

GAO

Report to the Chairman, Subcommittee on
Energy and Power, Committee on Energy
and Commerce, House of Representatives

September 1988

NUCLEAR WASTE

Repository Work Should Not Proceed Until Quality Assurance Is Adequate



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**Resources, Community, and
Economic Development Division**

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September 29, 1988

The Honorable Philip R. Sharp
Chairman, Subcommittee on
Energy and Power
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

As requested in your March 24, 1987, letter and as agreed in a subsequent meeting with your office, we have examined the Department of Energy's progress in developing a quality assurance program for characterizing the Yucca Mountain, Nevada, site for possible use as a nuclear waste repository. We have also assessed the effectiveness of interactions between the Department and the Nuclear Regulatory Commission in identifying and resolving potential quality-related licensing problems.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to appropriate congressional committees; the Secretary of Energy; the Chairman, Nuclear Regulatory Commission; and other interested parties. We will also make copies available to others upon request.

This work was performed under the direction of Keith O. Fultz, Senior Associate Director. Other major contributors are listed in appendix IV.

Sincerely yours,

A handwritten signature in cursive script that reads 'J. Dexter Peach'.

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Between 1989 and 1995, the Department of Energy (DOE) plans to spend about \$1.5 billion investigating whether Yucca Mountain, Nevada, is a suitable site for the permanent disposal of highly radioactive waste. A sound quality assurance program is critical to this process because the information collected will be used to support a license from the Nuclear Regulatory Commission (NRC) permitting DOE to construct a deep geologic repository.

At the request of the Chairman, Subcommittee on Energy and Power, House Committee on Energy and Commerce, GAO reviewed, among other things, NRC's assessment of DOE's progress in developing the required quality assurance program and the effectiveness of DOE and NRC's consultations in identifying and resolving quality assurance issues.

Background

The Nuclear Waste Policy Act of 1982, as amended, charges DOE with disposing of highly radioactive wastes in a repository. DOE must investigate the Nevada site and, if it is found suitable, apply to NRC for a repository construction license. DOE's Office of Civilian Radioactive Waste Management is responsible for implementing the investigation program through a project office within DOE's Nevada field office. The detailed technical work will be done by contractors.

Until DOE applies for a license, NRC's role in the repository program is limited to providing regulatory guidance and oversight of DOE's program. In 1983, the agencies signed an agreement covering interagency consultations prior to licensing. The consultations are intended to encourage timely identification and resolution of potential licensing issues.

The work needed to determine if Yucca Mountain is suitable for a repository, called "site characterization," is complex. Information must be collected under a quality assurance program sufficient to demonstrate that it can be relied on in making licensing decisions. To help ensure that DOE's program will produce information that is adequate for licensing, NRC has been reviewing DOE's plans and procedures and observing quality assurance activities in the field. NRC has also conducted one audit of a Nevada contractor.

Results in Brief

NRC's oversight of DOE's quality assurance program has been limited by problems and delays in DOE's effort to develop the program. Nevertheless, NRC has identified specific concerns from the oversight activities it has performed. On the basis of these oversight results and its review of

DOE's January 1988 draft site characterization plan, NRC formally commented in March 1988 that it did not have confidence in the adequacy of DOE's quality assurance program. NRC has also identified broad concerns related to DOE's management of the project. According to NRC, its general concerns parallel commercial utility management and organizational deficiencies that have contributed to quality-related problems in the nuclear power industry. DOE officials acknowledge that the quality assurance program is not yet adequate. However, they state that the essential program will be in place and verified by NRC before DOE starts site characterization.

The pre-licensing agreement between DOE and NRC has not been effective in identifying and resolving problems early in the program. For example, despite NRC's intention to "aggressively" oversee the development and implementation of DOE's program, its oversight has largely been reactive to DOE's schedules and priorities. In addition, although NRC has raised concerns about DOE's program, most of the concerns remain unresolved. Further, NRC staff has not escalated its concerns to senior NRC or DOE management to help ensure that problems are resolved early in the program.

Principal Findings

NRC Found Quality Assurance Problems

Through 1987 NRC reviewed quality assurance plans and procedures provided to it by DOE and observed seven DOE quality assurance audits of Nevada project contractors. NRC also audited one of eight primary project contractors in 1987. NRC had anticipated doing more, but delays and competing priorities in DOE's repository program limited NRC's review opportunities. Nevertheless, NRC found, among other things, that

- contrary to DOE's prior determinations, none of the quality assurance documents that NRC reviewed met its regulatory standards;
- some work did not meet quality assurance standards and, therefore, might not be usable for licensing the repository; and
- DOE audits were not effectively evaluating the individual quality assurance programs of project contractors. (See ch. 2.)

Management and Organization Concerns

NRC's approach to overseeing DOE's quality assurance program is heavily influenced by the lessons it learned from regulating nuclear power plants. For example, NRC learned that certain project characteristics increase the likelihood that a project will encounter major quality-related problems. Among the characteristics that have led to past problems are (1) heavy reliance on contractors, (2) indirect project control, and (3) inadequate quality assurance program oversight. According to NRC staff, DOE's repository program and its organization for carrying out the program exhibit these characteristics.

Because DOE must rely on contractors to perform site work, NRC believes it is especially important for DOE to exercise direct administrative and functional control over the project to ensure that contractors implement adequate quality assurance programs. The office that is responsible for implementing the repository program, however, does not have direct administrative and functional control over the Nevada project. The work is managed by a project office located within the Nevada field office. That office, in turn, reports to the Under Secretary and primarily services DOE's atomic energy defense programs. The project office also does not have direct administrative control over project contractors because the field office administers the contracts. According to NRC, this arrangement creates opportunities for conflict between various DOE program priorities and could result in less than adequate emphasis on implementing adequate quality assurance programs.

Ineffective Consultations

The problems and concerns that NRC has identified remain largely unresolved. One contributing factor is that the agreement between the two agencies on pre-licensing consultations does not contain procedures for resolving issues. Also, DOE has assigned higher priority to other program activities and, therefore, has not demonstrated that problems identified by NRC have been corrected. In conjunction, NRC has not acted aggressively to ensure that it receives adequate opportunities to assess DOE's program. Finally, NRC's staff has done little to raise long-standing open issues to higher NRC or DOE management levels in an effort to resolve them.

Recommendations

Because an effective quality assurance program is critical to successful characterization, GAO is making a number of recommendations aimed at improving the effectiveness of consultations between DOE and NRC on this subject. Further, GAO recommends that until DOE has determined,

and NRC agrees, that DOE's quality assurance program meets NRC standards, DOE should not proceed with work that may be used to support its license application to NRC.

Agency Comments

DOE and NRC each stated that they agree with the intent of GAO's recommendations. However, they did not concur with particular aspects of these recommendations. For example, although both agencies agree that NRC's quality-related concerns should be resolved in a timely manner, neither believes that the pre-licensing agreement needs to be modified at this time. GAO believes, however, that the agreement needs to be modified so that the program is not unnecessarily jeopardized by a failure to resolve problems identified during the 5-to-6-year site characterization period. The agencies' comments and GAO's responses have been incorporated in the report where appropriate. The full texts of DOE's and NRC's comments are reprinted in appendixes II and III, respectively.

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Abbreviations

DOE	Department of Energy
GAO	General Accounting Office
NRC	Nuclear Regulatory Commission
NWPA	Nuclear Waste Policy Act of 1982
OCRWM	Office of Civilian Radioactive Waste Management
QA	quality assurance
USGS	U.S. Geological Survey

Introduction

The safe disposal of spent nuclear fuel and other highly radioactive wastes has been a national concern for almost 3 decades.¹ Because nuclear wastes are highly toxic and can remain hazardous for thousands of years, they must be isolated from the environment until the radioactivity declines to levels that will not threaten people or the environment. To help ensure the safe disposal of these wastes, the Congress enacted the Nuclear Waste Policy Act of 1982 (NWPA) (P.L. 97-425). Among other things, NWPA, when first enacted, established a process and schedule for screening, testing, and selecting sites for two underground repositories and for licensing, constructing, and operating the first one. The act established the Office of Civilian Radioactive Waste Management (OCRWM) within the Department of Energy (DOE) to carry out this program and assigned responsibility for licensing and regulating the repositories to the Nuclear Regulatory Commission (NRC).

In December 1987 the Congress amended the NWPA to redirect portions of the nuclear waste program.² The amendments direct the Secretary of Energy to investigate Yucca Mountain, Nevada, for its suitability as the first repository and to terminate all activities, except reclamation, at two other candidate repository sites.³ If DOE finds that the Yucca Mountain site is unsuitable, it must terminate activities at the site, notify the Congress, and await further congressional direction.

The work needed to determine if Yucca Mountain is suitable for nuclear waste disposal, called "site characterization," is complex, time-consuming, and costly. Because DOE will use the information to support an application to NRC for a repository construction authorization, the data must be collected under a quality assurance program acceptable for licensing. The rigors of the licensing process demand a demonstration that the information presented is of adequate quality for making licensing decisions. Toward this end, NRC's high-level waste repository regulations require DOE to implement a comprehensive quality assurance program for site characterization work. Failure to effectively implement such a program may result in NRC's denial of DOE's construction application.

¹Spent nuclear fuel is uranium fuel that has been removed from a nuclear reactor because it is no longer useful in the production of electricity.

²Nuclear Waste Policy Amendments Act of 1987, contained in title V of the Budget Reconciliation Act for Fiscal Year 1988 (P.L. 100-203).

³Prior to the 1987 amendments, DOE's first repository program emphasized the identification of candidate sites. In May 1986 the President approved three sites—Hanford, Washington; Yucca Mountain, Nevada; and Deaf Smith County, Texas—that DOE had recommended for detailed geologic investigation.

This report provides information on DOE's required quality assurance program, including NRC's assessment of DOE's progress in developing the program. It also evaluates the effectiveness of consultations between the two agencies on the subject of quality assurance and provides information on DOE stop-work orders at the Yucca Mountain, Nevada, site.

Site Characterization Phase

The Yucca Mountain site needs to be characterized to determine if it has natural properties that can safely keep nuclear waste isolated for thousands of years. If, after studying the site, DOE determines that the site would be a suitable repository location, it will recommend that the President formally recommend its selection as a repository site to the Congress. If the President's recommendation is not vetoed by the state of Nevada (or if the Congress overrides a veto), as permitted by NWPA, as amended, DOE will use the information acquired during site characterization to develop a construction application to NRC.

Site characterization includes a program of extensive field and laboratory work to collect and evaluate geologic, hydrologic, and geochemical information. The field program, for example, consists of surface-based activities such as geologic mapping, meteorologic monitoring, geophysical surveys, and seismologic and hydrologic studies. It also includes activities conducted in boreholes and trenches that will be used for groundwater monitoring; core extraction; laboratory testing; and studies of the earth's geological structure, chemical composition, and underground water. Finally, studies will be conducted in the host rock at repository depth through construction of exploratory shafts, horizontal drifts (tunnels), and underground test facilities. DOE began preliminary fieldwork at the Nevada site several years ago. Since 1977, DOE has mapped the geology of the Yucca Mountain area, conducted regional geophysical investigations, and recorded seismic data. DOE expects site characterization to last until 1995 and cost about \$1.5 billion (1986 dollars).

Site Characterization Plan

NWPA requires DOE to prepare and submit a site characterization plan for NRC's review and comment before sinking exploratory shafts for underground testing. The Nevada plan will identify issues that must be resolved to determine if the site is suitable for permanently storing the waste and outline steps for obtaining data needed to resolve the issues. In June 1987 testimony before the Senate Committee on Energy and Natural Resources, for example, NRC identified potential licensing issues at each of the three candidate sites. For Yucca Mountain the concerns

included the presence of potentially active faults, the potential for volcanism, and the origin and significance of mineral veins in the area. According to NRC, these issues could have serious implications for licensing the site if information obtained from site characterization does not satisfactorily resolve the concerns. As a result, DOE's plan will address these issues and lay out testing strategies to evaluate whether these conditions affect the site's ability to safely isolate nuclear waste. The plan will also describe quality assurance measures that DOE will implement to ensure that information obtained during site characterization will be of demonstrable quality so that it can be used for making licensing decisions about the site.

DOE issued the draft Nevada site characterization plan on January 8, 1988, to consult with involved parties such as NRC and the state of Nevada. DOE expects to release the final plan in December 1988, after it has completed the consultations and revised the plan. When the plan is final, affected parties will have 90 days for review and comment before DOE can proceed to sink shafts, now scheduled to begin in June 1989, and commence full-scale site characterization work. DOE is requesting about \$301 million to conduct full site characterization activities, including construction of the first exploratory shaft, at Yucca Mountain during fiscal year 1989. In the meantime, DOE will continue to plan and perform surface-based testing at Yucca Mountain.

Quality Assurance Is Critical to Successful Characterization

A sound quality assurance program is essential to winning NRC's approval for constructing a repository. To obtain a construction authorization (license) from NRC, DOE must demonstrate that the repository can be safely operated and that it can isolate waste for the required period of time. NRC regulations require a quality assurance program that provides a process for demonstrating that work results can be relied on in making licensing decisions about a site's suitability for a repository. The process requires, for example, that DOE (1) train personnel in quality assurance, (2) inspect activities that affect quality, (3) establish controls over testing programs and test equipment, (4) establish and maintain quality assurance records, including records documenting the qualifications of personnel performing repository work, (5) perform audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program, and (6) initiate corrective action to resolve identified problems.

The licensing process ensures that a proposed repository receives careful scrutiny. Among other things, the process will test whether DOE's

quality assurance program has been adequate for ensuring the quality of site characterization work. Because NRC anticipates that the repository's licensing application will be heavily contested by the state of Nevada, among others, it is important that DOE's quality assurance program be designed and implemented in accordance with NRC's regulations. In NRC's licensing experience, uncontested and contested proceedings show a marked difference in the degree to which applicants have had to defend the quality of their work. In contested proceedings for nuclear power plants, if the applicant had quality-related weaknesses, interveners were successful in surfacing the problems during licensing. As a result, plant projects were cancelled or incurred expensive and time-consuming delays while weaknesses were corrected. This situation could occur in the licensing proceeding for the Yucca Mountain site if DOE does not adequately document that site characterization work has been conducted in conformance with NRC's quality assurance standards.

Effective quality assurance is critical for at least two other reasons. First, the recent amendments to NWPA directing DOE to characterize the Yucca Mountain site mean that DOE will not have an alternate site in the event that it is not successful at Yucca Mountain. Second, there is the potential for adverse health, safety, and environmental effects if a repository is constructed and operated on the basis of data that are, unknowingly, unreliable or inaccurate. For these reasons, effective quality assurance at the outset of site characterization is critical to ensuring that the Yucca Mountain site does not fail in licensing or during its use because of the quality of the data obtained during site characterization.

To help avoid the possibility that DOE would conduct work that would not be adequate for licensing purposes, NRC and DOE agreed, in 1985, that DOE's quality assurance program for key site characterization activities should be in place before beginning site characterization. Specifically, DOE indicated in a September 1985 letter to NRC that it would have fully qualified quality assurance programs in place for each of the (then) three candidate sites prior to submitting the site characterization plans for NRC's review.⁴ DOE stated that it would request NRC to audit the programs before site characterization began to demonstrate its compliance with the requirements.

⁴According to DOE, quality assurance programs will not be fully implemented for all work areas when site characterization begins. Near-term site characterization work will meet NRC's requirements when DOE issues the Nevada site characterization plan, but programs governing future work will be developed as needed.

DOE's Project Organization and Quality Assurance Initiatives

OCRWM is responsible for siting, designing, constructing, and operating the repository. To fulfill these responsibilities, DOE has established an organizational framework for executing repository-related work. The OCRWM project management structure is consistent with DOE's overall philosophy of having program planning, guidance, and control handled by DOE headquarters and project execution handled by project offices established within DOE operations offices located in various states. Accordingly, overall quality assurance management and control within DOE are exercised by OCRWM, while the Nevada project office and its contractors are responsible for the day-to-day management of the Yucca Mountain project.

The Nevada operations office performs a variety of management and administrative functions—contract administration, accounting, budgeting, procurement, and quality assurance support for the project office.⁵ The operations office manager has delegated program management and execution to the project manager in the Nevada project office. Among other things, the project manager is responsible for establishing and implementing technical and quality assurance programs in accordance with OCRWM and NRC requirements.

The project office relies on prime contractors to perform most repository work and is responsible for providing detailed guidance to them and overseeing the work performed. Work that is not performed directly by the prime contractors is subcontracted to firms that have the technical expertise needed for specific tasks.

Early work at the Yucca Mountain site was not conducted under NRC's quality assurance standards because it was exploratory in nature and not intended for eventual use in licensing. According to DOE, the work was accomplished in a manner consistent with good scientific and engineering practices. Since DOE must ultimately comply with NRC's high-level waste disposal regulations, it is upgrading its quality assurance program to help ensure that it will comply with these regulatory standards. DOE's effort includes establishing organizational responsibilities, developing and implementing quality assurance plans and procedures, and overseeing the development and implementation of quality assurance programs by Nevada project contractors.

⁵The operations office delegated limited contractual authority over Nevada contractors to the project office manager.

DOE requires each project participant to have a quality assurance organization responsible for providing guidance and independent quality assurance oversight within that organization and for subordinate organizations. These organizations are to function as extensions of management and are responsible for independently communicating to management whether or not high-quality work results are being achieved. They are to accomplish this by, among other things, monitoring work performance, identifying problems and potential problems, and following up on corrective actions. Contractors, for example, are responsible for auditing their quality assurance programs to ensure that they are operating effectively and that work results will meet DOE and NRC standards. Project office and headquarters quality assurance staff, in turn, are responsible for determining that these audits have been performed and are effective in detecting and causing resolution of problems.

Just as DOE relies on contractors to perform most of its repository work, it also relies heavily on contractors to carry out its quality assurance responsibilities. The project office's quality assurance responsibilities, for example, are carried out in large part by a quality assurance support contractor. Among other things, the support contractor is responsible for developing and implementing project-level quality assurance plans and procedures, reviewing contractor-level quality assurance plans and procedures, and conducting quality assurance audits of project participants.

Each organization participating in the repository program must conduct annual management assessments and other oversight activities to verify the effectiveness of quality assurance programs and the adequacy of each organization's quality assurance personnel resources and training. The organizations are responsible for developing internal procedures for planning, performing, and documenting the assessments, including analyzing and reporting audit results and following up on corrective actions.

NRC's Role

NRC regulates the construction, operation, and decommissioning phases of the repository program and is responsible for assuring that DOE satisfies public health, safety, and environmental regulatory requirements. Eventually, NRC will review and decide on DOE's construction application

for a repository license.⁶ As part of this licensing proceeding, the NRC staff will review data supporting the application, conduct independent evaluations of repository performance to assess compliance with regulatory criteria, and recommend whether, and under what conditions, a construction authorization should be issued. In addition, NRC will convene an independent Atomic Safety and Licensing Board to conduct a public hearing addressing its concerns as well as those identified by affected parties. DOE plans to complete the site-selection process in 1994 and apply for a construction authorization in 1995.

Pre-Licensing Consultation

Until DOE submits an application for a construction authorization, NRC's formal role in the repository program is limited to observing repository program activities and providing regulatory guidance to DOE. NWPA and NRC's licensing regulations, however, require consultation between DOE and NRC prior to DOE's application for a construction authorization. One method of pre-licensing consultation mentioned in the act is NRC's review and comment on DOE's site characterization plan. In addition, during site characterization DOE is required to submit semiannual reports to NRC and the host state on the nature and extent of activities and the information developed from these activities.⁷

Pre-licensing consultation is intended to help identify and resolve potential licensing issues early so that years of site characterization work will not be found inadequate for repository licensing purposes. To facilitate this consultation process, DOE and NRC entered into a procedural agreement in June 1983 intended to ensure that both agencies receive adequate and timely program information. Under the terms of the agreement, pre-licensing consultation primarily consists of technical and management meetings, data and document reviews, and the prompt exchange of information between NRC's on-site representative and DOE project office personnel. NRC's regulations also require DOE to permit NRC staff to visit and inspect the site and observe excavations, borings, and other tests as they are performed.

⁶DOE must submit three license applications for NRC's approval during the lifetime of the program—before (1) construction begins, (2) waste emplacement, and (3) permanent closure of the repository. The most immediate licensing step is the construction authorization.

⁷DOE's semiannual progress reports will include the results of site characterization studies, including any new information that might affect design assumptions concerning waste form and packaging and the planned repository itself. The reports will also identify new issues, plans for additional studies to resolve the issues, studies that DOE believes are no longer necessary, decision points, and schedule modifications.

In the area of quality assurance, NRC's pre-licensing role is limited to providing DOE guidance and maintaining sufficient oversight of DOE's site characterization program to gain reasonable assurance that DOE's license application will meet regulatory requirements. Although DOE—not NRC—is responsible for implementing a quality assurance program that meets NRC's requirements, NRC has agreed to point out problems it identifies so that DOE can take timely corrective action.

NRC Requirements and Guidance

NRC has promulgated technical requirements and criteria applicable to licensing repositories. The regulations, "Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures" (10 CFR 60), consist of procedural rules for licensing repositories and technical criteria that DOE must satisfy to receive a construction authorization from NRC.⁸ One part of the technical criteria—Subpart G—requires DOE to implement a quality assurance program applicable to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities such as site characterization. It requires that DOE's quality assurance program comply with criteria contained in Appendix B of 10 CFR 50—"Quality Assurance Criteria For Nuclear Power Plants and Fuel Reprocessing Plants"—as applicable and as supplemented by additional criteria required by Subpart G.

NRC's principal quality assurance guidance document is "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." The review plan, which supplements Appendix B, describes the criteria and methods that NRC will use to review DOE's quality assurance programs for site characterization and provides additional guidance to DOE. NRC is also supplementing the review plan with technical positions that address specific quality assurance issues.

Beyond providing regulatory guidance, NRC has been overseeing the program to accumulate information about the status of DOE's development and implementation of a quality assurance program. Over time, the accumulation of program knowledge will provide NRC with the basis for determining if DOE's quality assurance program is adequate for licensing purposes. Toward this end, NRC has reviewed some of DOE's quality assurance plans and procedures, visited the Yucca Mountain site to

⁸NRC will also ensure that DOE complies with Environmental Protection Agency standards that protect the public from offsite release of radioactive waste materials.

acquaint itself with project activities, observed DOE quality assurance audits, and conducted one audit of its own. NRC has identified for DOE the problems it noted during the course of these activities so that DOE can correct the problems and strengthen its program.

Objectives, Scope, and Methodology

In a March 24, 1987, letter, the Chairman, Subcommittee on Energy and Power, House Committee on Energy and Commerce, identified seven issues related to DOE's nuclear waste program that we should plan to address during the 100th Congress. This report addresses three of these issues: DOE's quality assurance program, NRC's role in the quality assurance program and coordination of its activities with DOE, and information on stop-work orders at the Yucca Mountain, Nevada, site.

Through discussions with Subcommittee representatives, we agreed to focus on DOE's progress in implementing its quality assurance program. Specifically, we agreed to assess

- the extent to which NRC has monitored DOE's progress in developing a quality assurance program and, on the basis of NRC's oversight, whether DOE is likely to have an effective quality assurance program in place when it is otherwise ready to begin site characterization (chap. 2);
- the effectiveness of the agencies' interaction in identifying and resolving potential problems related to DOE's quality assurance program (chap. 3); and
- information describing the stop-work orders issued by DOE to contractors at the Yucca Mountain, Nevada, site (app. I).

In conducting our review, we did not attempt to independently evaluate DOE's state of readiness to begin site characterization from a quality assurance perspective. Because DOE must eventually demonstrate to NRC that its site characterization work was conducted according to NRC's quality assurance standards, we focused our work on reviewing the scope and results of NRC's oversight activities and the agencies' efforts to resolve problems identified by NRC.

Most of our work was conducted at NRC headquarters near Washington, D.C., between June 1987 and March 1988. We interviewed key NRC officials and reviewed NRC and DOE correspondence and documents contained in NRC's central filing system for repository-related information.

To document quality-related information, we reviewed NRC's records on DOE's quality assurance program and the Nevada project. We also

reviewed other files that provide additional information about interactions between the agencies. Among other things, the files contained documentation of (1) regulatory quality assurance requirements and supplemental NRC guidance; (2) the importance of quality assurance to the repository program; (3) NRC's approach to overseeing DOE's development and implementation of a quality assurance program, including its emphasis on measures to prevent the recurrence of major quality problems that have prevented some utilities from licensing their power plant projects; and (4) NRC's oversight results, including its comments on DOE's quality assurance documents, observations about DOE's quality assurance audits, correspondence on problems found during site visits to the projects, and minutes of NRC/DOE meetings documenting concerns about the repository program.

We also reviewed DOE documentation, such as its quality assurance plans and information about stop-work orders imposed on project contractors, to develop information about DOE's quality assurance development and implementation initiatives. In addition, we reviewed the personal work files of NRC's quality assurance section leader. We also contacted DOE headquarters and project-level quality assurance personnel to obtain 1987 audit results and information about DOE's progress in lifting stop-work orders at the site.

Our review was conducted in accordance with generally accepted government auditing standards. We provided draft copies of this report to both DOE and NRC for comment. Specific comments are summarized and addressed at the end of each chapter, and technical or editorial comments have been incorporated in the report where appropriate. The texts of DOE and NRC's comments are included in appendixes II and III, respectively.

DOE Has Not Demonstrated to NRC That Its Quality Assurance Program Meets NRC Standards

Although NRC's oversight of DOE's program has been limited by problems and delays in DOE's efforts to develop the program, NRC has identified many specific concerns from the oversight activities it has performed. On the basis of these oversight results and its review of DOE's January 1988 draft site characterization plan, NRC formally commented in March 1988 that it did not have confidence in the adequacy of DOE's quality assurance program. NRC has also identified broad concerns related to DOE's management approach to quality assurance. According to NRC, its general concerns parallel commercial utility management and organizational deficiencies that contributed to quality-related problems in the nuclear power industry. As a result, NRC believes that DOE's repository program is vulnerable to some of the same problems that electric utilities encountered unless weaknesses in DOE's quality assurance program are detected and corrected early.

DOE officials acknowledge that the quality assurance program is not yet adequate for conducting site characterization work and that the program is taking longer to implement than had been expected. However, a DOE official said that DOE has made considerable progress toward implementing a quality assurance program that will comply with NRC's requirements for conducting site characterization work and that the program will be ready for DOE's near-term work activities.

NRC Oversight Has Identified Weaknesses in DOE's Quality Assurance Program

Oversight by NRC is the principal external mechanism for identifying potential problems in DOE's quality assurance program that could, if not corrected, prevent or delay DOE from gaining approval to construct the repository. NRC activities—such as quality assurance document reviews, site visits, observations of DOE audits, and its own independent audits—provide information about the status of DOE's quality assurance program and an independent means of determining if the program is adequate. According to NRC, early NRC oversight is intended to (1) help DOE prepare for site characterization by providing information about observed quality assurance weaknesses or possible problems that may need to be resolved prior to full-scale site characterization and (2) develop NRC's confidence in the adequacy of DOE's quality assurance program prior to starting the work. NRC has been engaged in this process since 1984.

Although NRC had planned to perform an extensive amount of oversight early in the program, it has been unable to do so because of slippages in DOE's repository program schedule, the prolonged existence of stop-work orders imposed on project contractors while quality assurance program

improvements were made, and DOE's emphasis on other repository program objectives, such as preparing the site characterization plans. Nonetheless, NRC has identified a number of weaknesses in DOE's quality assurance program from the activities it has performed. According to NRC's staff, the significant number of identified problems—especially given the limited scope of their oversight activities—indicates that problems are probably widespread throughout DOE's quality assurance program.

As of January 1988, NRC had reviewed the quality assurance program document prepared by the Office of Geologic Repositories, the Nevada project office's quality assurance requirements document,¹ and the quality assurance plan² and selected implementing procedures of one Nevada prime contractor. In addition, NRC quality assurance staff visited the Yucca Mountain site; observed a total of 17 project office quality assurance audits, including 7 audits of Nevada project contractors; and conducted 1 independent audit involving a Yucca Mountain contractor. Except for the independent audit, all of NRC's activities related to the Nevada project were carried out in 1985 and 1986.

Quality Assurance Documents Reviewed Did Not Meet NRC Requirements

Quality assurance plans and procedures are the framework of a quality assurance program. The documents specify how DOE and its contractors will satisfy NRC's quality assurance requirements for acquiring licensing information and must meet regulatory requirements so that work conducted in accordance with the documents will be usable for licensing.

NRC has reviewed OCRWM, project-level, and contractor quality assurance plans and procedures to determine if these documents comply with NRC's quality assurance requirements.³ Since the documents provide only a foundation for the overall program, however, NRC's document reviews are only a preliminary step in assessing the adequacy of DOE's program.

¹The documents lay out program- and project-level quality assurance requirements. For example, the documents require project organizations to establish a quality assurance manager position and specify the manager's duties.

²Site quality assurance program plans provide specific information on how the project intends to implement quality assurance requirements. For example, the program plans specify how the quality assurance organization is set up and how the arrangement will meet the NRC requirement for organizational independence within DOE.

³Each program participant must prepare a quality assurance plan that describes how the organization intends to perform regulatory-related work so that it will comply with each of the 18 NRC quality assurance criteria. The organizations must also prepare procedures that address how the plans will be implemented.

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Document assessments do not allow NRC to determine if written plans and procedures are being followed to achieve high-quality work results, nor do they establish whether DOE is using the documents as management tools to achieve such results.

Before the recent NWPA amendments, NRC's objective was to (1) review and comment on the quality assurance plans of the Office of Geologic Repositories, the three candidate site project offices, and selected prime contractors; (2) perform detailed reviews of selected implementing procedures; and (3) resolve outstanding comments with OCRWM prior to issuance of the site characterization plans.

NRC first provided comments on the repository office's quality assurance document in 1985. In 1986, OCRWM provided most of its project-level documents to NRC for review. By December 1987, when the Congress redirected the program, NRC had reviewed documents that specify the quality assurance requirements applicable to the Yucca Mountain and Hanford projects, the quality assurance program plans for the Deaf Smith and Hanford sites, and the quality assurance plan of one of the eight Nevada prime contractors. NRC had not reviewed the quality assurance program plan and procedures of the Nevada project office because the documents had not been provided.

Although OCRWM had determined that these quality assurance documents were in compliance with NRC's quality assurance requirements before submitting them to NRC, NRC found that none of the documents met regulatory standards. For example, NRC's 1985 review of the geologic repository office's quality assurance plan revealed that the quality assurance organization structure did not meet regulatory requirements for independence. According to NRC, the quality assurance manager was assigned to the lowest management level within the office—too low in the organization to give top management complete and timely information on quality assurance problems.

NRC's assessments indicate that OCRWM's internal document reviews have not been effective in independently identifying and resolving weaknesses in the documents. According to an NRC quality assurance official, for example, it is not unusual for NRC to have questions and comments on even the best utility submittals; however, the 50 to 60 NRC comments on each DOE document is much more than for utility quality assurance documents submitted for NRC's review. As a result, NRC quality assurance staff stated in a November 1986 internal document that NRC should consider placing a greater burden on DOE for the adequacy of the plans

and procedures in view of the considerable NRC resources needed to resolve comments on the plans that had been reviewed.

Progress in establishing that DOE's quality assurance documents comply with NRC requirements has been slow because DOE has not released many of the documents for NRC's review and because DOE has not responded to NRC's written concerns and comments on the documents that NRC has reviewed in a timely manner. In January 1986, NRC expected DOE to act shortly thereafter on NRC's concern about the lack of quality assurance organizational independence within the geologic repository office. As of February 1988, however, DOE had not formally responded to NRC's review of the repository office's quality assurance plan. As a result, this and other potential issues identified by NRC remain unresolved. After our audit was completed, DOE reorganized its headquarters quality assurance organization so that the new office reports directly to the Director, OCRWM. DOE formally submitted this information to NRC; NRC reviewed it and determined that the organization now meets regulatory standards.

The Nevada project office also took about 16 months to respond to concerns and comments identified in NRC's review of its quality assurance requirements document. In August 1986, NRC requested additional information from the Nevada project office to complete its review. For example, it asked DOE to explain how Science Applications International Corporation, the project office's quality assurance support contractor, can avoid a conflict of interest because it is also a participating contractor in the site investigation work. DOE did not formally respond to NRC's request until January 1988. At the time we completed our review, NRC was reviewing this response.

Site Visits Found Quality Assurance Problems

NRC identified quality assurance problems during visits to candidate repository sites. In a September 1984 visit, for example, NRC found that the U.S. Geological Survey—an earth sciences contractor for the Nevada project—had not properly documented or maintained documentation of core samples obtained from boreholes near the Yucca Mountain site. In a March 1985 letter identifying the problems, NRC informed DOE that (1) the contractor's core library staff was apparently unfamiliar with applicable procedures for collecting and handling core samples, (2) the procedures were not available at the library, and (3) pertinent information on core samples had not been logged at the borehole sites. In subsequent correspondence, NRC pointed out that questions concerning proper handling and documentation of core samples could ultimately affect

DOE's ability to license the site. As a result, NRC identified procedures that DOE needed to implement to help establish the integrity of the core samples and to ensure the reliability of information that will be used to support DOE's license application.

Since that time, DOE has transferred Nevada's core facility responsibilities to another contractor. DOE has not yet demonstrated to NRC that existing core samples can be used for licensing or that the new contractor is effectively discharging its responsibilities to ensure that ongoing work will be adequate for licensing. However, DOE has selected one borehole location for work to determine if the samples from it can be "qualified" to meet NRC's standards. According to the NRC on-site representative's April 1988 report, the borehole location was chosen because it is the best documented. As a result, if that borehole cannot fulfill NRC's requirements, it is doubtful that samples from any other borehole can, according to the report. Qualifying this information soon is important because, according to DOE's draft site characterization plan, DOE intends to use these existing core samples, rather than drilling new boreholes and obtaining new samples, to establish essential geologic information about the site.

NRC Observations of DOE Audits Identified Weaknesses

NRC staff also assesses the effectiveness of DOE quality assurance audits of DOE's contractors by observing the audits as they are performed. Observations provide NRC with information on the status of DOE's quality assurance program development and assist NRC in establishing a level of confidence in DOE's quality assurance program. NRC's observations also enable it to provide feedback to DOE on the effectiveness of DOE's quality assurance program.

NRC started observing DOE audits in 1985. Between January 1985 and December 1987, NRC quality assurance staff observed 17 audits of various DOE program participants. Eleven of the 17 observations, including 7 pertaining to the Nevada site, were performed in 1985 during the early phases of DOE's quality assurance development effort. In 1986, NRC's quality assurance personnel planned to observe an extensive number of DOE audits in preparation for the anticipated release of the Yucca Mountain and Hanford site characterization plans in December 1986 and the expected request by DOE for program-wide NRC audits at that time. During the year, however, NRC observed only five audits, including one at Yucca Mountain, in part because DOE stopped work at the Yucca Mountain and Hanford sites.

The stop-work orders at Yucca Mountain and Hanford precluded NRC audit observations and other oversight activities while DOE and its contractors concentrated on meeting the re-start conditions that DOE imposed in the orders. (See app. I for additional information on these stop-work orders.) The stop-work orders also affected NRC's 1987 audit observation activities. Because stop-work orders continued into that year and it was uncertain when they would be lifted, the NRC quality assurance staff observed only one DOE audit (at Hanford) during 1987.

From its observations of DOE quality assurance audits, NRC developed concerns about the adequacy and effectiveness of DOE's overall quality assurance program and DOE's oversight of quality assurance program activities. On the basis of its 11 observations in 1985, for example, NRC concluded that the audits were ineffective for their intended purpose of measuring whether quality assurance procedures were being effectively implemented. As a result of its observations, NRC suggested improvements to strengthen future DOE audits.

The five DOE audits that NRC observed in 1986 contributed to DOE's decision to impose stop-work orders at the Yucca Mountain and Hanford projects. Although DOE believes that its discovery of the problems and the steps taken to correct them are evidence that its quality assurance program is working, NRC's observation reports on the audits document numerous concerns about their adequacy and effectiveness. For example, NRC expressed concern that the audits focused on assessing the contractors' compliance with quality assurance plans and procedures rather than the quality of work results. According to NRC, technical assessments of work quality are essential to evaluating the effectiveness of quality assurance programs because the assessments determine if the requirements are being followed and if the work will be usable for licensing. The following excerpts from NRC's 1986 observation reports highlight some of the NRC observers' more significant concerns:

- "Given the potential for weaknesses shown in the [contractor's] implementation of the quality assurance program and the weakness in the DOE-sponsored audit, the ultimate usefulness of [the contractor's] work for licensing purposes is in question and will require further review." (Hanford project audit, April 1986)
- "[The] audit lacked sufficient depth of review in many areas to draw a definitive conclusion as to the effectiveness of [the contractor's] implementation of the quality assurance program." (Deaf Smith project audit, August 1986)

- “[D]eviations detected by [the contractor’s quality assurance organization] during audits are not followed up to determine what actions are necessary to ensure that work completed under deviating conditions [is] appropriately dispositioned and the results defensible in licensing.” (Hanford project audit, March 1986)
- The prime contractor “is not conducting audits as scheduled and is not documenting the justification for not conducting the audits.” (Hanford project audit, March 1986)
- “NRC staff have noted that the scope of the audits conducted by DOE/DOE projects [has] been too optimistic in that they attempt to cover all 18 criteria in less than 4 days.” (General observation—Yucca Mountain project audit, March 1986)

Four of the five 1986 observations did not involve Nevada project participants. Nonetheless, the information represents NRC’s knowledge of DOE’s overall effort to develop and implement an adequate quality assurance program for characterizing the (then) three sites. Moreover, NRC’s observations from the one DOE audit of a Nevada project contractor conveyed similar concerns about the adequacy and effectiveness of DOE’s audit. The NRC observer noted, for example, that although the DOE audit was an improvement over earlier observed audits, it focused on compliance with quality assurance procedures rather than the technical quality of the work.

NRC’s Audit Identified Problems

NRC and DOE have agreed that NRC audits of DOE’s quality assurance program are needed to help identify potential licensing problems early. NRC has been preparing for these audits since 1986. For example, in June 1986, NRC offered to perform a series of “mini-audits” of completed or nearly complete work areas prior to DOE’s release of the Yucca Mountain and Hanford site characterization plans, then expected in December 1986. According to NRC, the mini-audits would provide DOE with an early opportunity to observe how NRC measures quality assurance program effectiveness and regulatory compliance. They would also provide DOE time to take corrective action on deficiencies before issuing the plans. To date, NRC has conducted only one audit of selected work activities of a Nevada project contractor, the Los Alamos National Laboratory. However, NRC has informed DOE that it needs to conduct additional audits in the near future to gain confidence in the adequacy of DOE’s quality assurance program.

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In December 1986, DOE identified 12 work areas within the Texas and Nevada projects that, in DOE's view, met NRC's quality assurance requirements and, therefore, were ready for NRC to audit. These areas were considered by DOE to be among the best examples of compliance with NRC quality assurance requirements. From these, NRC selected the mineralogy and petrology area at the Los Alamos National Laboratory for audit. The contractor and the project office quality assurance organizations audited the work areas before NRC to assure themselves that the areas met regulatory standards. Each organization found quality assurance deficiencies; however, none of the deficiencies affected DOE's overall assessment that the work areas were fully qualified.

NRC conducted programmatic and technical assessments of the contractor's quality assurance program during the week of June 8, 1987. The programmatic portion of the audit focused on the contractor's compliance with NRC's quality assurance requirements and its quality assurance plan and procedures. The technical portion of the audit—conducted by NRC staff and NRC-contractor geochemists familiar with the Nevada project—assessed the detailed technical procedures used in Los Alamos' mineralogy and petrology program to determine if (1) the procedures reflected accepted scientific practice, (2) the contractor's work products appeared adequate for licensing, and (3) the contractor's staff was following the procedures.

Prior to the audit, DOE excluded three quality assurance program areas—computer software controls, quality assurance records, and field sample controls external to the contractor—from the scope of NRC's audit because they were not ready for audit. Despite the limitations on the scope of NRC's audit, NRC found enough deficiencies in Los Alamos' quality assurance program to conclude that it did not meet all NRC quality assurance requirements. NRC indicated, for example, that although the contractor's work appeared to be of high technical quality, inadequate documentation of work quality might preclude its use in licensing 10 years later. NRC's report on its June 1987 audit identified 3 quality

assurance findings⁴ and 14 quality assurance deficiencies⁵ that the earlier project office and contractor readiness audits had not detected. The following information highlights NRC's audit findings:

- Procedures for activities affecting quality were (1) not developed for some activities, (2) not being followed in all instances, and (3) not fully understood by all contractor staff.
- Los Alamos' internal audit program needs to be strengthened. Its audit did not detect several significant deficiencies that were subsequently discovered by the project office's audit and did not detect deficiencies later identified by NRC.
- Personnel qualifications and training documentation for individuals performing the work was incomplete. Related procedures did not require sufficient evidence of the qualifications and training of personnel, and existing procedures were not being followed in all cases. Although NRC expressed confidence in the qualifications and experience of contractor personnel and in the quality of work being performed, it noted that the lack of adequate documentation—demonstrating that individuals performing the work are qualified to do so—may preclude its use in licensing some 10 years later if the work is challenged.⁶

NRC's audit report identified a number of steps that Los Alamos needed to complete successfully before it could achieve a fully qualified program in the mineralogy and petrology work areas. First, it needed to revise its quality assurance plans and procedures to address NRC concerns. Second, the contractor needed to address all findings and deficiencies that it, the project office, and NRC identified.⁷ Third, the contractor and DOE needed to conduct a thorough assessment of the contractor's entire quality assurance program to help ensure that other areas do not contain similar deficiencies. None of these steps have been completed.

⁴Findings are errors, inconsistencies, or procedural violations relating to regulations, codes, procedures, specifications, and project commitments that have an actual or high potential to affect public health and safety. For the purpose of this audit, NRC considered instances of inadequate documentation to be findings because of their potential impact on DOE's ability to use the information for licensing.

⁵Deficiencies relate to minor safety concerns and do not create an immediate or increased risk to public health and safety.

⁶According to an NRC quality assurance official, this is particularly important because the work would not be challenged in the licensing proceeding for another 7 to 8 years. By that time, it may not be possible to reconstruct the records because some, if not many, of the investigators may no longer be working on the project.

⁷This would include taking corrective action as well as identifying the root cause of problems to determine if underlying conditions could be causing quality-related problems elsewhere in the program.

However, when DOE and Los Alamos have completed these steps, NRC will reassess the program to, among other things, determine if the corrective actions are adequate. NRC also intends to audit the three quality assurance areas that were not ready for its audit when DOE determines the areas are ready.

NRC's Comments on Draft Site Characterization Plan Express Concern About DOE's Quality Assurance Program

As a result of information obtained from its limited oversight activities, NRC staff concluded that problems are probably pervasive in the program and that improvements are necessary before site characterization begins. NRC staff reiterated concern about DOE's program in its March 1988 comments on DOE's draft site characterization plan. At that time, NRC staff raised five concerns that it considered of such immediate seriousness to the site characterization program that DOE should not start work until they are satisfactorily resolved. One of the five major concerns, called "objections," related to DOE's quality assurance program.

According to the NRC staff, it has an insufficient basis for confidence in the adequacy of DOE's quality assurance program at this time. In part this is because none of the quality assurance documents reviewed by NRC have fully complied with its quality assurance requirements and unresolved comments exist on these documents. Also, NRC has not reviewed the quality assurance documents for all project participants. For example, it had not reviewed the project office's quality assurance plan or the documents of seven of the eight principal contractors because DOE had not yet released them for NRC's review. Further, NRC had not selectively verified, through audits, that an adequate quality assurance program was in place for repository-related site characterization work. According to the NRC staff, selective verification is essential for NRC to gain confidence in the adequacy of DOE's program.

The NRC staff pointed out that data collected under quality assurance programs that do not comply with NRC's quality assurance requirements may not be usable later in the licensing proceeding. The NRC staff stated, therefore, that DOE should not start any new testing programs until its quality assurance program meets regulatory standards. As a first step toward getting such a program in place, NRC stated, DOE should provide NRC with the schedule for completion of activities required to establish and qualify the portions of the quality assurance program that are needed for near-term site characterization work. The staff also recommended that DOE (1) furnish the latest revisions to project and headquarters quality assurance documents, (2) respond to outstanding staff comments on quality assurance plans, and (3) facilitate opportunities

for NRC audits and other methods for verifying the adequacy of DOE's quality assurance program.

On March 10, 1988, DOE publicly acknowledged receipt of the NRC staff's comments on the draft site characterization plan. DOE indicated that NRC's concerns would be discussed in forthcoming meetings between the agencies to ensure that DOE fully understands and considers the comments in completing the plan, but that NRC's objections should not have a major effect on DOE's testing program. Subsequently, DOE repository officials stated that, since it is not prudent to proceed with site characterization until NRC's objections have been resolved, DOE's goal is to provide NRC with sufficient information so that NRC can feel comfortable about lifting the objections. In the area of quality assurance, they stated, this should not be a problem because DOE intends to ask NRC to assess the program before site characterization begins.

NRC's Oversight Is Influenced by Its Experience With Nuclear Power Projects

NRC's approach to reviewing DOE's quality assurance initiatives is heavily influenced by the lessons it learned from licensing and regulating nuclear power plants. In 1984, NRC published a study of existing and alternate programs for improving quality assurance and quality control in the construction of nuclear power plants.⁸ The study examined the underlying causes of (1) some nuclear construction projects' having experienced significant quality-related problems while others did not and (2) NRC's and the utilities' not detecting and acting on the problems in a timely manner.

One lesson NRC learned is that certain project characteristics increase the likelihood of major quality-related problems. In NRC's view, for example, the repository program and OCRWM's organization for carrying it out exhibit characteristics that make achieving high-quality results difficult. First, the program is large, complicated, and unique. It involves state-of-the-art testing programs for which no technical standards or requirements have been established. Also, although DOE and its contractors have been designing, constructing, and operating nuclear facilities for years, they have not had to obtain an NRC license for a facility and are

⁸The study—Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants, (NUREG 1055)—was required by an amendment to the NRC Authorization Act for fiscal years 1982 and 1983. Commonly referred to as the Ford Amendment study after its principal sponsor, Senator Wendell Ford of Kentucky, it was conducted between November 1982 and April 1984 and included six case studies of nuclear power plant construction projects that either had experienced or did not have major quality-related problems.

inexperienced with NRC's quality assurance and other licensing requirements.

Further, the repository program's size and DOE's decentralized management structure make communicating quality assurance requirements and overseeing their implementation a difficult management task. At least three DOE organizations (OCRWM, the Nevada operations office, and the project office) and eight prime contractors are involved in the Yucca Mountain project. Moreover, four of the eight principal contractors are located in three states—Colorado, California, and New Mexico. The geographic distance between the various organizations may hamper OCRWM's quality assurance communication and oversight objectives. According to NRC, project organizations like DOE's are highly susceptible to quality-related problems because the organization responsible for the project—in this case OCRWM—lacks direct control over project execution.

Management and Organizational Concerns

Because NRC believes DOE's program is vulnerable to some of the same problems that electric utilities encountered when licensing their projects, NRC has also identified management and organizational concerns about DOE's repository program that appear to closely parallel the utility management and organizational deficiencies that NRC identified in its study of problem nuclear plant projects. Although management and organizational arrangements are beyond NRC's direct authority to regulate, NRC is interested in them because their effectiveness has a direct bearing on those matters that are regulated.

Since these areas are not directly regulated by NRC, however, NRC has identified the concerns but left it up to DOE to resolve them. In June 1986, for example, NRC met with OCRWM to discuss specific problems observed by NRC staff during the preceding 18 months. The problems included core sample handling and collection problems at Nevada and the attitudes toward quality assurance exhibited by repository project participants. At that time, NRC indicated that the observed problems appeared to be related to OCRWM's (1) heavy reliance on contractors, (2) indirect project control, and (3) inadequate quality assurance programs and oversight. The NRC staff indicated that it was raising these concerns with DOE before major problems had occurred so that DOE could take appropriate action. At other times, NRC raised other general concerns that also have the potential for causing quality-related problems.

Reliance on Contractors

OCRWM has a small staff with which to manage its contractors and, therefore, relies heavily on the contractors to provide quality assurance oversight throughout the repository program. In studying its experience with nuclear power plant projects, NRC found that utilities that relied extensively on contractors frequently developed major quality-related problems. The utilities appeared to have delegated quality assurance responsibility to their contractors and had not independently ensured that the contractors' work was adequate. As a result, the utilities had lost knowledge and control of their projects. NRC recognizes that DOE must rely heavily on contractors for site characterization work. Therefore, it believes that direct project control and an effective quality assurance program are especially important.

Indirect Project Control

According to NRC, utilities with decentralized project organizations did not provide direct control over their projects and did not adequately insulate projects from competing organizational activities. They also had long command and communication chains that hindered effective identification and resolution of problems. Because DOE's organization also exhibits these characteristics, NRC has identified them as potential problems in the repository program.

In its study of nuclear power plant experiences, NRC found that relatively successful nuclear plant projects were managed by independent organizations with direct administrative and functional project control. Conversely, utilities that had serious quality-related problems tried to fit project management into existing corporate frameworks. In the latter case, the utilities typically split administrative and functional responsibilities within the project. As a result, the projects did not have personnel dedicated both functionally and administratively to the project. This put the projects in competition with other corporate activities and objectives.

According to NRC, direct project control is particularly important because of DOE's reliance on contractors to perform repository work. OCRWM does not have both direct administrative and functional control of the Yucca Mountain project because the Nevada project office, which is responsible for project execution, reports directly to the Nevada operations office rather than to OCRWM. The operations office primarily services DOE's atomic energy defense programs and reports to the Under Secretary, DOE. The project office also does not have direct control over its contractors because the contracts are administered by the Nevada

operations office. For example, the Nevada project office cannot independently issue stop-work orders to all project contractors. Instead, it must coordinate some proposed orders with the Nevada operations office contracting officer. On several occasions, including the June 1986 meeting with OCRWM officials, NRC has indicated that indirect project control by OCRWM could hinder achievement of DOE's quality assurance program goals. DOE indicated at that meeting, however, that its existing organizational arrangement is working adequately.

Indirect OCRWM and project office control creates opportunities for conflicts between quality assurance goals and other project priorities. The quality assurance organization in Nevada, for example, functions as an extension of DOE project office management and is responsible for independently assessing the quality of work performed by contractors on behalf of the project manager. As a result, the project manager, who reports to the operations office, may be influenced by competing goals such as the project's cost and schedule, and he could prevent concerns from being passed to higher organizational levels for resolution.

According to NRC, one important factor in achieving an effective quality assurance program is ensuring that the emphasis placed by top project management on quality, and communicated to all program levels, is as strong as the emphasis placed on cost and schedule. In addition, quality concerns must be escalated to higher management levels without regard for any adverse effects on these other program goals.

A 1986 NRC report on its observations of a DOE quality assurance audit illustrates a potential problem in this area and indicates that the Nevada project office's quality assurance support contractor may not be sufficiently insulated from other project goals. The report identified a potential problem with the independence of the quality assurance support contractor from cost and schedule concerns. In the NRC observer's opinion, the support contractor's audit team gave undue attention to what it thought contractor and project office management would want to hear, and the lead auditor "was concerned about" contacting the quality assurance manager to discuss the situation. The NRC observer added that if DOE intends to use contractors as extensions of DOE project staff in the quality assurance area, the contractors should feel free to act with project authority and exhibit necessary independence from cost and schedule considerations. In an April 1986 meeting with OCRWM, NRC expressed a similar concern about the level of attention directed at schedules and what NRC staff viewed as OCRWM's reluctance to stop work when it was obvious that its quality assurance program was not adequate.

Nuclear power plant projects with significant quality-related problems also frequently had long command and communication chains between site quality assurance managers and senior corporate officials. The three to four layers between the quality assurance managers and top management prevented vital quality-related information from being properly acted upon. NRC's 1985 review of DOE's Office of Geologic Repositories' quality assurance plan disclosed similar problems within DOE. NRC found that the office's quality assurance manager was too low in the OCRWM organizational structure to give top management complete and timely information on quality assurance problems. In addition, NRC found that the reporting chain between that individual and those capable of effecting the necessary action would be likely to dilute the information as it flowed upward from the quality assurance manager.

DOE's process for resolving quality assurance concerns may similarly hamper the effective resolution of quality-related problems because the number of organizational levels involved and the opportunity for each level to influence the message flowing upward from the project's quality assurance manager are similar to what NRC found at problem nuclear plants. If disputes arise between the project's quality assurance manager and project participants, for example, they are arbitrated first by the project office manager. If unsatisfied with the outcome, the project's quality assurance manager may seek a decision by the operations office manager. If still unsatisfied, the project's quality assurance manager can appeal to the quality assurance manager in DOE headquarters. Although DOE's new headquarter's quality assurance organization eliminates one reporting layer, the existing reporting chain still provides opportunities for intervening managers to influence whether and how quality-related concerns will be acted upon.

Adequacy of Quality Assurance Program Oversight

NRC's examination of nuclear power plant projects revealed that utilities with major quality-related problems had not exercised sufficient oversight to ensure that their quality assurance programs were adequate for regulatory purposes. Because little can be done about DOE's reliance on contractors, according to NRC, the need to implement effective quality assurance programs is especially important. According to NRC, license applicants, including DOE, must provide comprehensive oversight of all aspects of their projects so that they can demonstrate the adequacy of their quality assurance programs during licensing.

Over the years, NRC has often expressed concern about the adequacy of DOE's quality assurance oversight program for ensuring that quality

assurance programs are being effectively implemented. Some of the general concerns contained in NRC's reports on its observations of DOE audits in 1986 and its 1987 audit have already been discussed. The following discussion provides detailed information about other deficiencies found in DOE's quality assurance oversight of the repository program.

First, prompt attention to identifying and resolving quality-related problems is an important characteristic of effective quality assurance programs, because problems that are not resolved early can become more serious as additional site characterization work is done. The Nevada project office, however, did not take immediate action to correct known core handling and collection problems at the Yucca Mountain site. NRC informed the project office about the problems in March 1985, and in January 1986—10 months later—the DOE project office's quality assurance support contractor identified serious problems in the core handling contractor's quality assurance manual. Despite the earlier indications of these problems, the project office did not initiate corrective action until April 1986, when DOE issued a stop-work order because of "long-standing" deficiencies in the contractor's quality assurance practices.

This situation illustrates problems in the quality assurance program of both the contractor and the Nevada project office. The contractor knew that significant problems existed in its quality assurance program prior to the March 1986 project office audit. In fact, it had drafted a stop-work order in anticipation of such a recommendation. Also, according to the NRC observation report, the contractor acknowledged that its quality assurance staff was too small. The observer noted further that, because the contractor was aware that quality assurance problems were serious enough to merit a stop-work order, it did not seem that a project office audit should have been necessary to cause its issuance. In addition, the project office did not act immediately upon learning of the problems. By the time DOE acted, it recognized the "long-standing" nature of the problems.

Second, according to NRC, an effective internal quality assurance oversight program should detect most significant quality assurance program deficiencies within a program area. Although some problems are expected to be detected by outside organizations, such as the project office, each higher-level audit should detect fewer and less significant problems. This was not the case, however, in the Los Alamos audits. Instead, the contractor found the fewest, and NRC the most, problems. NRC concluded that Los Alamos' internal quality assurance oversight program needs strengthening because of the "breadth and significance"

of deficiencies subsequently discovered by the project office and NRC audits.

Other information from NRC's audit also points to weaknesses in DOE's overall quality assurance program. The audit performed by the contractor prior to NRC's audit, for example, was conducted by only 3 people over a 2-to-3-day period and covered only 7 of NRC's 18 quality assurance criteria. NRC staff reviewed the contractor's oversight plan and schedule and identified "major concerns" about the lack of audits, both planned and scheduled, and the lack of a complete quality assurance program audit and verification coverage. NRC concluded that the contractor's audit practices, including its earlier audit, were not comprehensive enough to detect quality assurance program problems. NRC also concluded that Los Alamos' oversight program was incomplete, as it did not provide comprehensive coverage of the entire technical work program.

According to an NRC quality assurance official, the Nevada project office did not question the adequacy or effectiveness of the contractor's audit for ensuring that its quality assurance programs were being effectively implemented. Instead, the project office focused its audit on nonsubstantive paperwork issues. For example, the only deficiency noted in the project office's audit was that the contractor's quality assurance audit procedures did not contain the proper level of detail.

NRC has also expressed concern about OCRWM's exclusive reliance on audits to assess the adequacy and effectiveness of repository program participants' quality assurance programs. OCRWM requires each project level to regularly oversee the scope, status, adequacy, and effectiveness of its quality assurance program. One method of accomplishing this is through audits. According to NRC staff, however, OCRWM appears to be relying exclusively on audits—conducted annually—to provide program oversight. The audits have usually lasted less than 1 week. According to NRC documentation, audits alone are not likely to be sufficient evidence that OCRWM's oversight has been comprehensive enough to demonstrate that its program is adequate for licensing purposes.

In December 1987, the Office of Geologic Repositories' quality assurance contractor recommended that the project offices (1) increase audit and other oversight activities and (2) take a more aggressive approach to reporting, tracking, and following up on audit findings. The contractor stated that most project-level contractors are being audited only once a

year and that annual audits may not be able to detect and correct unsatisfactory conditions prior to site characterization. The quality assurance contractor further stated that project offices were not timely in submitting audit reports. Similarly, contractors were not responding to project office audit findings in a timely manner.

Adequacy of DOE Quality Assurance Staff

According to NRC, utilities that underestimated the scope of the quality assurance job had difficulty in avoiding quality assurance problems and in successfully completing their projects. NRC has expressed concern that DOE may not have sufficient numbers of qualified staff to effectively oversee its contractors' work.

Information that we obtained from the Nevada project office also suggests that DOE may not have allocated enough resources to the quality assurance function to ensure that it meets its commitment to have fully qualified quality assurance programs in place for site characterization. According to the Nevada project office, for example, progress in completing the quality assurance documents necessary to permit it to lift the stop-work orders was slow. This was due primarily to the conflicting commitments of technical personnel to preparing both the site characterization plan and quality assurance documents. Also, sufficient project office staff was not available to review both sets of documents. Finally, before lifting the last two stop-work orders, the project office indicated that technical staff working on quality assurance documents would be diverted to preparing detailed study plans for release with the site characterization plan.

NRC staff have also questioned whether DOE has sufficient quality assurance personnel with licensing experience. According to the minutes of an April 1986 meeting between OCRWM and NRC, NRC staff expressed its continued concern about the size and related licensing experience of DOE's quality assurance staff. One of the major conclusions of NRC's audit of Los Alamos, for example, was that the contractor's staff had an insufficient appreciation of quality assurance documentation needs for licensing. In a July 1987 meeting held to discuss NRC's audit, NRC staff told OCRWM personnel that Los Alamos needs to bring in persons experienced in the licensing process. NRC staff also indicated that OCRWM should initiate action to ensure that the contractor addresses this concern.

Attitudes of Project Participants Toward Quality Assurance Requirements

NRC found that utilities with successful nuclear power plant construction projects exhibited positive attitudes toward quality assurance and a commitment to achieving quality, despite cost and schedule considerations. The utilities created work environments that encouraged looking for problems and solving them, and the positive attitude and commitment to quality filtered down to employees at all levels. Moreover, successful applicants developed constructive working relations with NRC and an understanding of NRC's licensing experience. In contrast, utilities that experienced quality-related problems did not view quality assurance as a management tool to help them exercise project control. Instead, they viewed quality assurance requirements as added government regulation not present in their earlier fossil-fueled plant projects that could potentially slow the rate of plant construction.

NRC found that participant attitudes have an important bearing on whether a project is likely to experience quality-related problems. As a result, NRC has expressed its concern to OCRWM about what it perceives to be negative attitudes toward quality assurance on the part of some Nevada project participants. During a 1984 NRC visit to Nevada, for example, some project participants had expressed the view that quality assurance is "unnecessary, burdensome, and an imposition." OCRWM officials responded that NRC's observation was derived from an isolated instance that was not representative of the majority of project personnel and, therefore, should not be overemphasized.

Subsequent statements and documents indicate, however, that the above example was not an isolated event. For example, the following excerpt from the Nevada project office's April 28, 1986, stop-work order issued to the U.S. Geological Survey (USGS)—a prime contractor on the project—expresses concern about the attitude toward quality assurance requirements of some contractor technical staff. It also recognizes the importance of quality assurance to achieving project success:

"It has been reported to me that the USGS technical staff, people who are committed to executing scientific studies, have not achieved a full appreciation of the importance of QA [quality assurance] on this program. This is clearly a USGS management problem. After these many years of effort and expenditures the practice of QA at the USGS has not reached the level necessary to satisfy our standards. Also, it is doubtful that the present USGS work would meet the U.S. Nuclear Regulatory Commission's (NRC) expectations.

I have reviewed your memorandum suspending work at the USGS pursuant to the [DOE] audit. Your actions are a positive management step necessary to correct the long-standing organizational deficiencies at the USGS in the practice of QA. We

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believe that your expeditious action in this area was essential in communicating USGS management recognition of the seriousness of this problem within the USGS, and a resolve toward meeting the requirements that are customary in the regulatory arena. It is essential that your scientific staff fully understand the situation, commit to meeting the requirements, and conform to the process as defined in your internal operation manuals. There is no longer any place in this Project for a scientific staff that does not accept and perform in accordance with the requirements established for QA.”

In June 1987, the Director, OCRWM, stated that participant attitudes were slowing the pace of DOE’s implementation of its quality assurance program. He indicated that many of the people working on the project were from backgrounds that did not practice similar levels of quality assurance and that the individuals were having to learn the requirements applicable to the repository program.

NRC recently recommended additional briefings to relate NRC’s nuclear power plant quality-related experiences to Nevada project participants. The objective of these briefings is to improve project participants’ attitudes toward quality assurance and to reinforce the importance of quality assurance within the project.

According to an NRC quality assurance official, during NRC’s June 1987 exit conference following the Los Alamos audit, NRC found that attitudes of project participants toward quality assurance were still a problem. At that time, the official said, project personnel expressed negative attitudes about the importance of quality assurance and the significance of NRC’s audit findings; specifically, the participants appeared to lack a full appreciation for what it takes to get a facility licensed by NRC. Material used to brief DOE management about the audit, for example, indicates that the NRC staff told DOE that contractor participants did not have an adequate appreciation for quality assurance documentation standards.

An NRC official who was present during the exit conference stated that contractor personnel appeared to view NRC’s audit findings as challenges to their professional integrity. Further, some contract personnel questioned NRC’s right to perform the audit. Others, the official said, complained that NRC had overstated the significance of its findings because the findings do not have an actual or likely impact on public health and safety. According to the NRC official, these participants argued that the quality assurance problems identified by NRC are less important than they would be if they related to a nuclear power plant project because the repository project does not present the same potential for a serious accident as does a nuclear facility. The official noted that this may be

true, but that NRC termed the problems “findings” because they were sufficiently important that they might affect DOE’s ability to use information acquired during site characterization in a future licensing proceeding.

As previously indicated, NRC also found that successful applicants developed constructive working relations with NRC and an appreciation and understanding of NRC’s licensing experience. They encouraged working with NRC to gain the benefit of NRC’s experience to help avoid licensing problems. Further, they tended to treat NRC’s standards as lower performance thresholds and attempted to exceed them.

The following example, however, further suggests that DOE may not have adopted a similar approach to working with NRC. DOE has not taken the conservative approach recommended by NRC in assigning levels of quality assurance controls to individual site characterization activities on the basis of their importance to safety and nuclear waste isolation objectives. The highest quality level—level 1—applies to activities that are critical to safety or waste isolation. Quality level 1 designations require a comprehensive quality assurance program. Quality levels 2 and 3 apply to work activities of less importance, and the quality assurance program required for activities with these designations is less extensive.

This graded approach to quality assurance has been a subject of discussion between DOE and NRC since at least December 1984. NRC’s regulations permit the use of a graded approach to quality assurance. However, in a June 1985 written response to DOE’s questions on quality assurance matters, NRC indicated that grading quality assurance approaches early in the repository program may be difficult because insufficient data are available on how important individual activities might be to safety and waste isolation. NRC added that the prudent approach would be initially to treat everything as requiring a high quality level and then, as appropriate, reduce the extent of quality assurance applied to some areas when such action can be properly justified. Finally, NRC pointed out that the adequacy of the quality assurance controls applied to any aspect of the repository program will be judged in the NRC licensing process and public hearings. Therefore, DOE needs a logical, defensible, and documented approach to whatever graded quality assurance approach it implements.

Subsequently, at a December 1985 meeting, NRC noted that Nevada project research activities may have questionable value in licensing if DOE

does not apply sufficient quality controls to the activities. DOE responded that research activities it expects to use in licensing would be subjected to the same degree of quality control as will be applied to activities important to safety and waste isolation, but that research not important to safety and waste isolation or for supporting DOE's license application may not have the same degree of quality controls. In response, NRC said that DOE would be wise to adopt a conservative approach to quality assurance for research activities because some research projects originally assumed to have no use in the licensing proceeding may actually produce results that could provide substantial license support.

Despite NRC's advice, in July 1987, DOE designated as quality level 2 those activities having the "strong potential for being added to the 'Q-list' [quality level 1], and whose failure or degradation could adversely affect the performance of structures, systems and components important to safety or waste isolation." In November 1987, NRC wrote DOE expressing concern about this action, noting that the definition implies that some of the affected activities may later be upgraded to quality level 1. In NRC's view, it will be difficult for DOE to demonstrate, after the fact, that the activities were conducted in compliance with quality level 1 requirements. NRC believes that DOE may end up retrofitting quality assurance and design measures to these activities. According to NRC, a number of nuclear power plants were faced with this situation and either cancelled their projects due to the difficulties encountered or incurred long delays and large cost increases. NRC's March 1988 staff comments on DOE's consultation draft site characterization plan reiterate the importance of classifying all data collection activities as quality level 1 if the resulting data may possibly be relied on in licensing. According to NRC, DOE's approach to classifying its work activities is a significant concern requiring DOE's early attention.

DOE Acknowledges Its Quality Assurance Program Is Not Yet Adequate

DOE recognizes that its quality assurance program is not yet adequate for beginning site characterization and that it is taking longer to implement effective programs than it had expected. DOE's June 1987 Mission Plan Amendment, for example, identified a need for quality assurance improvements at the candidate repository sites before site characterization begins and stated that DOE would make use of schedule extensions⁹ for, among other things, implementing a quality assurance program that

⁹DOE's June 1987 Mission Plan Amendment extends the time frame for waste acceptance at the first repository by 5 years—from 1998 to 2003.

will fully satisfy NRC's requirements for the acquisition of data to be used eventually in the licensing process. In a June 1987 DOE briefing for the NRC Commissioners, an OCRWM Associate Director said that DOE's quality assurance program would emphasize quality assurance measures necessary for near-term site characterization activities. While DOE's program would not be "absolutely perfect," he said, the "essential program" would be in place prior to issuing the site characterization plans.

In May 1988 testimony before the House Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment, the Acting Director of OCRWM stated that DOE is increasing its emphasis on quality assurance. For example, he said, DOE had recently restructured its headquarters quality assurance organization by creating a separate Office of Quality Assurance that reports directly to the OCRWM Director. The new organization is intended to ensure that an effective quality assurance program is developed and implemented. According to DOE, this is essential to obtain the required licenses from NRC and public confidence in the program's technical quality.

Conclusions

DOE expects to issue its Yucca Mountain site characterization plan late in 1988 and, following a public comment period, embark on full-scale characterization of the site. Site characterization, which is expected to take about 6 years and cost about \$1.5 billion (1986 dollars), is a critical phase of the repository program in which DOE must establish the technical basis for the site's suitability for a repository. If, after characterizing the site, DOE finds it suitable, it will recommend its selection to the President. Absent a successful veto by the state of Nevada, DOE would then seek a repository construction authorization from NRC. If the site is unsuitable, DOE must await further congressional direction.

In view of the time, expense, and risk associated with characterizing a repository, it is imperative that DOE carry out a high-quality site characterization program. Therefore, it is essential that DOE take all reasonable measures to ensure that the quality of site characterization activities, and the information developed from these activities, meet applicable NRC regulatory standards. The correctness of this approach is amply demonstrated by past failures to receive licenses or added costs and delays in numerous nuclear power plant construction projects.

Although NRC's oversight of DOE's quality assurance program has been limited by problems and delays in DOE's efforts to develop the program, NRC has identified many specific problems and broad concerns related to

DOE's quality assurance management approach. According to NRC staff, the extent of specific problems identified in NRC's limited oversight to date is an indication that problems are likely to be widespread within DOE's repository program. Also, NRC has identified many similarities between DOE's approach and the way utilities that encountered serious quality-related problems in constructing nuclear power plants approached quality-related issues. To date, however, DOE has not demonstrated to NRC that the problems and concerns have been resolved satisfactorily.

Recommendation to the Secretary of Energy and the Chairman, Nuclear Regulatory Commission

Because site characterization is critical to the successful development of a waste repository, embarking on site characterization before DOE has satisfied NRC that it has implemented an adequate quality assurance program places both agencies and, more importantly, the repository program at risk. Therefore, we recommend that the Secretary of Energy proceed with site characterization work segments only after

- the Secretary determines that all quality assurance programs related to regulatory-related work are in place and meet NRC standards and
- NRC has notified DOE that it concurs with the Secretary's determination.

Agency Comments

Both DOE and NRC stated that they agree with the intent of our recommendation. In general, DOE reaffirmed its position that site characterization should not proceed until an adequate quality assurance program that meets NRC's requirements is in place. NRC stated that it would not lift its objection to proceeding with site characterization until its quality assurance concerns are resolved. Both commitments are fully consistent with the intent of our recommendation.

Both agencies, however, qualified their comments with respect to the specifics of this recommendation. In our view, their qualifications are a matter of semantics. DOE stated that NRC will be issuing a safety evaluation report on a DOE quality assurance plan indicating its "acceptance" of, not "concurrence" with, the plan. NRC stated that, while the act does not require NRC's concurrence on DOE's quality assurance program before DOE proceeds with site characterization work, NRC would not consider its quality assurance concerns to be resolved until DOE's program meets regulatory standards. Our use of the word "concur" simply means that DOE should not begin near-term site characterization work until NRC agrees with DOE's determination.

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In its comments, DOE also stated that it had recently taken aggressive action to implement program improvements. According to DOE, these actions are an appropriate and effective response to quality assurance problems identified in this report. NRC also pointed to two of these recent actions as evidence of program progress.

The actions described in DOE's comment letter are steps in the right direction; however, they occurred only after NRC publicly objected to DOE's starting site characterization before NRC's quality assurance concerns were resolved. Our analysis of these actions also indicates that the extent of actual program progress is less than DOE describes. Further, the results of a recent DOE audit and NRC's 1988 observation audits show continuing problems and raise additional questions about the extent of DOE's progress. Our detailed comments are provided in appendix II.

Pre-Licensing Consultation on Quality Assurance Matters Has Been Ineffective

As discussed in chapter 2, NRC's oversight of DOE's quality assurance program over several years has led NRC to conclude that it has an insufficient basis for having confidence in the program; therefore, NRC believes DOE should not begin site characterization until quality assurance issues are satisfactorily resolved. This situation has occurred, at least in part, because pre-licensing consultation between DOE and NRC on quality assurance issues has not been effective for early identification and resolution of potential licensing issues. For example, NRC's oversight of DOE's quality assurance program has been limited by problems and delays in DOE's effort to develop the program. Also, despite NRC's intentions to aggressively oversee the development and implementation of DOE's quality assurance program, NRC has not been aggressive in securing early oversight of DOE's program. As a result, NRC's oversight has been more reactive than proactive. Further, even when NRC has raised concerns, DOE has not responded by demonstrating that weaknesses do not exist or that the weaknesses have been corrected. One contributing factor is that the pre-licensing consultation agreement does not specify how or when issues are to be resolved. Further, the NRC staff has not "aggressively" pursued its unresolved concerns to ensure that the issues are resolved.

Pre-Licensing Consultation Has Not Identified Potential Problems as Early as Possible

To facilitate pre-licensing consultation, DOE and NRC entered into a procedural agreement in June 1983 to ensure adequate and timely exchange of program information and to help achieve their respective repository licensing objectives. This agreement was designed to help avoid licensing problems because issues would be identified and resolved early in the program. In the area of quality assurance, effective pre-licensing consultations should help (1) DOE fulfill its goal of having a fully qualified quality assurance program in place prior to beginning site characterization and (2) NRC meet its objective of gaining confidence in the effectiveness of DOE's quality assurance program.

Despite the importance that both agencies attached to identifying and resolving potential problems prior to the start of full-scale site characterization, neither agency has done all it could do to realize the objectives. For DOE's part, as discussed in chapter 2, DOE has taken longer than anticipated to develop its quality assurance program. DOE has also been slow to act on NRC's offers to assess the adequacy of DOE's program. In June 1986, for example, NRC suggested that it should begin performing audits of complete or nearly complete work in the "next few months." DOE did not identify candidate audit areas until December 1986, however, and was not ready for the first audit until June 1987—

1 year after NRC's offer. Since then, DOE has indicated that similar NRC audits may not be appropriate for another year.

Similarly, NRC has not done all it could to convince DOE of the necessity of its early involvement. For example, NRC has not clearly articulated to DOE the scope of quality assurance program oversight necessary for it to conclude, consistent with DOE's repository program plans and schedules, that an adequate DOE quality assurance program is in place for site characterization. In the absence of a clearly stated position on the essential scope of its early oversight activities, NRC has allowed the pace and scope of its activities to be determined on the basis of DOE's evolving plans and schedules for planning and conducting site characterization activities.

NRC Planned an Aggressive Oversight Approach

In February 1986, NRC issued a 5-year plan for assessing DOE's overall repository program. According to the plan, NRC intended to move into a more proactive, rather than reactive, mode by focusing its assessment activities on the early identification and resolution of licensing issues. Shortly before the 5-year plan was issued, the Director of NRC's Office of Nuclear Material Safety and Safeguards¹ announced that NRC would take an aggressive assessment approach so that identified problems could be corrected before the start of site characterization. He stated that DOE must establish and implement an effective quality assurance program early in the repository program. Also, the NRC staff should perform sufficient early review of DOE's program to determine if the program is adequate to demonstrate the quality of DOE's site characterization work during a subsequent repository licensing proceeding.

In response to the Director's statement, NRC's quality assurance staff developed proposals for auditing DOE's quality assurance program prior to site characterization. The proposals were predicated on DOE's (then) schedule for issuing site characterization plans in late 1986 or early 1987 and to begin site characterization after a 3-month comment period on the plans. The proposals recognized DOE's primary responsibility for quality assurance; nonetheless, they set out an ambitious plan for meeting NRC's oversight objective. NRC's effort would provide the additional benefit of determining if DOE's quality assurance program was developing quickly enough to be fully qualified by the time DOE issued its site characterization plans and expected to demonstrate its quality assurance compliance to NRC. According to the NRC quality assurance staff, it

¹NRC's staff responsible for reviewing DOE's nuclear waste program is a part of this office.

is necessary to determine this as early as possible because waiting until DOE issued its site characterization plans to find major quality assurance program deficiencies could delay the start of site characterization by 6 months to 1 year.

Aggressive Approach Has Not Been Realized

NRC staff continued observing DOE project office audits of contractors in preparation for the expected release of DOE's site characterization plans. The level of NRC staff oversight, however, was much less than had been envisioned in the oversight proposals. In part, this was because of NRC management's concern over the adequacy of NRC resources to implement the proposed level of oversight. In addition, NRC management questioned whether such an aggressive level of oversight was needed, given NRC's expectation that DOE would not begin site characterization as early as then planned. The latter concern was subsequently confirmed when DOE issued stop-work orders at Hanford and Yucca Mountain and postponed its schedule for issuing site characterization plans for all three candidate sites. These factors, together with DOE's emphasis on other project activities, such as preparing the plans and lifting the stop-work orders on project participants, have limited NRC's opportunities to identify potential quality-related problems early.

In the absence of an approved NRC plan for reviewing DOE's quality assurance program, the NRC staff has found itself in the position of periodically negotiating the scope of its review activities with DOE on an incremental basis. In effect, DOE has been deciding, on the basis of its overall repository program plans and schedules, what quality assurance review activities the NRC staff would perform and when. We recognize that NRC does not have authority to regulate DOE's repository activities at this stage; however, its assessment experience to date, as discussed in chapter 2, clearly does not reflect the aggressive approach that it announced in early 1986. Further, as discussed below, NRC appears to be further reducing the scope of its effort to assess DOE's quality assurance program.

In an October 1987 letter to DOE transmitting a report on its June 1987 audit of a Nevada project contractor, NRC stated that it needs to conduct additional audits in the near future to gain confidence in DOE's quality assurance program. It encouraged DOE to quickly identify additional audit areas. The letter noted work areas previously identified by DOE as ready for NRC audit and suggested that these and certain other areas might be good candidates for future audits. According to NRC, the audits needed to be completed early so that necessary corrections could be

made before DOE had conducted an extensive amount of site characterization work. At a meeting 1 month later, however, NRC informed DOE that it would not be able to conduct more audits for approximately 6 months because it planned to devote its resources to reviewing drafts of the three candidate site characterization plans that DOE expected to issue in January 1988.

At that meeting, DOE and NRC agreed to conserve NRC resources by having NRC staff observe DOE program audits rather than conduct audits of its own. The minutes of the meeting indicate that the NRC staff's observations would provide the primary mechanism for NRC to identify quality assurance program issues and gain confidence in DOE's program. According to an NRC quality assurance official, NRC is now confident that the 8 to 9 audit observations anticipated between February and September 1988 will provide a sufficient basis for assessing DOE's quality assurance program during fiscal year 1988.

NRC's current emphasis on observing DOE audits appears to conflict with its emphasis on the importance of performing its own audits to assess the adequacy of DOE's quality assurance program. Observations of DOE quality assurance audits by NRC staff members, for example, are not as comprehensive as NRC audits in identifying weaknesses in DOE's quality assurance program or confirming that the program is working satisfactorily.

Numerous NRC documents relate the importance of NRC audits. For example, in NRC comments on issues discussed in a 1984 meeting between NRC and DOE, NRC stated that audits would be an important vehicle for determining whether there are any real problems with DOE project and contractor quality assurance staffing levels, the effectiveness of project participant quality assurance staffs, DOE's ability to manage numerous contractors, and attitudes of participants toward quality assurance. Further, a November 1986 NRC statement outlining its staff's approach to assessing DOE's quality assurance program indicates that reviews of project participants' quality assurance implementation would be NRC's most important method of assessing the adequacy of DOE's overall quality assurance program. The statement noted the importance of the reviews for providing the NRC staff with support for stating, in NRC's comments on DOE's site characterization plan, that its oversight was sufficient to evaluate the adequacy of DOE's quality assurance program.

NRC's current emphasis on observations of DOE audits also appears to reduce the scope of its overall effort to assess the program prior to site

characterization. This reduction in scope comes after NRC had identified problems in DOE's quality assurance program and had expressed concern that the way DOE is organized to carry out the repository program increases the likelihood that DOE will experience major quality-related problems. The reduction also conflicts with NRC's March 1988 staff comments on DOE's draft site characterization plan. At that time, the staff stated that it does not currently have a sufficient basis for confidence in the adequacy of DOE's quality assurance program.

Two of the three candidate sites have been eliminated from further consideration as potential repository locations. This change, according to the NRC staff, will allow it to conduct simultaneous activities such as document reviews, technical meetings, and on-site technical reviews because additional staff can be assigned to various project activities. Despite the major reduction in the scope of the repository program, NRC's position that the change will free up project resources, and the need for more comprehensive information on the adequacy of DOE's program prior to site characterization, NRC had not revised its planned approach when we completed our review.

Pre-Licensing Consultation Has Not Resulted in the Early Resolution of Identified Problems

As described in detail in chapter 2, NRC has identified numerous weaknesses in DOE's quality assurance program. Despite the obvious benefits of resolving problems early, as intended by the pre-licensing agreement, most of the issues remain unresolved. One contributing factor is that the pre-licensing consultation agreement does not specify how or when issues are to be resolved. In the absence of a formal mechanism, timely resolution depends on the good faith effort of both DOE and NRC. The approach has not worked. For example, in September 1986, DOE proposed and NRC agreed that each agency would independently develop lists of outstanding issues between the agencies so that they could develop strategies for resolving them. More than 1-1/2 years later, however, neither agency had completed and submitted its list to the other agency.

DOE's Involvement

For its part, DOE has not responded to the issues identified by NRC by demonstrating that weaknesses do not exist or that corrective actions have been taken. Thus, the issues have not been resolved. On the basis of meeting summaries, correspondence between DOE and NRC, and other documentation we reviewed at both agencies, it appears that DOE has assigned a relatively low priority to resolving the quality assurance program weaknesses identified by NRC. DOE has given higher priority to

developing key program documents such as the May 1986 site environmental assessments and the draft site characterization plans. This arrangement appears to conflict with DOE's September 1985 commitment to have a quality assurance program in place for early site characterization activities that fully complies with NRC standards. To achieve this objective, DOE must develop the quality assurance program simultaneously with other program activities. Therefore, too much emphasis on preparing site characterization plans can only necessitate "catching up" later with the quality assurance program.

A June 12, 1986, management meeting between NRC and Nevada project personnel illustrates the issue of conflicting DOE program priorities. DOE staff indicated that with only 6 months remaining before the (then) anticipated release of its site characterization plan, all project resources were being directed toward completing the plan; therefore, the project office's ability to interact with NRC would be severely limited. In response, the NRC staff indicated that it was DOE's choice whether to put off interactions, but the lack of commitment on the part of DOE to interact with NRC early was not consistent with the recognized need for early pre-licensing consultation in the interagency procedural agreement. According to the NRC staff's February 9, 1988, quarterly waste program status report to the NRC Commissioners, limited staff interaction between DOE and NRC has been a continuing problem in the repository program.

NRC's Involvement

NRC also has not done all that it could to help ensure that problems are resolved early. In January 1986, the Director of NRC's Office of Nuclear Material Safety and Safeguards stated that he expected NRC's staff to make known any concerns it may have about DOE's quality assurance program so that early corrective actions could be taken. Although the NRC staff has alerted DOE to the problems it has found in DOE's program to date, it has not aggressively pursued the concerns to ensure that DOE is addressing them satisfactorily. We found very little evidence, for example, that NRC's staff has escalated long-standing unresolved concerns to senior NRC or DOE management for resolution.

In June 1987, the NRC staff began submitting quarterly progress reports to the NRC Commissioners on the pre-licensing phase of DOE's nuclear waste program. Quality assurance is one of seven key aspects of pre-licensing consultation addressed in the reports. In the first quarterly report, the NRC staff indicated that DOE continues to make steady but slow progress in developing its quality assurance programs and

described NRC's general approach to evaluating DOE's programs. The second quarterly report, submitted in October 1987, described NRC's audit of a Nevada project contractor, identified three general areas where the contractor needed to improve its quality assurance program, concluded that the contractor's quality assurance program is not yet fully in place, and stated that NRC would be monitoring DOE corrective actions. Neither of these reports, nor the third quarterly report of February 1987, addressed the unresolved management concerns—(1) OCRWM's heavy reliance on contractors, (2) OCRWM's indirect project control, and (3) the overall lack of an effective quality assurance program—that NRC staff raised with DOE in June 1986. At that time, NRC staff identified the issues as possible root causes of observed quality-related problems at the Yucca Mountain and Hanford candidate sites and suggested that DOE take appropriate action before major problems developed.

Further, the reports do not address, with one exception, issues such as (1) the timeliness of DOE's efforts to resolve issues identified by NRC, (2) limitations on the scope of NRC's quality assurance oversight to date, (3) unresolved weaknesses in DOE's program, or (4) other indicators of potential problems. For example, the reports do not convey the NRC staff's concern about DOE's unilateral decision in July 1987 to revise its definitions for applying levels of quality assurance to work activities.

Only the February 1988 quarterly report addresses DOE's efforts toward the timely resolution of outstanding issues and limitations on NRC's quality assurance program oversight. Although the issues are long-standing, it appears that NRC staff raised them in the status report only after it thought the issues had been resolved. According to the report, DOE and NRC met in December 1987 and January 1988 to discuss methods of increasing interactions and improving DOE's responsiveness to NRC's comment letters on its review of the project's quality assurance requirements document and one contractor's quality assurance plan. The meetings were necessary because DOE had not provided responses to three NRC comment letters (in August 1986, November 1986, and October 1987) providing comments on these documents, nor had DOE identified sufficient opportunities for NRC oversight during 1988. As a result of the discussions, DOE provided formal responses to NRC's comment letters, scheduled audits of project contractors (which had previously been postponed through May 1988), and agreed to allow NRC to observe the audits.

While the February 1988 quarterly discusses the problems generally, it does not address them in the context of other observed quality assurance problems or the current state of DOE's readiness for site characterization from a quality assurance standpoint. Moreover, none of the quarterly reports reflect the staff's concern that future NRC audits will probably be more limited than the June 1987 audit of a Nevada project contractor. According to the minutes of a November 1987 management meeting between the two agencies, DOE does not believe that audits similar to the earlier one will be appropriate for another year.

It appears that NRC staff has not pursued or escalated these outstanding issues because the agency's formal role at this juncture is to consult, rather than regulate, and because NRC has decided that issues related to DOE's approach to managing the repository program are beyond the scope of its authority. However, as its experience with nuclear plants has shown, NRC must act aggressively on early indications of quality assurance problems in order to ensure that they do not turn into larger problems.

NRC's study of its experience with the nuclear power industry found that its reluctance to address utility management issues early and aggressively materially contributed to costly quality-related problems in the construction of nuclear power plants. In that study, NRC found that it had not adequately screened utility construction permit applicants for their overall capability to effectively manage their nuclear plant projects. NRC had been reluctant to address this issue until the need for major remedial programs at nuclear plant construction projects became evident. Since then, NRC has decided that management and organizational matters are not appropriate subjects for direct regulation. It has, therefore, adopted other approaches to evaluate utility management performance based on the operating performances of nuclear plants.

Conclusions

Pre-licensing consultations between DOE and NRC are intended to reduce future licensing difficulties by encouraging the early identification and resolution of potential problems. In the area of quality assurance, however, the timely identification of potential problems has not been realized because NRC has not had sufficient, early program involvement. Also, NRC has not been aggressive in ensuring that it receives adequate opportunities to assess DOE's program. Absent a clear, comprehensive statement of what NRC must do to determine that DOE has a satisfactory quality assurance program in place for site characterization, NRC has allowed DOE to largely determine the pace and scope of its oversight

activities. This has occurred despite NRC's announced intention to adopt an aggressive pre-licensing role to avoid the type of licensing difficulties identified in its study of nuclear power plant construction problems.

Nevertheless, NRC has identified numerous specific deficiencies in DOE's quality assurance program and has raised more general concerns over DOE's ability to carry out a high-quality site characterization program. These specific deficiencies and general concerns remain unresolved because DOE has not demonstrated that they have been corrected. In part, this is due to the absence of a specific procedural mechanism in the pre-licensing consultation agreement for resolving problems and concerns identified by NRC. It is also due to the lower priority DOE assigned to resolving these issues in comparison to the emphasis it has placed on completing other key repository steps, such as issuing the site characterization plan. Such a priority scheme appears to be inconsistent with DOE's commitment to having a satisfactory quality assurance program in place when it is ready to begin site characterization. Also, the NRC staff has not elevated unresolved quality assurance concerns to senior management levels within NRC or DOE. As a result, concerns identified by the NRC staff essentially have been allowed to go unresolved.

We recognize that NRC's legal role is limited to consultation until DOE applies for a construction authorization and that in a future licensing proceeding on the application the burden of proof will be on DOE to establish that a repository can be built and operated to NRC's regulatory standards. Nevertheless, NRC is the agency that will decide if the proposed repository can be built and operated at the selected site. In this regard, NRC, not DOE, will ultimately decide whether DOE has done an adequate job of supporting its repository license application. Clearly, timely identification and resolution of potential licensing problems through pre-licensing consultation will help both DOE and NRC to better discharge their repository-program responsibilities.

Recommendation to the Chairman, Nuclear Regulatory Commission

To help ensure that quality assurance concerns are addressed in a timely manner, we recommend that the Chairman, NRC, use NRC's nuclear waste quarterly progress reports as a vehicle for bringing these concerns to the attention of senior NRC management.

Recommendation to the Secretary of Energy and the Chairman, Nuclear Regulatory Commission

To ensure that issues raised as a result of the interaction between NRC and DOE are resolved early, we recommend that the Secretary of Energy and the Chairman, NRC, incorporate into the pre-licensing consultation agreement procedures for ensuring that issues will be resolved on mutually agreeable schedules.

Agency Comments

NRC agreed with our recommendation to use the quarterly progress reports as a vehicle to bring staff concerns to the attention of senior NRC management and stated that future quarterly reports would include detailed information. NRC also said it has taken other actions to inform senior NRC management about program problems, such as highlighting staff concerns about DOE's quality assurance program at a recent briefing of the Commission.

Neither agency agreed that the pre-licensing agreement needs to be modified at this time, but we believe there is still a need to do so. Recently, both agencies agreed that before site characterization begins, DOE must satisfactorily address NRC's outstanding quality assurance concerns. Once site characterization begins, however, no mechanism exists for DOE and NRC to reach timely resolution of future quality assurance issues. In our view, a modified agreement that provides procedural mechanisms for early resolution of NRC concerns will help ensure that the program is not unnecessarily jeopardized by a failure to resolve problems identified during the 5-to-6-year site characterization period.

In a draft of our report, we also proposed that the Chairman, NRC, develop and provide to DOE and the public a description of the type and scope of oversight activities necessary to assess whether DOE's quality assurance program is satisfactory for beginning full-scale site characterization at Yucca Mountain. In June 1988, NRC met with DOE to describe its overall strategy for assessing DOE's program prior to site characterization and a plan for implementing the strategy. The strategy includes (1) NRC's review and acceptance of all participant quality assurance plans, (2) NRC observations of DOE audits to ensure each organization is adequately implementing its programs, and (3) repetitions of these steps

Chapter 3
Pre-Licensing Consultation on Quality
Assurance Matters Has Been Ineffective

until both DOE and NRC agree that the programs are acceptable. Information about NRC's oversight strategy and plan is also available to the public. We believe that the actions taken by NRC fully respond to our proposal and, as a result, we deleted it from our final report.

NRC also commented on two areas of the report that it believed needed further clarification. NRC's comments and our analysis are provided in appendix III.

Information on Nevada Project Stop-Work Orders

DOE has been conducting exploratory work at the Yucca Mountain site since 1977. The research, however, was not conducted under NRC's rigorous quality assurance standards. Because DOE must eventually demonstrate that it has complied with NRC's regulatory standards, it is upgrading its quality assurance program. One result of this effort was DOE's determination in 1986 that technical and management controls over work at Yucca Mountain were inadequate for licensing purposes and that the controls were not being improved at a satisfactory pace in preparation for full-scale site characterization. DOE ordered some contractors to stop work until the necessary improvements were made. In the interim, affected staff were reassigned to develop and upgrade the required procedures and controls and were given intensified training in quality assurance. DOE completely lifted the last of these Nevada stop-work orders in November and December 1987.

Each project level is responsible for providing oversight of the work that it performs in addition to overseeing the quality assurance activities of subordinate project levels in order to detect and resolve quality-related problems. Quality assurance oversight includes conducting audits and other verification efforts to establish that quality assurance programs are being effectively implemented and that work results will meet regulatory standards. During 1986, DOE's project offices conducted 23 audits of repository project contractors to assess the effectiveness of the contractors' quality assurance programs. The audits identified a number of problems relating to the implementation of quality assurance programs.

As a result of these audits, DOE imposed stop-work orders on six of the eight prime contractors working on the Nevada project. DOE imposed the stop-work orders because it found, during a series of audits and surveillances conducted between February and April of 1986, that project participants had not fully implemented quality assurance program requirements, such as assigning quality level designations to work activities so that work would be conducted under appropriate quality assurance controls. According to the project office, three of the contractors were required to make "substantial" revisions to their quality assurance programs before restarting affected work. Table I.1 highlights DOE's findings, the duration of the orders, and conditions imposed on contractors.

**Appendix I
Information on Nevada Project Stop-
Work Orders**

Table I.1: Information on Nevada Project Stop-Work Orders

Contractor	Work performed	Surveillance findings	Audit findings	Duration of stop-work order	Actions that must meet project office approval before work could be resumed
U.S. Geological Survey	Geologic and hydrologic exploration and data analysis	Operating without QA level assignments or to unapproved QA level assignments (Feb. 23-28, 1986)	Identified 22 significant findings and 5 observations, indicating a total lack of QA program implementation (Mar. 11-14, 1986)	4/28/86-12/87 (Two findings relating to custody of core samples were dropped because the core facility was transferred to another project participant.)	(1) Propose corrective action on audit findings; (2) revise QA program plan; (3) provide plan for adequate QA coverage at all work locations; (4) complete QA indoctrination and training of personnel; and (5) complete assignment of QA levels to work efforts
Science Applications International Corp.	Technical and management support services, including QA project support	Operating without approved QA level assignments (Mar. 13-19, 1986)	N/A	6/10/86-4/87	(1) Complete assignment of QA levels to work efforts
Los Alamos National Laboratory	Geochemical, mineralogic, and petrographic properties of host rock volcanism studies and coordination of exploratory shaft testing	Operating without QA level assignments or to unapproved QA level assignments (Feb. 26-27, 1986)	N/A	6/10/86-11/86	(1) Complete assignment of QA levels to work efforts
Lawrence Livermore National Laboratory	Waste package design, testing, and analysis	Operating without QA levels assigned to work efforts (Feb. 18-21, 1986)	N/A	6/10/86-11/87	(1) Assign QA levels to work efforts
Sandia National Laboratory	Thermal and mechanical properties of host rock, conceptual design of repository, performance assessment, development of repository seals and equipment development	Operating without QA level assignments or to unapproved QA level assignments (Feb. 25-28, 1986)	N/A	6/10/86-12/86	(1) Obtain project office approval of QA program plan and (2) assign QA levels to work efforts

(continued)

**Appendix I
Information on Nevada Project Stop-
Work Orders**

Contractor	Work performed	Surveillance findings	Audit findings	Duration of stop-work order	Actions that must meet project office approval before work could be resumed
Reynolds Electrical and Engineering Company, Incorporated	Nevada Test Site support services, including drilling, roads, trenching, and personnel radiological monitoring	N/A	Identified 21 significant findings, indicating a total lack of QA program implementation (Apr. 14-18, 1986)	10/31/86-1/87	(1) Propose corrective actions to audit findings, (2) obtain project office approval of QA program plan, and (3) complete indoctrination and training of personnel

QA: quality assurance

N/A: not applicable

The stop-work orders suspended work on (1) drilling surface-based boreholes to support geology, hydrology, and geochemistry programs and (2) some laboratory work and field investigations. In addition, the affected contractors were not permitted to initiate new site characterization investigations or environmental, socioeconomic, and engineering studies until they had obtained project office approval of graded quality level assignments for work activities and all additional stop-work order provisions had been lifted.

Many work efforts continued without interruption, however, because they met established criteria for exemption from stop-work orders. Activities exempt from stop-work orders were the following:

- work necessary to implement quality assurance programs (i.e., development of procedures, assignment of graded quality levels to work efforts, and correction of quality assurance program deficiencies);
- administrative and management work, with the exception of procurement of equipment, materials, supplies, and services for technical activities (procurement was allowed to continue if the details, including applicable quality requirements, were provided to the project office for concurrence in advance);
- internal planning efforts, such as the development of the Yucca Mountain site characterization plan;
- preparation and processing of abstracts for meetings if the submission deadline was July 1986 or earlier;
- prototype testing, experimentation, and other research intended to develop and/or evaluate techniques or procedures if approved by the project office and if they did not prevent adequate manpower from

being applied to the upgrade and implementation of the quality assurance program requirements;

- work-in-progress on degradable samples and laboratory measurements on “natural-state” samples that would degrade if the measurements were interrupted; and
- ongoing monitoring activities where suspension of work would cause an irretrievable loss of information about transient natural phenomena (e.g., seismic, meteorological, or streamflow monitoring).

According to the Nevada project office, stop-work orders have had very little negative impact on the site characterization schedule because other situations developed that continue to have a greater impact on the site characterization schedule. These situations include

- the acceleration of plan preparation schedules, which required DOE to devote personnel subject to stop-work orders to plan preparation tasks,
- the need to renegotiate a land access agreement for the site with the U.S. Bureau of Land Management, and
- an agreement between NRC and DOE’s Office of Geologic Repositories that site characterization—except those activities related to monitoring natural phenomena—would not proceed until the plan is issued.

The project office lifted the stop-work orders in increments, as the contractors satisfied re-start conditions imposed in the orders. According to the Nevada project office, progress in lifting the orders was slow because of the conflicting commitment of technical personnel to preparing both the site characterization plan and quality assurance documents necessary to satisfy its re-start conditions. A second conflict was the availability of project office staff to review both the plan and quality assurance documents. DOE completely lifted the last of its 1986 Nevada stop-work orders in November and December 1987.

Comments From the Department of Energy

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



THE SECRETARY OF ENERGY
WASHINGTON, D.C. 20585

JUL 26 1988

Mr. Keith O. Fultz
Senior Associate Director
Resources, Community, and
Economic Development Division
U. S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fultz:

The Department of Energy (DOE) appreciates the opportunity to review and comment on the General Accounting Office (GAO) draft report entitled "Nuclear Waste: Repository Work Should Not Proceed Until Quality Assurance Is Adequate" (GAO/RCED-88-159).

The Department reaffirms its commitment, which is fully consistent with GAO's conclusion, that site characterization work should not be undertaken until an adequate quality assurance program is in place that meets Nuclear Regulatory Commission (NRC) requirements. Furthermore, DOE recognizes that improvements are required in its quality assurance program, and the Department has taken aggressive actions to implement these improvements. Since the Nuclear Waste Policy Amendments Act was passed in December 1987, the Department has:

See comment 1.

- o Made fundamental changes in its organizational structure, including the establishment of an Office of Quality Assurance reporting directly to the Director, Office of Civilian Radioactive Waste Management;
- o Resolved 119 of the 130 quality assurance issues existing between DOE and NRC since enactment of the Nuclear Waste Policy Act in 1983 and identified DOE actions needed to close out the remaining 11 issues, 8 of which require closure to establish a qualified quality assurance program for new site characterization activities;
- o Resolved outstanding issues on the Nevada Nuclear Waste Storage Investigation (NNWSI) Project Quality Assurance Plan, with formal NRC acceptance expected shortly; and
- o Reached agreement with NRC on a schedule to obtain NRC acceptance of all DOE and contractor quality assurance plans prior to the start of any new site characterization activities.

See comment 2.

See comment 3.

See comment 4.

See comment 5.

The Department cannot at this time state that the quality assurance program (plans and implementation) is sufficiently mature; however, DOE is confident that actions have been taken which represent an appropriate and effective approach and response to quality assurance problems identified internally within DOE, and in discussions with the NRC and the State of Nevada as well as in the GAO draft report. The Department is committed to addressing the state of the quality assurance efforts on a continuing basis.

Appendix II
Comments From the Department of Energy

2

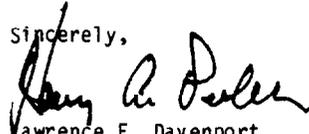
Now on p. 41.

Now on p. 52.

While the Department agrees with the intent of both GAO recommendations, DOE is unable to concur with some of the particulars. Regarding the recommendation that site characterization work proceed only after the Secretary of Energy determines, and NRC concurs, that all quality assurance programs are in place and meet NRC standards, it is our understanding that the NRC will issue a Safety Evaluation Report of DOE's Quality Assurance Plan, thereby indicating its "acceptance" of, not "concurrence" in, the Plan. With respect to modifying the DOE/NRC Procedural Agreement, the Department believes that this is unnecessary in light of agreements reached with NRC on July 7, 1988, outlining NRC's acceptance of DOE and contractor quality assurance plans prior to starting any new site characterization activities. These agreements emphasize the Department's commitment not to begin new site characterization activities until appropriate quality assurance programs are implemented in consultation with the NRC.

The Department appreciates the perspective of the GAO and hopes that these comments will be helpful to GAO in its preparation of the final report. Additional editorial comments are being provided directly to Mr. Dwayne Weigel.

Sincerely,



Lawrence F. Davenport
Assistant Secretary
Management and Administration

The following are GAO comments on recent program activities discussed in DOE's letter dated July 26, 1988.

GAO Comments

1. DOE established an Office of Quality Assurance within OCRWM in April 1988. This resolved a major NRC concern about the structure of DOE's quality assurance organization. The previous organization did not meet regulatory standards because OCRWM's senior quality assurance manager had been assigned too low a management level in the OCRWM organization to provide top management complete and timely information on quality assurance problems. Although DOE's recent action indicates progress, it also occurred about 3 years after NRC expressed its concern. Thus, the example illustrates how long it has taken DOE to address important NRC quality assurance concerns.

2. It appears that DOE and NRC have made substantial progress in addressing issues identified since the program began. Our review of the disposition of these issues, however, indicates that most of the issues were not actually "resolved" because the agencies did not deal with the issues by either agreeing to change DOE's quality assurance program or by agreeing that change was unnecessary.

Specifically, some issues were "resolved" by DOE describing and committing to an approach for addressing an outstanding concern that was acceptable to NRC. For example, NRC's 1987 comments on the Los Alamos quality assurance plan were "resolved" by DOE's commitment that it would respond to the comments. It remains to be seen whether NRC will be satisfied with DOE's response. Other issues were "resolved" because they pertained to outdated documents. For example, NRC's review comments on OCRWM's headquarters plan were considered to be "resolved" because DOE will be revising and resubmitting the plan for NRC's approval. Issues that were related and could be consolidated into a single like item were also considered resolved. For example, specific issues on DOE's handling of core samples were "resolved" because NRC's broader concern about core sample controls was left open for later resolution. Finally, some issues relating to the adequacy and effectiveness of DOE and contractor quality assurance programs were "resolved" with the expectation that, if similar problems are found in NRC's future audit observations, they would be carried as open items requiring DOE's action prior to NRC's acceptance of the program.

3. The anticipated approval of this cornerstone quality assurance plan is a significant step because it will be the first such document to be

approved by NRC. Following NRC's approval of this document, however, DOE and its contractors will need to revise their plans accordingly and submit them for NRC's review and acceptance.

Although DOE expects to receive approval of its headquarters' quality assurance plan by November 1988 and the eight remaining plans between December 1988 and March 1989, NRC's review and approval of these plans is only one part of its total assessment of DOE's quality assurance program. For example, DOE and its contractors must also determine, with agreement by NRC, that the plans are being implemented properly before DOE and NRC can each determine that DOE's quality assurance program is satisfactory.

4. In a July 1988 meeting, DOE and NRC agreed that after NRC reviews all individual DOE and DOE-contractor quality assurance plans and is satisfied that each program is being implemented adequately, NRC will accept each program as adequate for beginning site characterization. The agencies also agreed to a schedule for NRC's assessment of DOE's program. According to the schedule, DOE expects to receive NRC's acceptance of three quality assurance programs (including the headquarters program) in February 1989, followed by six additional program acceptances between March and May 1989.

NRC has expressed concern about DOE's schedules for developing the quality assurance program. According to a June 1988 NRC letter to DOE, the schedule is achievable only under "best case conditions." However, NRC also expressed concern that DOE's schedule is not consistent with the goal of having a qualified quality assurance program in place prior to beginning site characterization. According to a senior NRC management official present at a July 1988 meeting between the agencies, DOE's schedule for program approval is logical, but it is very tight and likely to slip.

5. We acknowledge that the steps taken by DOE are steps in the right direction. However, as indicated in the above comments, we believe DOE's letter overstates the actual amount of program progress. Additional quality assurance problems have surfaced recently, which further lead us to believe that actual progress on DOE's quality assurance program is less than described in DOE's comments.

First, a recent DOE audit of USGS identified serious problems in the implementation of USGS' quality assurance program, including the mislabeling of core samples taken from the site during the last 6 years. In a letter to

the Director of USGS dated June 30, 1988, OCRWM's Acting Director stated that preliminary audit results indicated that USGS work "is not being performed in the manner necessary for the nuclear licensing environment." Of particular concern was that

"the recent deficiencies, similar to those that have been observed in the past, reflect a fundamental and continuing problem in the attitude of some USGS personnel regarding quality assurance requirements and procedures and the manner in which they approach work in support of the repository program."

In response to the final audit results, DOE imposed a stop-work order on USGS on July 26, 1988. According to the order, the audit concluded that (1) USGS' quality assurance program is not being properly implemented in all areas and (2) the program's effectiveness, in specific areas, is questionable. The order prohibits USGS from analyzing, interpreting, publishing, and disseminating data and information generated from five work areas. It will remain in force until DOE determines that the affected areas have been brought into compliance with project quality assurance requirements.

NRC observation reports indicate that current quality assurance problems are not confined to the USGS. According to an April 1988 observation report, for example, DOE project office auditors recommended that DOE stop work at Fenix and Scisson—a contractor performing design work for the exploratory shaft facility. Their audit raised questions about whether the contractor's personnel are qualified to perform exploratory shaft work. In one case, for example, information about the lead design engineer did not indicate that the engineer had experience in the design of underground excavations or drill and blast mining methods, which will be used in constructing the exploratory shafts.

Similarly, further information indicated that the contractor had not designed a vertical conventional shaft since 1965 and that none of the design engineers or design managers who work on the exploratory shafts had taken part in the earlier work. According to the NRC observers' report of the audit, Fenix and Scisson has considerable experience in design and construction of shafts by "blind," large diameter, rotary drilling methods. However, the two exploratory shafts will be excavated by conventional drilling and blasting methods and, according to NRC's report, the two methods are significantly different in terms of design, equipment, and needed expertise. As a result, the NRC report states, immediate DOE and contractor management attention and corrective

Appendix II
Comments From the Department of Energy

action are necessary because design work on the shaft could have a direct impact on waste isolation at the site.

Comments From the Nuclear Regulatory Commission

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



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

July 15, 1988

Mr. Keith Fultz, Senior Associate Director
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fultz:

We appreciate the opportunity to comment on the draft GAO report, "Nuclear Waste: Repository Work Should Not Proceed Until Quality Assurance Is Adequate." The report makes four recommendations applicable to NRC which are useful to our quality assurance review of the high-level waste repository program. We believe the intent of all four recommendations is being implemented by the NRC staff.

The first major repository program milestone for the NRC mandated by the Nuclear Waste Policy Act is the review of DOE's Site Characterization Plan (SCP) for the Yucca Mountain site. In January of this year, DOE submitted to NRC the Consultation Draft Site Characterization Plan (CDSCP) for the Yucca Mountain site. Since completion of our initial review of the CDSCP on March 7, 1988, we have taken actions related to all of the recommendations in the GAO report (see Enclosure).

There are two areas in the report that we believe need to be clarified. First, it should be emphasized that under the Nuclear Waste Policy Act, which in this regard affirmed prior NRC regulations, the Commission's role during the current precicensing stage is an informal one. The Commission is authorized to review and comment on DOE plans. It has no power to direct or order DOE to be responsive to its concerns. In this regard, we believe the draft report, presupposes NRC's exercising a greater authority than it has been granted by law. Indeed, we believe the reviews which NRC has conducted to date, in advance of DOE's issuing the Site Characterization Plan required by law, demonstrates an aggressive approach to meeting our responsibilities.

Second, in Chapter 3 of the draft report, the GAO noted that the staff decided in late 1987 to conserve resources by observing DOE audits. This is not entirely correct. The driving force behind this strategy of observing DOE's audits was the NRC staff's attempt to implement a point in NRC's report to Congress in May 1984, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants," (the Ford Study, NUREG-1055): that licensees have the ultimate responsibility for achieving and assuring quality. The first plan prepared by the staff in 1985 relied on NRC rather than DOE to find and correct problems. We believe the current strategy of making DOE responsible for its quality assurance program through our evaluations of

See comment 1.

Now on p. 46.

See comment 2.

**Appendix III
Comments From the Nuclear
Regulatory Commission**

Mr. Keith Fultz

- 2 -

its auditing program will be far more effective than NRC performing the audits for it. The impact on NRC resources is a result of implementing this strategy, not a driving force for it. The combined resource impact on NRC and DOE should not significantly change. However, we still reserve the right to do our own independent audits and will do so from time to time.

Once again, we appreciate the opportunity to comment on this draft report.

Sincerely,



Victor Stello, Jr.
Executive Director for
Operations

Enclosure:
Current Status of Recommendations
to NRC in GAO Report

See comment 3.

**Appendix III
Comments From the Nuclear
Regulatory Commission**

ENCLOSURE

CURRENT STATUS
OF RECOMMENDATIONS TO NRC
IN GAO REPORT

RECOMMENDATION 1

Now on p. 41.

"Therefore, we recommend that the Secretary of Energy proceed with site characterization work segments only after

- the Secretary determines that all quality assurance programs related to regulatory-related work are in place and meet NRC standards and
- NRC has notified DOE that it concurs with the Secretary's determination."

STATUS

We agree with the intent of the recommendation. As stated in our objection on DOE's Consultation Draft Site Characterization Plan, we would not consider quality assurance to be resolved unless DOE's program meets our standards. While there is no requirement for NRC concurrence in the Nuclear Waste Policy Act, DOE has committed to addressing the concerns that we identify to ensure that NRC can have confidence that the QA program is acceptable.

RECOMMENDATION 2

Deleted.
See p. 52.

"Therefore, we recommend that the Chairman, NRC, develop and provide to DOE and the public, a description of the types and scope of oversight activities necessary to assess whether DOE's quality assurance program is satisfactory for the purpose of beginning full-scale site characterization work at Yucca Mountain."

STATUS

The NRC staff has prepared an oversight strategy and initial plan for implementing this strategy. These were presented to DOE in a meeting on June 8, 1988 and in a letter to the Director of Office of Civilian Radioactive Waste Management (OCWRM) dated June 24, 1988; to the NRC's Advisory Committee on Nuclear Waste on April 28, 1988; and to the American Nuclear Society's annual meeting on June 16, 1988. This information is publicly available and the State of Nevada is being kept informed.

RECOMMENDATION 3

Now on p. 51.

"We also recommend that the Chairman, NRC, use NRC's nuclear waste quarterly progress reports as a vehicle for bringing to the attention of senior NRC management those quality assurance issues that are not being satisfactorily resolved so that NRC's management can help ensure that matters are resolved early."

**Appendix III
Comments From the Nuclear
Regulatory Commission**

STATUS

The staff intends to include detailed information to the Chairman in its quarterly progress reports. The reports will specifically address progress in implementing the oversight strategy and plan discussed in Recommendation 2 and the tracking and resolution of open items discussed below.

In addition, the staff briefed the Commission on May 4, 1988 on the results of the review of the CDSCP and highlighted QA as one of the most important immediate issues facing the program. The Commission was briefed by DOE on May 17, 1988 and the Commission expressed the same message to the DOE's Director of OCRWM. Recognition of the importance of early Commission involvement in the resolution of QA issues prompted the Commission to request the Advisory Committee on Nuclear Waste that these issues should be reviewed on a priority basis.

In a letter of June 24, 1988, the NRC Director of Nuclear Material Safety and Safeguards (NMSS) outlined steps that needed to be taken to enable the staff to agree that the program is qualified and expressed his concerns to DOE's Director of OCRWM about the schedules for development of the DOE QA program. He proposed that they personally meet if necessary after the staff meeting on July 7, 1988, to resolve any items that were left outstanding on the plan for qualifying and accepting DOE's QA program.

RECOMMENDATION 4

"To ensure that issues raised as a result of interaction between DOE and NRC are resolved early, we recommend that the Secretary of Energy and the Chairman, NRC, incorporate into the pre-licensing consultation agreement procedures for ensuring that issues will be resolved on mutually agreeable schedules."

STATUS

We believe that modification of the pre-licensing consultation agreement may not be necessary at this time. The NRC and DOE staffs met on July 7 and 8, 1988 and agreed to a master list of open items (issues) that need to be resolved before the QA program is considered to be qualified. The staffs also agreed to schedules for their resolution. These items are being tracked in a computerized data base.

DOE recently resolved one of the long outstanding major QA issues which the staff identified in QA--the reporting level of the QA Director for OCRWM. DOE recently elevated the position to report directly to the Director of OCRWM and has named a full-time Director of QA.

Now on p. 52.

The following are GAO comments on NRC's letter dated July 15, 1988.

GAO Comments

1. Our draft acknowledged limitations on NRC's role during the pre-licensing phase of the repository program, including constraints on NRC because it cannot direct DOE to take action on concerns it identifies. Nevertheless, we believe NRC can, and should, be more aggressive in securing DOE's early closure on outstanding issues.

NWPA and NRC's licensing regulations require consultation between DOE and NRC prior to DOE's application for a construction authorization. To facilitate this consultative process, the agencies entered into a procedural agreement to help ensure that potential licensing problems are identified and resolved early in the program. As discussed in chapter 3, the agreement's objectives are not being realized, in part, because NRC has not done all it could to ensure its concerns are addressed in a timely fashion.

The result of a recent DOE audit of USGS emphasizes this point. The audit identified significant problems in the implementation of USGS' quality assurance program, including the mislabeling of core samples taken from the site during the last 6 years. Similar problems were identified by NRC in 1984. Thus, a problem that could significantly affect DOE's ability to license the site has been unresolved for 4 years. As we recommend in chapter 3, one means to ensure that the program is not unnecessarily jeopardized is to establish procedures in the pre-licensing agreement so that future concerns are acted upon in a timely manner.

2. We disagree that NRC's 1985 oversight plan placed undue reliance on NRC to find and correct problems within DOE's program. The plan explicitly stated that DOE had the burden of proof in establishing that its program was adequate and that NRC's role was limited to confirming that DOE's determination was correct. Consequently, the only difference between the earlier plan and NRC's recent, revised oversight approach is a reduction in the scope of work believed necessary to confirm that DOE's program is adequate for beginning site characterization.

3. Although we believe that independent audits are necessary to adequately assess DOE's program, our draft report did not state that NRC should only conduct these types of audits. Rather, we believe that NRC should supplement its observations of DOE audit with independent audits to gain firm assurances about the quality of DOE's program. Observation audits are necessarily limited by the scope of the DOE audit being

observed. The results of an April 1988 NRC observation of a DOE audit of USGS highlight this limitation. Although the NRC staff identified several significant concerns, DOE's audit scope was insufficient for NRC to determine if the audit findings represented either systemwide or isolated deficiencies. As a result, according to the NRC staff's report, additional investigations are needed to confirm the extent of their "preliminary staff findings."

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