
INSPECTION PROCEDURE 78010

10 CFR PART 21 PROGRAM

PROGRAM APPLICABILITY: 2300

78010-01 INSPECTION OBJECTIVE

To verify that the U.S. Department of Energy, as an applicant for, or holder of, a construction authorization or license to receive and possess source, special nuclear, or byproduct material under Title 10 of the Code of Federal Regulations (10 CFR) Part 63, "Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada," and suppliers of basic components for Part 63 facilities and activities (hereafter referred to collectively as "entity") have established a program and procedures to effectively implement 10 CFR Part 21, "Reporting of Defects and Noncompliance," requirements for reporting defects and failures to comply associated with substantial safety hazards (SSHs).

78010-02 INSPECTION REQUIREMENTS

02.01 Verify that the entity has implemented the requirements of 10 CFR 21.21(a) for evaluating deviations and failures to comply.

02.02 Verify that the entity has implemented the requirements of 10 CFR 21.21(b) for notifying purchasers or affected licensees of deviations and failures to comply.

02.03 Verify that the entity has implemented the requirements of 10 CFR 21.21(d) for notifying the U.S. Nuclear Regulatory Commission (NRC) of identified defects or failures to comply associated with SSHs.

02.04 Verify that the entity has implemented the requirements of 10 CFR 21.31 regarding specifying the applicability of Part 21 in procurement documents for basic components.

02.05 Verify that the entity has implemented the requirements of 10 CFR 21.51 regarding maintenance of records.

02.06 Verify that the entity has implemented the posting requirements of 10 CFR 21.6.

78010-03 INSPECTION GUIDANCE

03.01 Verify controls are in place for the evaluation of deviations and failures to comply

as required in 10 CFR 21.21(a) by performing the following:

- a. Verify that the entity has adopted procedures to evaluate deviations and failures to comply that provide for the following:
 1. Measures to evaluate a deviation or failure to comply as soon as practicable, and in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create an SSH if it were to remain uncorrected.
 2. If the evaluation cannot be completed within 60 days from discovery, measures to ensure that an interim report is submitted to the Commission within 60 days of discovery. The interim report should describe the deviation or failure to comply being evaluated and should state when the evaluation will be completed.
 3. A director or responsible officer is informed of a defect or failure to comply associated with an SSH as soon as practicable, and in all cases, within 5 working days after completion of the evaluation.
- b. Verify that the quality assurance processes to control nonconformances and corrective actions provide a direct connection to the Part 21 program and procedures.
- c. Select a sample of evaluated deviations that did not result in the identification of a defect or failure to comply and verify that:
 1. The item was identified for evaluation consistent with established procedures.
 2. The information and data used in the evaluation is clearly documented and complete.
 3. The finding of the evaluation that an SSH does not exist is a logical conclusion of the evaluation.

03.02 Verify that an entity supplying basic components has implemented the requirements of 10 CFR 21.21(b) for notifying purchasers or affected licensees of deviations and failures to comply if the entity determines it does not have the capability to perform the 10 CFR 21.21(a)(1) evaluation. Verify that measures are in place by performing the following:

- a. Verify the entity has established directions to inform all affected (or potentially affected) licensees or purchasers within 5 days.
- b. Select a sample of identified deviations and failures to comply for which the entity was not capable of performing a 10 CFR 21.21(a)(1) evaluation and verify that:

1. The item was identified for evaluation consistent with established procedures.
2. The entity identified and informed all affected (or potentially affected) purchasers or licensees within 5 days from the determination.

03.03 Verify that the entity has implemented the requirements of 10 CFR 21.21(d) for notifying NRC of identified defects or failures to comply associated with SSHs by performing the following:

- a. Verify that the entity's program and procedures provide that a director or responsible officer or designee will notify the Commission when he or she obtains information reasonably indicating a defect or failure to comply.
- b. Verify that the entity's program and procedures reflect the processes and time frames for reporting identified defects or failures to comply as follows:
 1. An initial notification is prepared and submitted by facsimile or by telephone to the Commission within 2 days of the receipt of information by the director or responsible officer of the identification of a defect or failure to comply.
 2. A written notification is prepared and submitted to the Commission within 30 days of the receipt of information by the director or responsible officer of the identification of a defect or failure to comply.
- c. Verify that the entity's program and procedures provide that the written notification of a defect or failure to comply includes the following information:
 1. Name and address of individual informing the Commission.
 2. Identification of basic component which contains the defect or fails to comply.
 3. Identification of the entity supplying the basic component.
 4. Nature of the defect or failure to comply and the SSH that could be or was created by the defect or failure to comply.
 5. The date on which the information of the defect or failure to comply was obtained.
 6. The number and location of all such basic components in use at the facilities subject to this regulation.
 7. The corrective action taken.

8. Name of individual responsible for the action.
 9. Length of time to complete the action.
- d. Select a sample of records in which the director or responsible officer notified the Commission of a defect or failure to comply and verify the timeliness and completeness of such notification consistent with the guidance in subsections 03.03(b) and 03.03(c), respectively, of this inspection procedure.

03.04 Verify the implementation of procurement document controls as required in 10 CFR 21.31 by selecting a sample of procurement documents for basic components and verifying that each procurement document specifies the applicability of Part 21.

03.05 Verify the implementation of records control as required in 10 CFR 21.51 by verifying that the entity has procedures and controls in place that provide for the following:

- a. Evaluations of all deviations and failures to comply are retained for a minimum of 5 years after the date of the evaluation.
- b. Entities supplying basic components retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification.
- c. Entities supplying basic components retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

03.06 Verify compliance with the posting requirements of 10 CFR 21.6 by selecting at least one posting location for inspection and verifying the following:

- a. The following information as required in 10 CFR 21.6(a) is posted in a conspicuous location where activities subject to Part 21 are conducted:
 1. Section 206 of the Energy Reorganization Act of 1974,
 2. The current version of Part 21, and
 3. The entity's procedures that implement the regulations in Part 21.
- b. If posting in accordance with 10 CFR 21.6(a) is not practicable, the following information as required in 10 CFR 21.6(b) is posted:
 1. Section 206 of the Energy Reorganization Act of 1974,
 2. A notice containing the following:
 - (a) A description of Part 21 and the procedures that implement the regulation,

- (b) The name of the individual to whom Part 21 reports may be made, and
- (c) The location where the Part 21 regulations and implementing procedures may be examined.

78010-04 RESOURCE ESTIMATE

Inspection resources necessary to complete this inspection procedure are estimated to be 40 hours of direct inspection effort.

78010-05 REFERENCES

U.S. Code of Federal Regulations. 10 CFR Part 21, "Reporting of Defects and Noncompliance."

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

END

Attachment 1 – Revision History for IP 78010

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	Initial issuance of IP 78010. Issued to support inspections described in IMC 2300, "Yucca Mountain Inspection Program: License Application Review Period." Researched commitments for 4 years and found none	N/A	N/A	ML082070293