

April 2004

YUCCA MOUNTAIN

Persistent Quality Assurance Problems Could Delay Repository Licensing and Operation



G A O

Accountability ★ Integrity ★ Reliability



Highlights of [GAO-04-460](#), a report to congressional requesters

Why GAO Did This Study

The Department of Energy (DOE) must obtain a license from the Nuclear Regulatory Commission (NRC) to construct a nuclear waste repository at Yucca Mountain, Nevada. In licensing, a quality assurance program helps ensure that the information used to demonstrate the safety of the repository is defensible and well documented. DOE developed a corrective action plan in 2002 to fix recurring problems with the accuracy of such information. This report assesses the status of corrective actions and the adequacy of DOE's plan to measure the effectiveness of actions taken.

What GAO Recommends

GAO recommends that DOE revise action plan goals and close the plan once sufficient evidence exists showing that the actions have succeeded. In commenting on the report, DOE disagreed with the findings and recommendations, stating, among other things, that GAO mischaracterized the action plan and the results of independent reviews. GAO disagrees—the report correctly describes the plan and the findings of the reviews. NRC agreed with GAO's conclusions but suggested that DOE be given the flexibility to choose alternative approaches to achieve and measure performance. GAO agrees, provided that any approach include objective measures and time frames to assess effectiveness.

www.gao.gov/cgi-bin/getrpt?GAO-04-460.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robin M. Nazzaro at (202) 512-3841 or nazzaror@gao.gov.

YUCCA MOUNTAIN

Persistent Quality Assurance Problems Could Delay Repository Licensing and Operation

What GAO Found

DOE has reportedly implemented most of the actions in its 2002 corrective action plan, but recent audits and assessments have identified lingering quality problems with data, models, and software and continuing management weaknesses. Audits revealed that some data sets could not be traced back to their sources, model development and validation procedures were not followed, and some processes for software development and validation were inadequate or not followed. DOE believes these problems have not affected the technical basis of the project; however, they could adversely affect the licensing process. Recent assessments identified continuing management weaknesses in the areas of roles and responsibilities, quality assurance policies and procedures, and a work environment that did not foster employee confidence in raising concerns without fear of reprisal. NRC has acknowledged DOE's effectiveness in identifying quality problems, but recently concluded that quality problems could delay the licensing process.

DOE cannot assess the effectiveness of its 2002 plan because the performance goals to assess management weaknesses lack objective measurements and time frames for determining success. The goals do not specify the amount of improvement expected, how quickly the improvement should be achieved, or how long the improvement should be sustained before the problems can be considered corrected. DOE recently developed a measurement tool that incorporates and revises some of the goals from the action plan, but most of the revised goals continue to lack the necessary time frames needed to determine whether the actions have corrected the recurring problems. A recently completed DOE review of the 2002 plan found that the corrective actions have been fully implemented. However, the review also noted the effectiveness of the actions could not be evaluated because many of the plan's goals lacked the level of objectivity and testing needed to measure effectiveness.

Quality Problems with Data, Models, and Software

| Quality problems by type | Year | | |
|--|------|------|------|
| | 1998 | 2001 | 2003 |
| Data | | | |
| Data sets could not be tracked back to original sources | • | | • |
| Failure to comply with data management procedures | • | | • |
| Data procedures not adequately defined | • | | • |
| Unqualified data used to support models | • | | • |
| Models | | | |
| Inadequate procedures for validating and controlling development of models | • | • | |
| Failure to implement procedures for model development and validation | • | • | • |
| Software | | | |
| Ineffective processes for ensuring performance of software to support models | • | • | • |
| Failure to comply with procedures for managing software | | • | • |

Source: GAO analysis of DOE documents.

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Abbreviations

| | |
|-------|---|
| DOE | Department of Energy |
| NRC | Nuclear Regulatory Commission |
| OCRWM | Office of Civilian Radioactive Waste Management |
| OMB | Office of Management and Budget |

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United States General Accounting Office
Washington, D.C. 20548

April 30, 2004

The Honorable Harry Reid
United States Senate

The Honorable John Ensign
United States Senate

High-level nuclear waste, created as a by-product of the nuclear power process in reactors, can remain highly radioactive for hundreds of thousands of years, endangering the public if not properly disposed. Storing this waste safely is therefore of vital interest to the nation. Currently, more than 50,000 metric tons of this waste is being stored at 72 sites across the country. In 2002, Congress approved the President's recommendation of Yucca Mountain, Nevada, 90 miles from Las Vegas, as a suitable site for the Department of Energy (DOE) to construct and operate a geologic repository to safely and permanently dispose of this waste. To construct and operate the repository, DOE must obtain a license from the Nuclear Regulatory Commission (NRC). As part of the license application, DOE must, among other things, demonstrate an effective quality assurance program that ensures the safe construction and operation of a repository, protecting public health and safety. DOE plans to submit a license application by December 2004 and is following a demanding schedule to meet this date. NRC is reviewing an extensive amount of data as part of a prelicensing agreement with DOE.

Before granting a license, NRC requires nuclear facilities to develop a quality assurance program that ensures that the technical information submitted in support of a license application—such as scientific data, models, and details on design and construction—is well documented and defensible. The quality assurance program involves a two-part process that (1) requires program staff to follow procedures to help ensure the reliability of information and (2) uses quality assurance auditors to verify that the procedures have been followed. Both program staff and quality assurance auditors are required to identify when procedures are not being followed or when they encounter problems with the procedures. DOE and contractor quality assurance auditors periodically assess compliance with

procedures.¹ In cases where a significant problem is found (DOE's criteria refer to significant problems as significant conditions adverse to quality), quality assurance personnel and program managers follow specific steps to analyze and correct the problem:

1. Quality assurance auditors or program personnel complete a corrective action report that describes the problem and the need for corrective action.
2. Program managers conduct a root-cause analysis of the problem.
3. Program managers identify corrective actions that address the root cause(s) to prevent the problem from recurring—these actions are included in a corrective action plan.
4. Program managers implement these corrective actions and quality assurance personnel verify that they have been implemented.
5. Quality assurance personnel close the corrective action report, and program managers later conduct an effectiveness review.
 - a. If actions are determined ineffective, the process begins again with the issuance of a new corrective action report.
 - b. In cases involving more significant problems, an effectiveness review may be conducted prior to closing the corrective action report.

In 1998, DOE's quality assurance auditors identified significant problems with data sources, validation of scientific models, and software development and issued three corrective action reports. For data sources, DOE reported that it could not ensure that all data needed to support the scientific models could be tracked back to original sources or that the data had been properly collected. For validation of models, DOE reported that it had no standardized process to develop the scientific models needed to simulate geological events. For software, DOE reported that it had no

¹DOE and its subcontractor, Navarro Quality Services, which is a division of Navarro Research and Engineering, Inc., are responsible for carrying out quality assurance oversight activities, including conducting audits. DOE's primary contractor at the site, Bechtel/SAIC Company, LLC, is responsible for implementing DOE's quality assurance requirements related to ongoing project activities and for conducting audits of line activities.

process for ensuring that the software being developed to support the models would work. As required by DOE's quality assurance procedures, the department conducted a root-cause analysis and issued a corrective action plan in 1999 that identified the needed corrective actions. Following implementation of the actions, DOE considered the issues resolved and closed the corrective action reports. However, problems with models and software resurfaced during 2001 quality assurance audits. As a result, new corrective action reports were completed in May and June 2001, beginning another iteration of the corrective action process.

Recognizing the need to correct these recurring problems, DOE (1) conducted a comprehensive root-cause analysis that included reviews of numerous past self-assessments and independent program assessments and (2) identified weaknesses in management systems, quality processes, and organizational roles and responsibilities. As a result, DOE issued a corrective action plan in July 2002 that addressed both the quality problems with data and models and the management weaknesses.² In addition to the 37 actions in the 2002 plan that addressed models and software, DOE added 35 corrective actions to address management weaknesses that it found in five key areas:

- roles and responsibilities,
- quality assurance processes,
- written procedures,
- corrective action plans, and
- a work environment that allows employees to raise quality concerns without fear of reprisal.

To correct these weaknesses, DOE completed a management reorganization and issued new policy statements to clarify roles and responsibilities, revised the primary quality assurance implementing document, reviewed and revised program procedures, revised the system to correct quality problems, and provided new training for employees to encourage them to raise concerns about quality. To assess the

²Department of Energy, Office of Civilian Radioactive Waste Management, *Management Improvement Initiatives* (Washington, D.C.: July 19, 2002).

effectiveness of its actions in correcting the management weaknesses, DOE developed 13 goals to determine whether the corrective actions were successful, such as achieving decreasing trends in problems attributed to unclear roles and responsibilities, reducing the time required to revise procedures and complete corrective actions, and reducing the number of employee concerns related to the work environment. Because of the significance of these problems, DOE stated in the 2002 corrective action plan that an effectiveness review would be completed prior to closing the corrective action reports and reporting the results to NRC.

In May 2003, at a congressional field hearing, we provided preliminary observations on the Yucca Mountain quality assurance program.³ Specifically, we noted DOE's poor track record in correcting recurring quality assurance problems and provided preliminary observations on recent actions taken to correct these problems. You requested that we continue our evaluation of the quality assurance program at Yucca Mountain, focusing on DOE's actions to correct the recurring quality problems. As agreed with your offices, this report (1) assesses the status of DOE's corrective actions to resolve recurring problems and (2) determines the adequacy of DOE's plan to measure the effectiveness of these actions.

In conducting our work, we met with DOE and contractor officials, assessed the status of DOE's corrective actions, reviewed audits and deficiency reports, and visited the Yucca Mountain project office. We met with NRC officials and reviewed NRC-prepared documents, including observation audits, on-site representative reports, and correspondence between DOE and NRC. We attended several DOE-NRC quarterly quality assurance meetings and met with representatives of the State of Nevada Agency for Nuclear Projects and with representatives of the Nuclear Waste Technical Review Board. Our work was performed from April 2003 to April 2004 in accordance with generally accepted government auditing standards. Our scope and methodology for this review are presented at the end of this letter.

Results in Brief

DOE reports that it has implemented almost all of the corrective actions detailed in its 2002 plan, but recent audits and assessments show that these

³U.S. General Accounting Office, *Nuclear Waste: Preliminary Observations on the Quality Assurance Program at the Yucca Mountain Repository*, [GAO-03-826T](#) (Washington, D.C.: May 28, 2003).

actions have not solved the quality assurance problems or corrected management weaknesses, and that further actions are needed. Quality assurance audits found continuing problems with data, models, and software, including unqualified sources for the data used in modeling repository performance, noncompliance with processes used for the development and validation of models, and ineffective processes for developing software. DOE officials have stated that these findings represent problems with procedures and documentation and do not invalidate the technical products produced using the data, models, and software. However, the persistence of these problems could adversely affect the licensing process because DOE must demonstrate an effective quality assurance program as part of this process. Recent assessments show that management weaknesses remain despite DOE's actions. For example, one assessment notes that staff roles and responsibilities remain poorly defined, and that personnel are still not following procedures. Another assessment concluded that despite communication mechanisms, DOE had not established a climate of trust in the workplace. NRC has acknowledged the ability of DOE's quality assurance auditors to effectively identify quality problems; however, a recent NRC evaluation concluded that quality problems could adversely affect the licensing process.

DOE cannot formally assess the overall effectiveness of its corrective actions because the plan's performance goals to assess management weaknesses lack objective measurements and time frames to determine whether corrective actions have been successful. Most of these goals fail to specify the amount of improvement expected, and none of them specify how quickly the improvement should be achieved or how long the improvement should be sustained before the problems can be considered corrected. For example, one goal calls for a decreasing trend in the average time needed to make revisions in procedures, but it does not specify the desired amount of the decrease, the length of time needed to achieve the decrease, or how long the decrease must be sustained. DOE has recently developed a project measurement tool that incorporates and revises some of the goals from the action plan, but most of the revised goals continue to lack the necessary time frames needed to determine whether the actions have corrected the recurring problems. A DOE independent review of the corrective action plan completed in March 2004 found that the corrective actions from the 2002 plan to address management weaknesses have been fully implemented. However, the review also noted the effectiveness of corrective actions under the plan could not be evaluated because many of the goals in the performance

measurement tool that are linked to the 2002 plan lacked the level of objectivity and testing needed to measure effectiveness.

To ensure proper assessment of the plan, we are recommending that DOE (1) revise the performance goals associated with the 2002 plan to ensure that they are measurable with specific time frames for achieving and maintaining success in each area of the plan and (2) close the plan after it develops evidence to show that the recurring quality assurance problems have been successfully corrected.

In commenting on the report, DOE disagreed with the findings and recommendations, stating, among other things, that we mischaracterized the action plan and the results of several independent reviews. We disagree—the report correctly describes the plan and properly specifies the findings of the reviews. NRC agreed with our conclusions but suggested that DOE be given the flexibility to choose alternative approaches to achieve and measure performance. We agree, provided that any approach include objective measurements and time frames for reaching and sustaining desired performance and include an end point for closing out the 2002 plan.

Background

In 2002, after more than 15 years of scientific investigation, Congress approved the Yucca Mountain site in Nevada as a suitable location for the development of a long-term permanent repository for high-level nuclear waste. DOE is responsible for developing and operating the repository, and NRC is responsible for licensing the repository. DOE is currently preparing an application to submit to NRC by December 2004 for a license to construct the repository. To obtain a license, DOE must, among other things, demonstrate to NRC that the repository will not exceed Environmental Protection Agency health and safety standards over a 10,000-year period. An ineffective quality assurance program runs the risk of introducing unknown errors into the design and construction of the repository that could lead to adverse health and safety consequences.

To demonstrate compliance with the health standards over this 10,000-year period, DOE must rely primarily on a “performance assessment” computer model that incorporates over 1,000 data sources, approximately 60 scientific models, and more than 400 computer software codes to simulate the performance of the repository. Given the prominence of computer modeling in the licensing of the repository, one of DOE’s most important tasks is to demonstrate the adequacy of the data, models, and software

used to perform the simulation. In addition, as part of the licensing process, DOE must demonstrate that its quality assurance program can effectively identify and correct deficiencies in areas important to the safe operation and long-term performance of the repository, such as the natural and engineered barriers of the repository and the program's data, models, and software. See appendix I for more information on the role of quality assurance in the licensing process.

DOE has a long-standing history of attempting to correct quality assurance problems. In 1988, we identified significant problems with the quality assurance program, noting that NRC had identified many specific concerns about the Yucca Mountain program, including

- DOE's heavy reliance on contractors and inadequate oversight would increase the likelihood that DOE might encounter quality-related problems;
- the possibility that Nevada would contest the licensing proceedings, thereby increasing the probability that DOE would have to defend its quality assurance program;
- additional expense and time-consuming delays to correct program weaknesses if DOE could not properly defend the quality of its work; and
- DOE staff's and contractors' negative attitude toward quality assurance.⁴

Since the late 1990s, DOE has attempted to correct continuing quality assurance problems in three areas critical to the repository's successful performance: the adequacy of the data sources, the validity of scientific models, and the reliability of computer software that have been developed at the site. These problems surfaced in 1998 when DOE began to run the initial versions of its performance assessment model. Specifically, DOE was unable to ensure that critical project data had been properly collected and tracked back to original sources. In addition, the department lacked a standardized process for developing scientific models used to simulate a variety of geologic events and an effective process for ensuring that computer software used to support the scientific models will work

⁴U.S. General Accounting Office, *Nuclear Waste: Repository Work Should Not Proceed Until Quality Assurance Is Adequate*, [GAO/RCED-88-159](#) (Washington, D.C.: Sept. 29, 1988).

properly. DOE implemented actions in 1999 to correct these deficiencies and prevent their recurrence.

In 2001, similar deficiencies associated with models and software resurfaced. DOE attributed the recurrence to ineffective procedures and corrective actions, improper implementation of quality procedures by line managers, and personnel who feared reprisal for expressing quality concerns. To ensure that it adequately addressed the problems to prevent future recurrence, DOE developed a more comprehensive corrective action plan in July 2002, concentrating on actions needed to address the causes of the recurring problems while improving the organizational culture and instilling a strong commitment to quality in all project personnel. The plan detailed specific actions for both DOE and its contractor, Bechtel/SAIC Company, LLC (Bechtel), to strengthen the roles, responsibilities, accountability, and authority of project personnel; develop clearer quality assurance requirements and processes; improve program procedures; create an improved programwide corrective action process; and improve processes for ensuring that employees can raise project concerns without fear of reprisals.

Quality Assurance Problems Persist at the Yucca Mountain Project

DOE reports that it has implemented almost all of the actions identified in its 2002 corrective action plan; however, recent audits and assessments indicate that recurring quality assurance problems have not been corrected. In 2003, DOE conducted three audits to evaluate the effectiveness of the corrective actions taken to address recurring problems with data, models, and software. Because each audit identified additional quality assurance problems, DOE concluded that there was insufficient evidence to demonstrate that the recurring problems had been corrected. DOE recently closed the corrective action reports for data and software, but did so without determining whether corrective actions have been effective. To examine actions taken to correct some of the management weaknesses identified in the 2002 corrective action plan, DOE conducted four management assessments late in 2003. Collectively, these assessments found continuing management weaknesses that DOE had identified as root causes of the recurring problems. NRC also conducted an assessment that was issued in April 2004. NRC's assessment noted some improvements but also found continuing weaknesses and noted that quality assurance problems could hinder the licensing process.

Audits Have Found Recurring Problems with Data, Models, and Software

In 2003, DOE's audits of data, models, and software identified continuing quality problems that could impede DOE's license application. As a result, DOE could not close corrective action reports for models and software for nearly 3 years. In a June 2003 audit, DOE found quality problems in developing and validating software. In September 2003, DOE quality assurance auditors found that some data sets were still not qualified or traceable to their sources. In October 2003, a DOE audit found continuing quality problems in model documentation and validation. DOE officials have stated that these findings represent problems with procedures and documentation and do not invalidate the technical products produced using the data, models, and software. In March 2004, DOE closed the corrective action reports for data and software but did so without evaluating the effectiveness of corrective actions—according to agency officials, they will evaluate effectiveness at a later date. DOE anticipates closing the corrective action report for models in August 2004 but also plans to do so without evaluating the effectiveness of corrective actions.

Data Qualification and Traceability Problems Are Still Being Corrected

In April 2003, DOE again reported significant problems similar to those originally identified in 1998 with the qualification and traceability of data sets. At the time, DOE implemented corrective actions to recheck all of its data sets to confirm that they were traceable and qualified. However, a September 2003 audit identified similar data problems and new problems in addition to those noted in the corrective action report.⁵ The audit found that some data sets did not have the documentation needed to trace them back to their sources; the critical process of data control and management was not satisfactory; and, as in 1998, faulty definitions were developed for data procedures, which allowed unqualified data to be used. In addition, DOE found that overall compliance with procedures was unsatisfactory. Similarly, the April 2003 corrective action report also noted a lack of management leadership, accountability, and procedural compliance, issues which are closely related to the key improvement area of roles and responsibilities. DOE officials noted that these findings represented noncompliance with procedures, and that the procedures and processes were effective in producing defensible technical products if properly followed. As of February 2004, DOE had not finished rechecking all of its data sets or correcting problems in its data sets. However, DOE closed the

⁵Department of Energy, Office of Civilian Radioactive Waste Management, *Report for Performance-Based Audit OQAP-BSC-03-14 of Technical Product Inputs at Bechtel SAIC Company, LLC, September 8-19, 2003* (Las Vegas, NV: Nov. 6, 2003).

corrective action report in March 2004 by making the rechecking process a continuing part of the Yucca Mountain repository's work. The corrective action report was closed without DOE evaluating the effectiveness of the rechecking process in correcting problems with data. DOE officials stated that they plan to evaluate effectiveness at a later date.

Models Still Lack Proper Validation

An October 2003 DOE quality assurance audit found continuing problems with the documentation and validation of models that DOE plans to use in its license application.⁶ Although auditors reported that processes were effective in producing defensible models to support the license application, they found that for some models sampled, project personnel did not properly follow model validation procedures. These problems were similar to those identified by audits conducted in 2001. Auditors compared results from the 2003 audit with actions taken to correct problems identified in 2001 and found that procedures still were not being satisfactorily implemented in the areas of model documentation and traceability, model validation, and checking and review. For example, an action was taken in 2001 to improve the self-identification of problems before issuing new model reports by allowing for sufficient scheduling time for model checking and review. However, the 2003 audit concluded that instances of new errors in model reports were evidence that the previous actions may not have been fully implemented. As a result, DOE has been unable to close the May 2001 model corrective action report for almost 3 years. DOE recently directed a team of industry experts to review its models and revise them to ensure consistency, traceability, and procedural compliance. DOE anticipates closing the corrective action report in August 2004 but will do so without conducting another audit of models to determine if corrective actions have been effective.

Software Development Problems Persist

In a June 2003 audit, DOE auditors discovered recurring software problems that could affect confidence in the adequacy of software codes.⁷ Specifically, the auditors found ineffective software processes in five areas:

⁶Department of Energy, Office of Civilian Radioactive Waste Management, *Report for Performance-Based Audit OQAP-BSC-03-10 of Analysis Model Report Processes and Products at Bechtel SAIC Company, LLC, October 21-31, 2003* (Las Vegas, NV: Jan. 20, 2004).

⁷Department of Energy, Office of Civilian Radioactive Waste Management, *Report for Audit OQAP-BSC-03-07 of Software and Software Activities at Bechtel SAIC Company, LLC, Lawrence Berkeley National Laboratory, and Lawrence Livermore National Laboratory, June 3-13, 2003* (Las Vegas, NV: Aug. 13, 2003).

technical reviews, software classification, planning, design, and testing. The auditors found several of the software development problems to be similar to previously identified problems, indicating that previous actions were ineffective in correcting the problems. For example, auditors again noted instances of noncompliance with software procedures. They also concluded that technical reviews during software development were inadequate, even though documentation indicated that corrective actions for this condition had been completed 3 months before the 2003 audit. Auditors also noted poorly defined roles and responsibilities as a cause of problems identified in the technical review of software, even though DOE had taken actions under its 2002 corrective action plan to clarify roles and responsibilities. Because of these results, DOE was unable to close the June 2001 software corrective action report. DOE employed a team of industry professionals in the fall of 2003 to examine software quality problems identified from 1998 through 2003. The professionals' February 2004 report concluded that software problems recurred because DOE did not assess the effectiveness of its corrective actions and did not adequately identify the root causes of the problems. In a January 2004 follow-up audit of software, auditors verified that unqualified software was used to run approved models, and noted that procedural controls for determining the adequacy of software were inadequate. In March 2004, without evaluating the effectiveness of corrective actions, DOE closed the software corrective action report. DOE officials plan to evaluate the effectiveness of its corrective actions for software sometime in the future.

Assessments Indicate Continuing Management Weaknesses

DOE reported in the fall of 2003 that it had implemented most of the actions identified in the plan focusing on management weaknesses, but four DOE management assessments of the Yucca Mountain project completed between September and November 2003 found that some of the identified management weaknesses had yet to be properly addressed. These assessments included one requested by project management comparing DOE's management practices at Yucca Mountain with external industry best practices,⁸ one required as an annual assessment of the adequacy and effectiveness of the quality assurance program,⁹ one

⁸Booz, Allen, Hamilton, Inc., *Performance Management Assessment: DOE Office of Civilian Radioactive Waste Management* (Las Vegas, NV: Sept. 30, 2003).

⁹D.L. English Consulting, Inc., *FY 2003 Quality Assurance Management Assessment of the Office of Civilian Radioactive Waste Management* (South Dartmouth, MA: October 2003).

requested by the project director that examined the effectiveness of selected DOE and contractor management systems,¹⁰ and one examining the project work environment.¹¹ Collectively, these assessments identified continuing weaknesses in the areas of roles and responsibilities, quality assurance procedures, and a work environment that did not foster employee confidence in raising concerns without fear of reprisal. DOE officials stated that they are presently reviewing the findings of these assessments, and have recently initiated additional corrective actions.

Unclear Roles and Responsibilities

Three of the four management assessments conducted late in 2003 identified significant continuing problems with the delineation and definition of roles and responsibilities for carrying out the quality assurance program. In its 2002 corrective action plan, DOE stated that it was not possible to build accountability into management without clearly and formally defining roles and responsibilities for DOE and its contractors. DOE's planned actions included clarification of roles and responsibilities within DOE and Bechtel through policy statements, communications, a new program manual, and realignment of the organization to support performance accountability. DOE reported that it had completed all corrective actions in this area by May 2003. The assessments noted that these actions had resulted in some improvements, but that some management weaknesses remained. The assessments found that the Yucca Mountain project

- lacked formal mechanisms for defining and communicating roles and responsibilities that meet both DOE and NRC requirements;
- did not have a systematic process for assigning authorities to DOE and Bechtel organizations and individuals;
- relied on program managers who had not fully assumed ownership and responsibility for quality assurance;
- lacked formal control of documents outlining roles and responsibilities, ensuring that they reflect the organization;

¹⁰Department of Energy, Office of Independent Oversight and Performance Assurance, *Management Assessment: Office of Repository Development* (Washington, D.C.: November 2003).

¹¹International Survey Research, *OCRWM 2003 Safety Conscious Work Environment Survey* (Walnut Creek, CA: Nov. 7, 2003).

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- lacked clear reporting relationships between the project and supporting national laboratories;
 - had not adequately established processes for reviewing procedures when needed;
 - had few systematic and effective approaches in place for assigning accountability to individuals and organizations; and
 - did not effectively plan and communicate reorganizations and assign appropriate authority levels, in the opinion of many project employees.

As a result of findings from these assessments, DOE is pursuing further corrective actions. For example, DOE plans to formally control the high-level document that defines its organizational structure. Also, Bechtel has initiated a management system improvement project, which includes issuing a new document defining roles and responsibilities. DOE officials expect that roles and responsibilities will continue to be a challenge in the future, but that efforts will continue.

Ineffective Procedures

Three of the four management assessments identified continuing problems with project procedures, one of the areas of management weaknesses addressed by the 2002 corrective action plan. Although the assessments noted that DOE and Bechtel had made improvements in the procedure management system and DOE had reportedly reviewed existing procedures, issued new or revised procedures, and ensured that personnel using the procedures were properly trained, the assessments noted that

- procedures were overly prescriptive,
- procedures did not cover all required processes, and
- continuing noncompliance with procedures remained a problem.

Although DOE completed actions under the 2002 plan to revise project procedures, DOE has initiated further corrective actions, including a plan to again revise Yucca Mountain project procedures by June 2005.

Inadequate Work Environment

Three of the four assessments identified continuing problems with efforts by DOE and Bechtel to ensure a work environment in which employees can freely raise concerns without fear of reprisal—one of the key areas of management weaknesses identified in the corrective action plan. DOE and

Bechtel implemented corrective actions to improve the work environment by revising and expanding policies, modifying DOE contracts to require implementation of program requirements, decreasing the backlog of employee concerns, and providing programwide training that is based on industry practices. However, the assessments revealed continuing problems with the work environment, including both DOE's and Bechtel's employee concerns programs, which provide personnel with an opportunity to formally raise concerns about the project outside the normal chain-of-command without fear of reprisal. Appendix II describes the requirements of the Yucca Mountain employee concerns programs. Although the assessments noted ongoing management actions to strengthen the implementation of the concerns programs, they also noted that

- neither DOE nor Bechtel have effectively controlled corrective actions under the employee concerns programs, sometimes closing cases on the basis of anticipated actions;
- both DOE and contractor employee concerns programs are not being utilized to their fullest;
- there is a general lack of employee confidence in reporting safety issues to management;
- DOE and Bechtel have not made effective resources available for determining the root causes of problems identified;
- DOE and Bechtel have not established a climate of trust despite communication mechanisms and messages; and
- a majority of DOE and contractor employees either do not consider the project's corrective action process to be effective or are not sure of its effectiveness.

Although the plan's actions to improve the work environment were completed in November 2003, DOE plans to take additional actions to improve employee confidence in raising issues without fear of reprisal.

NRC Is Concerned That Recurring Problems Could Adversely Affect Licensing

NRC has commented on DOE's lack of progress in making improvements to the quality assurance program. At an April 2003 management meeting with DOE, an NRC official commented that the quality assurance program had not produced the outcomes necessary to ensure that the program is compliant with NRC requirements. In response, DOE outlined the steps it was taking to ensure that its license application would meet NRC expectations for completeness, accuracy, and compliance with quality assurance requirements. The steps included additional actions to improve performance in five areas: license application, procedural compliance, the corrective action program, the work environment, and accountability. In October 2003, DOE reported to NRC that it had completed some of the actions and was making progress in the remaining open action items. While NRC officials noted that DOE's actions might enhance performance, they found that significant implementation issues persist. NRC officials stated that they were seeking evidence of incremental DOE progress in the implementation of the quality assurance program in order to gain confidence in the adequacy of data, models, and software supporting the potential license application. In a November 2003 management meeting with DOE, NRC officials expressed encouragement with DOE's progress in implementing an improved corrective action process and the continued performance of effective audits and the identification of areas for improvement. However, the NRC staff continued to express concerns with DOE's lack of progress in correcting repetitive quality problems with models and software.

NRC recently completed an evaluation of DOE's technical documents and supporting activities at Yucca Mountain. This prelicensing evaluation focused on an analysis of the technical information supporting three important repository models and the processes for developing and controlling the models. In addition, NRC evaluated the effectiveness of recent corrective actions in the areas of data, models, and software. The NRC report, released in April 2004, found that technical support for DOE's repository models was greatly improved, current models are more comprehensive and contain more data than those presented for site recommendation, software documentation was extensive, the management of databases was outstanding, and the trending program has been improved.¹² However, the report noted concerns regarding the clarity and

¹²U.S. Nuclear Regulatory Commission, *U.S. Nuclear Regulatory Commission Staff Evaluation of U.S. Department of Energy Analysis Model Reports, Process Controls, and Corrective Actions* (Washington, D.C.: Apr. 7, 2004).

sufficiency of the technical information used to support the models. The NRC evaluation again found instances where data could not readily be traced back to their sources, unqualified data were used as direct inputs to the models, unqualified software was used to generate data supporting a model, and the model development process relied on inadequate checking and review procedures. In addition, NRC reported that DOE and Bechtel have not been fully successful in carrying out effective actions to eliminate recurring quality problems. The report states that DOE and Bechtel had not integrated human performance concerns in their root-cause and corrective action efforts in response to past quality problems. The NRC report concluded the following:

“...if DOE continues to use its existing policies, procedures, methods, and practices at the same level of implementation and rigor, the license application may not contain information sufficient to support some technical positions in the application. This could result in a large volume of requests for additional information in some areas which could extend the review process, and could prevent NRC from making a decision regarding issuing a construction authorization to DOE within the time required by law.”

Corrective Action Plan Lacks Measurable Goals

DOE cannot formally assess the overall effectiveness of its 2002 corrective action plan because the performance goals to assess management weaknesses in the plan lack objective measurements and time frames for determining success. For example, the goals do not specify the amount of improvement expected, how quickly the improvement should be achieved, or how long the improvement should be sustained before the problems can be considered corrected. For example, whereas 1 goal calls for a decreasing trend in the average time needed to make revisions in procedures, it does not specify the desired amount of the decrease, the length of time needed to achieve the decrease, or how long the decrease must be sustained. DOE recently developed a management tool to measure overall project performance that includes more than 200 performance indicators with supporting goals, including 17 goals linked to the 13 goals included in the 2002 corrective action plan. These 17 goals specify the desired amount of improvement, but most still lack the time frames needed for achieving and sustaining the goals. DOE officials told us they intend to use this performance measurement tool to track the progress of the project, including actions taken under the 2002 corrective action plan. A DOE independent review of the corrective action plan completed in March 2004 found that the corrective actions from the 2002 plan to address management weaknesses have been fully implemented. However, the review also noted the effectiveness of corrective actions under the plan could not be evaluated because many of the goals in the performance

measurement tool that are linked to the 2002 plan lacked the level of objectivity and testing needed to measure effectiveness.

Goals Are Not Objectively Measurable and Lack Specific Time Frames

DOE's 2002 plan included 13 goals to be used to determine the effectiveness of the corrective actions that addressed the five areas of management weaknesses. However, these goals were poorly defined, thus limiting DOE's ability to evaluate the effectiveness of actions taken. Both GAO¹³ and the Office of Management and Budget (OMB)¹⁴ have stated that performance goals need to be measurable, and time frames need to be established in order to track progress and demonstrate that deficiencies have been corrected. Of the 13 goals in the corrective action plan, 3 indicated how much improvement was expected. For example, 1 of the 3 goals specified that the number of significant quality problems self-identified by program managers should be at least 80 percent of all significant quality problems, including those identified by program managers, quality assurance auditors, or other employees. In contrast, 1 of the other 10 goals called for the achievement of a decreasing trend in the time needed for revising procedures, but did not specify how much of a decrease is expected. Further, none of the 13 goals specified the length of time needed to reach and maintain the desired goal to demonstrate that the actions taken were effective. For example, the goal calling for self-identified significant quality problems to be at least 80 percent of all significant quality problems did not indicate the length of time needed to achieve the goal or how long this goal should be sustained in order to demonstrate effectiveness. DOE does not intend to revise the goals of the 2002 corrective action plan to include quantifiable measures and time frames. Without such quantifiable measures to determine whether a goal has been met, and without a specified time for the goal to be maintained, DOE cannot use these goals to determine the effectiveness of the actions taken.

¹³U.S. General Accounting Office, *Internal Control Standards: Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

¹⁴Executive Office of the President, Office of Management and Budget, *Circular No. A-123* (Washington, D.C.: June 24, 1995).

Subsequent Efforts to Improve Goals Still Lack Time Frames

DOE's recent efforts to improve performance measurement have not allowed it to adequately measure the effectiveness of its corrective action plan. DOE has developed a projectwide performance measurement tool to assess project performance that includes over 200 performance indicators with supporting goals related to the project. At our request, Bechtel was able to link 17 of the supporting goals to 12 of the 13 goals of the 2002 corrective action plan. Although these linked goals improved quantifiable measurement for 11 of the plan's goals by specifying the amount of improvement expected, most did not include the necessary time frames for meeting the goals and sustaining the desired performance. DOE officials stated that this tool was not specifically tailored to evaluate the corrective action plan's effectiveness, but that they have decided to use it in lieu of the original 13 goals to monitor improvements and progress in correcting the management weaknesses identified in the plan. Table 1 provides a comparison of the supporting goals in the performance tool with the 2002 corrective action plan goals.

Table 1: Comparison of Goals in the July 2002 Corrective Action Plan to Goals in the December 2003 Performance Tool

| Key area of management weakness | Original goals from corrective action plan, July 2002 | Goals related to the corrective action plan in projectwide performance tool, December 2003 | GAO comments/observations |
|--|---|---|--|
| Roles, responsibilities, accountability, authority | (1) Improving trend in quality and schedule performance. | (1) Amount of actual work completed is 98 to 115 percent of the amount of work scheduled. | Quality performance is not included in new goal. Partial improvement for schedule - quantitative measure added, time frame to meet and sustain goal lacking. |
| | (2) Decreasing trend in quality problems related to roles and responsibilities. | Goal is not covered in performance tool. | Not applicable. |
| Quality assurance process | (3) Numbers of high-priority (significant) quality problems that are self-identified are at least 80 percent of all significant quality problems. | (2) At least 80 percent of quality problems are self-identified. | Quantitative measure remains the same; goal is no longer focused on high-priority problems. Time frame to meet and sustain goal lacking. |
| | (4) Decreasing trend in average time to resolve significant quality problems and in number of delinquent corrective actions for significant quality problems. | (3) At least 90 percent of quality problems are closed in 60 days. (4) At least 90 percent of significant quality problems are closed in 100 days. (5) At least 80 percent of all problems are screened in 5 days. (6) At least 90 percent of all problems have corrective action plans in 30 days. (7) At least 80 percent of corrective action plans are on schedule. (8) 1 to 1.2 ratio of new problems to closed problems. | Partial improvement - quantitative measures added, time frames to meet and sustain goals lacking. |
| Written procedures | (5) Decreasing number of quality problems related to ineffective procedures. | (9) 15 percent or less of all quality problems are based on ineffective procedures. | Partial improvement - quantitative measure added, time frame to meet and sustain goal lacking. |
| | (6) Decreasing trend in time needed to revise procedures. | (10) Procedure revisions are made in 75 days or less. | Partial improvement - quantitative measure added, time frame to meet and sustain goal lacking. |
| | (7) Decreasing trend in average age of interim procedure changes. | (11) Interim procedure changes are made in less than 15 days. | Partial improvement - quantitative measure added, time frame to meet and sustain goal lacking. |

(Continued From Previous Page)

| Key area of management weakness | Original goals from corrective action plan, July 2002 | Goals related to the corrective action plan in projectwide performance tool, December 2003 | GAO comments/observations |
|---------------------------------|---|---|---|
| Corrective action plans | (8) Decreasing trend in number of repetitive quality problems. | (12) 5 percent or less of all corrective actions still have quality problems. (13) 5 percent or less of all quality problems are repeated. | Partial improvement - quantitative measures added, time frames to meet and sustain goals lacking. |
| | (9) Decreasing trend in average time to resolve significant quality problems. | (same as goals 3 and 4 in this column) | Partial improvement - quantitative measure added, time frames to meet and sustain goals lacking. |
| | (10) Less than 10 percent of quality problems are resolved late. | (same as goals 3 and 4 in this column) | Partial improvement - quantitative measures added, time frames to meet and sustain goals lacking. |
| Work environment | (11) Decreasing number of substantiated employee concerns for harassment, retaliation, intimidation, and discrimination. | (14) Zero concerns related to harassment, intimidation, retaliation, or discrimination are substantiated. | Partial improvement - quantitative measures added, time frame to meet and sustain goal lacking. |
| | (12) Evaluation of routine employee concerns in less than 30 days, or 90 days for complex employee concerns involving harassment or intimidation. | (15) 25-day or less response time for routine concerns. (16) 80-day or less response time for complex concerns or harassment, retaliation, intimidation, or discrimination concerns. | Partial improvement - quantitative measures changed, time frames to meet and sustain goals lacking. |
| | (13) External evaluation of work environment shows positive changes. | (17) At least 80 percent favorable response rates to six employee survey questions. | Partial improvement - quantitative measure added, time frame to meet and sustain goal lacking. |

Source: GAO analysis of DOE data.

Note: Performance goals in projectwide tool related to the corrective action plan represent a small fraction of the more than 200 goals being used for the project.

DOE Is Unable to Evaluate the Effectiveness of Corrective Actions

DOE has recently assessed the implementation of corrective actions, but it has not yet assessed the effectiveness of these actions in correcting recurring problems. In December 2003, DOE outlined the approach it used to determine whether corrective actions have been implemented.¹⁵ This approach is part of the overall process described in the 2002 action plan—appendix III provides an overview of the action plan and the status of the process. To determine if corrective actions had been implemented, DOE relied on the collective judgment of project managers regarding how

¹⁵Department of Energy, Office of Civilian Radioactive Waste Management, *Management Improvement Initiatives Transition Approach, Revision 1* (Washington, D.C.: December 2003).

effectively they have incorporated corrective actions into their regular project activities. A March 2004 DOE review analyzed the implementation of corrective actions for each of the management weaknesses but was not able to evaluate the effectiveness of the corrective actions.¹⁶

DOE's March 2004 review noted strong management commitment to improvement and described recent actions taken to ensure that work products meet quality objectives for a successful license application. However, the review identified continuing weaknesses in DOE's ability to determine the effectiveness of the actions it has taken. The review team attempted to measure how effectively DOE had met each of the plan's original 13 goals. The team was unable to measure whether 10 of the 13 goals had been met, but concluded that the project had met 2 of the goals and made progress toward another goal, based on an analysis of trends in quality problems identified. However, these conclusions were not based on an evaluation of quantifiable goals with time frames for meeting and sustaining the desired performance. The review also concluded that the performance indicators developed to evaluate the success of the actions lacked the level of objectivity and testing needed to measure effectiveness and that some lacked the data needed to assess effectiveness. The review recommended that DOE continue its corrective actions and refine performance indicators so that the effectiveness of corrective actions in meeting the plan's goals can be more readily measured.

In April 2004, DOE notified NRC that it had completed, validated, and independently assessed the commitments it made in the 2002 corrective action plan, institutionalized the corrective actions, and established a baseline to foster and sustain continuous improvement. DOE officials stated they have achieved the initial goals of the 2002 plan through these actions. These officials indicated they would continue to refine and improve project tools used to evaluate the effectiveness of corrective actions. However, because of the limitations noted in its March 2004 review, DOE has not yet evaluated the effectiveness of corrective actions.

Conclusions

Despite working nearly 3 years to address recurring quality assurance problems, recent audits and assessments have found that problems

¹⁶Longenecker & Associates, Inc., under contract to Booz Allen Hamilton, Inc., *OCRWM Management Improvement Initiatives (MII) Independent Review Report* (Las Vegas, NV: Mar. 19, 2004).

continue with data, models, and software, and that management weaknesses remain. As NRC has noted, quality assurance problems could delay the licensing process. Despite recurring quality problems, DOE has recently closed the corrective action reports for data and software and intends to close the corrective action report for models in August 2004 without first evaluating the effectiveness of the corrective actions taken to address the problems in these areas. DOE also does not intend to improve the goals of the 2002 plan associated with management weaknesses so that they can be adequately measured. Instead, DOE continues to plan and implement further actions to correct its quality problems and management weaknesses. This approach provides no indication regarding when DOE may be in a position to show that corrective actions have been successful. Entering into the licensing phase of the project without resolving the recurring problems could impede the application process, which at a minimum could lead to time-consuming and expensive delays while weaknesses are corrected and could ultimately prevent DOE from receiving authorization to construct a repository. Moreover, recurring problems could create the risk of introducing unknown errors into the design and construction of the repository that could lead to adverse health and safety consequences. Because of its lack of evidence that its actions have been successful, DOE is not yet in a position to demonstrate to NRC that its quality assurance program can ensure the safe construction and long-term operation of the repository.

Recommendations for Executive Action

To better evaluate the effectiveness of management actions in correcting recurring quality problems, we recommend that the Secretary of Energy direct the Director, Office of Civilian Radioactive Waste Management, to

- revise the performance goals in the 2002 action plan to include quantifiable measures of the performance expected and time frames for achieving and maintaining this expected level of performance and
- close the 2002 plan once sufficient evidence shows that the recurring quality assurance problems and management weaknesses that are causing them have been successfully corrected.

Agency Comments and Our Evaluation

We provided a draft of this report to DOE and NRC for their review and comments. DOE's written comments, which are reproduced in appendix IV, expressed disagreement with the report's findings and

recommendations. DOE commented that the report did not properly acknowledge improvements the department has made in the quality assurance program; failed to properly characterize the 2002 Management Improvement Initiatives as a “springboard” to address management issues; did not consider DOE’s use of the full range of performance indicators related to quality assurance; and mischaracterized the results of several independent, external reviews, taking a solely negative view of the findings.

We disagree with most of DOE’s comments. Our draft report acknowledged that DOE has taken a number of actions to address past problems in the quality assurance program, but to ensure clarity on this point, we have incorporated additional language to this effect in the report. However, our primary focus for this review was to evaluate the effectiveness of DOE’s corrective actions in addressing the recurring quality problems. Despite the many actions taken to improve the quality assurance program, the management weaknesses and quality problems with data, models, and software have continued, indicating that the corrective actions have not been fully effective. Regarding DOE’s views on our treatment of the 2002 Management Improvement Initiatives, DOE itself characterized the initiative as a “comprehensive corrective action plan.” DOE stated that the implementation of the plan has been successful based on the evidence that responsible managers have taken agreed-upon action. This approach can be misleading, however, because it does not incorporate a determination of whether these actions have been effective. In fact, DOE has not evaluated the effectiveness of these actions in solving recurring problems. DOE further stated that we did not consider the full range of performance indicators related to quality assurance that DOE uses to manage the project. We agree. We asked DOE staff to compare their new performance indicators to the goals in the 2002 plan, and those are the goals that we presented for comparison in table 1 of our report. A discussion of the remainder of the hundreds of other goals was beyond the scope of our review and would not have added to an understanding of the overall problems with DOE’s goals. Finally, we disagree with DOE’s comment that we mischaracterized the results of recent independent reviews. We noted instances in these reports where improvements were found. However, we also devoted appropriate attention to evidence in these reports that address whether DOE’s corrective actions have been effective. As our report states, these reports consistently found that these actions have not yet had their intended effect.

In NRC’s written comments, reproduced in appendix V, the agency agreed with our conclusions but suggested that DOE be given the flexibility to

choose alternative approaches to achieve and measure quality assurance program performance. We agree that alternative approaches could be used to measure performance; however, to ensure the success of any approaches, DOE must include objective measurements and time frames for reaching and sustaining desired performance and include an end point for closing out the corrective action plan.

Scope and Methodology

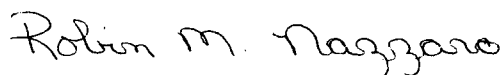
To assess the status of DOE's corrective actions to resolve recurring quality problems, we reviewed audits and deficiency reports written by the program over the past 5 years that identified problems with data, models, and software. We did not independently assess the adequacy of data, models, and software, but rather relied on the results of the project's quality assurance audits. In addition, we reviewed numerous documents that NRC prepared as part of its precicensing activities at Yucca Mountain, including observations of quality assurance audits, NRC on-site representative reports, and correspondence between NRC and DOE on quality matters. We also observed an out-briefing of a quality assurance audit to obtain additional knowledge of how quality problems are identified and reported. To document the status of actions taken, we reviewed evidence used by DOE's Office of Civilian Radioactive Waste Management to prove corrective actions had been implemented and interviewed officials with DOE, at the Yucca site and in headquarters, and officials with Bechtel, the primary contractor. We also reviewed the results of four DOE assessments completed in the fall of 2003 that included the quality assurance program, interviewing the authors of the assessment reports to obtain a clear understanding of the problems identified. We attended quarterly meetings held between DOE and NRC to discuss actions taken under the plan and met with representatives of the State of Nevada Agency for Nuclear Projects and with representatives of the Nuclear Waste Technical Review Board, which was established to advise DOE on scientific and technical aspects of the Yucca Mountain project.

To determine the adequacy of DOE's plan to measure the effectiveness of the actions it has taken, we examined the July 2002 corrective action plan and subsequent project performance measurement documents to determine how DOE intended to use goals and performance measures to evaluate the plan's effectiveness. We asked Bechtel officials to assist us in identifying and matching performance goals in the projectwide performance measurement tool with those in the 2002 corrective action plan. We compared DOE's approach in its corrective action plan and subsequent projectwide tool with GAO and OMB guidance on performance

measurement. We discussed the implementation of the corrective action plan and methods for measuring its effectiveness with various DOE and NRC officials and DOE contractors in Washington, D.C., and at the Yucca Mountain project office in Las Vegas, Nevada. We also interviewed other GAO personnel familiar with performance measurement to more fully understand the key elements needed for effective assessments.

We will send copies of this report to the appropriate congressional committees, the Secretary of Energy, and the Chairman of the Nuclear Regulatory Commission. We will also make copies available to others on request. In addition, this report will be available at no charge on the GAO Web site at www.gao.gov.

If you or your staffs have any questions about this report, please call me on (202) 512-3841. Major contributors to this report are listed in appendix VI.



Robin M. Nazzaro
Director, Natural Resources and Environment

Role of Quality Assurance in the Licensing Process

After the Department of Energy (DOE) submits its license application to the Nuclear Regulatory Commission (NRC), NRC will review it to determine whether all NRC requirements have been met and whether the repository is likely to operate safely as designed. NRC's review will be guided by its Yucca Mountain Review Plan, which NRC developed to ensure the quality, uniformity, and consistency of NRC reviews of the license application and of any requested amendments.¹ The review plan is not a regulation, but does contain the licensing criteria contained in federal regulations.² DOE's application is to include general, scientific, and administrative information contained in two major sections: (1) a general information section that provides an overview of the engineering design concept for the repository and describes aspects of the Yucca Mountain site and its environs that influence repository design and performance, and (2) a detailed safety analysis section that provides a review of compliance with regulatory performance objectives that are based on permissible levels of radiation doses to workers and the public, established on the basis of acceptable levels of risk. The general information section covers such topics as proposed schedules for construction, receipt, and emplacement of waste; the physical protection plan; the material control and accounting program; and a description of site characterization work. The detailed safety analysis is the major portion of the application and includes DOE's detailed technical basis for the following areas:

- the repository's safety performance before permanent closure in 100 to 300 years;
- the repository's safety performance in the 10,000 years after permanent closure, on the basis of the "performance assessment" computer model;
- a research and development program describing safety features or components for which further technical information is required to confirm the adequacy of design and engineered or natural barriers;
- a performance confirmation program that includes tests, experiments, and analyses that evaluate the adequacy of information used to demonstrate the repository's safety over thousands of years; and

¹Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, *Yucca Mountain Review Plan Final Report, NUREG-1804, Revision 2* (Washington, D.C.: July 2003).

²U.S. Code of Federal Regulations, Title 10, Part 63.

- administrative and programmatic information about the repository, such as the quality assurance program, records and reports, training and certification of personnel, plans for start-up activities, emergency planning, and control of access to the site.

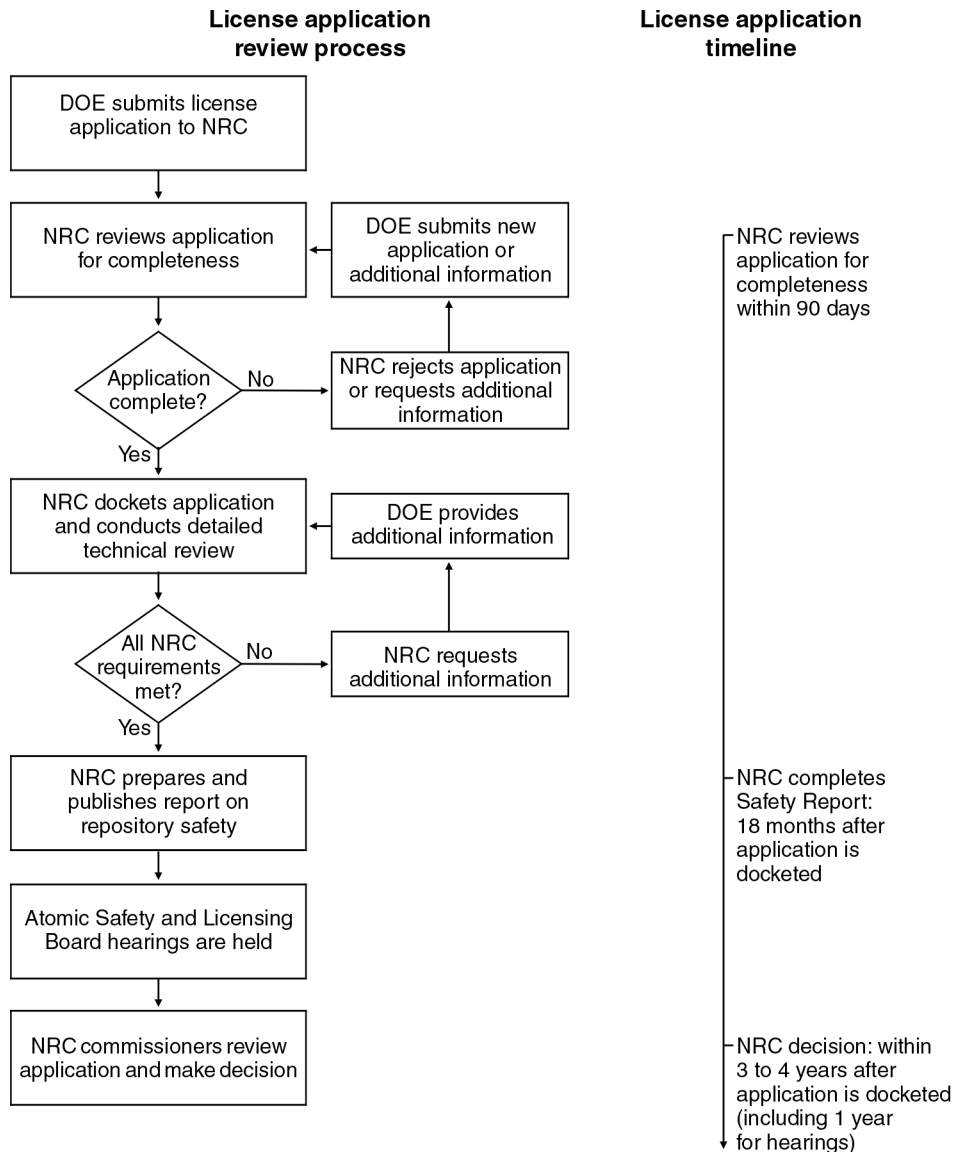
After DOE submits the license application (currently planned for December 2004), NRC plans to take 90 days to examine the application for completeness to determine whether DOE has addressed all NRC requirements in the application. One of the reviews for completeness will include an examination of DOE's documentation of the quality assurance program to determine if it addresses all NRC criteria. These criteria include, among other things, organization, design and document control, corrective actions, quality assurance records, and quality audits. If it deems any part of the application incomplete, NRC may either reject the application or require that DOE furnish the necessary documentation before proceeding with the detailed technical review of the application. If it deems the application complete, NRC will docket the application, indicating its readiness for a detailed technical review.

Once the application is docketed, NRC will conduct a detailed technical review of the application over the next 18 months to determine if the application meets all NRC requirements, including the soundness of scientific analyses and preliminary facility design, and the NRC criteria established for quality assurance. If NRC discovers problems with the technical information used to support the license application, it may conduct specific inspections to determine the extent and effect of the problem. Because the data, models, and software used in modeling repository performance are integral parts of this technical review, quality assurance plays a key role since it is the mechanism used to verify the accuracy of the information DOE presents in the application. NRC may conduct inspections of the quality assurance program if technical problems are identified that are attributable to quality problems. According to NRC, any technical problems and subsequent inspections could delay the licensing of the repository or, in a rare instance, lead to ultimate rejection of the application. NRC will hold public hearings chaired by its Atomic Safety and Licensing Board to examine specific topics. Finally, within 3 to

4 years from the date that NRC docket the application, NRC will make a decision to grant the application, reject the application, or grant it with conditions.³ Figure 1 presents the licensing process and timeline.

³A 4th year can be added to the process if NRC decides that the additional time is needed for hearings.

Figure 1: License Application Review Process and Timeline



Sources: NRC Yucca Mountain Review Plan and NRC officials.

Employee Concerns Programs at the Yucca Mountain Project

DOE and Bechtel/SAIC Company, LLC (Bechtel), have each established an employee concerns program to allow employees to raise concerns about the work environment without fear of reprisal. NRC requires licensees to establish a safe work environment where (1) employees are encouraged to raise concerns either to their own management or to NRC without fear of retaliation and (2) employees' concerns are resolved in a timely and appropriate manner according to their importance. DOE and contractor employees at Yucca Mountain have various means through which to raise concerns about safety, quality, or the work environment, including

- normal supervisory channels;
- a corrective action program—a process in which any employee can formally cite a problem on the project, including the work environment, that needs to be investigated and corrective actions taken;
- a DOE or contractor employee concerns program; or
- filing a concern directly with NRC.

NRC encourages, but does not require, licensees to establish employee concerns programs. Both the DOE and Bechtel concerns programs at Yucca Mountain have three main steps:

1. An employee notifies concerns program staff about an issue that he/she feels should be corrected, such as safety and health issues, free from harassment, retaliation, or quality assurance problems.
2. The concerns program staff documents and investigates the employee's concern.
3. The concerns program notifies the employee of the results of the investigation and notifies management of any need for corrective actions.

DOE and Bechtel each have established a communication network to allow employees to register concerns. These networks include brochures and regular newsletters on the program and numerous computer links to the program on the contractor's intranet where employees can obtain concerns program forms on line.

Recent statistics released by DOE show that most of the 97 concerns investigated by the DOE and Bechtel concerns programs in 2003 related to complaints against management. A summary of the concerns investigated in 2003 is shown in table 2.

Table 2: Employee Concerns Investigated by DOE and Bechtel in 2003

| Category of concern | Substantiated concerns | Concerns not substantiated | Total number of concerns |
|--|------------------------|----------------------------|--------------------------|
| Management problems or claims of mismanagement | 26 | 24 | 50 |
| Human resources | 8 | 6 | 14 |
| Harassment, intimidation, retaliation, or discrimination | 4 | 8 | 12 |
| Quality | 5 | 3 | 8 |
| Fraud, waste, and abuse | 2 | 1 | 3 |
| Safety | 0 | 2 | 2 |
| Equal employment opportunity | 0 | 1 | 1 |
| Security | 0 | 0 | 0 |
| Health | 0 | 0 | 0 |
| Environment | 0 | 0 | 0 |
| Workplace violence | 0 | 0 | 0 |
| Other | 5 | 2 | 7 |
| Total | 50 | 47 | 97 |

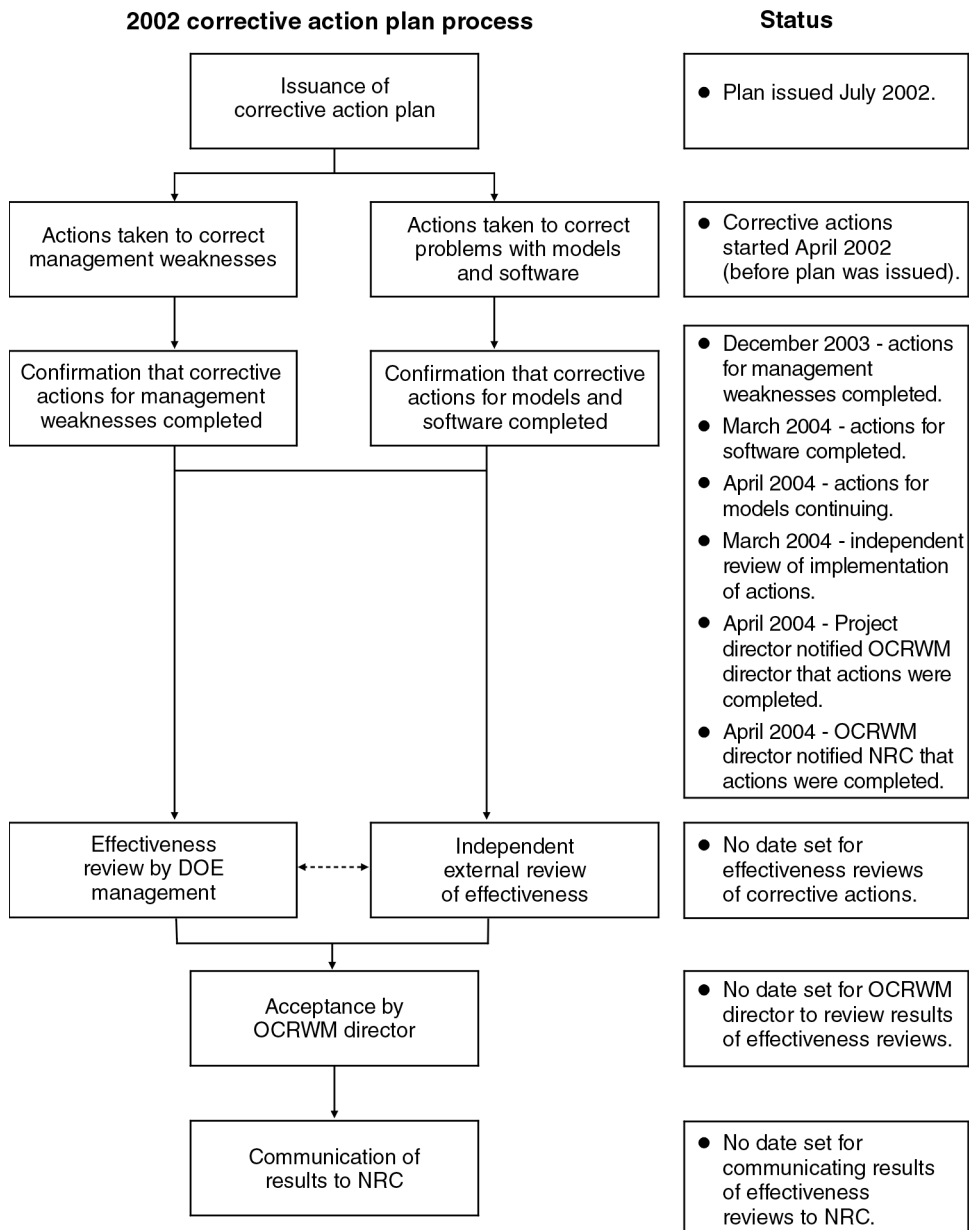
Source: DOE.

Note: Three concerns filed in 2003 were not included in this table. A concerns program official told us that two of these concerns were addressed by other organizations, and the resolution of the remaining concern was limited to providing information to management, as requested by the concerned individual.

2002 Corrective Action Plan Process and Status

DOE has established a process for completing corrective actions associated with the 2002 corrective action plan and evaluating their effectiveness. According to this process, after managers report they have taken actions to correct management weaknesses and specific problems with models and software, a confirmation team of DOE and contractor personnel verify that the actions have been completed. Once this step is completed, DOE conducts internal and external effectiveness reviews to determine if the actions have been effective in correcting the reported conditions. After the reviews of effectiveness, the results are assessed and reported to the Director of the Office of Civilian Radioactive Waste Management (OCRWM). The director then notifies NRC officials of the results of the effectiveness reviews, and the 2002 corrective action plan is closed. Figure 2 shows the corrective action plan process and the status of each step.

Figure 2: 2002 Corrective Action Plan Process and Status



Source: GAO summary of DOE documents.

Comments from the Department of Energy

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



Department of Energy

Washington, DC 20585

QA: N/A

April 19, 2004

Ms. Robin Nazzaro
Director, Natural Resources and Environment
U.S. General Accounting Office
441 G Street, NW
Washington, D.C. 20548

Dear Ms. Nazzaro:

Thank you for the opportunity to provide comments on the General Accounting Office (GAO) draft report, "Persistent Quality Assurance Problems Could Delay Repository Licensing and Operation." Unfortunately, the Department must respectfully disagree with the report's findings and recommendations, and therefore with the conclusion that forms its title.

I want to emphasize that the Office of Civilian Radioactive Waste Management (OCRWM) has shaped its quality assurance (QA) program to be consistent with Nuclear Regulatory Commission (NRC) requirements and standard industry practices. The role of QA is to verify that activities important to safety and waste isolation have been correctly performed. Detailed procedures address how technical work is documented so that the work and its results are reproducible, retrievable, transparent, and traceable. QA checks, audits, and inspections identify variances from procedures, and corrective actions are managed through a structured process. A nuclear QA program is effective if all personnel (not just those assigned to QA) proactively identify conditions that may affect quality or require attention, and if the organization can plan, implement, complete, and verify appropriate corrective actions in a timely manner. Evaluated against these criteria, I believe the OCRWM QA program has made significant progress and is operating effectively.

In the Department's view, the major deficiencies of the draft report are as follows:

- **The report authors did not acknowledge clear QA improvements we have made.** By the measures of effectiveness that are important in the nuclear regulatory context, OCRWM has made substantial QA improvements. A few examples:
 - In the last 15 months, self-identification by line management of conditions adverse to quality has increased by approximately 100 percent (Reference 1). This is a very positive development, showing that line managers are consistently reviewing their own work and ensuring that it is properly documented, reproducible, retrievable, transparent, and traceable, prior to being finalized.
 - Some corrective actions require the modification of procedures (e.g., to better define requirements for documentation of scientific work), and the procedural change itself must follow strict QA processes. We have improved our ability to ensure that QA procedures are appropriate to the quality objectives they support, reducing the average time it takes to modify a procedure from a past average of seven months to a current average of three months (Reference 2).



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See comment 1.

- Line managers are increasingly effective in developing corrective actions for identified issues. Since October 2003, 75% of line managers' corrective action plans were accepted upon the first review by QA personnel (Reference 1).
- Our ability to address and close quality issues was demonstrated by the closure of two major, longstanding Corrective Action Reports on data management and software qualification in March 2004.
- Our safety conscious work environment – in the nuclear context, an environment where employees feel free to raise concerns about quality or safety without fear of reprisal – has been strengthened, as shown by internal surveys, performance indicators, and a comprehensive independent survey conducted in August 2003 by International Survey Research (Reference 3). That independent survey characterized OCRWM as “significantly and largely more positive” in the area of safety conscious work environment than other Federal agencies associated with research and technology.

See comment 2.

- **The report authors failed to properly characterize the 2002 Management Improvement Initiatives (MII) effort, which is referred to inaccurately throughout the GAO draft report as the “2002 corrective actions plan,” and its relationship to ongoing QA and management activities.** The draft report asserts that although the 2002 MII is complete, there are “lingering quality problems with data, models, and software, and continuing management weaknesses.” As noted above, the corrective actions associated with data management and software were verified and closed in March 2004. The corrective action report on validation of model reports is on track for closure within four months. With regard to alleged management weaknesses, the 2002 MII was initiated by the Department as an aggressive “springboard” effort to address management issues and transition improvements into day-to-day line management activities. The 2002 MII addressed five areas: roles, responsibilities, authority, and accountability; quality assurance programs and processes; program procedures; the Corrective Action Program; and safety conscious work environment. The focus on roles, responsibilities, authority, and accountability was important because lack of clarity in those areas had been cited in the past as a root cause of QA problems. Implementation of the 2002 MII has been successful: responsible managers demonstrated with objective evidence that they completed the commitments set out in MII action plans, and an independent assessment by Longenecker and Associates confirmed that the MII action statements had been appropriately completed (References 4, 5, and 6). On April 5, 2004, I wrote to the NRC to indicate that we have completed, validated, and independently assessed MII implementation and have transitioned the 2002 MII goals to ongoing line management activities (Reference 7).

See comment 3.

- **The full range of performance indicators used by OCRWM to manage QA-related issues was not considered.** The draft report suggests that the Department cannot assess the effectiveness of the 2002 MII because performance goals lack objective measures and timeframes. The effectiveness indicators that we defined as part of the 2002 MII were management metrics that supported improvement goals by setting high expectations and describing a desired future state to work toward. Work execution metrics, by contrast, quantify performance and set timeframes as appropriate – GAO included a small selection of these metrics in its chart on page 20 of the draft. OCRWM has in fact more than 300 performance indicators that we use to assess progress and identify issues on a continuous basis (Reference 8). Performance indicators are evaluated in detail at Monthly Operating Reviews (Reference 9).

These elements of the OCRWM management tool inventory were not adequately addressed in the draft GAO report.

See comment 4.

- **The draft report mischaracterizes the results of several independent, external reviews.**
The report does not acknowledge the positive findings that external evaluators have made in several independent assessments and seems to take a solely negative view of the recommendations made by those evaluators (References 6, 10, 11, 12). We view the identification of issues as positive opportunities that should be routinely sought, listened to, and acted upon. Where GAO sees “continuing problems,” we see a measurable record of progress to date and a commitment to continuing improvement in the future. It is understood by the Department, by the NRC, and by knowledgeable outside observers that the repository program must meet rigorous quality assurance expectations for our license application to be acceptable to the Commission. The fact is, we are on schedule to submit our license application in December 2004, and we have an effective quality assurance program in place that will enable us to meet that objective.

See comment 5.

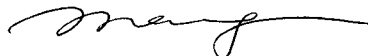
In summary, we have demonstrated steady and significant progress. We initiated the MII in 2002 to provide a special focus on specific improvement targets; we achieved the objectives of MII and have transitioned improvement initiatives to day-to-day management. Our continuous improvement culture means that we expect progress to continue, and our performance metrics enable us to assess that progress and direct management attention as needed. Based on these facts, we cannot concur with the findings and recommendations of the draft report.

See comment 6.

I urge GAO to further examine available information about our quality assurance program, performance indicators, safety conscious work environment, and other relevant aspects of the Program. Some highly pertinent information that was available during the time of GAO’s audit, between April 2003 and March 2004, is not reflected in the draft report. More recent documentation – for instance, the MII Independent Review Report, which was published on March 19, 2004 – is also significant. The enclosed list of references identifies documents that, we believe, are critical for GAO to review and fully consider prior to working further on the draft report. Without full consideration of this information, GAO’s findings on the Department’s progress in addressing quality assurance issues are incomplete, and its conclusions are broadly inaccurate.

I strongly urge you to review and incorporate additional information in your final report. You are welcome to revisit our offices, and we will provide any documentation you may require.

Sincerely,



Margaret S.Y. Chu, Ph.D.
Director
Office of Civilian Radioactive
Waste Management

Enclosure

ENCLOSURE:
LIST OF REFERENCES

1. DOE/NRC Quarterly Quality Assurance Meeting report, February 18, 2004.
2. Metric Definition Sheet 2.5.1.2 (part of Yucca Mountain Project Performance Indicators Database), March 2004.
3. International Survey Research, Survey Summary Report, October 2003.
4. Memorandum, John Arthur to Margaret Chu, April 2, 2004.
5. Management Improvement Initiatives Transition Approach, December 2003.
6. Longenecker and Associates, Inc., Management Improvement Initiatives Independent Review Report, March 19, 2004.
7. Letter, Margaret Chu to Martin Virgilio, April 5, 2004.
8. Yucca Mountain Project Performance Indicators Database, ongoing internal management tool.
9. Office of Repository Development, Monthly Operating Review Annunciator Panel, ongoing internal management tool.
10. DOE Office of Independent Oversight and Performance Assurance, Management Assessment of the Office of Repository Development, November 2003.
11. D.L. English Consulting, Inc., FY 2003 Quality Assurance Management Assessment of the Office of Civilian Radioactive Waste Management, November 2003.
12. Booz Allen Hamilton, Performance Management Assessment: DOE Office of Civilian Radioactive Waste Management, September 30, 2003.

The following are GAO's comments on the Department of Energy's letter dated April 19, 2004.

GAO Comments

1. We disagree. Our report states that the recent independent assessments have shown improvements in the key management areas identified in the 2002 corrective action plan. However, the assessments also showed that problems remain in these areas and thus the corrective actions have not yet been successful in correcting these weaknesses. DOE's examples of progress illustrate our point regarding improperly specified goals. For example, DOE states in its comments that line management's self-identification of conditions adverse to quality has increased approximately 100 percent in the last 15 months (as opposed to the identification of such conditions by quality assurance auditors). However, despite this seemingly dramatic increase, DOE has yet to meet its goal of line management's self-identifying 80 percent of all quality problems. (DOE's 100 percent increase brought them up to about 50 percent of all quality problems being self-identified by line managers.) Further, the goal continues to lack a time frame for when the 80 percent goal should be attained and for how long it should be sustained before the corrective actions can be judged successful. As our report points out, without such specificity, improvements cannot be evaluated in terms of overall success.
2. We disagree. The 2002 Management Improvement Initiatives clearly state that it was a "comprehensive corrective action plan necessary to address weaknesses in the implementation of [DOE's] quality assurance requirements and attain a level of performance expected of an NRC license applicant." Contrary to DOE's assertion, the initiative does not indicate it was a "springboard effort to address management issues and transition improvements into day-to-day line management activities." Although the transitioning of improvements to the line is laudable, the initiative focused on implementing corrective actions and evaluating the effectiveness of the actions in correcting problems. This approach is consistent with DOE's criteria for correcting significant conditions adverse to quality, and it is the criteria we relied on to determine whether the corrective actions specified in the initiatives were successful.
3. We agree. We did not include the full range of performance indicators (goals) that have recently been developed, and continue to change, to assess the 2002 plan. Instead, of the hundreds of indicators that are

being developed to manage the project, we relied on those few that Bechtel officials told us were connected to the goals of the 2002 plan. As table 1 shows, some improvements have been made in specifying the quantitative aspects of the goals, but weaknesses continue to exist in the new goals. In fact, table 1 shows that DOE no longer has a goal in its performance tool that specifically tracks the trend in problems related to roles and responsibilities. This omission is particularly important because the area of roles and responsibilities was noted in the 2002 plan as one of the biggest sources of problems in the quality assurance process, and, as the recent assessments have found, this is an area with continuing problems.

4. We disagree. We acknowledge that these reviews found positive improvements in a number of management areas. However, we also note that continuing problems were found with management weaknesses despite all corrective actions having been implemented in 2003.
5. While DOE believes that it has achieved the objectives of the 2002 plan, it lacks evidence that its actions have been effective in addressing the management weaknesses and correcting the recurring quality problems with data, models, and software. Evaluating performance against measurable goals with time frames for meeting and sustaining the goals would provide the needed evidence.
6. The draft report that we sent to DOE for review included reviews of 9 of the 12 documents listed in the enclosure of DOE's letter. We have since reviewed the 3 remaining documents. The information in the 3 documents did not change our assessment of DOE's efforts to correct its quality assurance program.

After full consideration of the information included in DOE's comments, we believe that our findings are complete and our conclusions are accurate.

Comments from the Nuclear Regulatory Commission

Note: GAO comment supplementing those in the report text appears at the end of this appendix.

See comment 1.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 16, 2004

Ms. Robin M. Nazarro
Director, Science Issues
Natural Resources and Environment
United States General Accounting Office
441 G Street, NW
Washington, D.C. 20548


Dear Ms. Nazarro:

I would like to thank you for the opportunity to review and submit comments on the draft report, "YUCCA MOUNTAIN: Persistent Quality Assurance Problems Could Delay Repository Licensing and Operation" (GAO-04-460). The U.S. Nuclear Regulatory Commission (NRC) appreciates the time and effort that you and your staff have taken to review this important topic.

The NRC agrees with the GAO conclusion that the Department of Energy (DOE) should continue to improve the Quality Assurance Program for the proposed Yucca Mountain Repository. With respect to the specific GAO recommendations contained in the draft report, NRC suggests that DOE be given the flexibility to choose alternative approaches to achieve and measure improved Quality Assurance Program performance, since alternatives may be more suitable for the situation as DOE nears, then moves beyond, submittal of the license application.

Two minor clarifying comments on the draft report are enclosed. If you have any questions, please contact Mr. Tom Matula at (301) 415-6700 or Mr. Ted Carter at (301) 415-6684, of my staff.

Sincerely,


William D. Travers
Executive Director
for Operations

Enclosure:
Specific Comments on Draft Report GAO-04-460

The following is GAO's comment on the U.S. Nuclear Regulatory Commission's letter dated April 16, 2004.

GAO Comment

1. We agree that alternative approaches could be used to measure performance; however, to ensure the success of any approaches, DOE must include objective measurements and time frames for reaching and sustaining desired performance and include an end point for closing out the corrective action plan.

GAO Contact and Staff Acknowledgments

GAO Contact

Daniel Feehan, (303) 572-7352

Staff Acknowledgments

In addition to the individual named above, Robert Baney, Lee Carroll, Thomas Kingham, Chalane Lechuga, Jonathan McMurray, Judy Pagano, Katherine Raheb, Anne Rhodes-Kline, and Barbara Timmerman made key contributions to this report.

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