

COMPLIANCE DETERMINATION STRATEGY

RR3017 QUALITY ASSURANCE

PRIMARY REGULATORY CITATION:

None.

PASS ID OF THE COMPLIANCE DETERMINATION STRATEGY:

RR3017/NS0001

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)

RATIONALE FOR TYPES OF REVIEW:

Acceptance Review (Type 1) Rationale:

This regulatory requirement is considered to be License Application-related because, as specified in the License Application content requirements of 10 CFR 60.21 and the Format and Content Regulatory Guide (Reference 1), it must be addressed by the DOE in its License Application. Therefore, the staff will conduct an Acceptance Review of the License Application for this Regulatory Requirement.

Safety Review (Type 3) Rationale:

This regulatory requirement is considered to be related to radiological safety and waste isolation. Because this requirement is in 10 CFR Part 60, Subpart G, it is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., regulatory requirements in Subparts E, G, H, I, and 10 CFR 60.21). Therefore, the staff will conduct a Safety Review of the License Application to determine compliance with the Regulatory Elements of Proof (REOP) for the regulatory requirement.

This regulatory requirement is considered to fall within the criteria of a Type 3 Review because it represents citations from 10 CFR Part 60 which could affect radiological health, safety, and waste isolation. For the two REOPs of this regulatory requirement, the staff can make its safety determinations by evaluating the quality assurance program descriptions and associated information submitted in the License Application. In the opinion of the analysts, no additional analyses (i.e., as in Type 4 or 5 Reviews) would be necessary because sufficient expertise and experience exist to allow for adequate investigations and evaluations of the submitted information. The criteria for quality assurance programs have been clearly identified and quality assurance programs meeting these criteria have been effectively implemented in commercial nuclear power plants for many years. Initial uncertainties regarding the application of quality assurance program criteria to scientific investigations have been resolved for the most part through NRC/DOE interaction and issuance of NUREGs 0856, 1297, & 1298.

REVIEW STRATEGY:

Acceptance Review (Type 1):

In conducting the review of the quality assurance regulatory requirement, the reviewer should determine if the information presented in the License Application is sufficient to address the topics identified in Reference 1. Specifically, the reviewer should determine if the quality assurance program descriptions submitted cover all of the affected activities, i.e., site characterization, design and construction, performance confirmation, and operations, permanent closure, decontamination, and decommissioning. In addition, the reviewer should confirm that applicable criteria of 10 CFR Part 50, Appendix B are addressed in the quality assurance program descriptions.

An acceptance review for the implementation of the site characterization quality assurance program should verify that DOE has submitted evidence of NRC acceptance of these programs during prelicensing consultation, and that NRC staff objections and open items have been resolved.

Safety Review (Type 3):

In conducting the safety review, the reviewer will determine the adequacy of the quality assurance program descriptions submitted by DOE in the License Application and determine the effectiveness of the implementation of DOE's quality assurance programs for site characterization.

The current version of the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, March 1989, (Reference 2) should be used as the basis for evaluating the sufficiency of the quality assurance program descriptions. The review plan has been applied extensively during site characterization, and provides criteria for determining compliance to quality assurance regulations, standards, and guidance, i.e., 10 CFR 60.152, 10 CFR Part 50, Appendix B, ANSI/ASME NQA-1 (Reference 3) and applicable NUREGs (References 4, 5, and 6). The reviewer will rely on personal expertise and knowledge of quality requirements and personal experience obtained in evaluating quality assurance program implementation during site characterization.

The safety review of the implementation of quality assurance programs will primarily focus on determinations whether they have been effectively implemented during site characterization. This review will include evaluations of a) all data and data analysis contributing to the License Application have been developed or qualified under acceptable quality assurance programs, b) scientific and engineering computer codes have been adequately documented in terms of verification and model validation, and c) peer reviews have been conducted in accordance with quality program requirements. These determinations will be made based on evidence submitted by DOE of NRC's acceptance of the effective implementation of quality assurance programs during site characterization. The reviewer's experience during site characterization quality assurance implementation activities will contribute to the ability to determine the adequacy of the evidence submitted by DOE.

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Contributing Analysts:

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Date of Analysis: 05/27/92

RATIONALE FOR REVIEW STRATEGY:

By agreement between DOE and NRC (Reference 7), DOE prelicensing quality assurance program adequacy and implementation effectiveness are determined by NRC staff. This action was taken to provide greater assurance that information submitted in a License Application will be acceptable from the quality assurance perspective. This process of continuous quality assurance evaluation will provide the primary basis for the staff determination of site characterization quality assurance program implementation effectiveness.

APPLICABLE REGULATORY ELEMENTS OF PROOF:

Type 3:

REOP

RR3017/EP0100

RR3017/EP0200

RR3017/EP0300

REFERENCES CITED:

1. U.S. Nuclear Regulatory Commission. Office of Nuclear Regulatory Research. 1990. Draft Regulatory Guide DG-3003, Format and Content For the License Application for the High-Level Waste Repository.
2. U.S. Nuclear Regulatory Commission. Division of High-Level Waste Management. 1989. Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2.
3. American Society of Mechanical Engineers. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities.
4. U.S. Nuclear Regulatory Commission. 1983. NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.
5. U.S. Nuclear Regulatory Commission. 1988. NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories.
6. U.S. Nuclear Regulatory Commission. 1988. NUREG-1298, Qualification of Existing Data for High-Level Waste Repositories.
7. Letter from J. Linehan to R. Stein, August 4, 1989. Transmittal of Meeting Minutes from July 6, 1989 QA Meeting and July 6-7, 1989 Design Control Meeting.