

NRC INSPECTION MANUAL

CQV/EQV

INSPECTION PROCEDURE 36100

INSPECTION OF 10 CFR PART 21 AND 10 CFR 50.55(e) PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE

PROGRAM APPLICABILITY: 2501, 2502, 2504, 2507, 2508, 2700, and 2515 (Part 21 only)

36100-01 INSPECTION OBJECTIVE

To verify that applicants and holders of a certified design, an early site permit (ESP), applicants and holders of a combined license (COL), holders of construction permits and operating licenses under 10 CFR Part 50, and suppliers of basic components (hereafter referred to collectively as: "entity") have established a program and procedures to effectively implement 10 CFR Part 21 and 10 CFR 50.55(e) requirements for reporting defects and failures to comply associated with a substantial safety hazard (SSH).

36100-02 INSPECTION REQUIREMENTS

02.01 Verify that the entity has effectively implemented the requirements of 10 CFR 21.21(a)(1) and 10 CFR 50.55(e)(1) for evaluating deviations and failures to comply.

02.02 Verify that the entity has implemented the requirements of 10 CFR 21.21(d) and 10 CFR 50.55(e)(1) regarding directors or responsible officers notifying NRC or informing affected customers (when applicable) of identified defects or failures to comply associated with SSHs.

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

02.04 Verify that the entity has implemented the requirements of 10 CFR 21.51 and 10 CFR 50.55(e)(9) regarding maintenance of records.

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

36100-03 INSPECTION GUIDANCE

03.01 Verify the controls for the evaluation of deviations and failures to comply as required in 10 CFR 21.21(a) and 10 CFR 50.55(e)(1) by performing the following:

- a. Verify that the entity has adopted procedures to evaluate deviations and failures to comply. Procedures should describe the following:
 1. Measures for the analysis of a deviation or failure to comply.
 2. If the evaluation cannot be completed within 60 days from discovery, measures are in place to ensure that an interim report is prepared and submitted to the Commission within 60 days of discovery of the deviation or failure to comply. The interim report should describe the deviation or failure to comply being evaluated and should state when the evaluation will be completed.
 3. Measures to determine whether the evaluated deviation or failure to comply could create a SSH if it were to remain uncorrected.
- b. Verify that the QA processes to control nonconformance and corrective actions provide a direct connection to the Part 21 program and/or 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 a SSH does not exist is a logical conclusion of the evaluation.

NOTES: As stated in 10 CFR 50.55(e)(5), for construction permit holders, the evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under 10 CFR 50.55(e) and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

As stated in 10 CFR 21.3(c), for 10 CFR Part 50 licensees, the evaluation of potential defects and appropriate reporting of defects under § 50.72, § 50.73, or § 73.71 satisfies each person's evaluation, notification, and reporting obligation to report defects under 10 CFR Part 21 and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

03.02 Verify that the entity has implemented the requirements of 10 CFR 21.21 and 10 CFR 50.55(e) regarding directors or responsible officers notifying NRC of identified defects or failures to comply associated with SSHs by performing the following:

- a. Verify that the entity's program and/or procedures accurately reflect the time frames of 10 CFR 21.21(d) and 10 CFR 50.55(e)(6) for reporting identified defects or failures to comply that could create a SSH as follows:
 1. A director or responsible officer is informed, as soon as practicable, and in all cases, within 5 working days after completion of the evaluation.
 2. An initial notification is prepared and submitted via fax to the Commission within 2 days of notifying the director or responsible officer of the identification of a defect or failure to comply associated with a SSH. Verification that the facsimile has been received should be made by calling the NRC Operations Center.
 3. A written notification is prepared and submitted to the Commission within 30 days of notifying the director or responsible officer of the identification of a defect or failure to comply associated with a SSH. For holders of a construction permit under 10 CFR Part 50 or COL holders under 10 CFR Part 52, the written notification must include a copy to the appropriate Regional Administrator and a copy to the appropriate Resident Inspector. Confirm that the report has been received by the NRC Operations Center by checking the section "Reports Associated with Events," on the NRC website.

NOTE: For those Part 52 processes which do not authorize continuing activities required to be licensed under the Atomic Energy Act, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with SSHs may be delayed until the time that the Part 52 process is first referenced.

- b. Verify that the entity's procedures accurately provide for the information that shall be included in the written notification as required by 10 CFR Part 21.21(d)(4) and 10 CFR 50.55(e)(8).
 1. Name and address of entity informing the Commission.
 2. Identification of basic component that contains the defect or failure to comply.
 3. Identification of the firm 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.
 5. The date that 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 taken to complete the action.

NOTE: For holders of a construction permit under 10 CFR Part 50 or COL holders under 10 CFR Part 52, the written notification must clearly indicate that the written notification is being submitted under §50.55(e).

- c. Select, if available, 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 03.02(a) and 03.02(b), respectively.
- d. For holders of a construction permit under 10 CFR Part 50 or COL holders under 10 CFR Part 52, verify that the entity's procedures include the requirements of 10 CFR 50.55(e)(4) for the notification of any significant breakdown in any portion of the Appendix B to 10 CFR Part 50, quality assurance program that could have produced a defect in a basic component. Such breakdowns are reportable whether or not the breakdown actually resulted in a defect.
- e. For suppliers of basic components, verify that measures are in place to inform purchasers or affected licenses in accordance with 10 CFR 21.21(b). Specifically, verify that:
 1. The entity has established directions to inform all affected (or potentially affected) licensees or purchasers within 5 days of the determination that the entity does not have the capability to perform the 10 CFR 21.21(a)(1) evaluation.
 2. Select, if available, a sample of identified deviations for which the entity was not capable of performing a 10 CFR 21.21(a)(1) evaluation and verify that:
 - (a) The item was identified for evaluation consistent with established procedures.
 - (b) The entity identified and informed all affected (or potentially affected) purchasers or licensees within 5 days from the determination.

03.03 Verify the implementation of procurement document controls as required in 10 CFR 21.31 by performing the following:

- a. Select a sample of procurement documents for basic components and verify that each procurement document specifies the applicability of 10 CFR Part 21.

NOTE: There are no procurement document requirements for 10 CFR 50.55(e).

03.04 Verify the implementation of record controls as required in 10 CFR Part 21.51 and 10 CFR 50.55(e) by performing the following:

- a. Verify that the entity has procedures and/or controls that accurately reflect the time frames of 10 CFR Part 21.51 and 10 CFR 50.55(e)(9) for maintenance of records. Specifically, verify that:
 1. Evaluations of all deviations and failures to comply are retained for a minimum of five years after the date of the evaluation.
 2. Suppliers of basic components retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of notification.
 3. Suppliers of basic components retain a record of the purchasers of basic components for ten years after delivery of the basic component or service associated with a basic component.
 4. Holders of a construction permit under 10 CFR Part 50 or COL holders under 10 CFR Part 52 comply with item 1. above and also retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the basic component.

03.05 Verify posting requirements of 10 CFR 21.6 by performing the following:

- a. Select at least one posting location for inspection and verify the following.

NOTE: There are no posting requirements for 10 CFR 50.55(e).

1. Verify that posting is conspicuously located where activities subject to 10 CFR Part 21 are conducted and includes the following information as required in 10 CFR 21.6(a)(1):
 - (a) Section 206 of the Energy Reorganization Act of 1974,
 - (b) The current version of 10 CFR Part 21, and
 - (c) The entity's procedures that implement this regulation.
2. If the entity determined that posting in accordance with 10 CFR 21.6(a)(1) was not practicable, verify that the entity implemented the requirements of 10 CFR 21.6(b). This subsection requires posting of the following information in a conspicuous location where activities subject to Part 21 are conducted:
 - (a) Section 206 of the Energy Reorganization Act of 1974,
 - (b) A notice containing the following:

- A description of Part 21 and the procedures that implement the regulation,
- The name of the individual to whom 10 CFR Part 21 reports may be made, and
- The location where the 10 CFR Part 21 regulation and implementing procedures may be examined.

36100-04 RESOURCE ESTIMATE

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

36100-05 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 50.55, "Conditions of Construction Permits."

U.S. Code of Federal Regulations. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

NUREG-0302, Rev. 1 "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance." (ADAMS Accession No. ML062080399)

LIC-403, "Procedures for Handling Deficiency Reports (10 CFR Part 21, 10 CFR 50.55(e)), " Revision 1.

END

Revision History Sheet
IP 36100

| Commitment Tracking Number | Issue Date | Description of Change | Training Needed | Training Completion Date | Comment Resolution Ascension # |
|----------------------------|-----------------------|---|-----------------|--------------------------|--------------------------------|
| N/A | 10/03/07 CN 07-030 | <p>1. Initial issue to support inspections of operational programs described in IMC 2504, NON-ITAAC INSPECTIONS</p> <p>2. Incorporates SRP 17.5 guidance</p> <p>3. A review for incorporation of generic requirements has been conducted. None found.</p> | N/A | N/A | ML063030096 |