
INSPECTION PROCEDURE 36100

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

PROGRAM APPLICABILITY: 2502, 2515

36100-01 INSPECTION OBJECTIVE

To provide assurance that applicants for a combined license (COL) and holders of operating licenses for nuclear power reactors have established procedures and program activities to effectively implement 10 CFR Parts 21 and 50.55(e) requirements for reporting defects and noncompliance.

36100-02 INSPECTION REQUIREMENTS

Procedure Review and Program Assessment. Determine whether licensees' procedures and program activities effectively implement the requirements of 10 CFR Parts 21 and 50.55(e).

02.01 Verify that the licensee has implemented the posting requirements of 10 CFR 21.6.

02.02 Verify that the licensee has implemented the requirements of 10 CFR 21.31 regarding specifying in appropriate procurement documents the applicability of 10 CFR Part 21.

02.03 Verify that the licensee has effectively implemented the requirements of 10 CFR 21.21(a) and 10 CFR 50.55(e) regarding evaluating identified deviations.

02.04 Verify that the licensee 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 related to significant safety hazards.

02.05 Verify that the licensee has implemented the requirements of 10 CFR 21.51 and 10 CFR 50.55(e) regarding maintenance of records by determining that the licensee has appropriate controls and/or procedures to ensure proper maintenance of records.

36100-03 INSPECTION GUIDANCE

General Guidance.

Revisions to 10 CFR Part 21 and 10 CFR 50.55(e) published in the Federal Register (56FR 36081) on July 31, 1991, and effective October 29, 1991, eliminated unnecessary

duplication of reporting by holders of construction permits for nuclear power reactors by shifting the focus for reporting identified defects or failures to comply to 10 CFR 50.55(e). Upon receipt of an operating license, the licensee's 10 CFR Part 21 program would be subject to the inspection guidance contained in this inspection procedure.

Inspection activities to ensure that vendors' 10 CFR Part 21 programs are in conformance with 10 CFR Part 21 are performed by personnel of the Plant Support Branch (IPSB) of NRR. Accordingly, this inspection procedure is not intended to be applied to vendors.

Inspection activities to ensure that applicants for a combined license (COL) and holders of operating licenses for nuclear power reactors have established procedures and programs that effectively implement 10 CFR Parts 21 and 50.55(e) requirements are performed by regional personnel in accordance with this procedure.

10 CFR Part 21 and 10 CFR Part 50.55(e) reports/notifications are screened and reviewed by NRR in accordance with LIC-403, "Procedures for Handling 10 CFR Part 21 and 10 CFR Part 50.55(e) Notifications of Deviations, Defects, and Failure to Comply Associated with Substantial Safety Hazards at Nuclear Power Reactors and Their Vendors."

Specific Guidance

03.01 Select at least one posting location for inspection.

03.02 Select at least five procurement documents for examination.

03.03 Review licensee evaluation of deviations.

- a. Determine if the licensee has established procedures and/or controls to evaluate identified deviations.
- b. Determine the effectiveness of the licensee's established procedures and/or controls to evaluate identified deviations by selecting at least three records of an evaluated deviation that did not result in the identification of a defect or failure to comply and verifying that:
 - (1) The item was identified for evaluation consistent with established procedures or by other means.
 - (2) The information and data used in the evaluation appear to be factual and complete.
 - (3) The finding of the evaluation that a substantial safety hazard or failure to comply does not exist is a logical conclusion of the evaluation.
 - (4) Determining that the licensee's controls and/or procedures identify a specific director or responsible officer to notify of identified defects or failures to comply.

03.04 Review the licensee's notification implementation

- a. Determine if the licensee's controls or procedures accurately reflect the provisions of 10 CFR 21.21 and 10 CFR 50.55(e) regarding time frames for reporting identified defects or failures to comply.
- b. Select (if available) at least two records of instances in which the identified director or responsible officer notified the Commission of a defect or failure to comply and determining that the notification complies with the provisions of 10 CFR 21.21 and

10 CFR 50.55(e) regarding time frames for reporting identified defects or failures to comply.

- c. Select (if available) at least two records of instances in which the identified director or responsible officer was notified of a defect or failure to comply but chose not to notify the Commission and verifying that this was an acceptable action.

36100-04 RESOURCE ESTIMATE

Inspection resources necessary to complete this inspection procedure are estimated to be 40 hours of inspection per reactor facility.

36100-05 REFERENCES

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." (Accession #8307120714)

LIC-403, "Procedures for Handling 10 CFR Part 21 and 10 CFR Part 50.55(e) Notifications of Deviations, Defects, and Failure to Comply Associated with Substantial Safety Hazards at Nuclear Power Reactors and Their Vendors"

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