NRC INSPECTION MANUAL

MANUAL CHAPTER 2300 NMSS/DWM/HLWB

YUCCA MOUNTAIN PRE-OPERATION INSPECTION PROGRAM

2300-01 PURPOSE

This Manual Chapter (MC) defines the Yucca Mountain Pre-Operation Inspection Program. This MC provides guidance for inspecting the U.S. Department of Energy's (DOE's) activity regarding the design and construction of a geologic repository for disposal of high-level radioactive waste at Yucca Mountain, Nevada. The purpose of this MC is to ensure that the geologic repository is designed, constructed, and tested in accordance with the applicable regulations and the construction authorization.

2300-02 APPLICABILITY

This MC applies to all systems, structures, and components (SSCs) important to safety, to design and characterization of barriers important to waste isolation, and to related activities, until the U.S. Nuclear Regulatory Commission (NRC) issues an operating license for the geologic repository to DOE. This would include activities performed during: (1) site characterization; (2) acquisition and analysis of samples and data; (3) scientific studies; (4) performance of tests and experiments; (5) controlling geological and engineering materials samples; (6) facility design; and (7) site construction. This MC is applicable to activities that are performed by DOE and its consultants, contractors, and suppliers.

DOE is required to implement a quality assurance (QA) program that meets the criteria of 10 CFR Part 63, Subpart G, "Quality Assurance." The DOE QA program is described in the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, and in the DOE application for a construction authorization. Inspection activities will focus on the control of activities affecting quality of the identified SSCs to an extent consistent with their importance to safety.

Implementation of this MC may begin approximately 12 months before DOE submits a license application, during the site characterization phase at Yucca Mountain, and will continue through site construction.

2300-03 OBJECTIVES

03.01 Establish the program for inspecting SSCs that are important to safety and waste isolation and inspecting associated activities that are conducted by DOE and its consultants, contractors, and suppliers before the NRC issues an operating license for the geologic repository.

03.02 Assure that technical, quality, and administrative activities that are important to safety and waste isolation are effectively executed.

03.03 Verify that DOE effectively executes its QA program which includes timely implementation of organizational staffing, procedures, instructions, QA activities, and administrative controls.

03.04 Verify that the DOE QA program, procedures, and instructions necessary to achieve quality objectives important to safety and waste isolation are adequate and effectively implemented.

03.05 Identify conditions that may adversely affect safety and waste isolation so that appropriate corrective actions can be taken.

03.06 Conduct inspections to support recommending the issuance or denial of a construction permit or operating license to DOE for a geologic repository.

2300-04 DEFINITIONS

04.01 Geologic Repository. A system that is intended to be used for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the engineered barrier system and the portion of the geologic setting (i.e., the geologic, hydrologic, and geochemical systems of the region) that provides isolation of radioactive waste.

04.02 Important to Safety. With reference to SSCs, includes but is not limited to those engineered features of the geologic repository operations area whose function is:

a. To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of 10 CFR 63.111(b)(1) for Category 1 event sequences; or

b. To prevent or mitigate Category 2 event sequences that could result in doses equal to or greater than the values specified in 10 CFR 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

04.03 Important to Waste Isolation. With reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable assurance that high-level waste can be disposed without exceeding the requirements of 10 CFR 63.113(b).

04.04 Inspection. Measures consisting of examinations, observations, or measurements to determine the conformance of materials, parts, SSCs, services, or processes to predetermined quality requirements. Activities include performing audits, inspections, surveillance, and observations.

04.05 Inspection Types. Inspections are classified as performance-based or compliance-based and are defined as follows:

a. Performance-based inspections emphasize inspection of actual activity performance and results. Performance-based inspections require measurable, or calculable, parameters and objective performance assessment criteria. Note that a performance-based approach to inspection does not change the need for compliance with NRC requirements.

b. Compliance-based inspections emphasize inspection of compliance with prescriptive requirements that specify features, actions, or programmatic elements.

04.06 QA Program. Provides a management control system to assure the attainment of quality objectives.

2300-05 DISCUSSION

05.01 General. This MC provides the inspection requirements for selectively assessing QA program implementation and completion of established QA objectives before NRC issues an operating license to DOE for the geologic repository. Inspection activities should be performance-based, when possible, and should focus on the control of activities affecting quality of the identified SSCs to an extent consistent with their importance to safety. Compliance-based inspections will be conducted in addition to performance-based inspections, as necessary, to determine the effectiveness of the DOE QA program.

Emphasis should be placed on inspecting implementation of the QA program requirements retained by DOE and its principal contractors who are delegated authority to conduct activities that are important to safety and waste isolation. This MC also provides for the direct inspection of activities performed by DOE consultants, contractors, and suppliers to verify that delegated elements of the QA program are being effectively implemented and to assess DOE's level of control over its contractors. The scope of this MC comprises two phases, site characterization and construction.

05.02 Site Characterization Phase. The inspections performed during site characterization are both technically-based and quality-based, with emphasis placed on performance-based technical inspections.

a. Technically-based inspections include activities such as confirming, assessing, and verifying that the agreements from the technical exchanges between NRC and DOE have been performed and are adequate. The technical aspects of site characterization are reviewed to assure that the technical basis is adequate and properly supported by appropriate analysis, research, tests, and experiments.

b. Quality-based inspections include activities such as verifying the qualifications of personnel, inspecting the programmatic aspects of the DOE QA program with respect to the QA criteria of Subpart G to 10 CFR Part 63, and reviewing selective performance areas such as data and software qualification, design and procurement activities, and control of suppliers.

05.03 Construction Phase. The basis for construction inspections is to confirm that the requirements of Part 63 are met. The inspections will confirm, assess, and verify the adequacy of selected technical and quality aspects of the construction permit.

2300-06 RESPONSIBILITIES AND AUTHORITIES

06.01 Director, Office of Nuclear Material Safety and Safeguards. Responsible for regulatory oversight of the Yucca Mountain Project.

06.02 Director, Division of Waste Management. Responsible for the overall development, maintenance, and implementation of the inspection program.

06.03 Chief, High-Level Waste Branch

a. Responsible for developing and implementing the Agency's regulatory, licensing, and inspection programs for the geologic repository.

b. Coordinates the development of and approves inspection procedures.

c. Oversees the implementation of the MC elements to ensure effectiveness.

06.04 Chief, Projects and Engineering Section

a. Identifies any special inspection resources necessary to resolve technical or regulatory issues.

b. Assesses the regional implementation of the established MC and inspection procedures.

c. Serves as a source of technical expertise for questions about the geologic repository.

d. Assists in the development, modification, and revision of inspection guidance to ensure that geologic repository-related activities are conducted in accordance with appropriate regulations and standards.

e. Provides resources to support regionally-led inspections regarding the geologic repository.

06.05 Project Manager, High-Level Geologic Repository

a. Serves as the point of contact for technical and regulatory issues that affect the geologic repository.

b. Serves as the point of contact for regional requests to obtain High-Level Waste Branch inspection and technical resources.

c. Serves as the focal point for collecting lessons learned from previous inspections. Incorporates lessons learned into MC and inspection procedures under Division of Waste Management purview. Recommends changes to other organizations for MC and inspection procedures under their purview.

06.06 Regional Administrator, Region IV

a. Responsible for ensuring adequate implementation of the MC elements that are performed by the Region IV office.

b. Ensures that the Region IV office staff includes adequate resources necessary to carry out the inspection process described in this MC.

06.07 Director, Division of Nuclear Materials Safety, Region IV

a. Responsible for implementing the MC elements that are performed by Region IV.

b. Concurs on the approval of the MC and inspection procedures for activities relating to the geologic repository.

c. Ensures that adequate resources are assigned to the geologic repository inspection program.

06.08 Chief, Fuel Cycle, Decommissioning, and High-Level Waste Branch.

a. Manages the planning, scheduling, and performance of geologic repository inspections.

b. Contacts the Project Manager, High-Level Waste Branch, to request additional inspection or technical resources, as necessary, to support geologic repository inspection activities.

c. Ensures that inspection staff is trained and qualified.

d. Ensure that inspections of geologic repository activities are properly documented and that inspection findings are appropriately characterized in accordance with their safety significance.

e. Ensures that appropriate enforcement actions are initiated when warranted.

2300-07 PROGRAM DESCRIPTION

07.01 Bases. This MC emphasizes systematic evaluation of the adequacy and effectiveness of the DOE QA program and its implementation. NRC will perform inspections of selected DOE activities at the DOE geologic repository site and at the facilities of DOE consultants, contractors, and suppliers. This MC establishes priorities for inspection by planned sampling of SSCs and related activities consistent with their importance to safety and waste isolation and should consider the past performance of DOE in the areas inspected. Region IV certified inspectors will typically lead inspections which may include Headquarters inspectors, technical personnel, and other support personnel as required.

07.02 Safety Classification of SSCs. DOE will develop a Quality List (Q-List) that reflects the safety classifications of SSCs. This Q-List includes SSCs that have been designated as important to safety and waste isolation. The Project Manager, High-Level Waste Branch, should be contacted with questions regarding the safety classification of SSCs.

07.03 Implementation. Region IV is responsible for implementing the inspection program described in this MC. This MC is intended to provide the framework for managing the inspection effort. This MC does not specify sample sizes, frequencies of periodic inspections, nor the time frame when certain inspection activities are to be performed. Region IV will plan and conduct audits, inspections, surveillances, and observations based on safety considerations, current activities, and past performance.

Inspectors have the latitude to independently inspect any area of safety concern. Independent inspection effort will be reported against the inspection procedure that most closely describes the activity being reviewed. Issues related to occupational health and safety should be evaluated in accordance with Manual Chapter 1007, “Interaction Activities Between Regional Offices and OSHA.”

07.04 Planning, Scheduling, and Documenting Inspection Activities. To adequately fulfill the requirements of this program, effective planning is required so that the various inspection requirements are completed in a reasonable time by properly qualified inspectors. Region IV should implement a system for planning, scheduling, and recording completed inspections of geologic repository activities.

Region IV management should develop, on an annual basis, a schedule of inspections to be conducted based on the anticipated site activities that are to be performed in the upcoming year. The annual schedule of inspections should be coordinated with the High-Level Waste Branch. Region IV management should review and revise the schedule as needed to account for changes in site activities. Region IV management should inform the High-Level Waste Branch and document any changes from the planned inspections. The activities for conducting inspections should include the following:

a. Developing inspection plans.

b. Scheduling inspections with DOE.

c. Notifying the State of Nevada, affected units of local government, and any affected Indian Tribe.

d. Documenting completed inspections, findings, and open items.

07.05 Inspection and Technical Personnel Considerations. Certified inspectors will lead inspections and will be qualified in accordance with the requirements of Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Inspectors and technical representatives will be assigned responsibility for performing inspections consistent with their qualifications.

07.06 Inspection Requirements. Inspections will be based on 10 CFR Part 63 and other applicable regulations, commitments, conditions contained in the license and technical specifications, and the DOE Safety Analysis Report. Inspections will confirm that applicable regulations and requirements are met. The procedures listed in the Appendix to this MC represent the inspection procedures to be implemented. Selection of inspections procedures will be based on safety considerations, status of work activities, and past performance.

Inspection of the QA program should be performed before conducting program implementation inspections. Although each inspection procedure contains many line items, these items are provided as guidance and the individual inspector is expected to apply professional judgment regarding the need for completing each specific item.

07.07 Focus of Inspections. The amount of inspection and activities selected for inspection should be consistent with the importance to safety of the SSCs and to related activities, and the past performance of DOE in those areas. Inspections should be performance-based, when appropriate. However, in the early stages of the project, the majority of inspections may be compliance-based and will focus on QA program implementation. Inspection activities should emphasize the early identification of problem areas.

It is the prerogative of Region IV management to determine which areas or activities are to be emphasized by the assigned inspectors.

a. The inspection requirements pertinent to previously identified problems or common problem areas should be emphasized or performed again.

b. Inspection efforts should focus on problems that indicate programmatic weaknesses.

c. Emphasis should be placed on verifying the adequacy of the DOE corrective action program to identify, track, trend, resolve, and prevent problem recurrence.

07.08 Inspection Findings. Inspectors should notify their management and the Onsite Representatives of any safety concerns. Inspection findings will be documented in inspection reports in accordance with MC 0610, "Inspection Reports." Inspection issues that cannot be resolved at the time of the inspection will be documented as open items or unresolved issues. Region IV will track open items and unresolved issues and future inspections will include resolution of these issues. Violations will be evaluated in accordance with NUREG 1600, "Enforcement Policy."

The inspection procedures listed in the Appendix to this MC cover only a small sample of DOE activities in any area. Thus, it is important that inspectors evaluate whether noted

problems represent isolated cases or are symptomatic of broader, more serious problems. To provide the perspective to perform this evaluation, inspectors should:

a. Review deficiencies, audit findings, and problems identified by DOE or by its consultants, contractors, or suppliers.

b. Ascertain whether additional NRC inspection effort is merited in the areas of concern.

END

YUCCA MOUNTAIN INSPECTION PROGRAM
YUCCA MOUNTAIN PRE-OPERATION PHASE - INSPECTION PROCEDURES
(INSPECTION PROCEDURES WILL BE ADDED AS REQUIRED)

Quality Assurance Inspection Procedures

IP 78010	10 CFR Part 21 Program
IP 78020	Quality Assurance Programmatic Review
IP 78030	Management and Organizations
IP 78040	Training and Qualifications
IP 78050	Quality Assurance Program Implementation
IP 78060	Design Control
IP 78070	Procurement Document Control
IP 78080	Instructions, Procedures, and Drawings
IP 78090	Document Control
IP 78100	Control of Purchased Material, Equipment, and Services
IP 78110	Identification and Control of Materials, Parts, and Components
IP 78120	Control of Special Processes - Welding
IP 78130	Control of Special Processes - NDE
IP 78140	QA Inspection Program
IP 78150	Test Control
IP 78160	Control of Measuring and Test Equipment
IP 78170	Handling, Storage, and Shipping
IP 78180	Inspection, Test, and Operating Status
IP 78190	Nonconforming Material, Parts, or Components
IP 78200	Corrective Action
IP 78210	Quality Assurance Records
IP 78220	Audits
IP 78230	Software Validation
IP 78240	Sample Control
IP 78250	Scientific Investigation
IP 78260	Field Surveying
IP 78270	Control of The Electronic Management of Data
IP 78280	Graded Quality Assurance
IP 78290	Commercial Grade Item Dedication
IP 78300	Supplier/Vendor Inspection
IP 78310	Quality Assurance Program Changes (10 CFR 63.144)
IP 78320	Safety Evaluations (10 CFR 63.44)

Construction Inspection Procedures

IP 78410	Structural Concrete
IP 78510	Structural Steel and Rock Bolt Inspection
IP 78610	Construction of Fuel Handling Building

Operational Inspection Procedures

IP 78710	Radiation Safety
IP 78720	Security Safeguards
IP 78730	Emergency Planning
IP 78740	Resolution of Employee Concerns

Performance Confirmation Activities and Compliance Evaluations

IP 78800	Seepage Monitoring
IP 78801	In Situ Waste Package Monitoring
IP 78802	Long-Term Materials Testing
IP 78803	Ventilation Monitoring
IP 78804	Rock Mass Monitoring
IP 78805	In-Drift Monitoring
IP 78806	Introduced Materials Monitoring
IP 78807	Recovered Material Coupon Testing
IP 78808	Dummy Waste Package Testing
IP 78809	Recovered Waste Package Testing
IP 78810	Postclosure Simulation Testing
IP 78811	Geologic Observations and Mapping
IP 78812	Subsurface Sampling and Testing
IP 78813	Baseline Analyses and Evaluations
IP 78814	Unsaturated Zone Testing
IP 78815	Near-Field Environment Testing
IP 78816	Waste Form Testing
IP 78817	Waste Package Testing
IP 78918	Borehole Seal Testing
IP 78819	Ramp and Shaft Seal Testing
IP 78820	Groundwater Quality
IP 78821	Groundwater Level and Temperature Monitoring
IP 78822	Surface Uplift Monitoring
IP 78823	Subsurface Seismic Monitoring

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