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## INSPECTION PROCEDURE 36100

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### INSPECTION OF 10 CFR PART 21 AND PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE

PROGRAM APPLICABILITY: IMCs 2501, 2502, 2507, 2508, 2515 C

#### 36100-01 INSPECTION OBJECTIVE

To verify that applicants and holders of a certified design, an early site permit (ESP), or applicants and holders of combined license (COL) under *Title 10 of the Code of Federal Regulations (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants,"* as well as licensees under 10 CFR Part 50, *"Domestic Licensing of Production and Utilization Facilities,"* and suppliers of basic components (hereafter referred to collectively as: "entities") have established a program to effectively implement the requirements of 10 CFR Part 21 *"Reporting of Defects and Noncompliance,"* 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) for evaluating deviations and failures to comply.
- 02.02 Verify that the entity has implemented the requirements of 10 CFR 21.21(d) regarding directors or responsible officers notifying NRC or informing affected customers (when applicable) of identified defects or failures to comply associated with a SSH.
- 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 regarding maintenance of records.
- 02.05 Verify that the entity has implemented the posting requirements of 10 CFR 21.6.

#### 36100-03 INSPECTION GUIDANCE

The applicable inspection manual chapter will be followed for additional guidance.

- 03.01 Verify the controls for the evaluation of deviations and failures to comply as required in 10 CFR 21.21(a) by performing the following:
  - a. The inspector should review the entity's Part 21 program and verify the applicable procedure(s) include the following:

1. Measures for the analysis of a deviation or failure to comply. **Counterfeit and fraudulent items are considered to be deviations. Counterfeit items are those that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so. Fraudulent items are those that are intentionally misrepresented with the intent to deceive.**
  2. Measures to ensure an interim report is prepared and submitted to the Commission within 60 days if the evaluation cannot be completed within 60 days from discovery. The interim report should include a description of 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.
  4. Measures to ensure the entity's director or responsible officer is informed within 5 working days after completion of the evaluation of the deviation or failure to comply.
- 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.

NOTE: As stated in 10 CFR 21.2(c), for 10 CFR Part 50 or 10 CFR Part 52 applicants, 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(d) regarding directors or responsible officers notifying NRC of identified defects or failures to comply associated with a SSH by performing the following:
- a. Verify that the entity's implementing procedures accurately reflect the time frames of 10 CFR 21.21(d) for reporting identified defects or failures to comply that could create a SSH including:
    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 NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 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 Document Control Desk, U.S. Nuclear Regulatory 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. The inspector should confirm that the report has been received by the NRC Operations Center by checking the section "Reports Associated with Events," on the NRC website.
- 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), as appropriate:
1. Name and address of individual or individuals informing the Commission.
  2. Identification of the facility, the activity, or the basic component supplied for such activity or such activity that contains a defect or fails to comply.
  3. Identification of the firm constructing the facility or supplying the basic component that contains a defect or fails to comply.
  4. Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.
  5. The date on which the information of such defect or failure to comply was obtained.
  6. In case of a basic component which contains defect or fails to comply, the number and location of all such basic components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to this regulation.
  7. The corrective action that has been taken or will be taken.
  8. Name of individual or organization responsible for the corrective action.
  9. The length of time that has been or will be taken to complete the action.
  10. Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.
  11. In the case of an ESP, the entities to whom an ESP was transferred.
- 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 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 that it does not have the capability to perform the evaluation to determine if a defect exists.
- 03.03 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 10 CFR Part 21.
- 03.04 Verify the implementation of record controls as required in 10 CFR Part 21.51 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 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. Applicants for standard design certifications under subpart B of 10 CFR Part 52 and others providing a design which is the subject of a design certification, retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of notification, and retain a record of the purchasers for fifteen years after delivery of design.
    5. Applicants for or holders of a standard design approval under subpart E of Part 52 and others providing a design which is subject of a design approval retain any notification sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for fifteen years after the delivery of the design that is subject to the design approval or service associated with the design.
- 03.05 Verify posting requirements of 10 CFR 21.6 by performing the following:
- a. Select a posting location for inspection and verify the following.
    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) by posting 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:
    - (1) A description of Part 21 and the procedures that implement the regulation,
    - (2) The name of the individual to whom 10 CFR Part 21 reports may be made, and
    - (3) 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

10 CFR Part 21, "Reporting of Defects and Noncompliance"

10 CFR Part 50.55, "Conditions of Construction Permits"

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" (ML062080399)

LIC-403, "Procedures for Handling Deficiency Reports (10 CFR Part 21, 10 CFR 50.55(e))," Revision 2

IMC 2501, "Construction Inspection Program: Early Site Permit (ESP)"

IMC 2502, "Construction Inspection Program: Pre-Combined License (Pre-COL) Phase"

IMC 2507, "Vendor Inspections"

IMC 2508, "Construction Inspection Program: Design Certification"

IMC 2515, "Light-Water Reactor Inspection Program--Operations Phase"

IMC 2515 Appendix C, "Special and Infrequently Performed Inspections"

END

Attachment 1: Revision History for IP 36100

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML072000053 10/03/07 CN 07-030	1. Initial issue to support inspections of operational programs described in IMC 2504, NON-ITAAC INSPECTIONS  2. Incorporates SRP 17.5 guidance  3. A review for incorporation of generic requirements has been conducted. None found.	N/A	ML063030096
N/A	ML110871845 04/25/11 CN 11-007	Revised Inspection Procedure to refer to the applicable Manual Chapter. Added the applicable Manual Chapters to the references. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)).	No	N/A
N/A	ML113190538 02/13/12 CN 12-002	Removed the requirements concerning 10 CFR 50.55(e) applicability. Revised to meet current 10 CFR Part 21 regulations	No	ML113190564
N/A	ML19087A149 05/16/19 CN 19-015	Periodic review of procedure. Minor grammatical edits. No substantive revision to this procedure was warranted at this time.	No	N/A
N/A	ML22340A480 02/10/23 CN 23-003	Revised inspection procedure to add clarification to the term "CFSI" to ensure consistency when addressing related NRC oversight activities.  Revised inspection procedure to make minor editorial corrections.	N/A	N/A