

YUCCA MOUNTAIN INSPECTION PROGRAM: LICENSE APPLICATION REVIEW PERIOD

2300-01 PURPOSE

To provide policy and guidance for implementation of the U.S. Nuclear Regulatory Commission (NRC) Yucca Mountain Project Inspection Program during the period between receipt of the U.S. Department of Energy (DOE) license application and potential issuance of the construction authorization.

2300-02 OBJECTIVES

02.01 To evaluate implementation of quality assurance (QA) measures for work being performed by DOE during the license application review period that could affect the performance of systems, structures, and components (SSCs) important to safety (ITS) and engineered barrier systems and natural barriers important to waste isolation (ITWI). This would include design, procurement, and fabrication activities and ongoing performance confirmation work.

02.02 To evaluate QA programs of DOE contractors, and DOE's oversight of its contractors, providing services, equipment, and components for long-lead-time ITS and ITWI items. This may include inspections at facilities where actual design, fabrication, and testing are performed.

02.03 To maintain an overall awareness of the status of programs and activities affecting safety and waste isolation.

2300-03 DEFINITIONS

03.01 Contractor. Any organization or individual that is under contract to furnish items or services to DOE. This includes, where appropriate, the terms consultant, vendor, supplier, and other titled sub-tier organizations.

03.02 Finding. An observation made during an inspection that has been placed in context and assessed for significance.

03.03 Inspection. An NRC planned and documented activity to investigate, examine, or evaluate, through observation or objective evidence, work activities and products to determine the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents.

03.04 Quality Assurance. All those planned and systematic actions necessary to provide adequate confidence that a SSC, engineered barrier system, or natural barrier will perform satisfactorily in service.

03.05 Violation. Failure to comply with any portion of a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

2300-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Division of High Level Waste Repository Safety (HLWRS). Provides overall direction for the inspection program.

04.02 Deputy Director, Licensing and Inspection Directorate (LID), HLWRS.

- a. Directs the implementation of policies, programs, and procedures related to the inspection program.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the inspection program.
- c. Approves changes to the inspection program.

04.03 Regional Administrator, Region IV.

- a. Provides program direction for management and implementation of the inspection program elements performed by the Region IV office.
- b. Within budget limitations, ensures the regional office staff includes an adequate number of inspectors necessary to carry out the portions of the inspection program that are within the regional office's responsibility.

04.04 Director, Division of Nuclear Material Safety, Region IV.

- a. Oversees regional implementation of the inspection program.
- b. Recommends and assists in the development and revision of the inspection program.

2300-05 DISCUSSION

During the license application review period, the NRC may conduct inspections of selected DOE Yucca Mountain Project activities. In addition to performance confirmation activities, DOE may proceed with design activities and procurement of long-lead-time items prior to NRC reaching a determination on construction authorization. Prior to issuance of a construction authorization, there is no regulatory requirement for a QA program that meets the requirements of Subpart G of 10 CFR Part 63. However, DOE is expected to have adequate QA controls in place for activities that might affect design or construction of ITS or ITWI SSCs. HLWRS/LID and Region IV Repository and Spent Fuel Safety Branch (RSFS) will determine the inspections to be performed, and their priorities, based on the activities performed by DOE. The inspections will be risk-informed and performance-based to the extent practical. Where quality-affecting activities have been contracted by DOE to other organizations, this inspection program also applies to those organizations.

06.01 Inspection Planning. The Region IV RSFS Branch Chief will schedule the inspections and assign the lead inspectors. Scheduling will consider inspection priority and the availability of inspection resources.

06.02 General Inspection Process. For each inspection, the lead inspector should implement the process described below for pre-inspection, onsite inspection, and post-inspection activities. Applicable inspection procedures provide specific guidance for onsite inspection activities. Attachment 1 of this Inspection Manual Chapter (IMC) lists certain inspection procedures applicable to this inspection program. Other inspection procedures may be developed or used as appropriate.

- a. Pre-inspection activities. To facilitate management of inspection resources and tracking of inspection activities, the lead inspector should develop an inspection plan. The inspection plan should describe the scope and major areas of emphasis that will be inspected. In addition, the inspection plan should identify the team members and the inspection schedule. This plan will be reviewed and approved by the Region IV RSFS Branch Chief and the HLWRS/LID Project Management Branch A Branch Chief. The NRC Office of General Counsel (OGC) will review the inspection plan, as appropriate.
- b. Onsite inspection activities. In advance of the inspection, the lead inspector should schedule entrance and exit meetings with DOE management or their representative, including a representative who has responsibility for the areas to be inspected. At the entrance meeting, the lead inspector should discuss the inspection scope and other administrative matters, such as interviews with staff and document reviews. Whenever possible, the lead inspector should schedule a daily status meeting with DOE management to discuss the inspection progress and issues identified.

The lead inspector should conduct an exit meeting with DOE management at the conclusion of the inspection. The lead inspector should determine whether their supervisor and HLWRS management should be briefed on the preliminary inspection findings prior to the exit meeting. The lead inspector should present the results of the inspection, including preliminary findings, emphasizing their impact on safety. The lead inspector should make clear to DOE that preliminary findings are always subject to management review.

- c. Post-inspection activities. The lead inspector should provide an inspection debrief to Region IV management and, as appropriate, will include HLWRS management and OGC. Inspection reports should be issued using IMC 0610, "Nuclear Material Safety and Safeguard Inspection Reports," and Region IV Policy Guide (PG) 4090, "Inspection Reports," as guidance. Inspection reports should be approved and issued by the Region IV RSFS Branch Chief with review by OGC, as appropriate.

NRC inspections may identify issues and generic implications that could have a bearing on the review of the license application. Relevant inspection findings should be presented to appropriate HLWRS management and technical review staff for consideration in the review of the licensee application. Issues needing additional clarification or resolution may require follow-up inspections.

06.03 Enforcement Actions. Enforcement actions associated with DOE's license application are not anticipated during the license application review period. However,

as an applicant, DOE is subject to applicable NRC regulations regarding Title 10 of the Code of Federal Regulations (10 CFR) 63.9, "Employee Protection," 10 CFR 63.10, "Completeness and Accuracy of Information," and 10 CFR 63.11, "Deliberate Misconduct." If and when the license application (LA) is docketed, DOE will also be subject to the regulations regarding 10 CFR Part 21, "Reporting of Defects and Noncompliance." Inspection Procedure (IP) 78010, "10 CFR Part 21 Program," provides guidance for conducting inspections to determine if DOE and its suppliers have established a program and procedures to effectively implement 10 CFR Part 21 requirements for reporting defects and failures to comply associated with a substantial safety hazard. Issues identified regarding these regulations may result in violations. Potential violations identified through inspection activities will be processed in accordance with NRC's Enforcement Policy.

06.04 Licensing Board Notification. If an issue is identified during the inspection debriefs that is new and pertinent to safety and environmental issues (e.g., contentions) in ongoing adjudicatory proceedings, Region IV PG 0603 "Procedures for Board Notifications Including the Commission," should be used to make the appropriate notifications. OGC should be consulted concerning the need to make notifications under PG 0603.

06.05 Inspector Qualification. NRC inspectors should be assigned responsibility for those inspection requirements consistent with their qualifications. All inspections should be led by an NRC Inspector certified to IMC 1246, Section XIV, "High-Level Waste Repository Inspector." Support during the inspection may be provided by NRC or contracted technical experts. Support personnel are not required to be certified in accordance with IMC 1246, but will conduct activities under the lead of a certified inspector.

2300-07 TYPES OF INSPECTIONS

07.01 Data Collection/Analysis Activities. Subpart F of 10 CFR Part 63 requires that the performance confirmation program must have started during site characterization and continue until permanent closure. During the license application review period, data collection and analysis supporting the performance confirmation program, site characterization, and other activities such as design qualification testing are expected to be ongoing. Inspections may be conducted to assess the implementation of QA requirements for data collection and the use of data in analysis and models for work being performed. Inspections may include observation of significant ongoing data collection activities conducted at the Yucca Mountain site or related Yucca Mountain Project facilities.

Inspections should place emphasis on QA measures, document control, and methodologies for ongoing work activities. This includes a review of the methodology for data collection, analysis, and evaluation of chemical and physical parameters for natural barriers important to waste isolation and to determine environmental conditions that may impact engineered features designed for the repository. Inspections should include the review of data analysis processes for use of data in modeling, including the revision of software codes since the submittal of the LA. This effort should focus on the transparency and traceability of data to verify that new data being collected and new analyses being performed are properly documented and appropriately selected for use in modeling and that modeling software has successfully completed validation and verification processes such that model outputs are reliable.

Additionally, inspections may review DOE's oversight of contracted activities to verify effective quality measures are being applied to ongoing work.

07.02 Engineering Design Activities. Selected building and facility design documents may be inspected in their early development stages to verify adequate implementation of the design process. DOE may proceed with engineering design after LA submittal but before a decision is reached on a construction authorization. The objective of these inspections is to verify that adequate QA measures have been established and implemented for the design of ITS SSCs and ITWI engineered barriers. The inspections should evaluate the measures taken to translate applicable regulatory requirements, and the design basis described in the license application, into specifications, drawings, procedures and instructions.

07.03 Vendor Activities. When DOE begins procurement of long-lead-time ITS SSCs, the NRC may begin inspections to verify implementation of the contractor's QA program and to observe development and testing activities. Potential inspections should be determined based on the significance to safety of the SSC provided, the importance of the SSC for waste isolation in DOE's safety analysis, and the overall frequency and significance of problems previously identified with the contractor's SSCs, including problems identified by third-party auditing organizations. Inspection emphasis should be placed on manufacturing processes, particularly new or state-of-the-art processes, employed during the design, fabrication, and testing of basic components. The inspections should verify that the contractor's processes meet applicable industry codes, standards and regulatory requirements. The NRC may also observe audits and surveillances conducted by DOE of its contractors to assess DOE's procurement process.

END

Attachments:

1. Inspection Procedures
2. Revision History for IMC 2300

Attachment 1 – Inspection Procedures

Inspection Procedure Number	Inspection Procedure Title
40002	Inspections to Review Allegations
78010	10 CFR Part 21 Program

Attachment 2 – Revision History for IMC 2300

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	09/11/08 CN 08-026	<p>Initial issuance. IMC 2300 was previously issued and deleted under document name, "Yucca Mountain Pre-operation Inspection Program."</p> <p>IMC 2300 is being issued to establish policy and guidance for inspections of the Department of Energy's Yucca Mountain Project activities during the license application.</p> <p>Researched commitments for 4 years and found none.</p>	None	N/A	N/A