

NRC REVIEW PLAN FOR
QUALITY ASSURANCE PROGRAMS
DURING THE SITE CHARACTERIZATION
PHASE OF THE HIGH-LEVEL NUCLEAR WASTE REPOSITORY

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PREFACE

Under the Nuclear Waste Policy Act of 1982, as amended, the Department of Energy (DOE) is to characterize the Yucca Mountain site for a geologic repository to determine if it is suitable for safely isolating high-level nuclear waste. The Nuclear Regulatory Commission's (NRC) role as a regulatory agency during the site characterization phase is to review and comment on the DOE program in order to identify and help resolve potential licensing issues.

The NRC regulations in 10 CFR Part 60 Subpart G require the repository program, including site characterization, to be performed under a quality assurance (QA) program. As required by the regulation, this quality assurance program shall be based on the quality assurance criteria established in 10 CFR Part 50 Appendix B for nuclear power reactors as it applies to the repository program. In addition the regulation requires that the 10 CFR Part 50 Appendix B criteria for quality assurance be supplemented as necessary. In June of 1984 the NRC published the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." This document outlined the methods by which the NRC staff would oversee the DOE QA program. In addition the document provided in Appendix A the specific QA criteria which the NRC staff would use to review the DOE QA program. Appendix A was based on the Section 17, Quality Assurance, of the NRC Standard Review Plan (SRP) for nuclear power reactors. Some criteria in the SRP were modified and supplemented to address the items and activities in the repository program.

The revision to the NRC Review Plan was undertaken in 1987 to accomplish the following:

- * incorporate recommendations (lessons learned) from the power reactor program. The staff issued the 1984 NRC Review Plan shortly after the Ford Amendment Study (NUREG-1055) was published and before many of its recommendations were implemented by the NRC. The Ford Amendment Study was performed at the request of Congress and investigated the

causes of quality and quality assurance problems in nuclear power plants under construction in the late 1970's and early 1980's. The study also provided recommendations for improvements for both utility QA programs and NRC's oversight of those programs.

- * endorse for the repository program the use of NQA-1, the industry standard for quality assurance programs for nuclear facilities. NQA-1 provides detailed guidance on quality assurance based on the NRC's quality assurance requirements in 10 CFR Part 50 Appendix B. The NRC staff endorsed the the use of this standard for nuclear power plants in Regulatory Guide 1.28, August 1985.
- * reference several generic technical positions issued by the NRC staff in the last year. These positions address peer review, the qualification of existing data, and the identification of items and activities important to safety or waste isolation (Q-List).
- * make changes based on 3 years of DOE and NRC staff experience in the use of the 1984 NRC Review Plan.

The revision to the NRC Review Plan incorporates lessons learned such as the use of technical audits and readiness reviews, endorses NQA-1 and where necessary accounts for differences between power reactor projects and the high-level nuclear waste repository program, references the staff's GTP's, and addresses comments received from DOE on improvements that it believes need to be made to the 1984 plan.

In addition, the revision incorporates positions, as applicable, from the draft's of NQA-3, "American National Standard, Quality Assurance Program Requirement Site Characterization of High-Level Nuclear Waste Repositories." This document contains QA guidance specifically for data collection and analysis activities including guidance similar to the generic technical positions referenced by the revision. When published as a final standard the staff will endorse the standard and may eliminate the reference to the technical positions if appropriate.

The revision to the NRC Review Plan has been divided into two documents: The NRC Review Plan for Quality Assurance Programs for the Site Characterization Phase of the High-Level Nuclear Waste Repository and the Technical Position on Quality Assurance for the High-Level Nuclear Waste Repository. The first document outlines the methods that the NRC staff will use to review the DOE QA program. The second document outlines the criteria the NRC staff will use in commenting on the DOE's QA program. These documents are being issued as drafts for public comment. Upon receipt of public comments, the staff will resolve each comment in writing and anticipates meeting with commentors prior to issuing the final document to review the proposed responses to comments and revisions to the draft. In addition, the response to DOE comments and a cross reference between the 1984 NRC Review Plan Appendix A and the 1988 Draft Technical Position on QA is being published concurrently.

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I. INTRODUCTION

The Department of Energy (DOE) is conducting a site characterization program at the Yucca Mountain site in Nevada. The purpose of this program is to collect and analyze data to determine if natural and engineered barriers can safely isolate high-level nuclear waste from the accessible environment. The information developed during the site characterization phase will be used in an application for a license submitted to the NRC to receive and possess source, special nuclear, or byproduct material.

During the site characterization phase of the repository program the NRC staff is conducting a prelicensing consultation and guidance program with the DOE. The staff will familiarize themselves with the DOE program and identify and resolve issues as early as possible and before a license application is submitted to the NRC. Through these interactions the staff will attempt to gain confidence that the DOE meets all of the applicable regulatory requirements for licensing. The staff, however, does not have the resources to independently evaluate all or even a major part of the detailed activities associated with siting, designing, constructing, and operating a waste repository prior to a licensing hearing. As a result the NRC regulations specify that the DOE implement a quality assurance (QA) program that will assure quality in the work carried out in the prelicensing phase of the program. The staff will rely on the DOE QA program and the staff's evaluation of that program to generalize the results of the staff's limited review of the work conducted in the repository program. In addition, the documentation produced under the QA program will form the record upon which the suitability of the site will be judged in the NRC licensing process.

The NRC staff has published a technical position (TP) on quality assurance for the site characterization phase of the repository program. This TP provides DOE with guidance concerning the NRC staff's positions on quality assurance and with specific QA criteria necessary to assure quality and the demonstration of quality in a licensing hearing. The NRC staff guidance is

designed to provide confidence that data and analyses are valid, retrievable, and reproducible.

As part of the NRC staff's effort in reviewing the overall DOE program, the staff will review and assess the adequacy and effectiveness of the DOE QA program. The QA staff will select and review important aspects of the DOE QA program through such methods as review of DOE QA plans, observation of audits conducted by DOE and NRC audits of the DOE QA program. A description of these methods and the acceptance criteria that will be used by the QA staff are described in this plan. The onsite visits, audits, and readiness reviews will be conducted by teams of technical and QA staff. The technical staff will assess the technical adequacy of certain aspects of the QA program such as the technical adequacy of technical procedures, the effectiveness of their implementation, and the adequacy of the records maintained for licensing reviews. In addition, the technical staff will use these onsite visits, audits, and readiness reviews as part of their overall plan to review the technical work conducted during the site characterization process. Their review plans and review criteria will be published separately.

In this document, DOE means the DOE organizations participating in the repository program and its contractors, consultants, etc. The QA plans and procedures referred to include the QA plan, administrative and technical plans, and administrative and technical implementing procedures that meet the acceptance criteria outlined in Section IV.1 of this document.

II. REGULATORY FRAMEWORK

NRC regulations (10 CFR Part 60, Subpart G) require that DOE implement a QA program that applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. The regulations also identify when the DOE will submit information on quality assurance to the NRC and what NRC monitoring of QA activities will be permitted during site characterization. DOE is required to submit, for NRC review, the Site Characterization Plan, containing a description of quality assurance plans that will be applied to site characterization activities. With regard to NRC monitoring activities, the

regulations state that during site characterization the NRC is permitted to visit and inspect the locations at which activities are carried out and to observe excavations and in situ tests as they are done.

III. REVIEW PLAN

The methods by which the staff will review and assess the DOE quality assurance program for the site characterization phase of the repository program are described in this section. The DOE QA program consists of the QA plans for each organization which interpret and elaborate on the criteria in the NRC's regulations in 10 CFR Part 60 and the staff's guidance documents (TP's). The QA program also includes test plans and technical procedures which translate those requirements for specific items and activities. These documents form the basis for the application of the DOE QA Program to the site characterization phase activities.

In order to assess the adequacy and effectiveness of the DOE QA program, the NRC staff must evaluate the QA plans and procedures. In addition, the staff must evaluate the implementation of these plans and procedures. The implementation of the QA program will be accomplished by observing the implementation process and by reviewing documents resulting from implementation such as data records, audit and inspection reports, calibration records, and administrative procedures.

A. Plan and Procedure Reviews

The principal QA program documents to be reviewed by the NRC staff are the Site Characterization Plan, the QA plans and selected implementing procedures for each of the major DOE offices (i.e., HQ and the NNWSI project office), the major participants in the program (Sandia National Laboratories, Fennix and Scisson, etc.), and the other organizations supporting the DOE Headquarters, such as the Defense Waste Processing Facility.

1. Site Characterization Plan

The staff will review and comment on Section 8.6 of the Site Characterization Plan and any other sections containing pertinent information on the QA

program. The areas of review and acceptance criteria are defined in the "Technical Review Plan for NRC Staff Review of DOE's Site Characterization Plans."

2. QA Plans and Implementing Procedures

The staff will review and comment on the QA plans and selected implementing procedures of the various program organizations. Those implementing procedures controlling important and/or complex activities during site characterization will have first priority for NRC review. For example, it is expected that the implementing procedures covering peer review and qualification of existing data will be reviewed by the staff. In addition, technical documents, such as plans and detailed procedures associated with the exploratory shaft testing and construction, will be formally reviewed by the QA staff to determine if the specific quality assurance requirements in these documents are appropriate. Other implementing procedures will be reviewed as a part of NRC staff activities described in Section B below.

The QA plans will be reviewed and their adequacy assessed based on acceptance criteria outlined in Section IV. The NRC will issue comments based on this review to DOE. DOE should address these comments and revise the plans and procedures as necessary. The DOE should resubmit the plans, if revised, along with responses to staff comments for a second staff review. Completion of this process and resolution of issues will be documented in a letter to DOE.

B. Implementation Reviews

In addition to the above activities, the NRC staff will review the implementation of the DOE QA program at the organizations performing work for the program. As noted in the introduction to this Review Plan, the staff will conduct a selective review of the implementation of the DOE program in order to gain confidence in its adequacy and effectiveness. The staff's assessment focuses on whether systems are in place for controlling, documenting and verifying quality, on

whether problems in implementation are being detected by that program, and whether work of adequate technical quality for licensing is being produced.

The staff implementation review will focus on the performance of the organization being assessed. The staff assessment will include reviews of selected technical work being produced by an organization as a measure of the adequacy and effectiveness of the QA program. The staff also will assess the effectiveness of the QA program in establishing the record needed for licensing. QA program elements such as detailed planning, bid evaluation, etc., which do not directly relate to the quality of work produced or the record needed for licensing, will be given less attention by the staff. The staff implementation reviews will consist of onsite technical visits, audits and readiness reviews as discussed below.

1. Onsite Visits

NRC QA staff will visit various organizations in the repository program to obtain information on the QA programs being implemented. In most cases QA staff visits will be in conjunction with visits by technical staff whose primary goal is to gain technical information on select technical issues.

2. Audits

An audit is a planned and documented activity to determine by investigation, examination or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation (NQA-1). As used in this Review Plan, staff audits are included within the inspections and visits permitted during site characterization, as described in 10 CFR 60.18(h).

Two types of audits will be performed by the staff: team audits and staff observation audits of audits conducted by organizations within the DOE program. The former will consist of NRC QA and technical staff and contractors directly auditing DOE program organizations. The latter will consist of NRC staff observing and assessing the adequacy of audits conducted

within the DOE program. In both cases audits will focus on DOE's compliance with the procedures applicable to the work activities. The NRC staff will use detailed audit procedures to define the scope of the audits, responsibilities, and reporting requirements. These audits will review documents resulting from the implementation of the QA program such as data records, audit and inspection reports, and calibration records. The audits also will review work in progress.

3. Readiness Reviews

When DOE conducts readiness reviews, the staff may participate as an observer to obtain information on the implementation of the quality assurance program. The information gained will be utilized in the staff reviews described in other sections of this plan. A reduction in the number of audits or inspections may result from staff observation of DOE readiness reviews.

IV. ACCEPTANCE CRITERIA

As noted above, the NRC staff will review and assess the adequacy and effectiveness of the DOE QA plans and procedures and the implementation of these procedures. In this review and assessment, the staff will use the acceptance criteria outlined below.

1. The plans and procedures will be acceptable to the NRC staff if:
 - a. The QA plans and procedures for specific items, processes, services, or activities are established prior to the use of the items, services, and processes, and prior to initiation of activities.
 - b. NRC staff determine, in their review of the SCP Section 8.6 and other pertinent sections, that only minimal inadequacies exist with regard to the staff's acceptance criteria in the SCP review plan.
 - c. NRC staff determine, in their review of the DOE QA plans and procedures, that only minimal inadequacies exist with regard to the staff's

acceptance criteria in the technical positions listed below. If the DOE deviates from the criteria listed below, the NRC staff will determine if the deviation and the rationale for the deviation are acceptable on a case-by-case basis.

- Technical Position on Quality Assurance for the Site Characterization Phase of the High-Level Nuclear Waste Repository.
- Generic Technical Position on Qualification of Existing Data for the High-Level Nuclear Waste Repositories (NUREG-1298).
- Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories (NUREG-1297).
- Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements.

2. The implementation of the QA plan and procedures will be acceptable to the NRC staff if:

- a. DOE staff and the staff of participating organizations determine as a result of audits, inspections, and/or other reviews that the QA plans and procedures are implemented (i.e., the audits, inspections, and other reviews identify no inadequacies or only minimal inadequacies in implementation); or
- b. DOE staff and the staff of participating organizations identify, through audits, inspections, or other reviews, inadequacies in plans, procedures, and implementation; and they correct these inadequacies in a timely and acceptable manner. The program will be acceptable if these inadequacies are other than major deficiencies in the

program that would seriously affect the quality of items or activities related to safety or waste isolation; and

- c. NRC staff determine, through onsite visits, audits, and readiness reviews, that no inadequacies or only minimal inadequacies in implementation exist.