACNW) 9/98 (to Commission)

Fiscal Year 1999

Commission Approves Publication of Proposed Regulations	10/98
Public Comment Period Closes	1/99
Analyses of Public Comment	4/99
Draft Final Rule Package (Commission Paper)	6/99
Commission Approves Publication of Final Regulations	7/99

Fiscal Years 2000 and 2001

Complete Regulatory Guidance in the Form of Standard Review Plan