

HLWYM NPEmails

From: Vincent Everett
Sent: Monday, February 04, 2008 10:29 AM
To: Blair Spitzberg; Leonard Willoughby; Jack Parrott
Cc: Vivian Mehrhoff
Subject: MC 2300 version 2/4/08
Attachments: IMC 2300 2_4_2008 draft.doc; Compare 1_24_08 with 2_4_08.doc

Attached is the latest version (2/4/08) of MC 2300 with comments incorporated from Blair, Jack and Leonard. Also attached is a compare version so you can see what got changes over the past week from the 1/24/08 version that was reviewed.

Comments from Frank & Tom are still expected.

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Sent Date: 2/4/2008 10:28:39 AM
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From: Vincent Everett

Created By: Vincent.Everett@nrc.gov

Recipients:

"Vivian Mehrhoff" <Vivian.Mehrhoff@nrc.gov>
Tracking Status: None
"Blair Spitzberg" <Blair.Spitzberg@nrc.gov>
Tracking Status: None
"Leonard Willoughby" <Leonard.Willoughby@nrc.gov>
Tracking Status: None
"Jack Parrott" <Jack.Parrott@nrc.gov>
Tracking Status: None

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Files	Size	Date & Time
MESSAGE	289	2/4/2008 10:28:39 AM
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NRC INSPECTION MANUAL

MANUAL CHAPTER 2300

YUCCA MOUNTAIN INSPECTION PROGRAM: LICENSE APPLICATION REVIEW PERIOD

Draft 2/4/08

OFFICIAL USE ONLY – SENSITIVE INTERNAL INFORMATION

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ATTACHMENT 1, Inspection Procedures

YUCCA MOUNTAIN INSPECTION PROGRAM: LICENSE APPLICATION REVIEW PERIOD

2300-01 PURPOSE

To provide inspection policy and guidance for the implementation of the inspection program at Yucca Mountain for ongoing DOE work during the period between receipt of the license application and potential issuance of the construction authorization, and to maintain an overall awareness of the status and implementation of programs and activities affecting safety and waste isolation.

2300-02 OBJECTIVES

02.01 To verify that ongoing work is being performed in accordance with commitments made in the license application and as specified in 10 CFR Part 63.

02.02 To verify effective implementation of the quality assurance (QA) process for work being performed during the license application review period that would affect the performance of important to safety systems, structures, and components (SSCs) and important to waste isolation engineered barrier systems and natural barriers. This would include review of ongoing performance confirmation work.

02.03 To provide guidance for the early inspection of ongoing engineering design activities to verify that facility design specifications, drawings, procedures and instructions are being developed, reviewed and finalized consistent with commitments made in the license application.

02.04 To provide guidance for the evaluation of vendor quality assurance programs for companies providing services, equipment and components for long lead time items important to safety and important to waste isolation. This may include inspections at facilities where actual design, fabrication and testing is performed.

02.05 To address allegations received by the NRC in a timely manner and in accordance with NRC policy that are related to the NRC's review of the license application.

2300-03 DEFINITIONS

03.01 Allegation. A declaration, statement or assertion of impropriety or inadequacy associated with NRC regulated activities, the validity of which has not been established.

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

03.03 Design Qualification Testing. A test to assure that a system and/or component performs as designed.

03.04 Finding. An observation made during an inspection that is provided to the NRC technical review staff for their determination of significance and impact on the license application review. Findings may result in Requests for Additional Information (RAI).

03.05 Inspection. An NRC planned and documented activity to investigate, examine, or evaluate, through objective evidence, work activities and products to determine the

adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and to verify effective implementation of the QA program.

03.06 Quality Assurance. Quality Assurance (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component (SSC), engineered barrier system, or natural barrier will perform satisfactorily in service.

03.07 Quality Assurance Requirements Document (QARD). DOE's quality assurance document that defines the quality assurance policy and program, describes the method(s) by which the policy will be implemented through procedures and instructions, and identifies the parties responsible for implementation.

03.08 Safety Evaluation Report. The safety evaluation report (SER) provides the technical, safety, and legal basis for the NRC's disposition of a license request or license amendment request. The safety evaluation report is written and issued by the NRC.

03.09 Supplier. Any organization that supplies basic components to a vendor or applicant.

03.10 Surveillance. Applicant and contractor activities such as reviews, observations, inspections, and audits to determine if an item or activity conforms to QA program commitments.

03.11 Vendor. Any company or organization that provides products such as material, equipment, components or services to be used in an NRC-licensed facility or activity. In certain cases the vendor may have NRC certificates (e.g., a transportation cask).

03.12 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, High Level Waste Repository Safety (HLWRS). Provides overall direction for the NRC Yucca Mountain inspection program.

04.02 Deputy Director, Division of Licensing and Inspection.

- a. Directs the implementation of policies, programs, and procedures related to the inspection program for Yucca Mountain.
- 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 Yucca Mountain inspection program.
- b. Recommends and assists in the development and revision of the inspection program.

2300-05 DISCUSSION

This inspection manual chapter (IMC) will initially be applied when the Department of Energy (DOE) submits an application to the NRC and will continue to be applied during the review process until the NRC issues a Construction Authorization. The NRC will implement this IMC to assess DOE's implementation of its QA program for activities performed during the period the license application is being reviewed. Where the performance and/or surveillance of activities have been contracted to other organizations, this IMC also applies to those organizations.

2300-06 INSPECTION POLICIES AND GUIDANCE

06.01 Inspection Emphasis. Inspection emphasis is placed on the application of quality assurance processes related to ongoing data collection, modeling, software development, engineering design and procurement activities, and prototype development and testing.

06.02 General Inspection Process. For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection, and post-inspection activities. The inspection procedures listed in Attachment 1 provide more specific guidance for onsite inspection activities.

- 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 will describe the scope and major areas of emphasis that will be reviewed, evaluated, or assessed. In addition, the inspection plan should identify the team members and the inspection schedule. This plan is to be reviewed and approved by the Region IV Repository and Spent Fuel Safety Branch Chief and the responsible HLWRS Branch Chief and Technical Project Manager, as applicable. The NRC Office of General Council (OGC) will review the inspection plan, as appropriate.
- b. Onsite inspection activities. An entrance and exit meeting with DOE management or their representative, including a representative who has responsibility for the areas to be inspected, should be scheduled in advance. At the entrance meeting, the lead inspector should discuss the inspection scope and other administrative matters, such as interviews with staff and/or document reviews. Whenever possible, the lead inspector should schedule a daily status meeting with DOE representatives to discuss the inspection progress and issues identified.

An exit meeting should be conducted at the conclusion of the inspection. The results of the inspection, including preliminary findings, should be presented emphasizing their impact on safety. The lead inspector should emphasize that preliminary findings are always subject to management review. Prior to the exit, the lead inspector should determine whether his/her supervisor should be briefed on the preliminary inspection findings.

- c. Post-inspection activities. The lead inspector will provide an inspection debrief to NRC management, and as appropriate, will include HLWRS and OGC. Inspection reports will 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 will be approved and issued by the Region IV Repository and Spent Fuel Safety Branch Chief with review from OGC.

NRC inspections are expected to result in early identification and resolution of problems, their root causes and generic implications. Because of their potential for affecting the NRC's license application review, inspection findings will be provided to the NRC HLWRS technical review staff for incorporation into the technical review process underway of the licensee application. Issues found by the technical review staff needing additional clarification or resolution will be resolved through the Request for Additional Information (RAI) process or may result in a follow-up inspection. Listed below are the two categories into which inspection findings will be placed.

- Finding. An observation made during an inspection that is discussed with the NRC technical review staff for their determination of significance and impact on the license application review. Those findings determined by the NRC technical review staff as impacting their review will be documented in the inspection report.
 - Violation. Failure to comply with any portion of a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification. Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.
- d. Assessment of Inspection Results. The NRC will periodically review inspection activities to determine if the current level of inspection effort should be changed. The review of inspection activities will focus on changing demands on the inspection staff related to areas such as: (1) ongoing engineering design work, (2) ongoing experiments and tests, (3) vendor activities related to long lead time items, (4) requests for support from the HLWRS licensing review organization, (5) work load related to allegations, and (6) issues concerning the implementation of the licensee's quality assurance program.
- e. Participation by Outside Agencies. (To be developed with input from OGC)
- f. Public Availability of Inspection Reports. (To be developed with input from OGC)

06.03 Licensing Board Notification. If an issue is identified during the inspection debriefs that is new and pertinent to safety and environmental issues or to contentions under review in adjudicatory proceedings underway, Region IV Policy Guide PG 0603 "Procedures for Board Notifications Including the Commission" will be used to make the appropriate notifications. The NRC's Office of General Council will be consulted concerning the need to make notifications under PG 0603.

06.04 Inspector Qualification. All inspections will be lead by an NRC Inspector certified to IMC 1246, Section XIV "High-Level Waste Repository Inspector." Support during the inspection may be provided by NRC staff 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.

07.01 Data Collection/Analysis Activities. Inspections will be conducted to assess the implementation of QA requirements for data collection and the use of data in analysis and models for work being conducted during the period the license application is under review by the NRC. Inspections may include observation of significant ongoing data collection activities conducted at the Yucca Mountain site or related Yucca Mountain Project facilities. Information in the NRC's Risk Insights Baseline Report will be used to focus inspection activities on data identified as having medium or high risk significance.

Inspections will place emphasis on QA program implementation, document control, and methodologies for ongoing work activities such as the performance confirmation studies or work done in response to NRC Requests for Information (RAI). 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 will impact engineered features designed for the repository. Inspections will include the review of data analysis processes for use of data in modeling, including the revision of software codes since the submittal of the license application to ensure changes to the code satisfy 10 CFR 63.44. This effort will focus on the transparency and traceability of data to verify that new data being collected or new analysis being performed under the QA program 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.

Because the science and engineering planned for use at Yucca Mountain presents a number of design concepts that are not currently standard industry practices, there is a need to demonstrate, either through analysis, appropriate test programs, experience, or a combination thereof, the performance of the safety features that will be relied upon to meet the design objectives of 10 CFR Part 63. Requirements to perform testing is specified in 10CFR63.124(d)(2)(i) which states "*If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualification testing of a prototype unit under the most adverse design conditions.*" As necessary, and based on design considerations, design qualification testing inspections may be performed of experiments and tests being conducted to verify effective implementation of QA requirements for data collection and analysis in support of commitments and conclusions stated in the license application.

Additionally, the inspection team will review DOE's oversight of contracted activities to verify effective quality controls are being applied to ongoing work. Inspections will include review of a suitable sample of documents related to additional site characterization activities to support construction activities to verify the effective implementation of the QA programs. Observations of these activities should determine whether QA program requirements are being adequately implemented as required by DOE and/or contractor procedures. Early involvement of NRC staff will facilitate and support prompt identification and resolution of issues.

07.02 Engineering Design Activities. The objective of the engineering design inspections is to verify that the design process has been established and implemented for important to safety SSCs and important to waste isolation engineered barriers consistent with the requirements in 10 CFR Part 63, Subpart G and design commitments made in the license application. The inspections will verify that adequate measures have been taken to translate applicable regulatory requirements, and the design basis described in the license application, into specifications, drawings, procedures and instructions. Selected building and facility design documents may be reviewed in their early development stages to verify adequate implementation of the design process.

07.03 Vendor Activities. The NRC may begin vendor inspections when DOE begins procurement of long lead time components important to safety or important to waste isolation in order to verify implementation of the vendor's quality assurance program and observe development and testing activities. Vendors will be selected based on the significance to safety or waste isolation of the equipment or service provided, the importance of the equipment or service relative to assumptions and uncertainties used in making the risk significant determinations described in the NRC's Risk Insights Baseline Report, and the overall frequency and significance of problems previously identified with the vendor's materials, equipment or services, including problems identified by third-party auditing organizations. Inspection emphasis will be placed on manufacturing processes, particularly new or state-of-the-art processes, employed by vendors during the design, fabrication and testing of basic components. The inspections will verify that the vendor processes meet applicable industry codes, standards and regulatory requirements.

In addition to verifying the implementation of the 10 CFR Part 63 Appendix G criteria, inspections will include a review, where applicable, of requirements related to commercial grade dedication programs implemented in compliance with Appendix G. Inspections will also include review of recent third-party audit reports, audits/surveillances conducted by DOE, condition reports and nonconformance reports associated with the facility that may be relevant to work performed to support the design basis described in the license application. The NRC may also observe audits and surveillances conducted by DOE of vendors and suppliers to verify effective implementation of the audit process to ensure that the requirements of 10CFR63.142(h) "Control of Purchased Material," are satisfied.

07.04 Allegation Follow-up. Allegations received by the NRC, once the license application is received, will be processed in accordance with Management Directive 8.8 "Management of Allegations, Region IV Policy Guide (PG) - 0858 "Management of Allegations," and Inspection Procedure 4002 "Inspections to Review Allegations." Allegation follow-up may be combined with other inspection activities.

2300-08 ENFORCEMENT ACTIONS (OGC REVIEW NEEDED)

Possible enforcement actions associated with DOE's application are not anticipated in the pre-docketing application phase. However, the information submitted with the application will become subject to NRC regulations, including enforcement actions for employee protection (10 CFR 63.9 "Employee Protection"), willful wrongdoing (10 CFR 63.11 "Deliberate Misconduct"), or fraudulent information (10 CFR 63.10 "Completeness and Accuracy of Information") and DOE may be subject to enforcement actions, such as notices of violation. Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

2300-09 REFERENCES

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

NUREG-1804, Yucca Mountain Review Plan, Rev. 2

NRC Risk Insights Baseline Report (ML040560162/ML040560302), dated April 2004

Management Directive 8.8 "Management of Allegations"

Region IV Policy Guide 0858 "Management of Allegations"

NRC's Enforcement Policy

DOE Quality Assurance requirements Document (QARD)

END

Attachments:

1. INSPECTION PROCEDURES

ATTACHMENT 1

Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
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NRC INSPECTION MANUAL

MANUAL CHAPTER 2300

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YUCCA MOUNTAIN INSPECTION PROGRAM: LICENSE APPLICATION REVIEW PERIOD

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2300-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, High Level Waste Repository Safety (HLWRS). Provides overall direction for the NRC Yucca Mountain inspection program.

04.02 Deputy Director, Division of Licensing and Inspection.

- a. Directs the implementation of policies, programs, and procedures related to the inspection program for Yucca Mountain.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the inspection program.
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04.03 Regional Administrator, Region IV.

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03.07. Quality Assurance

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d. Assessment of Inspection Results. The NRC will periodically review inspection activities to determine if the current level of inspection effort should be changed. The review of inspection activities will focus on changing demands on the inspection staff related to areas such as: (1) ongoing engineering design work, (2) ongoing experiments and tests, (3) vendor activities related to long lead time items, (4) requests for support from the HLWRS licensing review organization, (5) work load related to allegations, and (6) issues concerning the implementation of the licensee's quality assurance program.

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e. Participation by Outside Agencies. (To be developed with input from OGC)

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f. Public Availability of Inspection Reports. (To be developed with input from OGC)

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06.03 Licensing Board Notification. If an issue is identified during the inspection debriefs that is new and pertinent to safety and environmental issues or to contentions under review in adjudicatory proceedings underway, Region IV Policy Guide PG 0603 "Procedures for Board Notifications Including the Commission" will be used to make the appropriate notifications. The NRC's Office of General Council will be consulted concerning the need to make notifications under PG 0603.

06.04 Inspector Qualification. All inspections will be lead by an NRC Inspector certified to IMC 1246, Section XIV "High-Level Waste Repository Inspector." Support during the inspection may be provided by NRC staff 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.

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07.01 Data Collection/Analysis Activities. Inspections will be conducted to assess the implementation of QA requirements for data collection and the use of data in analysis and models for work being conducted during the period the license application is under review by the NRC. Inspections may include observation of significant ongoing data collection activities conducted at the Yucca Mountain site or related Yucca Mountain Project facilities. Information in the NRC’s Risk Insights Baseline Report will be used to focus inspection activities on data identified as having medium or high risk significance.

Inspections will place emphasis on QA program implementation, document control, and methodologies for ongoing work activities such as the performance confirmation studies or work done in response to NRC Requests for Information (RAI). 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 will impact engineered features designed for the repository. Inspections will include the review of data analysis processes for use of data in modeling, including the revision of software codes since the submittal of the license application to ensure changes to the code satisfy 10 CFR 63.44. This effort will focus on the transparency and traceability of data to verify that new data being collected or new analysis being performed under the QA program 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.

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Because the science and engineering planned for use at Yucca Mountain presents a number of design concepts that are not currently standard industry practices, there is a need to demonstrate, either through analysis, appropriate test programs, experience, or a combination thereof, the performance of the safety features that will be relied upon to meet the design objectives of 10 CFR Part 63. Requirements to perform testing is specified in 10CFR63.124(d)(2)(i) which states “*If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualification testing of a prototype unit under the most adverse design conditions.*” As necessary, and based on design considerations, design qualification testing inspections may be performed of experiments and tests being conducted to verify effective implementation of QA requirements for data collection and analysis in support of commitments and conclusions stated in the license application.

Additionally, the inspection team will review DOE’s oversight of contracted activities to verify effective quality controls are being applied to ongoing work. Inspections will include review of a suitable sample of documents related to additional site characterization activities to support construction activities to verify the effective implementation of the QA programs. Observations of these activities should determine whether QA program requirements are being adequately implemented as required by DOE and/or contractor procedures. Early involvement of NRC staff will facilitate and support prompt identification and resolution of issues.

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07.02 Engineering Design Activities. The objective of the engineering design inspections is to verify that the design process has been established and implemented for important to safety SSCs and important to waste isolation engineered barriers consistent with the requirements in 10 CFR Part 63, Subpart G and design commitments made in the license application. The inspections will verify that adequate measures have been taken to translate applicable regulatory requirements, and the design basis described in the license application, into specifications, drawings, procedures and instructions. Selected building and facility design documents may be reviewed in their early development stages to verify adequate implementation of the design process.

07.03 Vendor Activities. The NRC may begin vendor inspections when DOE begins procurement of long lead time components important to safety or important to waste isolation in order to verify implementation of the vendor's quality assurance program and observe development and testing activities. Vendors will be selected based on the significance to safety or waste isolation of the equipment or service provided, the importance of the equipment or service relative to assumptions and uncertainties used in making the risk significant determinations described in the NRC's Risk Insights Baseline Report, and the overall frequency and significance of problems previously identified with the vendor's materials, equipment or services, including problems identified by third-party auditing organizations. Inspection emphasis will be placed on manufacturing processes, particularly new or state-of-the-art processes, employed by vendors during the design, fabrication and testing of basic components. The inspections will verify that the vendor processes meet applicable industry codes, standards and regulatory requirements.

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In addition to verifying the implementation of the 10 CFR Part 63 Appendix G criteria, inspections will include a review, where applicable, of requirements related to commercial grade dedication programs implemented in compliance with Appendix G. Inspections will also include review of recent third-party audit reports, audits/surveillances conducted by DOE, condition reports and nonconformance reports associated with the facility that may be relevant to work performed to support the design basis described in the license application. The NRC may also observe audits and surveillances conducted by DOE of vendors and suppliers to verify effective implementation of the audit process to ensure that the requirements of 10CFR63.142(h) "Control of Purchased Material," are satisfied.

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07.04 Allegation Follow-up. Allegations received by the NRC, once the license application is received, will be processed in accordance with Management Directive 8.8 "Management of Allegations, Region IV Policy Guide (PG) - 0858 "Management of Allegations," and Inspection Procedure 4002 "Inspections to Review Allegations." Allegation follow-up may be combined with other inspection activities.

2300-08 ENFORCEMENT ACTIONS (OGC REVIEW NEEDED)

Possible enforcement actions associated with DOE's application are not anticipated in the pre-docketing application phase. However, the information submitted with the application will become subject to NRC regulations, including enforcement actions for employee protection (10 CFR 63.9 "Employee Protection"), willful wrongdoing (10 CFR 63.11 "Deliberate Misconduct"), or fraudulent information (10 CFR 63.10 "Completeness and Accuracy of Information") and DOE may be subject to enforcement actions, such as notices of violation. Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

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2300-09 REFERENCES

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

NUREG-1804, Yucca Mountain Review Plan, Rev. 2

[NRC Risk Insights Baseline Report \(ML040560162/ML040560302\), dated April 2004](#)

Management Directive 8.8 "Management of Allegations"

Region IV Policy Guide 0858 "Management of Allegations"

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NRC's Enforcement Policy

DOE Quality Assurance requirements Document (QARD)

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Attachments:

1. INSPECTION PROCEDURES

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ATTACHMENT 1

Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
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