

August 19, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/  
Executive Director for Operations

SUBJECT: STATUS OF THE ISSUE RESOLUTION PROCESS IN THE HIGH-LEVEL RADIOACTIVE WASTE PROGRAM AT YUCCA MOUNTAIN, NEVADA

## PURPOSE:

To obtain Commission approval of the concept of using rulemaking as a way of furthering issue resolution by eliminating issues (other than compliance) from the licensing proceeding for a geologic repository for high-level radioactive waste (HLW) at Yucca Mountain, Nevada.

## BACKGROUND:

The U.S. Nuclear Regulatory Commission (NRC) HLW program was realigned during fiscal years (FY) 1996-1997. The realignment was in response to: (1) a reduction in Congressional budget appropriations for NRC in FY 1997; (2) the reorganization of the U.S. Department of Energy's (DOE's) geologic repository program at Yucca Mountain, Nevada; and (3) a 1995 report issued to the U.S. Environmental Protection Agency, by the National Academy of Sciences, on new geologic disposal standards for Yucca Mountain. In response to these developments, the NRC HLW program was realigned to focus pre-licensing work on those topics most critical to the post-closure performance of the proposed geologic repository (see SECY-96-122); these topics are called Key Technical Issues (KTIs).

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The current Division of Waste Management (DWM) approach is to focus most activities on issue resolution of the respective KTIs, at the staff level. Issue resolution is achieved when the staff has no further questions or comments regarding how DOE is addressing the issue in its program. However, such resolution at the staff level would not preclude the issue from being raised and considered during a potential licensing proceeding. (See Attachment 1 for a discussion of this process.) DWM activities have been subsequently reprioritized, and organizations have been restructured to support, improve integration of, and streamline the technical work necessary to achieve staff-level resolution.

## DISCUSSION:

Identifying KTIs, integrating their activities into a risk-informed approach, and evaluating their significance for post-closure repository performance helps ensure that regulatory attention is focused where scientific uncertainties will have the greatest impact on safety, and that all elements of the regulatory program are consistently focused on these areas. Early feedback among all parties is essential to define what is known, what is not known and where additional information is likely to make a significant difference in the understanding of future repository safety.

To support and integrate the technical work necessary to achieve the desired resolution in the pre-licensing phase, the staff has relied extensively on the use of systems analysis (performance assessment) techniques. These techniques are now focused on developing the analytical tools necessary to demonstrate compliance with a single pathway dose- or risk-based standard. It is important to emphasize that it is not NRC's intent to require that DOE accurately predict future repository performance, but rather, to assure that DOE has evaluated a reasonable range of possible outcomes based on what is currently known and understood, taking into consideration uncertainties in models, data, and interpretations. Insights acquired from the use of these techniques as well as extensive experience with, and knowledge of, Yucca Mountain site data have contributed to the identification of the ten KTI's that currently form the basis for NRC's pre-licensing reviews and interactions, as documented in *Issue Resolution Status Reports* (IRSRs). The use of these techniques has also contributed to the development of the staff's independent *performance assessment* capability as well as to the development of a *new risk informed, performance-based regulatory framework* specific to the Yucca Mountain site (see attached figure<sup>(1)</sup>). Finally, the staff expects to achieve additional progress in issue resolution through the staff's forthcoming *Viability Assessment* (VA) review - see Attachment 2).

Important progress has been made toward resolution of issues. Interactions between DOE and NRC during FY 1996-1998 have been successful in achieving and documenting a common understanding for many KTI subissues. Examples include: identifying areas of accord on performance assessment methodology; narrowing the range of tectonic models; identifying an acceptable seismic design methodology; identifying the upper bound for the probability of a direct extrusive disruption of the repository by a volcanic event; and the thermal testing program. The primary mechanism for providing feedback to DOE regarding progress toward resolving the subissues comprising the ten KTIs are the staff IRSRs. To date, eight IRSRs have been issued. The staff currently plans to issue or revise the nine IRSRs needed for the staff's review of DOE's VA by August 1998 so that they will be available before the VA is issued by DOE in the fall of 1998.<sup>(2)</sup> The staff believes that, to the extent that it can resolve issues before the VA, there would be greater confidence that the potential licensing vulnerabilities would be properly addressed by DOE in any future License Application.

As a means of achieving binding resolution in certain areas for which issue resolution has been achieved, the staff is proposing to consider rulemaking in selected cases.<sup>(3)</sup> For example, as a result of the KTI and total system performance assessment (TSPA) efforts, or through the NRC review of the VA or the draft Environmental Impact Statement, it may be possible to bound certain parameter/model assumptions, adopt acceptable

methodologies/approaches, or eliminate from further consideration certain types of features, events, and processes believed not to change the outcome of a performance assessment calculation (see figure). For issues such as these, it may be possible to codify the respective staff positions through the use of rulemaking and in doing so, further the goals of the issue resolution process by reducing the types, kinds, and numbers of issues (apart from compliance) that may be open to consideration during a potential licensing proceeding. This approach is consistent with SECY-97-300.

Because such rulemaking would be noticed for public comment, it would afford interested persons and the general public the opportunity to communicate their respective perspectives and concerns early in the process. The exact scope of a particular rulemaking would depend on the nature of the issue to be resolved.

RECOMMENDATION:

Current program assumptions do not envision DWM rulemaking activities beyond FY 1999. Moreover, the current budget structure does not include the use of rulemaking as an issue resolution device. Under the NRC staff's proposal, the staff would re-program a portion of resources currently budgeted for KTI resolution in FY 2000 and FY 2001 to conduct the proposed rulemakings, to codify their positions in those areas for which issues have been resolved.

If and when the staff identifies issues amenable to resolution through rulemaking, the staff will identify to the Commission the issues to be addressed, the amount of resources to be re-programmed, and the potential impacts (if any) on staff activities, from the re-programming efforts. This would be achieved as part of the development of the staff's rulemaking plan for DWM.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. There are no resource, information management, or information technology impacts expected as a result of the recommendations made in this paper.

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- Attachments:
1. [KTI Issue Resolution Process](#)
  2. [Major Elements of NRC's Issue Resolution Strategy](#)

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ATTACHMENT 1

**PROCESS FOR RESOLVING ISSUES IN THE  
HIGH-LEVEL RADIOACTIVE WASTE PROGRAM**

The process of resolving key technical issues (KTIs) in the Yucca Mountain high-level radioactive waste (HLW) program, with the U.S. Department of Energy (DOE), comprises four phases.

In the initial years following the refocusing of the HLW program, the emphasis has been on resolving issues at the staff level. Resolution at this level is achieved when the staff has no further questions regarding how DOE is addressing a particular KTI issue (or subissue). This first phase of work will continue to be the focus in most KTI areas through fiscal year (FY) 1999, and will continue in some areas through FY 2002. The results of issue resolution are currently being documented in a series of *Issue Resolution Status Reports* (IRSRs) that contain the current technical bases and acceptance criteria for issue resolution. IRSRs are progressively developed over time as the individual subissues comprising an issue are resolved. The acceptance criteria are provided to DOE as they are developed so that they can be properly addressed by the Department as it proceeds in preparing a possible License Application to construct a geologic repository. The results of KTI work reported in the IRSRs will also form the foundation for development of a site-specific regulation.

In a second phase of issue resolution, the Yucca Mountain Review Plan (YMRP) will be developed for use by the U.S. Nuclear Regulatory Commission (NRC) staff in conducting its review of the License Application. The YMRP will be a highly focused, site-specific document that integrates the regulatory basis of the site-specific regulation with the acceptance criteria and review methods contained within the IRSRs, to provide a consistent basis for review. Its principal aim is to assure that the bases for resolving issues during the pre-licensing phase are consistently used during the License Application review.

Although issues may be resolved at the staff level, additional work will remain to be done. In the third phase of the issue resolution process, staff will continue to undertake KTI-related work through FY 2002 to: (1) develop the review methods, computer codes (including both process-level and total-system performance models), and confirmatory databases needed to review the License Application; (2) conduct limited, focused studies aimed at developing confidence in the application of review methods to licensing the proposed repository; and (3) monitor and provide feedback to DOE regarding implementation of acceptable approaches. IRSRs will continue to be revised through FY 2002, on an as-needed basis, to incorporate new information developed by DOE, NRC, and other organizations; revised DOE designs; and the results of ongoing performance assessments.

A fourth phase of issue resolution work will be an outgrowth of certain activities begun during the initiation of DOE's site characterization programs, that continue through repository operations to final closure of the repository. This work, referred to as "performance confirmation," is crucial to supporting NRC decisions regarding construction authorization, issuance of a license to begin waste receipt, amendments to the license, and permanent closure and post-closure monitoring. (Because of the long time-scales of the processes affecting repository performance, DOE has already begun this phase and NRC

will begin related activities in FY 1999, as part of issue resolution, and continue them through licensing.)

Finally, it should be noted that NRC's on-site representatives, who are located in Nevada, will continue to perform their vital role throughout the pre-licensing and licensing phases of the program. It is anticipated that this role will intensify as exploratory investigations and testing continue and, later, repository construction activities commence. These individuals facilitate timely feedback and interaction between the DOE staff on site and the NRC Headquarters staff. In addition, the on-site representatives actively observe ongoing DOE construction and testing activities and inform NRC Headquarters staff regarding progress, results, and problem areas that need further attention.

ATTACHMENT 2

## MAJOR ELEMENTS OF NRC'S ISSUE RESOLUTION STRATEGY

### 1. ISSUE RESOLUTION STATUS REPORTS

An important step in the U.S. Nuclear Regulatory Commission staff's approach to issue resolution is to provide the U.S. Department of Energy (DOE) with feedback on the extent that progress has been achieved during the pre-licensing phase. Initial progress in issue resolution with DOE was documented in NUREG/CR-6513, the staff's *1997 High-Level Waste Program Annual Progress Report*, which summarized the significant technical work toward resolution of all Key Technical Issues (KTIs) during the preceding fiscal year. More recently, the staff has begun to use Issue Resolution Status Reports (IRSRs) as the primary mechanism for providing feedback to DOE regarding progress toward resolving the subissues comprising the ten KTIs, as DOE prepares its Viability Assessment (VA).

IRSRs include: (1) acceptance criteria and review methods for use in issue resolution and regulatory review; (2) technical bases for the acceptance criteria and review methods; and (3) the status of resolution, identifying where the staff currently has no comments or questions, as well as where it does. Open meetings and technical exchanges with DOE and other interested parties have provided opportunities to discuss issue resolution, identify areas of agreement and disagreement, and develop plans to resolve such disagreements. Finally, in addition to the review of the VA, the staff plans to use the IRSRs in the future to develop the review plan that it will use to evaluate a potential DOE License Application to construct a geologic repository at Yucca Mountain (as discussed below).

### 2. PERFORMANCE ASSESSMENT

In the context of issue resolution, the use of performance assessment techniques has also proven to be an effective means of evaluating the relative importance of the individual KTIs and whether there is a need for a change in KTI emphasis. Performance assessment is a type of systematic safety analysis that addresses: (1) what can happen; (2) how likely it is to happen; and (3) what the resulting impacts are. In characterizing Yucca Mountain, for example, performance assessment analyses have been conducted iteratively to identify potentially important performance issues, site conditions, and data needs that should be factored into DOE's program to investigate and evaluate the suitability of the site.<sup>(4)</sup> In addition to reviewing DOE's modeling assumptions, the staff is using its performance assessment capability to build confidence that DOE's computer codes operate as they are designed, address relevant features, events, and processes of the disposal system being modeled, and reflect the uncertainty in system knowledge at the site.

The integrated evaluations conducted as part of the staff's performance assessment work are providing the basis for continuing confirmation of, or revision of, the significance of the KTIs to repository performance, and identifying new issues that might need to be considered. These studies will also provide a systems perspective to evaluation of DOE's *Repository Safety Strategy*,<sup>(5)</sup> including DOE total-system performance assessments (TSPAs), which will be a centerpiece of DOE's VA and ultimately the License Application. Sensitivity and importance analyses performed by the staff will also facilitate an understanding of the relative significance, to repository performance, of features, events, and processes, and provide a basis for concluding that certain effects have been appropriately bounded. This information will be important to issue resolution and ultimately, compliance determination. These analyses will also indicate where additional detailed analyses or data may be necessary to narrow uncertainties. Finally, the integration activities of a TSPA will be essential for ensuring that interfaces among the KTIs are identified and correctly defined, and that there is consistent and appropriate information flow among these activities.

### 3. NEW REGULATORY FRAMEWORK

In a Staff Requirements Memorandum dated March 11, 1998, the Commission directed the staff to pursue development of new, site-specific regulations for Yucca Mountain, consistent with EnPA and the 1995 findings and recommendations of the NAS.<sup>(6)</sup> To draft such new requirements, the staff will bring together the insights acquired from: (1) national and international guidelines for radiation protection; (2) previous DOE and NRC TSPAs, including sensitivity and uncertainty analyses; (3) progress in KTI resolution; (4) consideration of existing site-specific data; and (5) sensitivity, uncertainty, and importance analyses.

In developing the new regulations, the staff is following the Commission's recent guidance that stems from its deliberations on risk-informed, performance-based regulation as part of the *Chairman's Strategic Assessment and Rebaselining Initiative*. In that guidance, the Commission indicated that those activities that are of higher risk should be the primary focus of the Agency's efforts and resources and encouraged the staff to look more broadly at how this approach could be used in the HLW repository program. As noted above, it is staff's intent 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 - a system with unique physical characteristics, failure mechanisms, spatial extent, and lifetime. This philosophy is also being applied consistently in the staff's pre-licensing interactions to focus and prioritize issues (i.e., KTIs) and to determine the status of resolution of these key issues.

### 4. VA REVIEW

DOE's VA is a management tool that will provide a basis for making an informed assessment of the feasibility to proceed with the process of licensing and constructing a potential repository at Yucca Mountain. DOE is currently scheduled to complete the VA by September 1998. There is no plan by DOE

to issue it in draft for comment, and NRC's review of DOE's VA is not an explicit statutory requirement. However, NRC expects to be asked to comment on DOE's VA, because NRC's independent licensing view is an important consideration in any judgment about the viability of the repository program.

The objectives of NRC's review of the VA are threefold: (1) to identify progress in the development of information necessary for a complete License Application; (2) to identify potential licensing vulnerabilities that could preclude, delay, or pose a major risk to licensing; and (3) to identify major concerns with DOE's test plans, design concepts (to the extent practicable), and TSPA that, if not resolved by DOE, might result in an incomplete or unacceptable License Application.<sup>(7)</sup> To identify potential licensing vulnerabilities, NRC will perform independent calculations to attempt to identify and assess the relative significance of uncertainties that could preclude successful demonstration of compliance in a licensing proceeding, if not resolved by the time of licensing.

The focus of staff's *TSPA-VA* review will be on those KTIs most important to post-closure repository performance because staff believes that these issues are most significant to a successful licensing case. Staff will review only that information in the VA that relates to the KTIs, using acceptance criteria and review methods defined in IRSRs prepared by the staff to document progress in resolving the KTIs. Independent calculations of repository performance will be prepared by staff using the TSPA computer code to provide a sound basis for critical evaluation of the TSPA-VA results. The staff is currently preparing acceptance criteria in the IRSRs for each KTI and reviewing draft DOE documents that will form the basis for the VA. This on-going review is being conducted concurrently with DOE's development of VA supporting documentation.

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1. The approach depicted in this figure is consistent with the staff's strategy for preparing the Yucca Mountain-specific regulations, previously described in SECY-97-300. This figure shows that the KTIs and their related subissues comprise the key elements that the staff has identified to be considered in a dose- or risk-based performance calculation. Following the IRSR approach, the staff is developing review methods and acceptance criteria (lower tier of figure) to be used in review of DOE's compliance demonstration. See discussion of IRSRs in Attachment 2.

2. The eight IRSRs address the following subissues: (1) fault slip and tectonics; (2) range of future climates, hydrologic effects of climate change, and present-day shallow ground-water infiltration; (3) evolution of the near-field environment and effects of coupled processes on seepage, waste package lifetime, radionuclide release, and radionuclide transport; (4) thermal effects on flow; (5) design control process for the exploratory studies facility and pre-closure seismic design methodology; (6) TSPA model abstraction; (7) probability and consequences of igneous activity; and (8) waste package container life and source term.

3. In the HLW program, the Commission has previously identified rulemaking as the most effective means of reducing uncertainty and streamlining the licensing process. See SECY-88-227; SECY-88-249; SECY-88-285; SECY- 89-339; and SECY-91-225.

4. Within the NRC program, performance assessment has been applied to the initial formulation of NRC's high-level radioactive waste (HLW) regulations (10 CFR Part 60) as well as to the generation of formal and informal comments on the U.S. Environmental Protection Agency's (EPA's) standards at various stages of development. Also, the staff is applying its performance assessment capability in HLW to the on-going review of DOE's pre-licensing program, which includes the staff review of the forthcoming VA. Later, the staff will rely on its performance assessment capability to review and comment on DOE's draft Environmental Impact Statement (EIS), and to prepare for an effective and efficient review of a potential License Application for geologic repository construction. Currently, pursuant to the Energy Policy Act of 1992 (EnPA), NRC is using its performance assessment capability to develop a site-specific regulation consistent with the 1995 National Academy of Science (NAS) recommendations, as a part of the NAS re-evaluation of EPA's HLW standards, as they will apply to a proposed repository at Yucca Mountain.

5. Successor to the *Waste Containment and Isolation Strategy*.

6. The staff's strategy for preparing the Yucca Mountain-specific regulations is described in SECY-97-300.

7. As currently defined, the VA consists of four elements: (1) *Preliminary Design Concept*; (2) *TSPA* (or *TSPA-VA*); (3) *License Application Plan and Cost Estimate*; and, (4) *Costs of Construction and Operation*. Because of resource constraints, the staff's review of VA elements 1, 3, and 4 will be limited; the principal focus of the staff's review will be the *TSPA-VA* and the *License Application Plan and Cost Estimate*.