

NRC INSPECTION MANUAL

DWM/HLWB

INSPECTION PROCEDURE 78090

DOCUMENT CONTROL (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

78090-01 INSPECTION OBJECTIVES

01.01 To determine if adequate measures are established for properly controlling and maintaining documents affecting Systems, Structures, and Components (SSCs) important to safety, design, site characterization, and construction of barriers important to waste isolation and related activities.

78090-02 INSPECTION REQUIREMENTS

02.01 Document Control Program. To determine if the Document Control Program is described, and the types of controlled documents are identified.

02.02 Document Distribution. To determine if adequate measures are established to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality.

02.03 Document Changes. To determine if adequate measures are established to assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and used at location where the prescribed activity is performed.

78090-03 INSPECTION GUIDANCE

General Guidance

This inspection procedure applies to the implementation of the U.S. Department of Energy's (DOE's) quality assurance (QA) program during the design and construction of a geologic repository at Yucca Mountain. The DOE QA program is described in the Quality Assurance Requirements and Description (QARD) Manual, DOE/RW-0333P. This inspection procedure applies to SSCs important to safety; to design, characterization, and

construction of barriers important to waste isolation; and to related activities described in the Safety Analysis Report (SAR).

Selection of areas for evaluation during inspections shall be based on the risk significance of the SSCs, related activities, and past performance. The scope of inspections should also consider the cumulative effect of failures related to low-risk-significant SSCs, regarding their potential effects on overall system performance and reliability.

Specific Guidance

03.01 Document Control Program. Verify that a program is established and the types of controlled documents are identified. Controlled documents are required to include, as a minimum, design documents (e.g., calculations, drawings, specifications, analyses), including documents related to computer software; procurement documents; instructions and testing, and inspection; as-built documents; QA and quality control manuals and quality-affecting procedures; SAR; nonconformance/deficiency reports; and corrective action reports, including changes thereto.

Verify that procedures are established to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner. Verify that procedures for the review, approval, and issuance of documents and changes are established to assure technical adequacy and inclusion of appropriate quality requirements before implementation. Verify that procedures are established to assure that documents are available at the location where the activity will be performed before beginning the work.

Verify that procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval. Verify that a master list or equivalent document control system is established to identify the current revision of instructions, procedures, specification, drawings, and procurement documents. Also the list should be distributed to predetermined responsible personnel.

Verify that a process exists for expediting changes in a timely manner. Verify that the expediting change process identifies the level of management with the authority to make expedited changes. Verify that a process exists for the control and distribution of editorial changes; correcting grammar or spelling; renumbering sections or attachments that do not affect the chronological sequence of work; changing the title or number of the document; and updating organizational titles. Verify that editorial changes are approved by the responsible organization.

03.02 Document Distribution. Select in-process work locations and verify that work documents are made available and used at the work locations. Verify that effective dates are established for approved implementing documents. Verify that obsolete or superseded documents are not part of the work package. The organizational position responsible for approving the document for release shall be identified.

03.03 Document Changes. Select several work documents and verify that review criteria are established for document changes. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with

established requirements. Verify that the review of changes was performed by individuals other than the preparer. Verify that the reviewers are technically competent regarding the subject area of the document changes being reviewed. Verify that the work document defines the method used to incorporate changes. A history of changes shall be documented and maintained and reviewed each time additional changes are proposed.

78090-04 INSPECTION RESOURCES

An initial inspection of the program for document control may be conducted approximately 1 year before submittal of an application. This inspection will consist of one inspector on site for 2 weeks. Preparations for the inspection and documentation of the inspection will be of 2 weeks. Implementation of the first inspection is 4 inspector-weeks.

After the construction authorization is issued and construction starts, semiannual inspections of the program will be conducted by one inspector, for a total of 2 inspector-weeks per year.

Once construction is complete and the operating license is issued, an annual inspection will be conducted by one inspector, for a total of 1 inspector-week per year.

78090-05 REFERENCES

U.S. Nuclear Regulatory Commission, NUREG-1804, "Yucca Mountain Review Plan," Draft Revision 2.

U.S. Code of Federal Regulations, 10 CFR Part 63, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada."

U.S. Department of Energy, "Quality Assurance Requirements and Descriptions (QARD)," DOE/RW-0333P, Latest revision accepted by NRC.

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