
INSPECTION PROCEDURE 43005

NRC OVERSIGHT OF THIRD-PARTY ORGANIZATIONS IMPLEMENTING QUALITY ASSURANCE REQUIREMENTS

PROGRAM APPLICABILITY: IMC 2507

43005-01 INSPECTION OBJECTIVES

01.01 To verify, by direct observation, the effectiveness of the independent oversight activities performed by third-party organizations to qualify vendors in accordance with the requirements of Appendix B to 10 CFR Part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants” and 10 CFR Part 21, “Reporting of Defects and Noncompliance.”

43005-02 INSPECTION REQUIREMENTS

02.01 Observe third-party organization's implementation of oversight activities (i.e., safety-related audits, commercial grade surveys, and vendor certifications) used to qualify vendors who supply safety-related components or services to the nuclear industry.

43005-03 INSPECTION GUIDANCE

The applicable Inspection Manual Chapter (IMC) will be followed for additional guidance.

03.01 Observation of Oversight Activities

- a. Preparation activities. Notify appropriate contact person of the organization (e.g., Nuclear Utility Procurement Issues Committee Chairman) of intent to observe activities within a reasonable time frame, between 30 to 90 days, prior to the scheduled start date.

It is expected that the organization:

1. Communicate the NRC's interest to participate as an observer to the appropriate team leader.
 2. Include the NRC inspector(s) on distribution of all correspondence, including notification letter, activity plan, schedule and logistics, audit report and follow-up correspondence, including significant notifications issued to other members of the organization as a result of the activities performed.
- b. Observation activities. Observe the third-party organization's implementation of activities, including daily meetings. The NRC inspectors shall also independently assess the vendor's implementation of the quality assurance program, in order to evaluate whether the third-party auditor is effectively identifying and responding to any issues or

weaknesses. The NRC inspectors should ensure the third-party organization is appropriately focusing their audit effort on those Appendix B criteria most relevant to the activities that the vendor performs. The NRC inspector should also verify that the third-party organization is adequately considering the scope of supply for which the vendor is qualified.

This observation should normally include an independent review of the documents reviewed by the auditing organization. The NRC inspectors should also accompany the third-party auditors while they perform walkthroughs, observations of production, testing, or inspection activities, or interviews with vendor personnel.

If the third-party audit includes a focused review in a technical area by a technical specialist, the NRC inspectors should evaluate whether or not the technical specialist's review is focused on the proper areas and whether or not the technical specialist's conclusions are reflective of the vendor's performance in the area being reviewed. If the NRC inspector(s) need to review additional documents in order to draw their own conclusion, they may request them from the audited vendor. The NRC inspectors should do this independently and should not allow their activities to interfere with the conduct of the third-party organization's audit. The NRC inspectors should in no way attempt to direct or lead the third-party organization's audit. If the third-party audit appears to be inadequate or ineffective, this will be documented in the trip report.

In the event of a situation in which the organization's team is not recognizing a compliance issue, **allow enough time for the organization's team to recognize the issue before communicating it to the team leader. As a minimum, the inspectors should wait until the audit team conducts their daily debrief before concluding that the audit team has not recognized an issue.** Communicate the issue to the organization's team leader and, as appropriate, document the issue in the trip report, including any actions taken by the appropriate organization's team leader.

If the inspectors disagree with the team leader's actions to address the issue, the inspectors should discuss the disagreements with the IQVB branch chief. The inspectors should then have a meeting with the team leader after the audit exit meeting with the vendor. During the meeting, the inspectors should communicate their disagreement along with an explanation for the disagreement and inform the organization's team leader that it will be documented in the trip report.

- c. **Documentation.** Prepare a trip report documenting the effectiveness of the independent oversight activities performed by third-party organizations, including any issue discussed during the observation with the organization's team leader. **If the inspector disagrees or believes the issues identified by the third-party organization should be dispositioned differently, the inspector should document this in the trip report. The inspector should include the inspection area affected, provide a brief description of the issue, and the basis for the disagreement. The inspectors should only document what was observed during the audit week and any disagreements presented to the organization's team leader and should refrain from referencing the organization's report because they are not made publicly available.** The trip report is addressed to the Director of the Division of Reactor Oversight in the Office of Nuclear Reactor Regulation. **The trip report should be issued within 30 days after the inspectors have reviewed the third-party organization's final report.**

- d. Follow-up. As needed, send a letter to the organization to address any issue documented in the trip report. When possible, the NRC will discuss the trip report at the next scheduled periodic meeting with the organization.

43005-04 RESOURCE ESTIMATE

The resource estimate for this inspection procedure is approximately 80 hours of direct observation per audit observed.

43005-05 REFERENCES

IMC 2507, "Vendor Inspections"

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

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

END

Attachment

Attachment 1: Revision History for IP 43005

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Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
N/A	10/03/07 CN 07-030	Initial issue to support inspections of vendor programs described in IMC 2507 and 2700. Researched commitments for 4 years and found none.	N/A	N/A
N/A	ML110871959 04/25/11 CN 11-007	Revised Inspection Procedure (IP) to refer to the applicable IMC. Added the reference section, including the applicable IMCs. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)).	N/A	N/A
N/A	ML15198A460 10/08/15 CN 15-019	Revised IP to delete the requirement to inspect the vendor's 10 CFR Part 21 program, and applicable references. Removed reference to IMC 2700, which has been superseded by IMC 2507. Deleted requirement to address trip report to Director, Division of Engineering in NRR. Added guidance for observing without interfering with the third-party audit.	N/A	ML15198A462
N/A	ML22077A380 06/01/22 CN 22-011	Updated requirement to address trip report to Director of Reactor Oversight in the Office of Nuclear Reactor Regulation. Updated lead organization to IQVB.	N/A	N/A
N/A	ML24123A152 10/07/24 CN 24-026	Revised IP to provide guidance for communicating disagreements with third-party organization's assessments of vendor quality to the auditing team lead and documenting them in the trip report.	N/A	ML24176A157