

November 13, 2001

Mr. Robert G. Card, Under Secretary
Energy, Science, and Environment
U.S. Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585-0001

Dear Mr. Card :

As required by Section 114(a)(1)(E) of the Nuclear Waste Policy Act of 1982, as amended (42 U.S.C. 10134(a)(1)(E)), I am providing you with the preliminary comments of the U.S. Nuclear Regulatory Commission (NRC) regarding a possible geologic repository at Yucca Mountain, Nevada. These comments concern "...the extent to which the at-depth site characterization analysis and waste form proposal for such site seem to be sufficient for inclusion in any application to be submitted by the Secretary for licensing of such site as a repository." As described in more detail below and in the enclosures to this letter, the NRC believes that sufficient at-depth site characterization analysis and waste form proposal information, although not available now, will be available at the time of a potential license application such that development of an acceptable license application is achievable.

There are two important constraints related to NRC's preliminary comments. First, in making these comments, the NRC is making no conclusions concerning the actual site suitability of the Yucca Mountain site. Rather, the NRC comments address whether sufficient information will exist to begin a potential licensing review should DOE submit a license application. Second, NRC's licensing decisions, in terms of a potential repository at Yucca Mountain, will not occur until DOE submits a high-quality license application, the staff completes its independent safety review and issues a safety evaluation report, NRC provides an opportunity for a hearing, and NRC makes its final determination of whether the DOE license application meets NRC regulations. Any NRC licensing decision will be based on all the information available at the time of decision.

The NRC's preliminary comments reflect many years of extensive pre-licensing interaction among the NRC staff, DOE, and various stakeholders, including the State of Nevada, Indian Tribes, affected units of local government, representatives of the nuclear industry, and interested members of the public. NRC staff activities included: (1) engaging DOE in an issue resolution process on key technical issues including obtaining DOE's agreement to provide acceptable responses by the time of the submission of any license application; (2) issuing numerous publicly available technical and program status reports, over the last several years, that reviewed DOE's ongoing site characterization, waste package and waste form, and preliminary design work, and identified additional information that DOE would need to provide in any license application; and (3) interacting with representatives of the State

of Nevada and affected units of local government on technical information collected in their oversight role.

Based on its interactions with DOE and other stakeholders, the NRC provides the following preliminary comments:

1. DOE has or has agreed to obtain sufficient at-depth site characterization analysis and waste form proposal information required for a possible license application.
2. Although significant additional work is needed prior to the submission of a possible license application, we believe that agreements reached between DOE and NRC staff regarding the collection of additional information provide the basis for concluding that development of an acceptable license application is achievable.
3. DOE is exploring a flexible design concept to allow for the possibility of operating the repository over a range of thermal conditions. If DOE were to adopt a lower temperature operating mode or the approach used in the FY01 Supplemental Science and Performance Analyses, NRC believes that additional information would be needed for a potential license application.

The enclosures to this letter provide additional background information on the scope and conduct of NRC's review. In addition, we provide, for your information, the NRC staff's assessment of the quality of documentation supporting DOE's possible site recommendation.

If you have any questions or comments, please contact me.

Sincerely,

/RA/

Richard A. Meserve

Enclosures:

1. Background Information Supporting the NRC's Preliminary Comments on the Sufficiency of U.S. Department of Energy Information for Inclusion in a License Application for a possible Geologic Repository at Yucca Mountain, Nevada
2. NRC's Views on the U.S. Department of Energy Quality Assurance

cc: See enclosed distribution list.

Letter to R. Card from R. Meserve dated: November 13, 2001

cc:

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L. Jackson, Timbisha Shoshone Tribe
C. Meyers, Moapa Paiute Indian Tribe
V. Miller, Fort Independence Indian Tribe
A. Bacock, Big Pine Paiute Tribe of
the Owens Valley
R. Quintero, Inter-Tribal Council of Nevada
(Chairman, Walker River Paiute Tribe)
M. Bengochia, Bishop Paiute Indian Tribe
J. Egan, Egan & Associates, PLLC

L. Lehman, T-REG, Inc.
R. Bahe, Benton Paiute Indian Tribe
C. Bradley, Kaibab Band of Southern Paiutes
R. Joseph, Lone Pine Paiute-Shoshone Tribe
L. Tom, Paiute Indian Tribes of Utah
E. Smith, Chemehuevi Indian Tribe
J. Charles, Ely Shoshone Tribe
D. Crawford, Inter-Tribal Council of Nevada
H. Blackeye, Jr., Duckwater Shoshone Tribe
D. Eddy, Jr. Colorado River Indian Tribes
J. Leeds, Las Vegas Indian Center
W. Briggs, Ross, Dixon & Bell

**BACKGROUND INFORMATION
SUPPORTING THE NRC'S PRELIMINARY
COMMENTS ON THE SUFFICIENCY OF
U. S. DEPARTMENT OF ENERGY
INFORMATION FOR INCLUSION IN A
LICENSE APPLICATION FOR A POSSIBLE
GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN, NEVADA**

INTRODUCTION

The Nuclear Waste Policy Act of 1982, as amended in 1987 (i.e., the Act), requires the U.S. Nuclear Regulatory Commission (NRC) to provide preliminary comments in connection with any site recommendation on the proposed geologic repository at Yucca Mountain, Nevada. The objective of the preliminary comments is to address the extent to which the U.S. Department of Energy's (DOE's) at-depth site characterization analysis and waste form proposal seem to be sufficient for inclusion in any license application for the site. DOE must include NRC's preliminary comments as part of any site recommendation to the President of the United States. As noted below, NRC's comments are based on many years of extensive prelicensing interactions and issue resolution activities.

We make no site suitability conclusions in these preliminary comments. Rather, our comments focus on whether enough information exists to begin a potential licensing review, should a license application be submitted by DOE. Further, because our preliminary comments are based on informal interactions and review, in advance of a potential license application, we make no licensing determinations, nor do our comments, in any way, affect NRC authority if DOE files a license application. Moreover, the comments are without prejudice to any such determinations, which can only be made after a thorough safety review by the NRC staff on any DOE license application. The views expressed in this report remain subject to consideration if NRC receives a license application for Yucca Mountain.

BACKGROUND

The roles and responsibilities of Federal agencies involved in the disposal of high-level radioactive waste in a geologic repository are defined in the Act. DOE is responsible for conducting the site characterization activities at Yucca Mountain, Nevada. DOE is also responsible for conducting a site recommendation process, should the Secretary of Energy determine that the site is suitable for recommendation to the President. NRC, among other things, is required to interact with DOE during the site characterization phase of the geologic repository program.

After the Act was amended in 1987, NRC and DOE began prelicensing interactions relating to DOE's characterization of Yucca Mountain as a potential repository site and DOE's design of associated facilities. During this same period, the Commission began examining ways to focus its regulatory programs on those areas and issues most significant to risk and licensee performance. Accordingly, NRC staff worked to identify those features, events, processes, and design concerns that were most important to potential repository performance. This activity was integrated with the development of performance-based regulations specific to the Yucca Mountain site which began in the early 1990s and concluded in November of this year with the issuance of 10 CFR Part 63.

The NRC's risk-informed, performance-based approach to high-level waste disposal made use of results from NRC and DOE laboratory and field experiments, natural analog studies, expert elicitations, and performance assessments. Over time, these activities led to the identification in 1996 of what the NRC staff termed "key technical issues" that were important to performance. The NRC staff emphasized these key technical issues in the prelicensing interactions with DOE.

As understanding of the site, the potential design, and the key technical issues evolved through precicensing interactions with DOE and through results from NRC confirmatory studies, the individual key technical issues were refined into subissues that more clearly specify important areas that the NRC staff wanted DOE to address. In the process, NRC published numerous publicly available technical and program status reports that reviewed DOE's site characterization and design work and identified additional information that DOE would need in any license application. The NRC staff consistently emphasized that a key to the preparation of an acceptable license application was the extent to which DOE addressed the key technical issues in preparing any safety case for Yucca Mountain.

To address and document the key technical issues, the NRC staff initiated a formal issue resolution process as part of the precicensing interaction that was specified in the Act. The NRC issue resolution process includes reviewing DOE documents, interacting with DOE in public technical meetings, and identifying the information that DOE will need to provide in any potential license application. In this context, issues are defined to be resolved when there are no further questions at the staff level; however, issue resolution does not signify that a licensing decision has been reached. Pertinent additional information (e.g., changes in DOE design parameters) could raise new questions or comments regarding a previously resolved issue. The bases for the issue resolution process are acceptance criteria developed by the NRC staff that consider risk information and significance to performance. These acceptance criteria are the measurement by which the NRC staff judges the acceptability of DOE information for a possible license application. NRC has developed these acceptance criteria and their technical bases over the past several years and has documented them in a series of publicly available issue resolution status reports. A subset of the acceptance criteria provides the basis to judge the sufficiency of DOE's information in these preliminary comments, and these preliminary sufficiency comments have been prepared in consideration of, and as an integrated activity with, the issue resolution process.

Consistent with this issue resolution process, NRC staff intensified its precicensing interactions with DOE over the last two years to address and resolve remaining current questions and concerns. Since August 2000, DOE and NRC have held 16 technical exchanges focused specifically on issues relevant to these preliminary comments. These multi-day public meetings with DOE were used to discuss the status of issue resolution. Results from this increased precicensing interaction have been presented to DOE through formal letters and through public meetings between NRC and DOE. Finally, agreements that document additional work that DOE will need to complete before submitting any potential license application were reached. All this activity is summarized in Table 1. In areas covered by the agreements, NRC believes DOE's plans and schedules to get information represent a reasonable approach. Further, based on the agreements, NRC has reasonable confidence DOE will assemble the information before filing a possible license application. NRC has not, however, prejudged the outcome of a licensing review. Reliance on DOE's agreements to complete this work forms the basis for many conclusions regarding the sufficiency of information.

NRC's licensing decisions, in terms of a potential repository at Yucca Mountain, will not occur until DOE submits a high-quality license application, the staff completes its independent safety review and issues a safety evaluation report, NRC provides an opportunity for a hearing on issues raised by the parties, and NRC makes its final determination of whether the DOE

license application meets NRC regulations. Any NRC licensing decision will be based on all the information available at that time.

SCOPE OF THE NRC's EVALUATION

Our comments concerning DOE's "at-depth site characterization analysis" are based on our examination of the DOE information on events and processes that occur below the ground surface, even if their effects are seen at the surface, and DOE's investigation of features within the geosphere. Our comments on DOE's "waste form proposal" reflect our review of DOE information on the waste form, fuel cladding, waste package, drip shield, drift, and other engineered barriers.

We have evaluated repository safety for both the period of operations prior to permanent closure (i.e., preclosure) and after permanent closure (i.e., postclosure). The preclosure evaluation includes the staff's examination of the extent to which the DOE at-depth site characterization analysis and the waste form proposal seem to be sufficient to support the preclosure safety analysis. For safety after permanent closure (i.e., postclosure) period, we examined the extent to which DOE's at-depth site characterization analysis and waste form proposal support its scenario analysis and model development that would form the basis for any assessment of repository performance.

The DOE documents that we reviewed as the basis for our preliminary comments are the "Yucca Mountain Science and Engineering Report" and supporting technical basis documents; the "Preliminary Preclosure Safety Assessment for Monitored Geologic Repository Site Recommendation"; the "Total System Performance Assessment for the Site Recommendation"; and the "FY01 Supplemental Science and Performance Analyses." The supporting DOE technical documents include the DOE analysis and model reports and process model reports.

It should be noted that there are areas beyond the scope of at-depth site characterization analysis and the waste form proposal that any DOE license application would need to include. With respect to repository safety for the period of operations prior to permanent closure (i.e., preclosure), areas beyond the scope of these preliminary comments include the preclosure safety analysis and the design of the surface and subsurface geologic repository operations area and its structures, systems, and components important to safety. NRC continues to conduct preclosing issue resolution interactions with DOE on preclosure topics that are beyond the scope of these comments.

With respect to repository safety for the period after permanent closure (i.e., postclosure), areas beyond the scope of these preliminary comments include climate and infiltration, redistribution of radionuclides in soil, the lifestyle of the reasonably maximally exposed individual, and demonstration of compliance with the performance objectives.

Notwithstanding the above, issue resolution addresses all areas of repository safety. NRC believes DOE has, or has agreed to obtain, sufficient information in all postclosure areas.

ALTERNATIVE REPOSITORY DESIGNS

DOE is exploring a flexible design concept to allow for the possibility of operating the repository over a range of thermal conditions. The DOE "Yucca Mountain Science and Engineering Report" describes the flexible design concept. The DOE "FY01 Supplemental Science and Performance Analyses" describes exploratory and scoping evaluations to support the proposed range of thermal operating modes. NRC has reviewed these evaluations and met with DOE to discuss a list of additional information needs. If the DOE were to adopt a lower temperature operating mode or the approach used in the FY01 Supplemental Science and Performance Analyses, then NRC will meet again with DOE to discuss specific additional information needs required for a potential license application. If additional information becomes available before any DOE site recommendation, NRC reserves the right to supplement these preliminary comments.

VIEWS OF THE ADVISORY COMMITTEE ON NUCLEAR WASTE

Finally, it is also worthwhile noting that the Commission's perspective on the adequacy of at-depth site characterization analysis and waste form proposal information is consistent with the NRC's Advisory Committee on Nuclear Waste. Specifically, in letters of September 18, 2001, and September 28, 2001, the Committee appears to agree with the NRC staff's approach to issue resolution and its use of analytical tools as a means to conduct the sufficiency review. The Committee did note, similar to the NRC staff, that substantial additional work by DOE is needed prior to the submission of a potential license application. However, it is our understanding that the issues raised in the Committee's letters are focused on the adequacy of a possible license application and that resolution of its concerns can be achieved in the intervening period between a possible site recommendation and a possible license application.

CONCLUSIONS

NRC's preliminary comments are that DOE has obtained or has agreed to obtain sufficient at-depth site characterization analysis and waste form proposal information required for a possible license application. DOE will continue to develop information needed for a license application. DOE and NRC have reached numerous agreements, representing a broad scope of additional work DOE will complete before any license application. NRC believes the plans and schedules to collect more information represent a reasonable approach. Based on the agreements with DOE, the NRC has reasonable confidence DOE could assemble the information needed for a possible license application.

TABLE 1. DESCRIPTION OF DOE STATUS ON RESOLUTION OF KEY TECHNICAL ISSUES AND PRECLOSURE ISSUES

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Container Life and Source Term – This Key Technical Issue deals with the containers and waste form as the primary engineered barriers, and the source term resulting from their degradation, as well as other design features including the drip shield. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: Effects of corrosion processes • Subissue 2: Effects of phase instability and initial defects • Subissue 3: Rate of radionuclide release from spent nuclear fuel • Subissue 4: Rate of radionuclide release from waste glass • Subissue 5: Effect of in-package criticality • Subissue 6: Effects of alternative design features	Documentation of corrosion processes, waste package design and operating environments, laboratory data, fabrication processes and effects of fabrication on materials stability, corrosion, and mechanical failure. Information required for waste package, containers, waste forms, drip shield, and other engineered features, including evaluation of in-package criticality.⁴	This information is required to assess the susceptibility of the engineered barriers to potential degradation processes. The waste package is relied on to minimize the release of radionuclides for the first several 1,000 years following emplacement.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Evolution of the Near Field Environment – This Key Technical Issue examines the effects of coupled thermal-hydrologic-chemical processes on seepage and flow, waste package chemical environment, chemical environment for radionuclide release, radionuclide transport through engineered and natural barriers, and potential for nuclear criticality. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: Effects of coupled thermal-hydrologic-chemical processes on seepage and flow • Subissue 2: Effects of coupled thermal-hydrologic-chemical processes on the waste package chemical environment • Subissue 3: Effects of coupled thermal-hydrologic-chemical processes on the chemical environment for radionuclide release • Subissue 4: Effects of coupled thermal-hydrologic-chemical processes on radionuclide transport through engineered and natural barriers • Subissue 5: Effects of coupled thermal-hydrologic-chemical processes on	Documentation of coupled process models, crushed tuff experiments, effects of dust on salts analysis, laboratory solution chemistry, data used for model calibration and model validation, bounding colloid transport. Evaluation of sources of model and data uncertainty. Technical basis required for trace element concentrations, effects of engineered materials on hydrologic properties, suppression of mineral precipitation, low relative humidity modeling, range in water composition, treatment of reaction kinetics, use of bulk chemistry rather than local chemistry, and colloid treatment. ^{5,6}	This information is required to support reviews of waste package and drip shield performance and evaluations of parameters that could affect the quantity and chemistry of water contacting the waste package or waste forms and resulting thermal-mechanical effects on hydrologic properties. It also supports evaluation of the waste package environment and its effect on performance, including model and parameter uncertainties.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Igneous Activity – This Key Technical Issue predicts the consequence and probability of igneous activity, such as volcanic eruptions or intrusions, potentially affecting the repository. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: Probability of igneous activity • Subissue 2: Consequences of igneous activity	Development of igneous process models. Documentation of sensitivity analyses of igneous processes, analysis of new site aeromagnetic data, confirmation of model parameter ranges, incorporation of analog data, verification of model assumptions and any bounding analyses, validity of process models.^{7,8,9}	This information is required to derive the appropriate scenarios for consideration in postclosure performance assessment and for evaluating the processes and potential effects of igneous processes interacting with the repository.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Repository Design and Thermal Mechanical Effects – This Key Technical Issue reviews the design, construction, and operations of a geologic repository considering both preclosure and postclosure activities. The following are the associated subissues: Open:¹ None. Closed:² • Subissue 1: Design control process • Subissue 4: Design and long-term contribution of repository seals to performance Closed-Pending:³ • Subissue 2: Seismic design methodology • Subissue 3: Thermal-mechanical effects	Provide preliminary seismic design input data sets, site-specific properties of the host rock, modeling of drift and ground support performance, ventilation tests. Provide the technical basis for longevity of ground-support materials, effects of thermal and seismic loading on drift stability, rockfall size distribution, sustained loading on intact rock strength, rock movement in the invert, rock joint representation, and stress measures used for drip-shield and waste-package analyses. Provide verification of drift-degradation analysis, and a sensitivity analysis of thermal-mechanical effects on water flow.^{10,11}	This information is required to evaluate potential degradation and mechanical disruption of repository components and engineered barriers. The assessments consider fabrication processes and the evolution of the environment as well as natural events such as earthquakes and rockfall.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Radionuclide Transport – This Key Technical Issue evaluates processes controlling contaminant migration. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: Radionuclide transport through porous rock • Subissue 2: Radionuclide transport through alluvium • Subissue 3: Radionuclide transport through fractured rock • Subissue 4: Nuclear criticality in the far field	Documentation of expert judgements used to derive transport parameter values. Documentation of nuclear criticality analysis methodology. Plans for and results from field-based (e.g., alluvium) and laboratory testing of radionuclide transport. Documentation of the technical basis and supporting sensitivity analyses for effective porosity, flow paths below the repository, the alluvium transport path, colloid transport, and laboratory/field analog tracer data.^{5,12}	This information is required to evaluate the distribution and rate of radionuclide transport, and the contribution of various radionuclides to repository performance.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Structural Deformation and Seismicity – This Key Technical Issue evaluates the geology in and around the candidate repository that results from tectonic activity, such as earthquakes. The following are the associated subissues: Open:¹ None. Closed:² • Subissue 4: Tectonic framework of the geologic setting Closed-Pending:³ • Subissue 1: Faulting • Subissue 2: Seismicity • Subissue 3: Fracturing and structural framework of the geologic setting	Information required for the approach to evaluation of seismic fragility, technical justification for use of median versus mean, “fracture-informed” Enhanced Characterization of the Repository Block long-term test and Alcove 8 Niche 3 test, and review of Fracture Geometry Analysis and Modeling Report. Updates to features, events, and processes analysis and modeling reports and other reports relating to structural deformation and seismicity. Documentation of ground motion expert elicitation, excavation-induced fractures, and pre-test predictions for Alcove 8 Niche 3 test.¹³	This information is required to assess seismic effects on the engineered barriers and to establish boundary conditions, material properties, design criteria.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Thermal Effects on Flow – This Key Technical Issue examines processes that could affect the performance of the repository and considers changes to flow paths of water in the unsaturated zone that are important to degradation of engineered barriers. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: Features, events, and processes related to thermal effects on flow • Subissue 2: Thermal effects on temperature, humidity, saturation, and flux	Information required for representation of full model and parameter variability/uncertainty in results of thermal effects on flow simulations and abstractions, consideration of mass and energy losses through bulkhead of drift-scale test or incorporation of uncertainty caused by these losses, representation of cold-trap effect in appropriate models, comparison of analytical solution for refluxing with results from numerical model, Multi-Scale Thermohydrologic Model input and output files, detailed test plan for Phase III of ventilation test, updates to features, events, and processes database, and analysis and modeling reports relating to thermal effects on flow, and various analysis and modeling reports and process model reports supporting thermal effects on flow. Documentation relating to ventilation model and testing.¹⁴	This information is required to assess engineered barrier performance and the influence of thermal effects on hydrologic properties that affect seepage into repository drifts or transport properties to the saturated zone.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Total System Performance Assessment and Integration – This Key Technical Issue describes an acceptable methodology for conducting assessments of repository performance and uses these assessments to demonstrate compliance with the performance objectives. The following are the associated subissues: Open:¹ None. Closed:² None. Closed-Pending:³ • Subissue 1: System description and demonstration of multiple barriers • Subissue 2: Scenario analysis • Subissue 3: Model abstraction • Subissue 4: Demonstration of compliance with the performance objectives	Document the technical basis for barrier capability, including parameter and model uncertainty, and spatial and temporal variability. Provide the technical basis for screening of features, events, and processes, and support the statement that the considered list of features, events, and processes is comprehensive. Provide the technical basis for the abstraction of waste package performance, in-package chemistry, near-field environment, hydrologic flow paths, diffusion, geochemical conditions, radionuclide transport, biosphere and dose calculations. Documentation of consistent use of abstractions, software qualification, alternative conceptual model results, and stability of overall total system performance assessment results.^{15,16}	This information is required to verify that barrier capabilities are technically justified; that appropriate screening of features, events, and processes has occurred to support scenario analysis; and to ensure that data collection, model development, and treatment of uncertainties are adequate to provide a basis for performance assessments.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Unsaturated and Saturated Zone Flow Under Isothermal Conditions – This Key Technical Issue assesses processes and features associated with the movement of water throughout the natural system. The following are the associated subissues: Open:¹ None. Closed:² • Subissue 1: Climate change • Subissue 2: Hydrologic effects of climate change Closed-Pending:³ • Subissue 3: Shallow infiltration • Subissue 4: Deep percolation • Subissue 5: Saturated zone • Subissue 6: Matrix diffusion	Documentation for Monte Carlo simulation of infiltration, field tests, geochemical data used to support the flow field below the repository, and comparative modeling studies. Provide justification for seepage fraction and seepage flow, and parameters used for infiltration analysis. Provide test plans for and results from underground laboratory experiments on flow, well data, alternative conceptual model results, sensitivity analysis of matrix diffusion, updated regional saturated flow model, and the updated site scale hydrologic framework model.^{17,18}	This information is required to evaluate important aspects of the site-scale saturated zone model for identification of flow paths to the saturated zone and to assess hydrogeologic, thermal, chemical, and mechanical effects on seepage into repository drifts and on transport pathways from the proposed repository horizon to the underlying aquifer.

Key Technical Issue	Agreement Topics	Significance of Agreement Topics
Preclosure Safety – This area has not been identified as a Key Technical Issue; however, it addresses repository operations prior to permanent closure. The following are topics that will continue to be addressed in the issue resolution process: • Site description • Description of structures, systems, components, equipment, and operational process activities • Identification of hazards and initiating events • Identification of event sequences • Consequence analyses • Identification of structures, systems, and components important to safety; safety controls; and measures to ensure availability of the safety systems • Design of structures, systems, and components important to safety and safety controls • Meeting 10 CFR Part 20 as low as is reasonably achievable requirements for normal operations and category 1 event sequences • Plans for retrieval and alternate storage of radioactive wastes • Plans for permanent closure and decontamination, or decontamination and dismantlement of surface facilities	Information required for hazard analysis of aircraft crash on surface facilities, hazard analysis of tornado missile, waste package finite element analysis, and Integrated Safety Analysis Guide. Updates to Pre-Closure Criticality Analysis Process Report and Quality Assurance Procedure QAP 2-3. Demonstration of acceptable waste package mechanical properties after fabrication and closure. Demonstration that nondestructive evaluation methods are adequate for detecting defects in the Alloy 22 and type 316 nuclear grade plates and disposal container closure welds. Justification that mechanical properties of disposal container fabrication and waste package closure welds are adequately represented.^{10,19}	This information is required to support assessments of the design and stability of surface and underground facilities, the design of the waste form and waste packages, and the preclosure safety analysis.

¹Open means NRC has identified questions regarding the DOE approach or information, and the DOE has not yet acceptably addressed the questions or agreed to provide the necessary additional information in a potential license application.

²Closed means the DOE approach and available information acceptably address staff questions such that no information beyond what is currently available will likely be required for regulatory decision making at the time of any initial license application.

³Closed-pending means the NRC staff has confidence that the DOE proposed approach, together with any DOE agreements to provide the NRC with additional information (through specified testing, analysis, etc.), acceptably addresses the NRC's questions such that no information beyond that provided, or agreed to, will likely be required at the time of initial license application.

⁴U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Container Life and Source Term, September 12–13, 2000." Letter from C. William Reamer (NRC) to Dennis R. Williams (DOE). Washington, DC: NRC. 2000. [Agencywide Documents Access Management System, Accession Number: ML003760884]

⁵U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Criticality." October 23–24, 2000. Letter from C. William Reamer (NRC) to Dennis R. Williams (DOE). Washington, DC: NRC. 2000. [Agencywide Documents Access Management System, Accession Number: ML003765266]

⁶U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange on Evolution of the Near-Field Environment, January 9–11, 2001." Letter from C. William Reamer (NRC) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: ML010600181]

⁷U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Igneous Activity, August 29–31, 2000, Las Vegas, Nevada." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2000. [Agencywide Documents Access Management System, Accession Number: ML003763285]

⁸U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Igneous Activity, June 21-22, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: ML011840178]

⁹U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Igneous Activity, September 5, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: ML012560423]

¹⁰U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Range of Thermal Operating Temperatures, September 13-14, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: To-Be-Determined]

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¹²U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Radionuclide Transport, December 5–7, 2000." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2000. [Agencywide Documents Access Management System, Accession Number: ML003778752]

¹³U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Structural Deformation and Seismicity, October 11–13, 2000." Letter from C. William Reamer (NRC) to Dennis R. Williams (DOE). Washington, DC: NRC. 2000. [Agencywide Documents Access Management System, Accession Number: ML003765232]

¹⁴U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Thermal Effects on Flow, January 8–9, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2001. [Agencywide Documents Access Management System, Accession Number: ML010290382]

¹⁵U.S. Nuclear Regulatory Commission (NRC). "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Total System Performance Assessment and Integration - Features, Events, and Processes, May 15-17, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: ML011510147]

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¹⁷U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Unsaturated Zone Flow Under Isothermal Conditions, August 16–17, 2000, Berkeley, California." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2000. [Agencywide Documents Access Management System, Accession Number: ML003751891]

¹⁸U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Saturated Zone Flow under Isothermal Conditions, October 31–November 2, 2000, Albuquerque, New Mexico." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2000. [Agencywide Documents Access Management System, Accession Number: ML003778791]

¹⁹U.S. Nuclear Regulatory Commission. "Summary Highlights of U.S. Nuclear Regulatory Commission/U.S. Department of Energy Technical Exchange and Management Meeting on Pre-Closure Safety, July 24-26, 2001." Letter from C. William Reamer (U.S. Nuclear Regulatory Commission) to Dennis R. Williams (U.S. Department of Energy). Washington, DC: NRC. 2001. [Agencywide Documents Access Management System, Accession Number: ML012290017]

NRC'S VIEWS ON THE U.S. DEPARTMENT OF ENERGY QUALITY ASSURANCE

INTRODUCTION

This enclosure addresses the quality of the documentation supporting a possible site recommendation. The quality of DOE's collection of data; qualification and validation of software and models; and the various analyses supporting at-depth site characterization analysis and the waste form proposal is an important process element encompassing all of the key technical issues addressed by the preliminary comments. Further, because DOE has experienced problems implementing its quality assurance programs, we have included a discussion of DOE's path forward to correct its quality assurance problems before any potential license application.

QUALITY OF DOCUMENTS SUPPORTING SITE RECOMMENDATION

During our prelicensing interactions, DOE discussed the results of its reviews to verify the quality of the documents supporting a possible site recommendation, including the "Yucca Mountain Science and Engineering Report"; the "Total System Performance Assessment for the Site Recommendation"; and the "FY01 Supplemental Science and Performance Analyses." DOE performed vertical, horizontal, and technical reviews of these documents using, in some cases, personnel independent of the Yucca Mountain project. DOE also used independent personnel to perform an analysis for determining the root causes of the errors found in these documents. Although the NRC staff has not independently verified them, the staff believes that the reviews performed by DOE were necessary and appropriate to verify the quality of the documents supporting a possible site recommendation. Further, the NRC staff believes that the reviews did not reveal any significant errors or problems that would impact the conclusions in the "Total System Performance Assessment for the Site Recommendation" portion of the potential site recommendation.

Although DOE has not yet fully qualified data and software used in the "Total System Performance Assessment for the Site Recommendation" portion of the site recommendation, it has a reasonable approach to do so. Further, DOE has indicated that if the information contained in the "FY01 Supplemental Science and Performance Analyses" is used to support, or be a part of a possible license application, the information would be fully qualified and subjected to the same qualification controls as used for the "Total System Performance Assessment for the Site Recommendation." The staff accepts DOE's intention to fully qualify all data, software, and models if they are used in a potential license application.

If the data, software, and models supporting the possible license application are fully qualified before any license application, as agreed to by DOE, there will be sufficient basis for accepting the quality of the information encompassed in DOE's at-depth site characterization analysis and waste form proposal, and for the NRC to conduct its licensing review.

DOE'S PATH FORWARD TO CORRECT ITS QUALITY ASSURANCE PROBLEMS

DOE stated that it will develop a comprehensive corrective action plan that will address the causes of problems and a plan to improve the level of performance of its quality assurance program implementation. This plan will consider and address items such as: 1) results of DOE's reviews of the documents supporting the site recommendation; 2) root-cause analysis for the various quality assurance problems; 3) lessons learned from past corrective action

plans; 4) accountability; 5) performance measures; 6) upgrading and enhancing procedures; and 7) audits, surveillances, self assessments, and management oversight to confirm that the corrective actions are being implemented and are effective. Based on the above, the staff considers that:

- DOE's corrective action plan elements and approach appear reasonable. However, DOE has had problems implementing previous corrective action plans.
- Among the areas warranting management attention is improving the safety conscious work environment in the Yucca Mountain Project.
- The staff will continue to provide oversight of the implementation of DOE's quality assurance program, and review and follow the implementation of DOE's latest action plan to correct quality assurance problems before any potential license application.