

STATEMENT SUBMITTED
BY THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
TO THE
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING
YUCCA MOUNTAIN PROJECT:
PERSISTENT MANAGEMENT AND QUALITY ASSURANCE PROBLEMS

PRESENTED BY
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Mr. Chairman and members of the Subcommittee, it is a privilege to appear before you today to share with you the U.S. Nuclear Regulatory Commission's (NRC) perspective on the role of quality assurance (QA) in the Department of Energy's (DOE) preparation to apply for a license for a proposed high-level radioactive waste repository at Yucca Mountain, Nevada.

As you are aware, the Nuclear Waste Policy Act of 1982, as amended, assigns roles and responsibilities to various federal agencies for developing, licensing, and regulating a proposed repository. Through a process outlined in the Act, DOE is required to pursue development of a proposed repository, the Environmental Protection Agency (EPA) is responsible for establishing environmental standards specific for the proposed repository, and the NRC is required to establish regulatory requirements that implement EPA standards and to establish a licensing process for the proposed repository. As part of this licensing process, NRC is responsible for reviewing DOE's license application to ensure that the NRC's regulatory requirements, primarily in 10 CFR Part 63, are met.

The NRC observes and comments on the DOE quality assurance program as part of NRC's pre-licensing activities and has periodically identified deficiencies that DOE should address to meet NRC's expectations. For example, it appears that the Yucca Mountain Project staff's implementation of their quality assurance program is not consistent with the program, resulting in errors and problems that I will discuss later.

As required in 10 CFR Part 63, DOE's quality assurance program governs all activities necessary to provide adequate confidence that the geologic repository and its structures,

systems, and components will perform satisfactorily in service. DOE's quality assurance program applies to the design of structures, systems, and components important to safety and to the evaluation of natural barriers important to waste isolation. Demonstrating safety for a geologic repository over many years will require clear articulation of the safety of the integrated repository system including geologic and engineered barriers. It also will require a clear demonstration of the safety of preclosure operations for handling of spent nuclear fuel and other high-level radioactive waste. Implementation of an effective quality assurance program during the pre-licensing, licensing, and operational periods will ensure that planning and execution of repository activities are coherent, clear, and well documented, as well as consistent with safety requirements.

NRC's understanding of the importance of an effective quality assurance program comes from our extensive experience in licensing commercial nuclear activities. This experience suggests that establishing an effective quality assurance program is an essential aspect of a license application. The application should clearly articulate the technical basis for demonstrating compliance with the regulatory requirements of 10 CFR Part 63 in order for the NRC staff to make a timely licensing decision after a thorough regulatory review.

A quality assurance program helps ensure that a systematic approach is used to address all factors important to repository safety and ensure that corrective actions are taken when any inconsistencies or weaknesses are identified. The DOE's implementation of an effective quality assurance program to ensure that technical information, on which NRC would rely in making its licensing decision, must be traceable, transparent, consistent, and defensible. In addition, if NRC grants DOE authorization to construct a repository, the quality assurance

program would be critical to ensuring that DOE constructs the repository in accordance with licensing requirements and that the subsequent operation of the facility will be safe.

During the pre-license application phase of the Yucca Mountain Project, NRC staff is observing DOE activities, to verify that DOE clearly understands NRC requirements. NRC Headquarters' staff and On-Site representatives review the implementation and effectiveness of DOE's quality assurance program by performing independent reviews, observing audits and surveillances performed by DOE and its contractors, and monitoring significant quality-affecting activities. While no regulatory conclusions are made during these observation activities, NRC does provide its observations to DOE for their consideration and action, as appropriate.

For example, between November 2003 and January 2004, NRC staff performed an independent review of important DOE model reports that were intended to support DOE's safety case as well as some quality-affecting activities. Through independent technical work, NRC had identified the information in these reports as being significant to a safety demonstration. During the review, NRC staff identified concerns with the clarity and sufficiency of some aspects of the technical basis and information in the model reports. Also, NRC staff identified concerns with the effectiveness of some of DOE's corrective actions. NRC staff concluded from its review that the number and similar pattern of concerns that it found in the model reports suggest that other model reports may have similar deficiencies. NRC also concluded that if DOE continued to use its existing policies, procedures, methods, and practices at the same level of implementation and rigor, then the NRC staff's safety review of a potential license application could be significantly extended because of the NRC's need for a large

volume of additional information in some areas. Consequently, the NRC could be prevented from making a timely decision regarding issuance of a construction authorization to DOE.

NRC staff members also observe DOE audits of quality assurance program implementation to determine their effectiveness in identifying issues that pertain to safety in DOE's design for the proposed repository. Of the audits observed, we have noted that the auditors were qualified, trained, and independent of the areas being audited, and most audits were adequate in assessing the activities being audited and identifying issues. For example, NRC observers of a DOE September 2005 audit of design engineering products relating to the Fuel Handling and Canister Handling Facilities determined that the audit was effective in assessing the adequacy, implementation, and effectiveness of technical products and processes. NRC staff will continue to observe DOE activities in other areas of design work, such as Transportation, Aging, and Disposal Canister, to ensure that DOE's QA program is appropriately applied in developing the design and its safety basis.

Consistent with our pre-licensing role, NRC staff has sampled a number of DOE activities to determine the effectiveness of the quality assurance program implementation as it pertains to safety in DOE's design for the Yucca Mountain Project. NRC staff does not review all quality assurance program implementation activities; rather our observations are conducted on a sample basis with additional actions taken to address issues. On the other hand, NRC staff has identified other concerns during these observations as illustrated by the following examples:

(1) NRC observers of an August 2005 DOE audit of scientific activities supporting the Waste Package and Drip Shield Degradation models did not agree with the DOE auditors' conclusion that Lawrence Livermore National Laboratories effectively implemented certain aspects control of maintenance and test equipment and corrective action. As a result of the NRC's observations, DOE is performing additional reviews in this area.

(2) NRC observers of a December 2005 DOE audit of the adequacy, implementation, and the effectiveness of the Corrective Action Program commented that the auditors had elected not to perform the reviews necessary to determine the effectiveness of the overall corrective action process as described in DOE's audit plan. As a result of the NRC observers' comments, DOE reviewed corrective action effectiveness and found significant issues in the trend process. During the current year, NRC staff reviews have noted that DOE has made significant changes to its corrective action and trending process as a result of NRC comments and Yucca Mountain Project internal audit findings and condition reports. In particular, the trending process has been changed to include greater management attention to the review of condition reports for emerging trends, identification and monitoring of emerging and adverse trends, identification of the extent of conditions, and more effective and immediate action to address identified trends.

Current quality assurance program implementation issues are of concern to NRC staff. These issues include those identified at the United States Geological Survey, DOE's design controls and requirements flow-down, and test equipment calibration at Lawrence Livermore

Labs. These issues are of concern because they raise questions about the systematic and effective implementation of DOE's quality assurance program, which is an integral component of a high-quality license application. NRC staff will continue to review DOE's technical approaches, findings, and conclusions regarding quality assurance issues, will closely observe DOE's corrective actions, and will continue to bring these issues to DOE's attention.

To effectively communicate requirements, issues, and concerns, NRC management and staff met with DOE management and staff at Technical Exchanges and Management Meetings, which are open to the public. Technical Exchanges are also held as needed to gain an understanding of technical or regulatory issues. On March 21, 2006, a Quarterly Management Meeting between NRC and DOE was conducted at NRC headquarters in Rockville, Maryland, to discuss programmatic issues. During that Quarterly Management Meeting, many of these quality assurance program implementation issues were discussed and DOE presented its plans for resolving the issues. Recent NRC staff observations of Yucca Mountain Project activities have noted that the DOE plans for addressing current QA program issues with design control and requirements flow-down appear to be directed at the right problems and to be using good approaches for correcting the root causes. Recent Yucca Mountain Project staff additions have brought in management personnel with previous experience in implementing a quality assurance program for NRC-required activities at NRC-regulated facilities.

In March 2006, the Government Accountability Office (GAO) issued its report, "Yucca Mountain: Quality Assurance at DOE's Planned Nuclear Waste Repository Needs Increased Management Attention." In its report, the GAO drew three conclusions: (1) "DOE has had a

long history of quality assurance problems at the Yucca Mountain project”; (2) “... the project’s performance indicators and other key management tools were not effective...”; and; (3) “DOE continues to face quality assurance and other challenges.” NRC staff has reviewed the GAO report and found that these conclusions are consistent with what the NRC has observed, some of which I have mentioned today. For example, NRC has observed, and informed DOE, that the Yucca Mountain Project corrective action program has not been effective in identifying the extent and root causes of QA problems, and has not effected timely actions and resolutions.

In conclusion, the NRC staff has noticed improvements in the effectiveness of DOE’s quality assurance program implementation. We will, however, continue to review their QA implementation during the pre-license application period and will provide feedback to DOE on our observations. NRC review of any license application submitted by DOE will ensure that QA requirements will be satisfied, and that appropriate commitments have been made for the DOE QA program implementation for any subsequent activities. QA program implementation for any Yucca Mountain Project activities subsequent to a license application would be monitored by NRC QA oversight and inspection to ensure the adequate protection of public health and safety and the environment.