U.S. DOE APPROACH TO ADDRESS U.S. NUCLEAR REGULATORY COMMISSION KEY TECHNCIAL ISSUES FOR A HIGH-LEVEL RADIOACTIVE WASTE REPOSITORY LICENSE APPLICATION

Joseph D. Ziegler and Timothy C. Gunter
U.S. Department of Energy, Yucca Mountain Site Characterization Office
P.O. Box 364629, M/S 523, Las Vegas, NV

Robert P. Gamble, Booz Allen Hamilton Inc.
Robert B. Bradbury, Shaw Environmental & Infrastructure, Inc.
1551 Hillshire Dr., M/S 471, Las Vegas, NV

ABSTRACT

Interactions between the U.S. Department of Energy (DOE) staff and the U.S. Nuclear Regulatory Commission (NRC) staff prior to submittal of a license application (LA) for NRC review are focused on resolution of issues relevant to licensing a geologic repository at the Yucca Mountain site. These interactions take place in meetings that are open to the public, the State of Nevada, affected units of local government, and other interested parties. Consistent with a 1992 agreement between the DOE and NRC, resolution of an issue at the staff level can be achieved during the pre-licensing period when the NRC staff has no further questions or comments regarding how the DOE is addressing that issue. In no case does such resolution at the NRC staff level preclude an issue being raised during the licensing proceedings by the NRC or another party to the proceedings.

Beginning in 1996, interactions between the DOE and NRC began to focus significant attention on the nine topical areas, called Key Technical Issues (KTIs), that the NRC staff considers to be important in evaluating the post-closure performance of a Yucca Mountain repository. DOE-NRC meetings to discuss each KTI and achieve technical agreement on the information needed to resolve the issues were held between August 2000 and September 2001. As a result of these meetings, 293 agreements were reached regarding information to be developed by the DOE to supplement the basis for NRC review of the initial LA.* As of April 23, 2003, 77 of these agreements are considered by the NRC to be complete based on information provided by the DOE.

Consistent with the NRC licensing criteria at 10 CFR Part 63, the DOE is taking a risk-informed approach in addressing the remaining KTI agreements. This approach is intended to ensure that the focus is on providing information significant to the evolving DOE compliance case for post-closure repository safety and the supporting total system performance assessment (TSPA). Pre-licensing interactions with the NRC will continue to be linked to the completion of documentation to address the remaining KTI agreements, including discussions on the specific nature of the information to be provided in a risk-informed context and the timing for completion of the agreement items. The KTI agreements will be adequately considered and addressed by the time the LA is submitted to provide sufficient information to support for NRC acceptance and docketing of the LA.

INTRODUCTION

The U.S. Department of Energy's (DOE's) primary near-term objective is submittal of a complete and defensible license application (LA) to the U.S. Nuclear Regulatory Commission (NRC) for authorization to construct a geologic repository for disposal of spent nuclear fuel and high-level radioactive waste at the Yucca Mountain site in Nevada. The LA submitted to the NRC must provide sufficient information to satisfy the content requirements and licensing criteria in 10 CFR Part 63 [1]. It must also address guidance in the NRC's Yucca Mountain Review Plan (YMRP), currently in draft final form [2], to facilitate its acceptance by the NRC staff for docketing and to support the subsequent NRC safety review.

ISSUE RESOLUTION PROCESS

Interactions between the DOE and the NRC staff prior to submittal of a LA are focused on the early resolution of issues relevant to licensing a geologic repository at the Yucca Mountain site. These interactions take place in meetings that are open to the public, the State of Nevada, affected units of local government, and other interested parties. Consistent with a 1992 agreement between the DOE and NRC [3], resolution of an issue at the staff level can be achieved during the pre-licensing period when the NRC staff has no further questions or comments regarding how the DOE is addressing that issue. There may be cases where resolution is limited to documenting a common understanding of the differences in the DOE and NRC technical positions. Additional information obtained by the DOE could raise new NRC questions or comments regarding a previously resolved issue. In no case does resolution at the NRC staff level prior to LA submittal preclude an issue being raised during the licensing proceedings by the NRC or another party to the proceeding.

FOCUS ON KEY TECHNICAL ISSUES

Beginning in 1996, pre-licensing interactions between the DOE and NRC staff began to focus significant attention on those topics the NRC staff considers to be the most important in evaluating the post-closure performance of a Yucca Mountain repository. The NRC calls these topics Key Technical Issues (KTIs) [4]. Information obtained by the DOE during site characterization and from testing conducted as part of the performance confirmation program prior to submittal of a LA is being used to address the nine KTIs defined by the NRC and to respond to NRC staff questions related to the topics covered by these KTIs:

1. unsaturated zone and saturated zone flow under isothermal conditions,
2. repository design and thermal-mechanical effects,
3. evolution of the near-field environment,
4. waste package container life and radionuclide source term,
5. thermal effects on flow,
6. radionuclide transport,
7. structural deformation and seismicity,
8. igneous activity, and
9. total system performance assessment and integration.

The NRC divided each KTI into a number of sub-issues, resulting in a total of 37 sub-issues for the nine KTIs. These sub-issues were the subjects for a series of interactions with the NRC staff in 2000 and 2001, and the basis for agreements the DOE made with the NRC to provide the information needed to close open sub-issues and resolve the KTIs. A sub-issue is considered closed if the DOE approach and available information acceptably address NRC staff questions such that no information beyond that currently available is likely to be required for regulatory decision making at the time of the initial LA. A sub-issue is considered "closed-pending" if the staff has confidence that the DOE approach, together with additional information the DOE agrees to provide, will acceptably address the NRC's questions such that no further information will likely be required at the time of initial submittal of the LA. Closure of a sub-issue designated as closed-pending is subject to NRC staff review of the additional information provided by the DOE. A sub-issue is considered open if the DOE has not yet acceptably addressed NRC staff questions or agreed to provide the additional information identified by the staff as necessary to address these questions. The subject area covered by any sub-issue can be raised and reconsidered during the licensing proceedings.

Prior to 2002, progress toward resolving the KTIs was reported by the NRC staff in separate Issue Resolution Status Reports (IRSRs) for each KTI. These reports provided the DOE with feedback regarding the NRC staff's current view of issue resolution status and were updated by the staff, as appropriate, based on its review of information provided by the DOE. The last such update was in January 2001. The NRC staff subsequently replaced the nine separate IRSRs with a single, Integrated IRSR (IIRSR), NUREG-1762 [5], which was published in July 2002. The staff stated in the IIRSR that this action was taken because the issue resolution process was mature enough to develop a single integrated document that clearly and consistently reflects the interrelationships among the various KTI sub-issues and the overall issue resolution status. The IIRSR is consistent with the draft final YMRP in that it covers post-closure repository safety, including information related to the topics addressed by the KTIs, as well as the other areas that will be subject to NRC safety review in licensing, including pre-closure repository safety and performance confirmation. The IIRSR, as issued, captures the status of issue resolution based on technical information reviewed by the NRC staff though October 2001. According to the IIRSR, the staff intends to update the report approximately once a year until the beginning of any NRC licensing review.

Consistent with the draft final YMRP, the IIRSR makes the transition to a structure based on the 14 integrated sub-issues identified in the KTI on total system performance assessment and integration, which correspond to the 14 model abstraction areas defined in the YMRP. Information needed to address the integrated sub-issues and model abstraction areas will be presented by the DOE in its LA and will be considered by the NRC in evaluating compliance with post-closure licensing requirements. Although the 14 integrated sub-issues will replace the 37 sub-issues related to the nine KTIs, the NRC has indicated that this does not affect the agreements made with the DOE regarding the information needed to address NRC staff questions and support a licensing review.

STATUS OF KEY TECHNICAL ISSUE RESOLUTION

DOE-NRC meetings to discuss each KTI and achieve technical agreement on the information needed for closure of the related sub-issues and resolution of the KTI were held between August 2000 and September 2001. The total system performance assessment (TSPA) developed by the DOE for site recommendation (SR) and the technical documents supporting the TSPA-SR were considered by the NRC staff in identifying additional information it considered necessary to resolve the issues and support its review of the license application (LA).

As a result of these meetings, five of the 37 KTI sub-issues are considered by the NRC staff to be closed based on the DOE approach and available information. The remaining 32 sub-issues were determined by the NRC staff to be closed-pending based on 293 agreements reached with the DOE regarding the information to be provided by the DOE to supplement the basis for NRC review of the initial LA.* The agreements identify DOE actions, including providing documents that clarify or enhance the technical basis for the TSPA and its component models, and providing documentation for additional analysis of existing data, or of results from additional testing and analysis of new data. Most agreements are tied to DOE technical products with specified dates or timeframes for completion. There are no open sub-issues.

As of April 23, 2003, 77 of the 293 agreements are considered by the NRC staff to be complete based on information provided by the DOE. The DOE has submitted information to the NRC to address 13 additional agreements. Completion of these additional agreements is pending NRC staff review of the information provided by the DOE. Based on its review of DOE submittals, the NRC staff has requested that additional information be provided to complete 35 other agreements.

APPROACH TO RESOLUTION OF REMAINING KEY TECHNICAL ISSUES

The DOE's approach to completing the remaining agreements and reaching closure with the NRC staff on closed-pending sub-issues is a significant factor in developing a LA that contains sufficient information for the NRC to accept the LA and docket it for review in an expeditious manner. Reaching closure on the KTI agreements will also provide some assurance that adequate information will be available to support the NRC's safety review of the LA and facilitate a NRC decision on construction authorization. The KTI agreements and any NRC requests for additional information to complete these agreements will be adequately considered and addressed by the time the LA is submitted to provide support for NRC acceptance and docketing. Wherever possible, agreement items will be completed prior to LA submittal based on available information or information from ongoing activities, and updates of technical documents to reflect this information, provide clarification, or enhance discussion of the technical basis for the post-closure compliance evaluation.

Completion of the KTI agreements to support resolution of the KTIs is based on documented technical analyses designed to represent the current state of knowledge regarding reasonably expected repository performance, supported by the best information available at the time of the analyses. In keeping with the risk-informed, performance-based (RIPB) approach reflected in 10 CFR Part 63 and the YMRP, the DOE believes that, where appropriate, the basis for completion

of the KTI agreements should include the use of sensitivity studies supporting risk-prioritization analyses.

Since September 2001, DOE has completed risk-prioritization evaluations of the TSPA component models to aid in defining the work needed to support the LA and complete KTI agreements. Specific plans for developing the LA and addressing KTI agreements were developed based on consideration of the RIPB provisions of 10 CFR Part 63. The evaluations that were conducted employed the best-available information, including the *TSPA-SR* [6] completed in early fiscal year (FY) 2001, the *Supplemental Science and Performance Analyses* (SSPA) [7] completed in late fiscal year (FY) 2001, and the *Total System Performance Assessment – Analyses for Disposal of Commercial and DOE Waste Inventories at Yucca Mountain – Input to Final Environmental Impact Statement and Site Suitability Evaluation* (TSPA-FEIS/SSE) [8] completed in early FY 2002. This information was supplemented in late FY 2002 with a report on *Risk Information to Support Prioritization of Performance Assessment Models* [9]. The results of these evaluations were used to inform management decisions about the priorities for and scope of work to be conducted to support LA submittal and completion of KTI agreements, based on the relative importance of the information to the evaluation of repository system performance and the demonstration of compliance with the NRC's post-closure performance requirements.

These sensitivity studies and analyses represent the best available information (data, software, and models) and have provided a sound technical basis for key DOE documents. In addition, these studies and analyses provide insight into a RIPB foundation for completion of KTI agreements. Results from these supplemental studies can contribute to the development of a technical argument to support the basis for closure of an agreement and ensure that the focus is on providing information significant to the evolving DOE compliance case for post-closure repository safety and the supporting TSPA. The DOE is using supplemental sensitivity studies to complete agreements where the results demonstrate that the information requested has limited significance to the evaluation of risk (i.e., dose during the 10,000 year regulatory period), or is not needed to support the basis for modeling, including the understanding of uncertainty, that will be relied upon for the TSPA-LA.

The results of the recent sensitivity analyses are consistent with the results of the TSPA for the Viability Assessment [10] and the TSPA-SR, and continue to demonstrate overall system performance that is well below post-closure regulatory limits. The latest TSPA results in the TSPA-FEIS/SSE input report (derived from the SSPA but updated to reflect the final Environmental Protection Agency compliance standards for a Yucca Mountain Repository) and the Risk Information report represent the best information currently available. The DOE believes that the use of these results is appropriate for NRC's pre-application review and should be sufficient to close those KTI agreements that are identified as being most amenable to using the risk-informed approach to focus attention on the information most important to the evaluation of post-closure performance. No changes in the conclusions and no significant changes in the numerical results of these sensitivity analyses are expected as a result of the evolution of the TSPA-LA and its technical basis. Any changes in data, models and software that could potentially affect the results of these sensitivity analyses will be evaluated based on the TSPA-LA models, data, and software following completion of the TSPA-LA analyses.

Following this RIPB approach, the remaining KTI agreements have been categorized based on risk significance (i.e., contribution to calculated dose), as well as disposition method and timing for completion. One category of agreements includes those that are no longer considered to be relevant to the TSPA-LA because of the low risk significance of the requested information under the current DOE approach to evaluating compliance with post-closure requirements. The documented basis for proposed changes to such agreements must clearly explain why the originally proposed work is no longer considered by the DOE to be necessary. Any alteration to the technical content of an agreement item resulting from this process requires review and mutual agreement by DOE and NRC management. Other categories of agreements are being addressed consistent with the intent of the original agreements, although the disposition methods may vary depending on the risk-significance of the agreement under the planned approach to developing the TSPA-LA and the information that supports the evaluation of post-closure performance.

Pre-licensing interactions with the NRC staff will continue to be linked to the completion of documentation to address the remaining KTI agreement items, including discussions on the specific nature of the information to be provided in a RIPB context and the timing for completion of the agreement items. DOE actions for nearly all of the remaining KTI agreements are projected to be complete by the time the LA is submitted to the NRC. A few agreements may rely on results from tests that will begin prior to LA submittal but continue after LA submittal. Documentation will be provided to the NRC staff for these agreement items to explain why the information that will be available at LA submittal should be adequate to support the NRC's safety review. The DOE will also define any testing that might be needed after LA submittal to support or confirm the basis for completion of the agreements. Such testing would most likely be conducted as part of the performance confirmation or research and development (R&D) programs described in the LA. A significant deviation from expected test results following LA submittal would require prompt reporting to the NRC.

Regardless of the categorization of the KTI agreements, the DOE will seek a resolution or path forward with the NRC staff for each of the remaining KTI agreements prior to submittal of the LA. The goal is to reach closure on the KTI agreements prior to receiving a construction authorization, with the potential need for confirmatory results from continued testing covered under license conditions associated with the performance confirmation program, or with the R&D program, that are described in the LA. There should be no need to track KTI agreements after issuance of a construction authorization.

SUMMARY

The DOE's primary near-term objective is submittal of a complete and defensible LA to the NRC as quickly as practicable. The approach to address the NRC's KTIs and the remaining agreement items related to each KTI are major elements in defining the path forward to submittal of a LA that the NRC will be able to accept and docket for review in an expeditious manner. The KTIs and agreement items must be adequately considered and addressed by the time the LA is submitted to provide support for NRC docketing. Consistent with the NRC licensing criteria (10 CFR Part 63), the DOE is taking a risk-informed approach in addressing the remaining KTI

agreements to ensure that the focus is on providing information significant to the DOE's compliance case for post-closure repository safety. Pre-licensing interactions with the NRC will continue to be linked to completion of documentation to address the KTI agreements, including discussions on the specific nature of the information to be provided in a risk-informed context and the timing for completion of agreement items prior to submittal of the LA.

The currently available information, including information from supplemental risk-prioritization/sensitivity studies, provides a risk-informed approach that should permit the NRC to assess the adequacy of the DOE's technical approach to completing KTI agreements. This should provide the NRC with confidence that the DOE is focusing on the issues that are important to waste isolation and that adequate information will be available to support LA review. The DOE also believes that the models and information developed to support the LA, when complete, will be consistent with the conclusions reached based on the information provided to close the KTI agreements.

The relevant information for the NRC staff's licensing review will be in the LA and its supporting documents, and will build on the body of work developed up to the time of LA submittal. This body of work includes previous versions of the TSPA, the supplemental sensitivity analyses, and the information provided to the NRC in response to KTI agreements prior to LA submittal. The LA will provide the licensing case of record to address post-closure repository performance requirements and support required NRC findings. If any of the pre-application results cannot be determined to be consistent with analyses conducted for the LA, a revised approach will be developed to address each impacted KTI agreement item. The NRC staff will be informed if the basis for its earlier review of KTI agreements changes as a result of the analyses supporting the LA.

FOOTNOTES

* Although NRC does not consider pre-closure safety to be a KTI, interactions with the NRC staff have resulted in nine agreements regarding information to be provided by the DOE to address pre-closure topics. These nine agreements are included in the 293 agreements referenced in this paper. Completion of these pre-closure agreements is tracked in the same manner as completion of the KTI agreements. This paper deals only with the approach to completing agreements directly related to the KTIs, which focus on information important to the evaluation of post-closure performance.

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