

NRC INSPECTION MANUAL

IQVB

INSPECTION PROCEDURE 36100 ATTACHMENT 01

INSPECTION OF 10 CFR 50.55(e) PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE DURING CONSTRUCTION

PROGRAM APPLICABILITY: IMC 2504 A

36100.1-01 INSPECTION OBJECTIVE

To verify that holders of a construction permit (CP) or holders of a combined license (COL) under **Title 10 of the Code of Federal Regulations (10 CFR) Part 52 “Licenses, Certifications, and Approvals for Nuclear Power Plants,”** (hereafter referred to collectively as “entities”) have established a program to effectively implement the requirements of 10 CFR 50.55(e) for reporting defects and failures to comply associated with a substantial safety hazard (SSH) during the construction phase.

36100.1-02 BACKGROUND

Section 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses,” of 10 CFR, imposes conditions on entities that hold a CP, or a COL (until a § 52.103(g) finding is made by the Commission), related to certain notifications that must be made to the U.S. Nuclear Regulatory Commission. Subpart 50.55(e) imposes a requirement on such entities to report to the Commission, through a director or responsible officer or designated person, whenever information is obtained reasonably indicating: (1) any failure to comply with the Atomic Energy Act (AEA), as amended, or any applicable regulation, order, or license of the Commission, relating to an SSH; (2) the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture (including on basic components supplied for such facility of activity), or (3) that the quality assurance (QA) program (or any portions thereof) conducted under the requirements of Appendix B to 10 CFR Part 50 has undergone any significant breakdown which could have produced a defect in a basic component.

An entity must establish and implement a program that assures all reportable defects, and failures to comply are identified and reported. In addition, an entity must impose through its procurement documents the applicable reporting requirements on its contractors, and subcontractors.

36100.1-03 INSPECTION REQUIREMENTS

03.01 Verify that the entity has effectively implemented the requirements of § 50.55(e)(2) for posting.

03.02 Verify that the entity has effectively implemented the requirements of § 50.55(e)(3) to adopt appropriate procedures for evaluating deviations and failures 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.

- 03.03 Verify that the entity has effectively implemented the requirements of § 50.55(e)(4) regarding the responsibility of directors or responsible officers or designated persons for notifying the Commission of identified defects or failures to comply associated with an SSH or any significant breakdown in any portion of the QA program that could have produced a defect in a basic component.
- 03.04 Verify that the entity has effectively implemented the requirements of § 50.55(e)(5) regarding the timeframe and methods for submitting a notification to the NRC.
- 03.05 Verify that the entity has effectively implemented the requirements of § 50.55(e)(6) with respect to the content of the written notification to be submitted to the NRC.
- 03.06 Verify that the entity has effectively implemented the requirements of § 50.55(e)(7) with respect to specifying the applicability of § 50.55(e) or 10 CFR Part 21 “Reporting of Defects and Noncompliance,” in procurement documents for basic components.
- 03.07 Verify that the entity has effectively implemented the requirements of § 50.55(e)(9) regarding retention of records.

36100.1-04 INSPECTION GUIDANCE

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

- 04.01 Verify that the entity has effectively implemented the requirements of §50.55(e)(2) for posting by performing the following:
 - a. Select a location for inspection and verify that the following information is posted in a conspicuous location where activities subject to § 50.55(e) are conducted:
 - 1. Section 206 of the Energy Reorganization Act of 1974;
 - 2. the current version of § 50.55(e); and
 - 3. the entity’s procedure(s) that implement § 50.55(e) requirements.
 - b. If the entity determined that posting of § 50.55(e) requirements or the procedure(s) adopted under § 50.55(e) was not practicable, verify that the entity has implemented the requirements of § 50.55(e)(2)(ii) by posting the following information in a conspicuous location where activities subject to § 50.55(e) are conducted:
 - (a) Section 206 of the Energy Reorganization Act of 1974; and
 - (b) a notice containing the following:
 - (1) a description of § 50.55(e) and the procedure(s) that implement the regulation,
 - (2) the name of the individual to whom § 50.55(e) reports may be made, and

(3) the location where the § 50.55(e) regulation, and implementing procedure(s), and reports may be examined.

04.02 Verify that the entity has effectively implemented the requirements of § 50.55(e)(3) to adopt appropriate procedures for evaluating deviations and failures to comply associated with an SSH by performing the following:

- a. Review the entity's § 50.55(e) procedure(s) to confirm the following information is included:
 1. Measures for the evaluation of a deviation or failure to comply within 60 days of discovery.
 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 establish a deadline for when the evaluation will be completed.
 3. Measures to determine whether the evaluated deviation or failure to comply could create an SSH should it remain uncorrected.
 4. Measures to ensure that the entity's director or responsible officer is informed within 5 working days after completion of the evaluation of a deviation or failure to comply, if the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity:
 - (a) fails to comply with the Atomic Energy Act, as amended, or any applicable regulation, order, or license of the Commission relating to an SSH;
 - (b) contains a defect; or
 - (c) undergoes any significant breakdown in any portion of the QA program conducted under the requirements of Appendix B to 10 CFR part 50 which could have produced a defect in a basic component.
- b. 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/review consistent with established procedure(s).
 2. The information and data used in the evaluation/review was documented and complete.
 3. The finding of the evaluation/review that an SSH or a defect did not exist is a logical conclusion of the evaluation.
 4. The finding of the evaluation that a significant breakdown in any portion of the QA program did not occur is a logical conclusion of the evaluation.

04.03 Verify that the entity has effectively implemented the notification requirements of § 50.55(e)(4) by performing the following:

Review the entity's § 50.55(e) procedure(s) and determine their adequacy by verifying that adequate provisions are included for assignment of responsibilities to directors or responsible officers or designated persons for notifying the Commission when information is obtained indicating:

- (a) the existence of any failure to comply with the Atomic Energy Act, as amended, or any applicable regulation, order, or license of the Commission relating to an SSH;
- (b) the existence of any defect in the construction, or manufacture, or in the final design of a facility as approved and released for construction or manufacture (including on basic components supplied for such facility of activity); or
- (c) a significant breakdown in any portion of the Appendix B, QA program that could have produced a defect in a basic component.

NOTE: As stated in § 50.55(e)(4), the entity's obligation to meet the requirements of 10 CFR Part 21 is satisfied when defects or failures to comply associated with an SSH are evaluated and reported under § 50.55(e)(4). Additionally, the requirements of § 50.55(e)(4) satisfy the responsibility of an entity's individual directors and responsible officers to report defects and failures to comply that are associated with an SSH under section 206 of the Energy Reorganization Act of 1974.

04.04 Verify that the entity has effectively implemented the requirements of § 50.55(e)(5) with respect to the timeframe and methods for submitting a notification to the NRC by performing the following:

- a. Review the entity's implementing procedure(s) to confirm that the following timeframe and methods for submitting a notification to the NRC have been established:
 - 1. 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 the director or responsible officer being notified that a defect or failure to comply associated with an SSH or a significant breakdown in any portion of the Appendix B, QA program that could have produced a defect in a basic component has been identified. The NRC Operations Center is called to verify the facsimile was received; and
 - 2. A written notification is prepared and submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, within 30 days following receipt of information by the director or responsible officer on the identification of a defect or failure to comply associated with an SSH or of a significant breakdown in any portion of the Appendix B, QA program that could have produced a defect in a basic component. A copy of this written notification must be forwarded to the appropriate Regional Administrator and to the appropriate NRC resident inspector. The inspector should confirm that the report was received by the NRC Operations Center by checking reports associated with events on the NRC website.
- b. Select, if available, a sample of § 50.55(e) records in which the director or responsible officer notified the Commission of a defect or failure to comply associated with an SSH

or of a significant breakdown in any portion of the Appendix B, QA program that could have produced a defect in a basic component and verify the timeliness of such notification is consistent with the guidance in section 04.04.a of this procedure.

NOTE: As stated in § 50.55(e)(8), the requirements of § 50.55(e) are satisfied when a defect or failure to comply associated with an SSH has been previously reported under 10 CFR Part 21, § 50.55(e), § 50.73, or § 73.71.

04.05 Verify that the entity has effectively implemented the requirements of § 50.55(e)(6) with respect to the contents of the written notification to be submitted to the NRC.

- a. Review the entity's § 50.55(e) implementing procedure(s) to confirm that the following elements of the written notification have been addressed:
 1. Name and address of the individual or individuals informing the Commission.
 2. Identification of the facility, the activity, or the basic component supplied for the facility or the activity that contains the defect or failure to comply.
 3. Identification of the firm constructing or manufacturing the facility or supplying the basic component, which fails to comply or contains a defect.
 4. The nature of the defect or failure to comply and the safety hazard, which is created or could be 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. In the case of a basic component which contains a defect or fails to comply, the number and location of all related basic components in use at facility subject to this regulation.
 7. In the case of a completed reactor manufactured under part 52 of this chapter, the entities to which the reactor was supplied.
 8. The corrective action, which has been taken, is being or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete this action.
 9. 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 other entities.
 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 other entities.
- b. Select a sample (if available) of § 50.55(e) records in which the director or responsible officer notified the Commission of a defect or failure to comply associated with an SSH or of a significant breakdown in any portion of the Appendix B, QA program that could have produced a defect in a basic component and verify the completeness of such notification(s) is consistent with the guidance in section 04.05.a of this procedure.

NOTE: The written notification must clearly indicate that it is being submitted under § 50.55(e) requirements.

- 04.06 Verify that the entity has effectively implemented the requirements of § 50.55(e)(7) regarding specifying the applicability of § 50.55(e) in procurement documents by selecting a sample of procurement documents for a facility, activity or a basic component and confirm the procurement documents specify the applicability of § 50.55(e).
- 04.07 Verify that the entity has effectively implemented the requirements of § 50.55(e)(9) regarding maintenance of records by performing the following:
- a. Review the entity's implementing § 50.55(e) procedure(s) and/or controls to ensure that time frames for record retention accurately reflect the regulations. Specifically, verify that:
 1. Procurement specifications of a facility or a basic component are retained for the lifetime of the facility or basic component.
 2. Records of evaluations of all deviations and failures to comply are retained for the longest of:
 - (a) 10 years from the date of the evaluation;
 - (b) 5 years from the date that an early site permit is referenced in an application for a combined license; or;
 - (c) 5 years from the date of delivery of a manufactured reactor.
 3. Records of all interim reports or notifications sent to the Commission are retained for the minimum time frames specified in the sections 04.07.a.1 and 04.07.a.2 of this procedure.
 4. Suppliers of basic components must retain records of:
 - (a) All notifications sent to affected entities or purchasers for a minimum of 10 years after the date of notification; and
 - (b) The facilities or other purchasers to whom basic components or associated services were supplied for a minimum of 15 years from the delivery of the basic component or associated service.

NOTE: As stated in § 50.55(e)(9), maintaining records in accordance with § 50.55(e) satisfies the entity's recordkeeping obligations under 10 CFR Part 21, including directors or responsible officers subject to this section.

36100.1-05 RESOURCE ESTIMATE

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

36100.1-06 REFERENCES

10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"

10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"

10 CFR Part 21, "Reporting of Defects and Non-Compliance"

NUREG 1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants"

IMC 2504, "Construction Inspection Program: Inspection of Construction and Operational Programs"

END

Attachment 1: Revision History IP 36100.01

Attachment 1: Revision History IP 36100.01

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	02/13/12 CN 12-002 ML113191307	Initial issuance to support inspections of construction programs described in IMC 2504	N/A	ML113191314
	ML19280A796 11/13/19 CN 19-035	Periodic review of procedure. Revision to support merger with NRR and minor grammatical and wording corrections to be consistent with the CFR. No substantive revision to this procedure was warranted at this time.	N/A	N/A
N/A	ML23025A396 03/08/23 CN 23-007	Revised the inspection procedure to identify counterfeit and fraudulent items as deviations, consistent with NRC approved guidance. Revised inspection procedure to make minor editorial corrections.	N/A	N/A