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FEB 16 1989

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Dear Mr. Lau1:

Enclosed is my paper entitled "U.S. Nuclear Regulatory Commission Overview of Repository Quality Assurance" for publication in the Nuclear Fuel Cycle Journal. This paper has been revised in response to the comments you forwarded with your letter of September 23, 1988. If you have any questions, please call me at FTS 492-3402 or (301) 492-3402.

Sincerely,

ORIGINAL SIGNED BY

James E. Kennedy, Section Leader
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Enclosure:
As stated

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U.S. NUCLEAR REGULATORY COMMISSION OVERVIEW
OF REPOSITORY QUALITY ASSURANCE

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ABSTRACT

The U.S. Department of Energy (DOE) is on the threshold of an extensive site characterization program at Yucca Mountain in Nevada to determine if it is a suitable site for the permanent disposal of high-level nuclear waste. Many of the data collection and analysis activities in this program will be the primary basis for a license application to be submitted to the U.S. Nuclear Regulatory Commission (NRC) in 1995, if the site is found to be suitable. The NRC, therefore, requires that these activities be performed under a quality assurance (QA) program to help assure the validity of the data and analyses. There are three major areas of the NRC staff review: (1) developing staff guidance on QA issues; (2) reviewing DOE QA plans and procedures; and (3) observing DOE audits of the implementation of the program.

INTRODUCTION

The U.S. Department of Energy (DOE) will be conducting extensive site characterization activities at Yucca Mountain in Nevada in the near future to evaluate its suitability for permanently isolating high-level nuclear waste from man's environment. Early in 1988, the DOE published the Consultation Draft Site Characterization Plan (CDSCP) for the Nevada site. This plan describes in some detail the studies that DOE needs to perform in order to determine the suitability of the site. In the near future, DOE is expected to issue the final Site Characterization Plan and begin large scale site characterization activities. The data and analyses resulting from the execution of that plan are expected to be the primary bases for the license application to the NRC.

Because of the importance of these data collection and analysis activities, the NRC requires, in 10 CFR Part 60, that they be performed under a QA program. The QA program is designed to provide confidence that data are valid, retrievable, and reproducible. The documentation produced by the program will form an important part of the record upon which the suitability of the site is judged in licensing. In addition, because the NRC staff cannot review all of the data collected by the numerous DOE contractors and subcontractors, the staff will need to rely on the control systems in the DOE QA program in developing the confidence it needs to issue a license to DOE.

During the site characterization phase of the repository program, the NRC staff's objective is to review DOE's QA program sufficiently to have confidence in its adequacy before the start of new work.

This paper addresses the NRC staff review of the DOE QA program for the repository. This review effort is divided into three areas: (1) development of staff guidance on the applicability of power reactor QA requirements to the repository, (2) review of DOE documents designed to meet the NRC's criteria, and (3) review of the implementation of the program through audits and inspections.

REQUIREMENTS OF THE NUCLEAR WASTE POLICY ACT

The Nuclear Waste Policy Act of 1982¹ defines milestones for DOE's implementation of the high-level nuclear waste repository program. These are shown in Figure 1 with the latest schedules from DOE's June 1987 Mission Plan amendment.² The key date is the year 2003, when DOE is to obtain a license from the NRC and begin emplacing waste. The long process leading to that milestone has already begun, but one of the first major program milestones, the issuance of the Site Characterization Plan (SCP) is just ahead. The SCP outlines the program of site and laboratory studies needed over the next seven years. At the end of site characterization (1995), DOE is planning on submitting a construction authorization application to the NRC. Data and analyses from the site characterization phase will be presented in the application. NRC is planning on a three year review period, and if the application is found acceptable, will issue a construction authorization in 1998. A five year period of construction follows the construction authorization, and if data continue to confirm the suitability of the site, an operating license to emplace waste can be issued by the NRC in the year 2003.

Figure 1
location

MISSION PLAN AMENDMENT, JUNE 1987

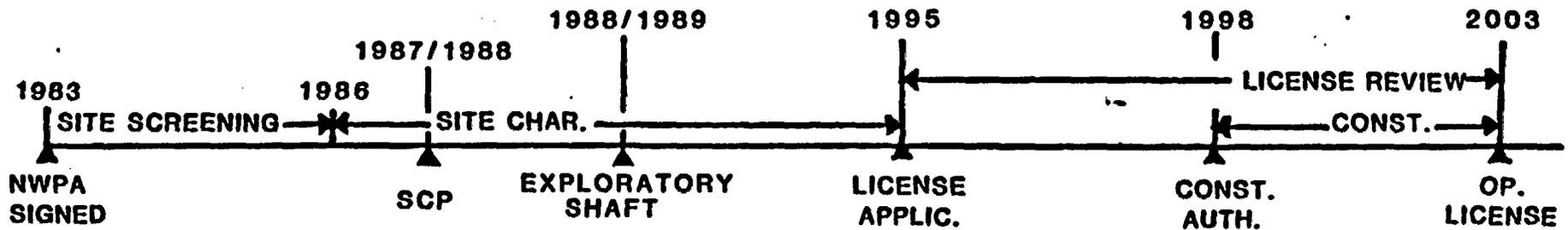


FIG. 1 DOE SCHEDULE -- FIRST REPOSITORY

Source: U.S. Department of Energy

OCRWM Mission Plan Amendment
DOE/RW-0128

NRC STRATEGY FOR REVIEW OF THE DOE REPOSITORY QA PROGRAM

The NRC strategy for reviewing the DOE QA program for the high-level waste (HLW) repository involves three broad areas: (1) development of QA program guidance which interprets the reactor QA program requirements in Appendix B of 10 CFR Part 50³ for use during the site characterization phase; (2) review of DOE documents such as QA plans and procedures which interpret this guidance; and (3) review of the implementation of the program (i.e., are the users following the procedures and achieving the quality of work needed). All areas will need to be accomplished to such a degree before extensive site characterization activities are accomplished that the NRC staff has confidence that the data collected will be useable in licensing.

In the development of this strategy, the NRC staff has utilized experiences in the power reactor program to help formulate the approach. The Ford Study,⁴ completed by the NRC staff in May 1984 at the request of Congress, examined the reasons for breakdowns in quality assurance programs of several nuclear plants under construction in the late 1970's and early 1980's such as Zimmer, Midland, South Texas, and others. The staff objective is to prevent similar occurrences in the repository program by learning from the mistakes of the past. Recommendations for improving NRC's program from the Ford Study have been factored into the review strategy. These include the following:

- ° Assessing product or data quality rather than just compliance with procedures as a measure of the effectiveness of quality assurance programs.

- ° Gaining sufficient confidence in the adequacy of the implementation of a quality assurance program early in its development rather than waiting until substantial work has been completed.
- ° Placing the burden of responsibility for identification and correction of program problems on DOE, rather than the NRC.

The three broad areas of staff review are discussed below.

Guidance Development

10 CFR Part 60⁵ contains the NRC regulations for licensing of a high-level waste repository, and includes procedural requirements and technical criteria for evaluating a selected site. The QA program criteria for site characterization are given in Subpart G of Part 60, which states that the Appendix B of 10 CFR Part 50 QA requirements utilized for design, construction and operation of nuclear power plants are also to be used "as applicable and appropriately supplemented by additional criteria..." for the repository. The staff efforts to date have concentrated on developing guidance which interprets this phase for the repository program.

In June 1984, the staff issued the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories,"⁶ which interprets each of the 18 criteria of Appendix B for use during the site characterization phase. Although differences exist between the repository and a reactor, most of the reactor program criteria can be applied directly to the

repository work. Establishing an independent QA organization, using procedures describing the work to be performed, conducting inspections and other verifications of work, and retaining records of completed work are the types of areas covered in Appendix B which apply equally as well to this program. These positions are affirmed in the staff's QA Review Plan.

The QA Review Plan is being revised to incorporate a number of improvements. The plan was issued shortly after the Ford Study of reactor program problems was published in 1984, and as a result, a number of the recommendations in that study for improving programs of the NRC and licensees were not included. In addition, DOE has had experience using the plan over the last several years and has made some specific recommendations for improvement for the NRC staff to consider. Finally, since the plan was originally issued, the NRC reactor program has endorsed the use of NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities,"⁷ the consensus standard developed by the American Society of Mechanical Engineers (ASME) which provides detailed guidance on the use of the NRC's quality assurance requirements in Appendix B, 10 CFR Part 50. NQA-1 will be endorsed in the revision to the Review Plan for use in the repository program.

The ASME is also preparing a quality assurance consensus standard for the repository program. This standard, entitled NQA-3, "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories,"⁸ is expected to be endorsed by the NRC staff after it is completed by the ASME. Much if

not all of the detailed guidance in the staff's QA Review Plan is expected to be replaced by the endorsement of NQA-3.

In addition to the QA Review Plan, the staff has also developed guidance for selected issues addressed only generally in the QA Review Plan. This guidance is contained in the staff's Generic Technical Positions (GTPs) which, like Regulatory Guides, describe acceptable approaches for meeting the Commission's regulations. Each of these is discussed below.

Q-List. An important consideration in the DOE program is the scope of items and activities within the overall repository program which are covered by the NRC's QA regulations. 10 CFR Part 60 Subpart G applies only to those which are important to waste isolation and/or important to safety, i.e., those items and activities which can affect the protection of the radiological health and safety of the public or the environment (the Q-list). This Technical Position on the Q-list⁹ addresses the technical criteria in Part 60 which define the scope of the program and the methods by which specific items and activities can be determined.

Items important to safety include those which prevent or mitigate the consequences of an accident leading to a dose of 500 millirem or more at or beyond the site boundary. By definition, the term "important to safety" applies only to the pre-closure phase.

Barriers important to waste isolation include any items and activities which contribute to meeting the numerical performance objectives in Part 60, viz. (a) the EPA standard¹⁰ for releases to the accessible environment, (b) the release rate after waste package failure, (c) the 300-1000 years lifetime for the waste package, and (d) the 1000 year groundwater travel time. By definition, "important to waste isolation" applies to the post-emplacment phase.

The final Technical Position was noticed in the Federal Register in May 1988 after resolving extensive public comments on two drafts.

Peer Review. In order to obtain a license to operate a high-level waste repository, the DOE must be able to demonstrate in the license application that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been fulfilled. Confidence in the adequacy of the data, data analyses, modeling, and other activities associated with the license application is obtained through the QA program. Expert judgment will be necessary due to the inherent uncertainty of geotechnical data and their analysis, the need to make projections over thousands of years, the lack of unanimity among experts, and the first-of-a-kind nature of geologic repository technical issues. Thus, peer reviews of the data, models, and associated activities will be a critical part of the QA program.

This GTP¹¹ provides guidance on the definition of peer reviews, the areas where a peer review is appropriate, the qualifications of peers, and the conduct and documentation of a peer review. It was completed in July 1987.

Qualification of Existing Data. Another important issue in this program is the usefulness of data collected prior to the establishment of, or outside of, the DOE QA program. DOE has not had a Subpart G QA program completely in place in recent years, even though data have been collected at the site. Some of these data could be useful in licensing if it can be shown that adequate QA measures were in place. There are also other sources of data such as from oil companies and universities not having Subpart G QA programs which may be useful and which would need to be examined.

This GTP¹² describes four methods by which "existing data" can be reviewed and a determination made as to whether they are acceptable for licensing. These methods are peer review, use of corroborating data, use of confirmatory testing, and demonstrating that the QA program in place was equivalent to that required in Subpart G. Like the peer review GTP, it was completed in July 1987.

Review of DOE QA Plans and Procedures

The next major part of the staff's review involves examination of the DOE and DOE contractor documents which interpret the NRC QA guidance. At present, the staff plans to review about a dozen QA plans and selected procedures including those of DOE Headquarters, the Nevada project office, and the DOE prime contractors. The regulatory criteria such as the staff's QA Review Plan and the Generic Technical Positions are the principal bases upon which the staff evaluates the various DOE QA program documents.

Review of the Implementation of the QA Program

Perhaps the most important and difficult of the NRC staff's tasks is the review of the implementation of the QA program. In the reactor program, this is the area where problems have most often been identified. Nuclear power plants had plans and procedures in place, but sometimes failed to follow them in their work activities. It is also the area requiring the largest effort. The repository program has numerous contractors and subcontractors managed by the Nevada Project Office and the DOE Headquarters. These contractors are in diverse locations and include national laboratories, site geotechnical contractors, architect-engineers, universities, and others. The NRC staff's responsibility is to review and audit enough of the activities related to public health and safety to have confidence that the program is working satisfactorily.

In its audits, the NRC staff will be examining selected technical products such as a design or a site characterization test program with a team of technical and quality assurance specialists. The quality of the work is assessed, with particular emphasis given to any QA program breakdowns that allowed problems to occur. In the case of observation audits, the NRC staff is determining whether the DOE audit team is adequately assessing technical products in addition to the QA program controls. It has been the staff's experience that to adequately assess the quality of work in audits, the technical audit team members must have a thorough understanding of the work themselves. To date, the staff has performed one team audit (at Los Alamos National Laboratory in June 1987) and observed five DOE audits (Fenix and

Scisson in February 1988, the Pacific Northwest Laboratory (PNL) in February 1988, Holmes & Narver in March 1988, and the USGS in April and June 1988). Recommendations for improving the programs and audits have been made by the staff and will be followed up in future audits.

Summary

DOE is continuing to put into place the necessary QA programs for future site characterization activities and the NRC staff is monitoring these activities and reviewing the program as it evolves. The NRC staff review should, if DOE's program develops satisfactorily, provide additional confidence that site characterization data will be useable in licensing and that significant problems will not develop late in the program.

ACKNOWLEDGEMENTS

The author wishes to express his sincere appreciation to the following individuals for their help in this effort:

- o Mr. Robert Browning, Director, NRC Division of High-Level Waste Management, for his continuing support over the last five years and for his many ideas in developing our regulatory program.
- o Mr. John Linehan and Mr. Joe Youngblood, NRC, for their guidance in managing and implementing the regulatory program.
- o Mrs. Joan Hoffman and Ms. Marlene Creviston for their skills and efficiency in supporting the program.

REFERENCES

1. U.S. Congress, 1983, Nuclear Waste Policy Act of 1982, Public Law 97-425.
2. U.S. Department of Energy, Draft 1987 Mission Plan Amendment, DOE/RW-0128, Washington, D.C., June 1987.
3. U.S. Nuclear Regulatory Commission, Title 10, Chapter 1, Code of Federal Regulations - Energy, Part 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, Washington, D.C., 1988.
4. U.S. Nuclear Regulatory Commission, Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants, NUREG-1055, Washington, D.C., 1984.
5. U.S. Nuclear Regulatory Commission, Title 10, Chapter 1, Code of Federal Regulations - Energy, Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories, Washington, D.C., 1988.
6. U.S. Nuclear Regulatory Commission, NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories, Washington, D.C., 1984.
7. ANSI/ASME, Quality Assurance Program Requirements for Nuclear Facilities, NQA-1, (New York, 1986).
8. ANSI/ASME, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories, NQA-3 (Draft), New York, 1988.
9. U.S. Nuclear Regulatory Commission, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements, NUREG-1318, Washington, D.C., 1987.
10. U.S. Environmental Protection Agency, Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level, and Transuranic Wastes, 40 CFR 191, Washington, D.C., 1985.
11. U.S. Nuclear Regulatory Commission, Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories, NUREG-1297, Washington, D.C., 1987.
12. U.S. Nuclear Regulatory Commission, Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories, NUREG-1298, Washington, D.C., 1987.