

**THE CENTER FOR NUCLEAR WASTE REGULATORY  
ANALYSES (CNWRA<sup>®</sup>) PERSPECTIVE ON  
PRELICENSING INTERACTIONS AND  
INFORMATION GATHERING**

*Prepared for*

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## **ABSTRACT**

Through the Nuclear Waste Policy Act of 1982 (NWPAA) and the Nuclear Waste Policy Amendment Act of 1987, Congress directed the U.S. Department of Energy (DOE) to engage the U.S. Nuclear Regulatory Commission (NRC) in precicensing consultations regarding activities at the proposed Yucca Mountain high-level radioactive waste repository in Nevada to facilitate identification and early resolution of complex technical issues. The NRC was assisted by the Center for Nuclear Waste Regulatory Analyses (CNWRA®) in these precicensing interactions. Based on the set of mutually agreeable guidelines, developed by the DOE Office of Civilian Radioactive Waste Management and the NRC Office of Nuclear Material Safety and Safeguards (NRC, 1999), the precicensing interactions were of the following types: Appendix 7 meetings, management meetings, and technical exchanges. In addition, project staff from DOE and NRC would interact biweekly for status updates. Furthermore, the NRC and CNWRA staff members visited the Yucca Mountain site, participated in observing DOE quality assurance audits, and conducted several public outreach meetings. CNWRA perspectives regarding these precicensing interactions are discussed in this report together with suggestions for potential improvements for implementation of similar processes in the future.

## **REFERENCE**

NRC. "Agreement Between U.S. Department of Energy/Office of Civilian Radioactive Waste Management and U.S. Nuclear Regulatory Commission/Office of Nuclear Material Safety and Safeguards Regarding Precicensing Interactions." SECY-99-031. Washington, DC: NRC. 1999.

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## QUALITY OF DATA, ANALYSES, AND CODE DEVELOPMENT

**DATA:** No CNWRA-generated original are contained in this report. Sources of other data should be consulted for determining the level of quality of those data.

**ANALYSES AND CODES:** No CNWRA-generated codes runs or results are included in this report. Other sources of analyses and codes are described and the referenced sources should be consulted for determining the level of quality of those analyses and codes.

# 1 INTRODUCTION

Through the Nuclear Waste Policy Act of 1982 (NWPAA) and the Nuclear Waste Policy Amendment Act of 1987, Congress directed the U.S. Department of Energy (DOE) to engage the U.S. Nuclear Regulatory Commission (NRC) in prelicensing consultations regarding activities at the proposed Yucca Mountain high-level radioactive waste repository in Nevada. The primary objective of these NRC-DOE prelicensing consultations was to facilitate identification and early resolution of complex technical issues via discussions between technical and management staff of the two agencies. It was expected that these early discussions would help in developing a high quality and substantially complete license application for constructing and operating a geologic repository for high-level radioactive waste that could be reviewed and litigated in the limited period of 3 years, as mandated in the NWPAA.

Before DOE submitted its license application on June 3, 2008, NRC had the following prelicensing responsibilities:

- Review the DOE Site Characterization Process
  - Review the DOE Quality Assurance (QA) Program
  - Resolve Key Technical Issues related to the high-level nuclear waste disposal
- Establish the high-level nuclear waste disposal regulations (e.g., 10 CFR Part 63)
- Review the DOE Site Recommendation
- Review the DOE Environmental Impact Statement for Yucca Mountain
- Develop guidance and licensing bases (e.g., Yucca Mountain Review Plan)
- Establish communications with stakeholders and DOE (e.g., public meetings and prelicensing interactions)

Throughout the prelicensing activities related to the proposed radioactive waste repository, NRC was assisted by the Center for Nuclear Waste Regulatory Analyses (CNWRA<sup>®</sup>). CNWRA was established in 1987 as a Federally Funded Research and Development Center, sponsored by NRC, to assist in resolving technical and regulatory issues related to the potential geologic repository.

In the rest of this document, CNWRA perspectives regarding these prelicensing interactions are discussed together with suggestions for potential improvements for implementation of similar processes in the future.

## 2 BACKGROUND ON SITE CHARACTERIZATION PROGRAM

The site characterization activities at the Yucca Mountain site began in earnest in 1988 when DOE published its Site Characterization Plan. The plan envisioned many scientific and engineering investigations to determine the site's waste isolation capabilities. During the course of investigations, the originally envisioned activities were modified, deleted, or supplemented, as needed. Surface based characterization activities, such as excavation of test pits and trenches and drilling of boreholes started in 1991 when the State of Nevada granted DOE the required permits. In 1994, DOE started to excavate the Exploratory Studies Facility (ESF) using a tunnel boring machine. The ESF consisted of a 7.5 m [25 ft] diameter and approximately 8 km [5 mi] long tunnel. It was designed as an area where underground *in-situ* experiments could be performed. Within the ESF, there were seven test alcoves and four test niches that were used to investigate hydrologic, hydro-chemical, and thermo-mechanical properties of the rock units at the Yucca Mountain site. The ESF also was used to map various geologic features, such as faults and fractures. To gather additional data regarding the rock characteristics at the repository horizon, DOE began excavating a smaller exploratory tunnel {5.5 m [18 ft] diameter and 3.2 km [2 mi]} across the main tunnel in 1997. This second tunnel was referred to as the "Cross Drift," and was formally part of the Enhanced Characterization of the Repository Block (ECRB) study. The main purposes of the Cross Drift were to allow DOE to examine specific volcanic strata not intersected by the ESF and to characterize the Solitario Canyon fault in the subsurface.

In addition, DOE drilled more than 450 deep and shallow boreholes to collect more than 23,000 m [75,000 ft] of core samples and 18,000 geologic and water samples. Additionally, DOE studied quaternary fault displacement in more than 60 trenches and several natural exposures.

The primary NRC objective of interactions during the site characterization phase of the project was to identify early any factors that may affect repository licensing. Towards that end, NRC and CNWRA staff members observed DOE site characterization activities, including excavation of the ESF and ECRB crossdrift.

To manage the interactions in a transparent manner, the NRC developed a framework of key technical issues (KTIs). There were ten KTIs covering general areas of study related to the postclosure performance assessment (e.g., unsaturated and saturated groundwater flow under isothermal conditions, structural deformation and seismicity, and igneous activity). Within each KTI, NRC and CNWRA staff members developed a number of subissues that more closely matched specific components of the performance assessment (e.g., under unsaturated and saturated flow under isothermal conditions KTI, there were climate change, hydrologic effects of climate change, shallow infiltration, and saturated zone subissues; under total system performance assessment and integration KTI, there were system description and demonstration of multiple barriers, scenario analysis and event probability, model abstraction, and demonstration of compliance with the postclosure public health and environmental standards subissues). The prelicensing interactions related to specific KTI subissues; NRC provided the status of their resolution in its periodic Integrated Issue Resolution Status Reports.

### 3 TYPES OF NRC-DOE PRELICENSING INTERACTIONS

The DOE Office of Civilian Radioactive Waste Management (OCRWM) and the NRC Office of Nuclear Material Safety and Safeguards (NMSS) developed a set of mutually agreeable guidelines for conducting the prelicensing interactions. These guidelines contained in SECY-99-031, Agreement Between the U.S. Department of Energy Office of Civilian Radioactive Waste Management and U.S. Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards Regarding Prelicensing Interactions (NRC, 1999) (referred to as the "Agreement" from here on) is reproduced as Attachment 1 to this document. Care was taken in developing this Agreement to ensure stakeholders that no action taken (e.g., resolution of technical issues) during these prelicensing interactions, "...shall be deemed to constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission..."

An Appendix 7 meeting between NRC/NMSS and DOE/OCRWM was defined as

*An Appendix 7 meeting is a meeting between the NRC onsite representative (OR), including any NRC personnel assigned to the OR, and DOE-Yucca Mountain Site Characterization Office (YMSCO), including contractors and subcontractors (NRC, 1999).*

These meetings, described in Appendix 7 of the Agreement between DOE/OCRWM and NRC/NMSS (NRC, 1999), did not constitute official interactions between these two organizations, and did not require any written reports or meeting summaries. These meetings were focused discussions on technical topics related to site characterization and related activities. External parties could observe these meetings at the discretion of these two organizations. No commitments were made at the Appendix 7 meetings.

A technical exchange between DOE and NRC was defined as

*A scheduled interaction between DOE and NRC technical/licensing staff expected to focus primarily on technical or regulatory issues and to: review and consult on interpretations of data; identify potential licensing issues; discuss specific technical and/or regulatory topics, the sufficiency of available information and data, methods and approaches for the acquisition of additional information, and data as needed to facilitate NRC reviews, and evaluations and for staff resolution of such potential licensing issues (NRC, 1999).*

Technical exchanges were used to understand and discuss technical or regulatory issues and accept planned actions on the part of both agencies. However, they were not used to officially establish or change positions or make commitments. These meetings were open to the public. The character of these meetings changed during the later part of the program when, in addition to the technical staff, management also started to participate. These meetings then shared the characteristics of both a technical exchange and a management meeting (see next paragraph); thus, in addition to technical discussions, commitments could be made.

Technical exchanges were formal meetings between DOE and NRC technical and licensing staff. These meetings focused primarily on mutually agreed, specific technical and regulatory topics. A teleconference between DOE/OCRWM and NRC/NMSS was held approximately 2 weeks prior to a technical exchange meeting to reach agreement on the agenda (NRC, 1999). Stakeholders were present in these meetings and were invited to participate, including providing



comments at the beginning and closing of the meeting. These meetings followed a strict protocol and a published agenda. Feedback from the public was specifically sought. Concise minutes of the meetings were developed summarizing briefly the presentations made and discussions that took place, regulatory or technical interpretations or positions, and points of agreement or disagreement, including any commitments made. Copies of the presentations and list of attendees were included as attachments to the minutes and were distributed to the State of Nevada, affected units of local government, affected Indian tribes, and public document rooms of NRC and DOE.

A site visit between NRC and DOE technical staff members was defined as

*A site visit is a scheduled interaction to explain technical information related to ongoing field or laboratory site characterization and related activities; visit locations at the site for field briefings; and discussions of preliminary data and interpretation derived from field work.*

A site visit did not require written reports or meeting summaries. Site visits were not used to officially establish or change technical and/or regulatory positions. No commitments were made and no course of action was agreed upon. Stakeholders were allowed to participate in site visits consistent with security requirements.

A Management Meeting between DOE and NRC was defined as

*A scheduled interaction held whenever necessary to review the summary results of technical exchanges; to review the status of outstanding items and issues; to discuss plans for resolution of outstanding items and issues; to update the schedule of technical exchanges and other actions needed for staff resolution of open items regarding the site characterization program; and to consult on what guidance is advisable and necessary for NRC to prepare (NRC, 1999).*

Unresolved management issues would be promptly elevated to upper management for resolution. Management meetings were conducted to discuss programmatic issues related to program policy, schedules, scope, and major assignments of resources. Any commitments that were made during these meetings were documented in correspondence.

In addition, another precicensing activity, which was not classified as an interaction between DOE and NRC (NRC, 1999) but provided important insights into the ongoing DOE technical activities, was participation in DOE internal QA audits of its Management and Operating Contractor and subcontractors—including the national laboratories—by the NRC and CNWRA staff members as observers. The DOE QA organization was responsible for and conducted these audits. NRC observed these audits in lieu of NRC-led inspections and similar QA assessments, which significantly reduced NRC resource requirements and also limited the impact on organizations that might be inspected. NRC observer teams consisted of QA specialists and technical staff with expertise in the technical area being audited. Representatives from the State of Nevada, local governments, and Indian tribes also attended these audit activities as observers. The objectives of NRC observers were to determine the effectiveness of the DOE audit process and implementation of the QA programs being assessed. NRC observers provided their comments, observations, and recommendations to the DOE audit leader, and also produced a formal audit observation report that was made available to all stakeholders.

The four kinds of permissible meetings and interactions and their characteristics are defined in Table 3-1. In addition, biweekly Yucca Mountain status meetings between DOE and NRC project staff members and visits to the DOE Licensing Support Office (LSO) by NRC and CNWRA staff members are also discussed in Table 3-1. Furthermore, NRC participated as observers in DOE internal quality assurance audits. Characteristics of these audits are discussed in Table 3-1.

As the prelicensing activities progressed, the nature of these interactions changed. For example, very early in the program, before about 1997, technical exchanges were the primary mode for direct interaction among DOE staff, DOE contractor scientists and engineers, NRC staff, and CNWRA scientists and engineers. These technical exchanges were relatively informal and even included field trips to examine volcanic features or paleoseismic trench investigations. They also included stakeholders (e.g., Nye and Clark counties) and the public, but involved few, if any, NRC or DOE managers. Appendix 7 meetings were used when a very small group of NRC staff members needed to interact with their DOE counterparts at the NRC onsite representative (OR) office in the presence of one of the NRC ORs.

In early 2000, NRC initiated a more formal process to identify and then close outstanding technical issues with DOE. Within each subissue, NRC and CNWRA staff developed a series of questions, which were discussed with DOE at a series of meetings that combined the characteristics of both technical exchanges and management meetings. In general, one meeting was held for each KTI. Before each meeting, DOE and NRC would hold one or more teleconferences to discuss NRC questions and proposed DOE answers. Later, DOE responses were presented formally at the meetings. Based on the response, NRC and DOE developed agreements that needed formal responses from DOE to be closed. DOE developed technical reports and provided additional information to NRC for each agreement. NRC staff evaluated the information and either closed the agreement or asked for additional information necessary to close the agreement.

<b>Table 3-1. Types of NRC and DOE Prelicensing Interactions and Their Characteristics</b>				
<b>Interaction</b>	<b>Objective</b>	<b>Characteristics</b>	<b>Participants</b>	<b>Discussion</b>
Appendix 7 Meeting	<ul style="list-style-type: none"> <li>•Discuss technical topics related to site characterization and related activities (e.g., field trips)</li> </ul>	<ul style="list-style-type: none"> <li>•Nonscheduled interaction</li> <li>•No commitments to be made</li> <li>•External parties <i>may</i> be notified and invited to observe</li> </ul>	<ul style="list-style-type: none"> <li>•NRC onsite representative (OR) and NRC personnel assigned to OR office</li> <li>•DOE-Yucca Mountain Site Characterization Office (YMSCO)</li> <li>•Contractors</li> </ul>	Written material was not expected to be distributed and a summary of the meeting was not required to be prepared. Meeting was meant to be an informal, open, free, and in-depth discussion of technical matters. At the beginning of the program, Appendix 7 meetings were not announced for stakeholder participation; this changed as DOE started developing its license application.
Technical Exchange	<ul style="list-style-type: none"> <li>•Discuss technical and regulatory topics, data interpretation, potential licensing issues, sufficiency of available information and data, and approaches for acquiring additional information and data for resolution of potential licensing issues</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled meeting</li> <li>•Meeting open to public</li> <li>•Could not be used to officially establish or change positions or make commitments</li> <li>•Meeting summaries were prepared, developed by DOE, and reviewed by NRC</li> </ul>	<ul style="list-style-type: none"> <li>•DOE and its contractor staff</li> <li>•NRC and its contractor staff</li> <li>•Members of the public</li> </ul>	Meeting and agenda was announced in advance. In initial stages of the program, technical staff of the two agencies interacted without the presence of management. In later stages of the program, management representatives from both agencies were present so that these meetings could be considered as "management meetings" also and commitments could be made. Written material was exchanged during the meeting.
Site Visit	<ul style="list-style-type: none"> <li>•Discuss technical information related to ongoing field and laboratory investigations and preliminary interpretations of field and laboratory data</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled meeting</li> <li>•No technical or regulatory commitments to be made</li> <li>•Written reports or meeting summary not required</li> <li>•Stakeholders invited as observers</li> </ul>	<ul style="list-style-type: none"> <li>•DOE and its contractor staff</li> <li>•NRC and its contractor staff</li> <li>•Members of the public</li> </ul>	Site visits provided opportunities for observing field and laboratory experiments and for making the link between data and its origin more transparent.
Management Meeting	<ul style="list-style-type: none"> <li>•Discuss summary results of technical exchanges</li> <li>•Identify outstanding items and issues and plans for resolving them</li> <li>•Update schedules of technical exchanges</li> <li>•Identify actions needed for staff resolution of open items</li> <li>•Identify guidance for NRC to prepare</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled meeting</li> <li>•Commitments on path to staff resolution of technical, programmatic, and regulatory issues were made</li> <li>•Written meeting summary with commitments were required</li> <li>•Stakeholders invited as observers</li> </ul>	<ul style="list-style-type: none"> <li>•DOE and its contractor staff</li> <li>•NRC and its contractor staff</li> <li>•Members of the public</li> </ul>	Management meetings were the primary forum to discuss resource, schedule, programmatic, and policy issues; and make commitments and discuss their status. Management meetings could be held when needed but were generally held on a quarterly schedule. For stakeholders and members of the public, this provided a window to the overall project status both from the perspective of the regulator and the implementer.

**Table 3-1. Types of NRC and DOE Prelicensing Interactions and Their Characteristics (continued)**

<b>Interaction</b>	<b>Objective</b>	<b>Characteristics</b>	<b>Participants</b>	<b>Discussion</b>
DOE Quality Assurance Audits	<ul style="list-style-type: none"> <li>•Observe DOE quality assurance audits</li> <li>•Assess effectiveness of DOE audit process and implementation of QA program</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled meeting</li> <li>•No technical or regulatory commitments to be made</li> <li>•NRC participated as observer</li> <li>•Stakeholder invited to observe</li> </ul>	<ul style="list-style-type: none"> <li>•DOE, its management and operating contractor, including the national laboratories</li> <li>•NRC project staff as observers</li> </ul>	Participation in DOE quality assurance audit as observers provided good source of information on ongoing DOE activities related to laboratory experiments; field observations, measurements, and experiments, and analyses. NRC observed the audits in lieu of NRC-led inspections, which significantly reduced resource requirements.
Biweekly Status Meetings	<ul style="list-style-type: none"> <li>•Update status of the project</li> <li>•Inform participants about upcoming activities</li> <li>•Discuss arrangements of upcoming technical exchanges</li> </ul>	<ul style="list-style-type: none"> <li>•Schedule meeting</li> <li>•No technical or regulatory commitment to be made</li> </ul>	<ul style="list-style-type: none"> <li>•DOE and its contractors project staff</li> <li>•NRC project staff</li> </ul>	CNWRA did not participate
Licensing Support Office Visits	<ul style="list-style-type: none"> <li>• Consult DOE documents and computer models in draft form before they were publicly available</li> </ul>	<ul style="list-style-type: none"> <li>• Not a meeting</li> <li>• No technical or regulatory commitments to be made</li> </ul>	<ul style="list-style-type: none"> <li>• NRC and CNWRA Technical staff</li> </ul>	Availability of draft documents benefitted NRC and CNWRA staff by sharing important technical documents early.

## 4 CNWRA PERSPECTIVES ON EFFECTIVENESS OF INTERACTIONS

### 4.1 Appendix 7 Meetings

The Appendix 7 meetings between DOE and NRC started as informal meetings with focused discussion on selected technical topics. No written reports or meeting summaries were prepared consistent with the DOE-NRC agreement (NRC, 1999). Useful, in-depth discussions took place in these meetings. Although not barred from attending, stakeholders initially did not take much interest in these meetings, as evidenced by their limited attendance at these meetings.

As DOE began to develop the license application for a permanent geologic repository at Yucca Mountain, stakeholders increased participation in Appendix 7 meetings. As DOE staff became mindful of the presence of stakeholders, meeting effectiveness decreased: discussions were less open among the technical staff of both organizations, and information was less forthcoming. The NRC and CNWRA staff members were not inclined to present information that was not close to “final,” and DOE staff presented only “tried and true” information. There was a sense that information on recent work was held back if it was not fully vetted within the respective organizations. Additionally, responses seemed to become well-rehearsed answers, reducing effectiveness and somewhat diminishing the original intent of these meetings. Furthermore, preparation time increased for Appendix 7 meetings. In addition, technical exchanges were favored over Appendix 7 meetings because NRC and DOE wanted to close open items within each KTI in a formal way. Lessons learned from the Appendix 7 meetings, as well as suggestions for improving effectiveness of similar meetings with potential applicants, are discussed in the following paragraphs.

#### Lessons Learned

- Appropriate staff members from the applicant should be available to explore the technical subject matters thoroughly, as intended. At some Appendix 7 meetings, appropriate staff members from DOE and its contractor were not available or available only on limited time basis. On the other hand, in some meetings, several DOE and contractor staff members were present who did not appear to be part of the focused discussion. Presence of too many persons sometimes imposed logistical issues and probably distracted from the discussion.
- Documents (reports and associated materials) related to the topic(s) of discussion should be available to the NRC and CNWRA staff members well in advance of the meeting to prepare appropriately for the discussion. When the NRC and CNWRA staff members received the documents early and had adequate time to prepare, the discussion was focused and productive, resulting in an effective and fruitful information exchange. Both sides benefited from the discussion. The NRC and CNWRA staff members developed a better understanding of the technical issues and better understanding of DOE approaches, assumptions, data, and analyses. At the same time, DOE and its contractor staff understood NRC and CNWRA staff member concerns, if any, on the proposed approaches. Conversely, in one preclosure Appendix 7 meeting on application of human reliability in the Preclosure Safety Analysis (PCSA), many inquiries by NRC and CNWRA staff members on the DOE approach met resistance from DOE to discuss adequately. As a result, NRC and CNWRA staff members were not able to gain insight into how DOE would introduce human reliability in its PCSA.

- NRC and CNWRA staff should ensure that all participants understand the scope, intent, and restrictions imposed by the DOE and NRC agreement (NRC, 1999) on the Appendix 7 meetings. For example, no agreements or commitments can be made in the Appendix 7 meetings because they were not considered formal interactions between these two organizations.

### **Suggestions for Improving Effectiveness**

The following suggestions are provided to improve the effectiveness of future Appendix 7 meetings with similar scopes with potential licensees.

- Information, such as reports, analyses, results, etc. related to the topic(s) of the meeting should be made available to NRC and CNWRA staff members well in advance so that staff attend the meeting with sufficient preparation. This may help in identifying the technical issues beforehand to keep the discussion focused on important topics.
- The policy of not keeping any official notes should be strictly adhered to so that the discussion can be open, as intended in NRC (1999).
- NRC and CNWRA staff should ensure that applicant staff members understand the purpose and objective(s) to be achieved. Valuable resources would be wasted if time were lost discussing unnecessary background materials and giving instructions on meeting constraints and purposes.
- The role of the regulator, especially during precicensing interactions, should be made clear to the applicant staff members present in the meeting (and in other types of meetings, such as technical exchanges and site visits).
- NRC and CNWRA staff members should ensure that appropriate applicant staff members will be available for effective discussion in a meeting; otherwise, alternative date(s) for the meeting should be selected. Additionally, the applicant should include all staff members directly needed for the focused discussion.
- It is necessary to design a convenient mechanism to readily share information as they are officially available, so NRC and CNWRA staff members do not have to ask for specific reports.

## **4.2 Technical Exchanges**

Technical exchanges were held with the expectation that all risk-significant issues would be discussed, debated, and paths for resolution would be formulated in a mutually agreeable manner so that DOE could develop a high-quality license application for the geologic repository at Yucca Mountain, and NRC could conduct an efficient license review of such a complex project in the stipulated time period. Initially, technical exchanges worked well: discussions were in-depth on technical and regulatory issues; and good technical information was exchanged during the meetings. However, as DOE progressed toward preparing and submitting the license application, meetings became less effective, especially in the preclosure areas. Presentations generally dealt with familiar “tested” information (e.g., methodologies to be used). Additionally, the presentations did not provide much depth on risk-significant issues beyond what were on the slides. Responses to clarification questions tended to be superficial in

some cases and follow-up staff questions generally would not bring out any further information. This extremely cautious approach to the technical exchange meetings undermined the intended purpose of the meetings.

Organizing technical exchanges (as well as Appendix 7 meetings) when DOE was preparing the license application became increasingly difficult. Technical exchanges appeared to be controlled by legal considerations and the format for information exchange became constrained, decreasing effectiveness of these exchanges. Although not stated, DOE may have been concerned that technical exchanges took resources that otherwise would be used to ensure on time completion of the license application.

## **Lessons Learned**

- NRC and CNWRA staff members did not receive documents related to some technical exchanges sufficiently in advance to prepare effectively as a team. This may have affected focusing on risk-significant issues. This issue is similar to the one in Appendix 7 meetings.
- NRC and CNWRA staff members lacked prior knowledge of some approaches DOE would adopt in the analyses in several areas before the license application was submitted. DOE did not agree to staff requests for a technical exchange on many risk-significant topics, especially when it was developing the license application. In the future, NRC staff should ensure that they have prior knowledge about the approaches to be taken by an applicant to implement a methodology in an analysis, especially in a risk-informed licensing review, so that the review can be more effective with minimum need for requests for additional information (RAIs). Prior knowledge of the approaches used in the analyses would have facilitated reviewing the license application more effectively and minimized the need for RAIs.
- Level of design details that would be included in the license application was a long standing issue that was not successfully resolved before submittal of the license application. As specified in the regulations at 10 CFR Part 63, PCSA should be used to identify the Structure Systems and Components (SSCs) important to safety that would be relied upon to prevent or mitigate the radiological consequences as a result of an initiating and associated event sequences. In addition, it should be shown in the license application that the design of the importance to safety SSCs would provide reliabilities of the systems and components, at least what had been assumed in assessing safety of the facility and operation in the PCSA. It is important for NRC staff and the applicant to have a clear and common understanding of the level of design details expected in the license application. The level of design details should focus on the information needed for appropriate review of the license application using the standard review plan [e.g., Yucca Mountain Review Plan (NRC, 2003)]. NRC staff developed an interim staff guidance (ISG) HLWRS-ISG-02 Preclosure Safety Analysis-Level of Information and Reliability Estimation (NRC, 2007), to address the level of design details. The ISG provides the level of design and operational details necessary for SSCs at the geologic repository operations area and examples that illustrate commonly used approaches for estimating reliability of an SSC. NRC staff presented the level of design details necessary in the license application through examples in a technical exchange. However, lack of sufficient information at the system and component levels in the license application made it difficult to trace an event sequence all the way through the design and, ultimately to the assigned reliability value. Had DOE presented a detailed,

“real-life” example of reliability assessment of a system in a technical exchange, instead of high-level discussion of its approaches or methodologies, the need for sufficient design details and information for an acceptable quality PCSA would have been clear and fewer RAIs would have been needed for reviewing the license application.

### **Suggestions for Improving Effectiveness**

- Topics and scope of a technical exchange (as well as an Appendix 7 meeting) should be established well in advance of the meeting. Staff should focus on topics relevant to risk-significant issues. For example, discussion of both methodologies and application of these methodologies to an actual problem are important to risk-informed reviews. Definition of the problem, assumptions made, and implementation of the methodologies in actual analyses may affect significantly the outcome of the analyses. Consequently, the meetings should address both of these aspects with appropriate emphasis, instead of concentrating on one (e.g., only discussing methodologies).
- Any interim staff guidance or other instructions to the applicant must be timely to be effective. Developing guidance earlier in the process, and updating it as necessary based on knowledge gained from applicant interactions, would have helped clarify NRC staff expectations and may have resulted in fewer RAIs.
- NRC and CNWRA staff members should develop risk insights regarding the outstanding technical issues as early as possible and focus on meeting with the applicant on risk-significant issues. NRC and CNWRA staff members should connect technical questions to total system performance or PCSA, as appropriate. NRC and CNWRA staff took time to develop and apply risk insights as part of the technical review. Furthermore, NRC and CNWRA staff members sometimes struggled with the difference between “a sound technical approach with defensible technical conclusions” and “a technical approach and conclusions good enough to reach a safety decision.” As a result, some technical exchanges (also Appendix 7 meetings) devoted too much time to scientific or technical issues that were not necessarily risk significant.

### **4.3 Site Visits**

Site visits in which the NRC and CNWRA staff members had the opportunity to meet with DOE and its contractors in the field in order to directly observe ongoing studies were an important component of the prelicensing review activities. Often these site visits were conducted as new information was being developed or new experiments were started. Examples include several site visits by NRC and CNWRA staff members to meet with DOE counterparts to observe paleoseismic records unearthed as new fault trenches were excavated, core recoveries as new drill holes were drilled, and the drift-scale heater test. In addition, the NRC and CNWRA staff members conducted their own field and laboratory experiments (e.g., Ferrill et al., 1996; Stamatakos et al., 2007). These independent analyses assisted the NRC and CNWRA staff members to develop their technical perspectives early and present their assessments in interactions with DOE and its contractor staff members. In some cases, DOE conducted additional field and/or laboratory studies to improve the quality of the license application. Lessons learned from site visits are given in the following section. There are no suggestions for improving the site visits.



## **Lessons Learned**

- The site visits provided opportunities to become more fully informed reviewers, who have observed collection of site-related information that formed the basis for developing the license application.
- Independent field data collections and limited scale experiments by NRC and CNWRA staff members were essential in developing position(s) on complex technical issues. In addition, conducting limited-scale field experiments helped staff guard against possible biases regarding field observations made by the applicant.

### **4.4 NRC-DOE Management Meetings**

These formal meetings were held quarterly with participation from senior level NRC and DOE managers, often including office directors. Policy and management matters were discussed and action items were tracked. These meetings were open to stakeholders and time was allocated for stakeholder statements. Participants often read prepared statements and these meetings rarely deviated from the agenda. Meeting notes were kept and tracking action items included assigning responsibility and completion dates. These meetings were useful in ensuring that the highest levels of management were engaged and aware of the status of the project and any ongoing programmatic, management, or technical issues that needed to be resolved. Effectiveness of management controls and implementation of the DOE quality assurance program were permanent topics for these meetings.

## **Lessons Learned**

- The formality of the meeting in the presence of high levels of management constrained discussion to planned thoughts and statements, thus discouraging a free exchange of views. However, these meetings met their objective of making public high-level management concerns related to policy, work quality, schedules, and other important matters that may have affected timely actions by either DOE or NRC.
- The meetings were effective in exposing DOE and stakeholders to NRC expectations with respect to the license application and to DOE plans for meeting these expectations.

### **4.5 Observations of DOE Quality Assurance Audits**

Observation of DOE QA audits also provided a good source of information on ongoing DOE activities related to laboratory experiments; field observations, measurements, and experiments; and analyses. The NRC staff could factor this knowledge into its development of regulations, regulatory guides, and other regulatory documents, in addition to preparing for license application review. Lessons learned and suggestions for improving future interactions are given in the following paragraphs.

## **Lessons Learned**

- The audit observation process provided an effective method for assessing quality assurance program implementation that would otherwise have required NRC-led inspections.

- The DOE-NRC agreement (NRC, 1999) placed constraints on audit observations and observers that, on some occasions, conflicted with the need to obtain detailed information on ongoing DOE activities.
- Active participation by audit observers required careful balancing to avoid interfering with the audit team while providing timely observations to the audit team to avoid any potential surprises at the end of the audit. In some instances, the DOE audit team took the recommendations of NRC observers into account in their own recommendations to DOE (e.g., NRC, 2005).

### **Suggestions for Improving Effectiveness**

- Future agreements should explicitly address audit observation activities to ensure sufficient detail is obtained about ongoing licensee activities. Technical observers should be instructed on proper conduct before each audit observation activity.
- Specific time should be allocated each day for observers to discuss their observations with the audit team. This would allow timely feedback to the audit team and avoid delaying the audit team. The audit observers should focus on implementation of the QA program rather than on technical details of analyses conducted by the potential applicant.

## **4.6 Biweekly Yucca Mountain Status Meetings**

Informal biweekly Yucca Mountain status meetings were held between NRC and DOE project staff without participation of stakeholders. The meetings updated the status of the project and informed participants of any forthcoming activities, including arrangements for technical exchanges. Because CNWRA staff generally did not attend these meetings, there is no discussion on lessons learned or suggestions for improving such interactions with a future applicant.

## **4.7 Visits to the DOE Licensing Support Office**

DOE created the LSO to allow NRC and CNWRA staff members to consult DOE documents that were in draft form and not yet publicly available. NRC routinely requested documents to be included in the LSO collection. DOE also made available in the LSO draft computer models, such as the total system performance assessment model developed in GoldSim (GoldSim Technology Group, LLC, 2004), for NRC and CNWRA staff members to become familiar with DOE approaches. Documents were not allowed to be taken outside the LSO facility. In general, availability of draft documents at the LSO benefitted both DOE and NRC by allowing early sharing of important technical information. For example, the NRC and CNWRA staff benefitted from learning early of planned changes in DOE performance assessment models. There are no lessons learned and suggestions for improvement for visits to the DOE LSO.

## **4.8 Public Outreach Meetings**

Public meetings were one of the most important methods of communication in the NRC Yucca Mountain public outreach program. These meetings served as a tool to educate and inform the public, as well as to gather important feedback and input for NRC decision making. The process and format of public meetings evolved as more experience was gained. Staff learned

many important lessons throughout the program that contributed to continued improvement and overall success.

The outreach program related to the Yucca Mountain repository started when 10 CFR Part 63 was in a draft stage. The first public meeting on Yucca Mountain issues was held in March 1999, to explain, gather additional input, and hear concerns from the general public and stakeholders about proposed rulemaking.

Over the years, several public meetings were held at different sites in Nevada on various topical areas, including roles and responsibilities of NRC, NRC licensing process, Licensing Support Network, and the NRC hearing process. Insights gained from these public outreach meetings and interactions with stakeholders also benefitted other programs at NRC. In 2003, NRC began to recognize needs to increase stakeholder confidence in NRC. Members of the public outreach team were invited to join the Commission's task force for evaluating public communications and providing strategies for enhancing communications at all levels of the agency. History and lessons learned from these public outreach meetings are elaborated in a separate report *Lessons Learned From Public Outreach Meetings*,<sup>1</sup> only pertinent points are presented here.

### **Lessons Learned**

- Knowledge of risk communication and preparation for anticipated follow-up questions help significantly in success of the meetings.
- An adequate number of NRC staff should be in the team for proper preparation for a public meeting. Additionally, team members should be encouraged to contribute freely, regardless of their position level in the agency.
- It is important to visit the venue ahead of time to ensure proper facility size, ancillary equipment, and seating accommodations.
- Dry runs of presentations to be delivered at the meeting help significantly in preparing for the meeting.
- Makeup of a community can affect the course and reception of a public meeting. Consequently, anticipate concerns of the community and explain how to put those concerns forward to appropriate regulatory bodies.
- NRC and CNWRA staff members should be prepared to deal with an elected official in the audience who may use the meeting as a personal campaign venue. Staff should be courteous to him or her and should answer the questions; however, staff should keep the discussion on the topic.
- Transcripts of the discussion should be prepared, which will help in sharing information about the meeting with the members of the public who could not attend. Transcripts are also helpful for internal review and demonstration of compliance with agency policies.

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<sup>1</sup>Submitted on April 7, 2011, to NRC as an intermediate milestone (14002.01.441.110) of CNWRA.

## **Suggestions for Improving Effectiveness**

- NRC and CNWRA staff members should ensure that the members of the public feel welcome in the public outreach meetings. Staff should not be defensive; however, preparation for unforeseen scenarios (e.g., security issues) should be accounted for in planning a public meeting.
- NRC and CNWRA staff members should prepare presentations in plain language for effective communication with the public.
- It is important to have the right staff members on hand to answer questions in a public outreach meeting. Both well-prepared technical experts ready to answer technical questions and legal staff to assist with policy and regulatory matters are needed.
- NRC and CNWRA staff members should ensure that stakeholders see evidence that their concerns are being heard.

## 5 SUMMARY

Several different modes of interaction between DOE and NRC and CNWRA staff members were available to discuss, understand, and resolve potentially complex technical issues during the precicensing phase. The protocols and restrictions, if any, of each type of interaction are described in SECY-99-031 (NRC, 1999). Each type had a different degree of success in fulfilling its objectives. In general, the effectiveness of Appendix 7 meetings and technical exchanges decreased when only “tried and true” information was presented, holding back any information about new work or approaches before it is fully vetted within the DOE organization and presentations and responses were too rehearsed. The effectiveness of these interactions declined further when DOE was preparing to submit the license application. In a project with significant complex technical issues with mandatory time limits on completing the review, it is essential that technical staff from both sides interact as early and effectively as possible to resolve the issues. A convenient mechanism is needed to readily share information as it becomes available for distribution.

## 6 REFERENCES

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**ATTACHMENT  
SECY-99-031**

January 28, 1999

FOR: The Commissioners

FROM: William D. Travers /s/  
Executive Director for Operations

SUBJECT: AGREEMENT BETWEEN U.S. DEPARTMENT OF ENERGY/OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT AND U.S. NUCLEAR REGULATORY COMMISSION/OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS REGARDING PRE-LICENSING INTERACTIONS

PURPOSE:

To inform the Commission of a revision to the agreement between the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), and the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards (NMSS), regarding general guidelines for communications between the two organizations with respect to all activities preparatory to DOE's submission of an application for authorization to construct and operate a geologic repository under section 114 of the Nuclear Waste Policy Act (NWPA).

BACKGROUND:

In 1983, NRC and DOE signed a Procedural Agreement and later a Project-Specific Agreement identifying guiding principles for interface during site investigation and site characterization. The agreements outlined procedures, for consultation and exchange of information that DOE and NRC would observe in connection with the characterization of sites for a geologic repository. The purpose of these procedures is to assure that an information flow was maintained, between the two agencies that will facilitate each agency's accomplishment of its responsibilities, under the NWPA. This agreement was last revised in 1993.

DISCUSSION:

The objective of this revision (attached) is to update, consolidate, and streamline the agreement. NRC and DOE staffs have worked jointly to incorporate changes to satisfy these objectives. The substantive changes include: (1) adding a provision stating that all interactions will comply with the "NRC Policy Statement on Staff Meetings Open to the Public"; (2) stating that management commitments will be documented in correspondence subsequent to the interactions; (3) streamlining the types of meetings



conducted to reflect current practice; (4) consolidating and eliminating redundant information to simplify the agreement; and (5) clarifying the use of terms by adding a "Definitions" section.

All changes to this agreement have been coordinated with DOE/OCRWM and reviewed by NRC/NMSS, and NRC's Office of the General Counsel (OGC). In an August 1998 public meeting, NRC and DOE staffs briefed representatives from the State of Nevada, Affected Units of Local Governments (AULGs), and other interested parties, on the proposed revision to the agreement, and solicited their comments. Copies of the proposed revised agreement were available at this meeting. Comments received from the State and AULGs were incorporated into the agreement.

OGC has reviewed the procedural agreement and has no legal objection. There are no resource, information management, or information technology impacts expected as a result of the revised Procedural Agreement.

William D. Travers  
Executive Director for Operations

CONTACT: Chad J. Glenn, NMSS/DWM  
(702) 794-5046

Attachment: [Agreement Between DOE/OCRWM and NRC/NMSS Regarding Pre-licensing Interactions](#)

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ATTACHMENT

## **AGREEMENT BETWEEN DOE/OCRWM AND NRC/NMSS REGARDING PRELICENSING INTERACTIONS**

November 16, 1998

### **1 PURPOSE**

- 1.1 This Prelicensing Agreement describes general guidelines for communications between the staffs and management organizations of the Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) and the Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards (NMSS), including senior management and contractors designated by either agency, during the prelicensing period with respect to all activities preparatory to DOE's submission of an application for authorization to construct and operate a geologic repository under section 114 of the Nuclear Waste Policy Act (NWPA).
- 1.2 This Prelicensing Agreement supersedes the Procedural Agreement@ and the Project-Specific Agreement", as revised in 1993.
- 1.3 No action taken pursuant to this agreement shall be deemed to constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, its officers, and staff, in any licensing proceeding.
- 1.4. Nothing in this agreement shall be construed to confer rights to any party other than to DOE and NRC.

### **2 DEFINITIONS**

Appendix 7 Meeting - An Appendix 7 Meeting is a meeting between the NRC On-Site Representative (OR), including any NRC personnel assigned to the OR, and DOE-Yucca Mountain Site Characterization Office (YMSCO), including contractors and subcontractors. These meetings, described in Appendix 7 of this Agreement, do not

constitute interactions within the intent of Section 3 of this agreement and will not require the preparation of written reports or meeting summaries. These meetings are intended to be focused discussions of technical topics on site characterization and related activities. At the discretion of DOE and NRC, external parties may be notified and invited to observe Appendix 7 meetings and field trips subject to identification requirements and compliance with applicable access control measures for security, radiological protection, and personnel safety. No commitments may be made at Appendix 7 Meetings.

**Commitments**—An explicit statement to take a specified action agreed to or volunteered by the OCRWM or NMSS to one another, an external governmental agency or entity identified in the NWPA as having a right to participate. Commitments require action within a specified period or by a specified date. All commitments will be documented in correspondence by the party(ies) making the commitment. Unless expressly provided in writing, no commitments made to NRC pursuant to this prelicensing agreement are to be interpreted as becoming licensing commitments or conditions.

**Interactions**—Technical Exchanges, Management Meetings, or Site Visits. Management Meetings and Technical Exchanges are planned interactions open to public observation subject to the *NRC Policy Statement: Staff Meetings Open to the Public*. Technical Exchanges or Management Meetings include but are not limited to planned or scheduled DOE/NRC face-to-face meetings as well as alternative forms of planned or scheduled DOE/NRC interactions such as videoconferences. These interactions will comply with the *NRC Policy Statement: Staff Meetings Open to the Public* whether conducted by NRC or DOE. Certain interactions require written reports, as described in Section 3.5, and are subject to public notification and observation.

**Management Meeting**—A scheduled interaction held whenever necessary to review the summary results of Technical Exchanges; to review the status of outstanding items and issues; to discuss plans for resolution of outstanding items and issues; to update the schedule of Technical Exchanges and other actions needed for staff resolution of open items regarding the site characterization program; and to consult on what guidance is advisable and necessary for NRC to prepare. Unresolved management issues will be promptly elevated to upper management for resolution. Management Meetings are conducted to discuss programmatic issues related to program policy, schedules, scope, and major assignments of resources. Any commitments that are made during these meetings will be documented in correspondence by the party(ies) making the commitment. These meetings are subject to the *NRC Policy Statement: Staff Meetings Open to the Public* whether conducted by NRC or DOE.

**Observers**—A representative(s) sent to primarily observe but not participate substantially in an activity (as in a meeting, audit, or surveillance). Observers may furnish questions, observations, and recommendations generally at the beginning and end of meetings. Direct communication between observers and meeting participants

during a meeting, audit, or surveillance is generally discouraged in order to minimize disruption.

**Programmatic Issues**—Issues discussed primarily at Management Meetings related to program policy, schedules, scope, and major commitments of resources.

**Site Visit**—A scheduled interaction held between DOE and NRC technical staff to: explain technical information related to ongoing field or laboratory site characterization and related activities; and visit locations at the site for field briefings and discussions of preliminary data and interpretation derived from field work. The primary purpose of a Site Visit is for both agencies to benefit from discussion of technical topics in the field. Site Visits will not require the preparation of written reports or meeting summaries. Site Visits will not be used as a forum to officially establish or change technical and/or regulatory positions, establish commitments, nor agree to courses of action. Representatives from the State of Nevada, affected units of local government, any affected Indian tribes, the public, and other interested parties may observe the proceedings of Site Visits consistent with security access, logistical arrangements, and safety rules. Proceedings covered by Appendix 7 of this agreement do not apply to Site Visits.

**Technical Exchange**—A scheduled interaction between DOE and NRC technical/licensing staff expected to focus primarily on technical or regulatory issues and to: review and consult on interpretations of data; identify potential licensing issues; discuss specific technical and/or regulatory topics, the sufficiency of available information and data, methods and approaches for the acquisition of additional information, and data as needed to facilitate NRC reviews and evaluations and for staff resolution of such potential licensing issues. Technical Exchanges may be the forum for gaining an understanding and discussing technical or regulatory issues and the acceptability of actions on the part of both agencies, however, they can not be used to officially establish or change positions or make commitments. These meetings are subject to the *NRC Policy Statement: Staff Meetings Open to the Public* whether conducted by NRC or DOE.

### **3 GUIDELINES TO CONDUCT OCRWM AND NMSS INTERACTIONS**

- 3.1 OCRWM and NMSS may conduct interactions on topics of mutual agreement at the request of either agency. Open, scheduled interactions may be either Management Meetings, Technical Exchanges, or Site Visits (see Section 2, "Definitions"). Proceedings covered by Appendix 7 of this agreement do not constitute interactions within the context of this agreement.
- 3.2 Technical Exchanges are expected to focus on technical or regulatory issues, and are intended to be staff-to-staff interactions, with respective contractor staff included as needed. Technical Exchanges may be the forum for gaining an understanding and discussing technical or regulatory issues and the acceptability

of actions on the part of both agencies, however, they cannot be used to officially establish or change positions or make commitments.

- 3.3 Management Meetings are generally expected to focus on programmatic issues. Verbal agreements can be made by the managers attending Management Meetings; however, any commitments will be documented in accordance with Section 3.5 of this agreement.
- 3.4 A teleconference between OCRWM and NMSS should be held approximately two weeks before each Technical Exchange and Management Meeting to reach agreement on an agenda.
- 3.5 Technical Exchanges and Management Meetings shall have bilateral minutes that summarize and document the meeting. The concise bilateral minutes shall include: (i) brief summaries of the presentations made and the discussions held; (ii) regulatory or technical interpretations or positions; (iii) identification of points of agreement and disagreement; and (iv) documentation of commitments made at Management Meetings by either organization. Attachments are to include a list of attendees and copies of presentation materials and any view graphs used at the meeting. Copies will be provided to the State, affected units of local government, affected Indian Tribes, and the NRC and DOE Public Document Rooms.
- 3.6 Representatives from the State of Nevada, affected units of local government, any affected Indian tribes, the public, and other interested parties may observe the proceedings of Technical Exchanges, Management Meetings, or Site Visits consistent with security access, logistical arrangements, and safety rules. Such representatives may provide comments at the opening and ending of the meeting.
- 3.7 Consistent with *NRC Policy Statement: Staff Meetings Open to the Public*, the NRC will assume the lead to keep all parties informed about schedules for all OCRWM and NMSS Technical Exchanges, Management Meetings, and Site Visits.
- 3.8 Unscheduled OCRWM-NMSS communications may occur by telephone, electronic mail, or in person. Unscheduled communications shall not be a substitute for an interaction as defined in Section 2 of this procedure.
- 3.9 Closed, scheduled interactions between OCRWM and NMSS may also be held, according to the limited exemptions and circumstances described in the *NRC Policy Statement: Staff Meetings Open to the Public*.
- 3.10 At the invitation of OCRWM and consistent with NRC policy, NRC staff may attend OCRWM sponsored or conducted meetings as observers and may

participate by providing comments. An OCRWM meeting attended by NRC staff as an observer shall not be a substitute for an interaction as defined in Section 2 of this procedure.

- 3.11 Both OCRWM and NMSS will identify management points of contact who have signature authority for correspondence to the other organization. Each organization will identify points of contact for informal communications and questions and will update these points of contact as necessary.
- 3.12 NMSS staff, and consistent with security access and safety rules, representatives from affected units of state, local governments, and Indian Tribes, may participate as observers at OCRWM quality assurance audits and surveillances provided that such participation does not unreasonably interfere with or delay such audits and surveillances. The OCRWM audit team leader is responsible for the direction of the audit. Observers are encouraged to participate fully by furnishing their questions, observations, and recommendations in written form to the team leader (or sub-team leader). All inquiries will be addressed. NMSS may perform audits of OCRWM and OCRWM contractor quality assurance programs. Quality assurance audits and surveillances are not considered interactions in the context of this agreement.
- 3.13 Interactions between NMSS and DOE program offices other than OCRWM concerning activities preparatory to DOE's submission of an application for authorization to construct and operate a geologic repository under Section 114 of the NWPA will be conducted in accordance with the provisions of this agreement.
- 3.14 Guidelines specific to project activities are included in the appendices to this Agreement.
- 3.15 The terms of this Agreement regarding these interaction guidelines may be amended at any time by mutual consent, in writing. This agreement and subsequent revisions will become effective upon the date of issuance.
- 3.16 Appendix 7, "Agreement Concerning the Nuclear Regulatory Commission On-Site Representatives for the Repository Project Prior to Licensing", provides a description of activities of the NRC On-Site Representatives.

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Lake Barrett, Acting Director  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy

Date

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Martin J. Virgilio, Deputy Director  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission

Date

## APPENDIX 1

### AGREEMENT BETWEEN YMSCO AND NMSS EFFECTIVE PRIOR TO THE SUBMITTAL OF A LICENSE APPLICATION

Appendix 1 specifies and implements provisions for activities and communication during the prelicensing period that may occur between the DOE Yucca Mountain Site Characterization Office (YMSCO) and the NRC Office of Nuclear Material Safety and Safeguards (NMSS) under the “Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions.” The activities include: (i) identifying YMSCO and NMSS points of contact for formal communications and informal points of contact for other communications and questions; (ii) accessing data, documents, and records by YMSCO and NMSS; and, (iii) accessing YMSCO site characterization samples and collection of samples by NMSS and contractor staff. Nothing in this Appendix shall be construed either to modify the “Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions” in any way or to confer rights on any party other than YMSCO and NMSS.

#### 1.0 Identification of YMSCO and NMSS Points of Contact

Points of contact identified by YMSCO and NMSS, for formal and informal communications, will be transmitted to the other organization through the point of contact designated for formal communication. Point of contact information will include the names of all points of contact, designation for formal or informal communication, their mailing and e-mail addresses, and telephone and fax numbers. YMSCO designates the following individual as the point of contact for formal communications with NMSS:

Assistant Manager for Licensing  
Yucca Mountain Site Characterization Office  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy  
P.O. Box 30307  
North Las Vegas, NV 89036-0307

NMSS designates the following individual as the point of contact for formal communications with YMSCO:

Director  
Division of Waste Management  
Office of Nuclear Material Safety and Safeguards



U.S. Nuclear Regulatory Commission  
11545 Rockville Pike  
Two White Flint North  
Rockville, MD 20850

## **2.0 Access to Site Data, Documents and Records**

- 2.0.1 Written responses will be provided to written questions, comments, requests for data, samples, or documents, and requests for evaluations that are made by either YMSCO or NMSS. Requests by either organization for large data sets are subject to negotiation of a schedule for availability. The requesting organization is responsible for obtaining and providing to the responding organization any clearances needed for internal reproduction of published documents covered by copyrights.
- 2.0.2 YMSCO has developed and will maintain a data base identifying site characterization technical data collected by YMSCO, except those data excludable by law. The information contained in this data base includes a description of the data, dates when the data were acquired or developed, the quality assurance status of the data, and the storage location of the data.
- 2.0.3 Data sets from the YMSCO technical data management system are available to the NMSS upon written request. Requests must specify the data sets' identifications to enable retrieval from YMSCO's Technical Data Base, and format parameters, such as hard copy or electronic format, and any other applicable format items, needed to assemble and provide the data. All data provided by the DOE to the NRC prior to the submittal of the License Application are given with the following caveat: "CAUTION: Interpretations based upon these data are subject to change as more data are acquired, developed, or evaluated."
- 2.0.4 Upon request, at NRC's or DOE's option, each organization will provide the other at least one controlled copy of any specially developed or modified noncommercial software and available documentation used to evaluate site characterization and related activities, performance assessments, and design analyses subject to resolution of proprietary, privileged, software licensing agreements, and availability of the code.
- 2.0.5 OCRWM records or documents must be authorized as available by YMSCO staff. Generally, records and documents that have completed a final DOE review shall be made available to the ORs upon request; however, DOE shall only provide access to view but not to copy or retain materials that are in preparation, if such access is specifically requested by the ORs. Records or documents may not be authorized as available by contractor staff.

### 3.0 Sample Access, and Sample and Data Collection by NMSS and Contractor Staff

Written requests from NMSS for collection of samples or field data will be reviewed for acceptance by YMSCO to ensure that the collection will not compromise site characterization and related activities, that procedures have been established for the collection of the sample(s) or data and provided that such requests do not unreasonably interfere with site characterization and related activities. Once a request has been accepted, YMSCO will arrange for timely collection of the sample(s) or data according to applicable YMSCO procedures, and prepare and ship the sample(s) or transmit the data. If collection and/or transport of the sample(s) or collection and/or transmittal of the data will be delayed, YMSCO will notify NMSS of the proposed schedule for collection and delivery.

If samples must be collected by NMSS or contractor staff, NMSS or contractor staff will follow applicable YMSCO, DOE Nevada Operations Office, and Nellis Air Force Base procedures and fulfill specified training requirements for access to the sample site(s), including surface and underground access control, site security, radiological safety, personnel safety, and protection of wildlife and the environment. For example, if samples or data are to be collected by NMSS or contractor staff, the NMSS and contractor staff will use YMSCO's sample acquisition and handling procedures to obtain samples acquired as part of the site characterization program. Requests will be made in writing for samples for which no process of acquisition has been identified in a YMSCO procedure. YMSCO will review the request with NMSS staff to ensure that the location of the sample or the amount of sample material does not adversely impact the needs of the site characterization program. If no adverse impacts are identified, YMSCO will arrange for the NRC to receive or collect the requested materials. NMSS will request, through the YMSCO Project Manager, use of DOE rights-of-way for access to sample collection sites and will comply with the land access and environmental protection requirements.

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J. Russell Dyer, Project Manager  
Yucca Mountain Site Characterization Office  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy

Date

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John T. Greeves, Director

Date

Division of Waste Management  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission

## **APPENDIX 2 - OWAST [RESERVED]**

This appendix is reserved for any future agreement applying to communications between the Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) and the Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards (NMSS) related to spent fuel storage or transportation authorized under the Nuclear Waste Policy Act (NWPA) and any future amendments to the NWPA. Such an agreement will become effective upon an exchange of letters between the parties agreeing to adopt this agreement for such activities.

**APPENDIX 3 - OTHER DOE PROGRAM OFFICES [RESERVED]**

**APPENDIX 4 - NRC POLICY STATEMENT: STAFF MEETINGS OPEN TO THE PUBLIC**

**APPENDIX 5 – RESERVED**

**APPENDIX 6 – RESERVED**

## APPENDIX 7

### AGREEMENT CONCERNING THE NUCLEAR REGULATORY COMMISSION ON-SITE REPRESENTATIVES FOR THE REPOSITORY PROJECT PRIOR TO LICENSING

The purpose and objective of the on-site representative (OR) is to serve as a point of prompt informational exchange and consultation, to preliminarily identify concerns about investigations relating to potential licensing issues, and to serve as a point of contact for informal communications between NMSS and YMSCO. This appendix is intended to supplement the base agreement and to detail the guidelines which will govern communication between the NRC OR, including any NRC personnel assigned to the OR, and DOE and its contractor personnel (prime and sub) through the project's Assistant Manager for Licensing. Any communications between the OR and DOE, its contractors, or subcontractors identified in this appendix will not constitute interactions within the intent of Section 3 of the base agreement and will not require the preparation of written reports or meeting summaries. These meetings are intended to be focused discussions of technical topics on site characterization and related activities. At the discretion of DOE and NRC, external parties may be notified and invited to observe OR meetings and field trips subject to identification requirements and compliance with applicable access control measures for security, radiological protection, and personnel safety. Communication between the OR and DOE and its contractors and subcontractors are not intended to interfere with or replace other channels of NRC/DOE communications and procedures for information release identified in the base agreement and Appendix 1.

The following points are agreed to:

1. The OR can attend any meetings on-site or off-site dealing with technical questions or issues related to precicensing work following notification of the cognizant DOE project representative responsible for the meeting as discussed below. Such notification shall be by memorandum, telephone or personal contact and will be given at least 24 hours in advance where DOE has provided adequate prior notification to the OR. The meetings may involve solely DOE or solely DOE's contractors (prime and sub), or any combination of DOE with their contractors. If objections to the OR attendance are voiced for any reason, the reason should be specified. Such objections will be infrequent and will be exceptions to the rule. If the OR does not agree with DOE objections, it will be raised to a higher management level for resolution. If resolution cannot be achieved, the OR will not attend the meeting in question.
2. The OR may communicate orally (in person or by phone) with persons employed by DOE, DOE's prime contractors or the prime's subcontractor, (on-site or off-

site), providing that the following procedures are followed. If practicable, the OR will arrange for all individual sessions with prime contractor and subcontractor staff by contacting the YMSCO point of contact, or designee. If they cannot be contacted, the OR will attempt to contact the proper prime contractor, section, or department manager. As a minimum, the OR will give timely notification of all such sessions to DOE and the affected contractor or participant(s) management as soon as possible. The OR will avoid discussions with personnel when it would appear to disrupt important duties and will seek to schedule meetings at a mutually convenient time. It is at the option of DOE, in consultation with participant management, as to whether or not a staff member, supervisor, or third party is to be present. No record of such discussions is required; however, questions that are raised or other issues that arise as a result of these interactions will be reported by the participant to the YMSCO point of contact, or designee.

When NRC headquarters or contractor staff is temporarily assigned to the OR office, the NRC Chief, Performance Assessment and HLW Integration Branch, or designee, will notify DOE's Assistant Manager for Licensing of the assignment at least one week prior to the assignment.

3. The DOE project office, DOE prime contractors, and their subcontractors will provide the OR access to records which would be generally relevant to a potential licensing decision by the Commission as follows. Upon request by the OR, DOE or the DOE contractor or subcontractor shall provide: (i) copies of any records of data; (ii) records which document the analyses, evaluations, or reduction of data; or (iii) records which contain information deduced by reason. These records will be made available to the OR, after the documentation has been reviewed and approved in accordance with the appropriate project office administrative procedure. Records that have not been reviewed and approved by the project office shall be made available for viewing, but not to copy or to retain, at any stage of completion. Requests by the OR for release of such records shall be made through and authorized by the YMSCO point of contact, or designee.
4. Copies of predecisional and preliminary drafts of documents required by the Nuclear Waste Policy Act of 1982 as amended, or related to prelicensing activities, which have not been approved by DOE, will not be provided to the OR without DOE approval. Documents of this type may be made available by authorized DOE personnel, for review in DOE or DOE contractor offices. Such documents may not be authorized as available by a DOE contractor alone. Any such documents made available are for the use of the OR and shall not be placed in any NRC public document room.
5. The OR does not have the authority to direct DOE, its contractors or subcontractors to perform any work nor does the OR have stop work authority.

Any formal identification of questions or issues for investigation by DOE that could result in contractor or subcontractor work must be formally presented to DOE through the NRC Chief, Performance Assessment and HLW Integration Branch in writing.

6. The OR will attend on-site meetings upon request by the DOE project office or prime contractor onsite whenever possible. The OR will provide any records which would normally be available under 10 CFR Part 2.790 of the Commission's regulations to project participants upon request to copy. If convenient, copies of such records will be provided by the OR.
7. The OR shall be afforded access to the site, research facilities, and other contractor and subcontractor areas to observe testing or other data gathering activities, in progress, as part of site characterization and related activities subject to compliance with the applicable requirements for identification, and applicable access control measures for security, radiological protection and personnel safety, provided that such access shall not interfere with the activities being conducted by DOE or its contractors and that any discussions conducted during such access shall comply with Point 2 above. Such access shall be allowed as rapidly as it is for DOE or DOE contractor employees upon display of an appropriate access identification badge, or, if badging is not possible for national security reasons, upon prior notification to DOE or cognizant contractor supervisory personnel (by memorandum, telephone, or personal contact). When an access identification badge is available to DOE or DOE's contractors and subcontractors on a routine basis, it shall be made available to the OR upon completion of the required security clearances and appropriate radiological and personnel safety training. DOE will ensure that any training required is provided to the OR.
8. NRC can videotape or photograph any inanimate objects or geologic features associated with site characterization and related activities at the Yucca Mountain Site consistent with Nevada Test Site security. Additionally, upon request from the OR, DOE will provide NRC videotape footage of personnel performing site characterization and related activities. If requested, the OR and other NRC staff will be permitted to accompany DOE during the videotaping.
9. DOE YMSCO may provide, to the NRC OR, the information required to execute DOE responsibilities under Appendix 7 of this agreement by informal note, by telephone, or by personal contact. Such communications shall adhere to the procedures for communication and information release specified elsewhere in this agreement.
10. Meetings and field trips conducted as described in this section are not to be considered as opportunities to establish or alter regulatory positions or commitments. No agendas, minutes, or records of these meetings or field trips



are required. Matters that arise may be (i) reported to YMSCO management by the ORs or other NRC representatives assigned to the OR's office through the YMSCO points of contact, or designees, or (ii) discussed in internal meeting summaries prepared for each organization's management.

11. Prior notification of external parties, including State, affected units of local government, any affected Indian Tribes, or the general public, is not required for field trips or meetings under this Appendix. At the discretion of DOE and NRC, external parties may be notified and invited to observe OR meetings and field trips subject to identification requirements and compliance with applicable access control measures for security, radiological protection, and personnel safety.
12. NMSS may station on-site representatives at any OCRWM project office or work site to serve as points of prompt information exchange and consultation. At such time as the NRC ORs are stationed at the site, they are to be provided with office space that is near the DOE project office and site activities.