

NRC INSPECTION MANUAL

NMSS/DWM/HLWB

INSPECTION PROCEDURE 78200

CORRECTIVE ACTION (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

78200-01 INSPECTION OBJECTIVES

01.01 To determine if the corrective action program is adequately defined by effective procedures that identify and correct conditions adverse to quality and preclude recurrence of significant conditions adverse to quality.

78200-02 INSPECTION REQUIREMENTS

02.01 Procedures. Determine if procedures pertaining to the corrective action program are approved and adequately implemented. Determine if procedures contain provisions for identifying, reporting and documenting conditions adverse to quality. Determine if procedures exist that describe the follow-up, closure and trending processes and ensure implementation in a timely manner.

02.02 Identification of Conditions Adverse to Quality. Determine if measures are established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances and significant conditions adverse to quality are promptly identified.

02.03 Documentation and Reporting of Conditions Adverse to Quality. Determine if a process and instructions exist for documenting and reporting conditions adverse to quality to appropriate levels of management responsible for the conditions, and to the organization responsible for tracking.

02.04 Follow-up, Closure and Trending. Determine if proper implementation and closure of corrective action are completed in a timely manner. Determine if criteria are established for quality trending.

Determine if trending information is distributed to affected organization management and used to identify significant conditions adverse to quality.

78200-03 INSPECTION GUIDANCE

This inspection procedure applies to the implementation of the U. S. Department of Energy's (DOE's) QA program during the design and construction of a geologic repository at Yucca Mountain. The DOE QA program is described in DOE/RW-0333P, "Quality

Assurance Requirements and Description (QARD) Manual. This inspection procedure applies to Structures, Systems, and Components (SSCs) important to safety; design, characterization, and construction of barriers important to waste isolation; and related activities described in the safety analysis report.

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.

03.01 Procedures. Verify that procedures are established that describe the corrective action program. Verify that the procedures have been reviewed and approved by the affected organizations. Verify that procedures describe a process for follow-up and closure of issues, including requirements for documenting closure.

Verify that a process and instructions exist for documenting and reporting conditions adverse to quality to appropriate levels of management responsible for the conditions and to the responsible organization for tracking.

Verify that criteria are established and a process described for identifying and tracking adverse quality trends.

03.02 Identification of Conditions Adverse to Quality. Select a sample of documented problems and verify the following:

- a. The problems are adequately described and labeled with unique identifiers.
- b. The problems are classified by significance and identify, as a minimum:
- c. Conditions adverse to quality (A state of noncompliance with quality assurance program requirements); and
- d. Significant conditions adverse to quality (Repetitive problems indicating programmatic failures or precursor of significant technical deficiencies, are identified as significant conditions.)

03.03 Documentation and Reporting of Conditions Adverse to Quality. Select a sample of completed conditions adverse to quality and verify that management determined the extent of the adverse condition, completed remedial action as soon as practical, and documented the results.

Verify that significant conditions adverse to quality are documented and reported to management responsible for the condition, their upper management, and to the QA organization for tracking.

Verify that the QA organization concurred with the proposed corrective action, including remedial action. For significant conditions adverse to quality verify that corrective actions for root causes have been taken and are effective. Ensure that the QA requirements described in the licensee's corrective action procedures are being implemented.

Select several problems that have been resolved and verify that proper implementation of corrective actions and closures were completed in a timely manner.

Verify that criteria for determining a significant condition adverse to quality are appropriately established. Verify that the cause of the significant conditions adverse to quality are determined by qualified personnel using approved methods and corrective action taken is adequate to preclude recurrence.

Verify that significant conditions adverse to quality were evaluated for a stop work condition by the QA organization to determine if stopping work was warranted. Verify that appropriate action was taken by QA management to issue stop work orders to the responsible management in a timely manner after a stop work condition was identified.

Verify that appropriate action was taken to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

03.04 Follow-up, Closure, and Trending. Verify that reports are generated to identify conditions adverse to quality and significant conditions adverse to quality, and to provide management with a tool for identifying root causes.

Verify that nonconformance documentation including reports are periodically analyzed by the QA organization to identify quality trends.

Verify that trend evaluations are performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Verify that trend evaluations are distributed to affected organization management. Verify that identified adverse trends are reported to the management of the organization responsible for corrective action. Verify that the documentation for closure of the adverse condition has been generated and is complete, signed off, and properly filed and logged into a system to allow for retrieval.

78200-04 INSPECTION RESOURCES

An initial inspection of the corrective action program may be conducted approximately 1 year before submittal of an application. This inspection will consist of one inspector on site for 1 week. Preparations for the inspection, and documentation of the inspection will consist of 3 weeks. Implementation of the first inspection is 4 inspector-weeks.

After the construction authorization is issued and construction starts, at least semiannual inspections of the corrective action program will be conducted by one inspector for a total of 4 inspector-weeks per year.

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

78200-05 REFERENCES

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."

"NUREG XXXX,"Yucca Mountain Review Plan, Draft Revision 1, dated August 2000.

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

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