
MANUAL CHAPTER 2507

CONSTRUCTION INSPECTION PROGRAM: VENDOR INSPECTIONS

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2507-01 PURPOSE

01.01 To establish the inspection program for vendors providing safety-related materials, equipment, and services in support of new reactor construction.

01.02 To provide requirements and guidance to NRC inspectors for conducting inspections at vendor facilities.

2507-02 OBJECTIVES

02.01 To verify effective implementation of vendor quality assurance programs as a means of assuring the quality of materials, equipment, and services supplied to the commercial nuclear industry.

02.02 To verify effective implementation of commercial-grade dedication programs for safety-related materials, equipment, and services.

02.03 To assure that vendors have an effective system for reporting defects under 10 CFR Part 21.

02.04 To conduct inspections at vendor facilities to help support the Commission determination that the acceptance criteria in a combined license **are** met in accordance with 10 CFR 52.99 and 10 CFR 52.103(g).

02.05 To obtain sufficient information through inspection activities at vendor facilities to assure that root causes of reported vendor related problems are being identified and suitable corrective actions are developed and implemented.

02.06 To assure that follow-up and resolution of allegations, 10 CFR Part 21 or 10 CFR Part 50.55(e) reports, and licensee event reports (LERs) assigned to the Quality and Vendor Branch (CQV) are accomplished in a timely manner.

02.07 To assure that fraudulently marketed products are traced to their source and that licensees are informed so that the fraudulent products can be removed from use or possible use.

02.08 To provide input to the NRC operating experience program of instances involving substandard, suspected counterfeit, or fraudulently marketed vendor products and to gather information in order to provide timely information to licensees and other users.

2507-03 DEFINITIONS

03.01 Announced Inspection. The licensee/vendor or any member of the licensee/vendor organization is notified by the lead inspector or any member of the NRC staff that an inspection is to be conducted. The announcement may be made by a written communication, telephone call, or other communication informing any member of the

licensee/vendor organization that an inspection may or will take place at a specific time or date.

03.02 Basic Component. A structure, system, component, or part thereof that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary;
- The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2), or 10 CFR 100.11, as applicable.

Basic components are items designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50, or commercial-grade items which have successfully completed the dedication process.

In all cases, a basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

03.03 Counterfeit or Fraudulently Marketed Items. Items that are deliberately manufactured or altered in such a way as to misrepresent the actual quality of the item with intent to defraud or deceive the purchaser.

03.04 Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). Those inspections, tests, analyses, and acceptance criteria identified in the combined license that if met are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the Commission rules and regulations.

03.05 ITAAC Family. A grouping of ITAAC that are related through similar construction processes, resulting products, and general inspection attributes.

03.06 Nonconformance. A vendor's or certificate holder's failure to meet contract requirements related to NRC-regulated activities (e.g., Appendix B to 10 CFR Part 50), where the NRC has not placed requirements directly on the vendor or certificate holder.

03.07 Quality Assurance Manual. A compilation of quality assurance documents that define the quality assurance policy and program, describe the method(s) by which the policy will be implemented through procedures and instructions, and identifies the parties responsible for implementation.

03.08 Reactive Vendor Inspection. Inspections performed for the purpose of obtaining additional information and/or verifying adequate corrective actions on reported problems or deficiencies involving vendor supplied products or services. Reactive inspections are

typically performed in response to a specific problem identified by any group within the NRC (e.g., including headquarters, the regional offices), or in response to allegations or other identified problems (e.g., 10 CFR Part 21 or 10 CFR 50.55(e) reports) from outside sources.

03.09 Routine Vendor Inspection. Inspections performed to verify effective implementation of a facility's QA program used to furnish basic components to the nuclear industry.

03.10 Supplier. For the purposes of this manual chapter, any organization that supplies basic components to a vendor, applicant, or holder of a 10 CFR Part 52 license.

03.11 Unannounced Inspection. The vendor or any member of the vendor organization is not notified by the inspector or any member of the NRC staff until the inspector arrives at the vendor's facility or at the site where the inspection is to be conducted.

03.12 Unresolved Item. Any inspection finding that requires more information in order to determine that it is an acceptable item or whether a violation or nonconformance may exist.

03.13 Vendor. For the purposes of this manual chapter, any company or organization that provides products such as material, equipment, components, or services to be used in an NRC-licensed facility or activity. In certain cases the vendor may be an NRC licensee (e.g., a nuclear fuel fabricator) or the product may have NRC certificates (e.g., a transportation cask).

03.14 Violation. For the purposes of this manual chapter, the failure to comply with any portion of a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

2507-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of New Reactors (NRO). Provides overall direction for the NRC vendor inspection program.

04.02 Director, Division of Construction, Inspection, and Operational Programs (DCIP).

- a. Directs the implementation of policies, programs, and procedures for inspecting vendors, applicants, licensees, and other entities.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the vendor inspection program.
- c. Approves changes to the vendor inspection program.

2507-05 DISCUSSION

The NRO Quality and Vendor branches (CQV) are responsible for implementing the construction vendor inspection program at facilities where basic components are designed, manufactured, or stored. Routine and reactive inspections are conducted to verify that the vendor QA programs are implemented and comply with the applicable regulatory requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

This manual chapter provides NRC guidance for inspection and assessment of vendor QA programs in support of new reactor licensing and construction activities. Specifically, this chapter defines the vendor inspection program for the following activities:

- Inspections of vendor QA program implementation during design and procurement activities in support of an application for a combined license (COL). This encompasses ITAAC-related activities associated with vendors, such as inspection of offsite fabrication, modular construction techniques, and fabrication of long-lead components.
- Inspections to assess whether the vendor QA programs address specific processes such as commercial-grade dedication practices, vendor/licensee and vendor/applicant oversight, and reporting of defects and noncompliance associated with safety-related components or services utilized in a nuclear power plant in accordance with 10 CFR Part 21.
- Inspections to verify that root cause analyses of reported defects and failures to comply are being identified and that suitable corrective actions are developed and implemented.
- Provide input to the NRC operating experience program in order to provide timely information to the nuclear industry of potential issues that are safety significant and with generic implications. These issues could include substandard, suspected counterfeit or fraudulently marketed vendor products.

2507-06 INSPECTION POLICIES AND GUIDANCE

06.01 Vendor Selection. The selection of vendors for inspection is based on several factors, that include:

- The significance to safety of the equipment or service provided,
- Verification of inspections, tests, analyses, and acceptance criteria (ITAAC) in support of onsite construction activities,
- Input from the technical staff necessary to support completion of design certification (DC) and combined license (COL) reviews,
- The frequency and significance to safety of problems identified with vendor-supplied materials, equipment, or services, including third-party auditing organizations,

- The number of licensees affected by the problem identified, the performance history of a vendor, and
- Other information received by CQV from allegations, Part 21 reports, 50.55(e) reports, Licensee Event Reports (LERs), and other NRC organizations.

The results of past inspections, event evaluations, and inspector and management reviews should be used to schedule and determine the focus of planned inspections at each vendor facility.

06.02 Inspection Emphasis. Inspection emphasis is placed on manufacturing processes employed by vendors during the design, fabrication, and testing of basic components. The inspectors will ensure that the vendor's quality processes meet applicable industry codes, standards, and regulatory requirements.

In addition to verifying the implementation of the Appendix B criteria described above, vendor inspections will include the review of the vendor's 10 CFR Part 21 or Part 50.55(e) procedures and, when applicable, activities performed as part of commercial-grade dedication.

For ITAAC-related activities, the inspectors may verify by visual observations, physical examinations, or review of records that the relevant analyses or special processes and testing activities are consistent with the applicable design description commitments in the certified design.

06.03 Inspection Plans. Inspection plans are required for all inspections. The lead inspector is responsible for preparation of the inspection plan. Inspection plans will follow the guidance contained in Section 06.07 of this manual chapter.

06.04 Development of Generic Communications. The CQV will prepare input to the NRO branch responsible for generic communications (bulletins, information notices, generic letters, or regulatory information summaries) for the development of generic communications to alert the nuclear industry and others of vendor-related product/service deficiencies.

06.05 Inspection Contractor Support. In the past, vendor inspections have used contractor support as one method for increasing the technical expert resources available to the NRC for carrying out its inspection responsibilities. Such contractor augmentations have proven to be extremely helpful for these headquarters-based inspection efforts. Like all NRC team inspections, contractor-supported team inspections are led by an NRC team leader having inspection authority and responsibility. There is no delegation of NRC inspection authority or responsibilities to a contractor.

06.06 Inspection Language Services. Translators and/or interpreters will be used as necessary to ensure that the utilization of foreign language documents or communication with foreign language speakers does not degrade the quality of the inspection. Considerations include host country language, language proficiency of the NRC inspection team, and participation of the regulatory authority of the host country. These services

should be arranged through the Office of International Programs as early as practicable in the planning of the inspection. Interpreter services to support the inspection team will be provided by the local US Embassy or the Interpreting Division of Language Services of the US State Department. All document translations will be done in accordance with Management Directive 3.12, "Handling and Disposition of Foreign Documents and Translations."

06.07 General Inspection Process. For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. The inspection procedures listed in Enclosure 1 provide more specific guidance for onsite inspection activities.

- a. Pre-inspection activities. To facilitate management of inspection resource allocations and tracking of inspection activities, the lead inspector should develop facility-specific inspection plans consistent with the guidance described below.

The responsible team leader will develop an inspection plan. The inspection plan will identify the vendor facility, describe the scope and major areas of emphasis that will be reviewed, evaluated, or assessed. In addition, the inspection plan should identify the inspection type, team members, and the inspection schedule. This plan is to be reviewed and approved by the responsible Branch chief. For inspections involving allegations, inspection plans shall be controlled at all times by the inspection team.

Inspections will be typically announced 30 calendar days in advance. The lead inspector will contact the vendor representative (preferably the QA Manager), announce the upcoming inspection, and discuss the inspection schedule. It may be appropriate to inform the vendor as to the purpose, estimated duration, and the number of NRC inspectors expected to take part in the inspection. The specific areas to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection. For inspections involving allegations, the lead inspector shall not disclose that the inspection is in response to an allegation.

The inspectors should review the vendor's recent inspection and enforcement history (if available), any outstanding open items, third-party audit report if available, and any events (e.g., §50.72 reports, Part 21 notifications) reported by the vendor.

- b. Onsite inspection activities. Entrance and exit meetings with vendor personnel should be scheduled in advance to minimize the impact on other vendor activities. The lead inspector should hold an entrance meeting with the senior vendor representative (preferably the facility's QA Manager) who has responsibility for the areas to be inspected. At the entrance meeting, the lead inspector should discuss the inspection scope with vendor management and other administrative matters, such as the observation of facility operations, interviews with staff, and/or document reviews. Whenever possible, the lead inspector should schedule a daily status meeting with vendor management to discuss the inspection progress and issues identified.

An exit meeting should be conducted with vendor management at the conclusion of the inspection. The results of the inspection, including preliminary findings, should be presented emphasizing their impact on safety. The lead inspector should emphasize that preliminary findings are always subject to management review before they are documented in an inspection report. Prior to the exit, the lead inspector should determine whether his/her supervisor should be briefed on the preliminary inspection findings.

In accordance with Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings," NRC vendor inspections are closed to the public. All representatives of outside organizations (e.g., purchasers, NRC applicants and licensees, or sub-contractors not directly involved with the inspection) are not permitted to present during the conduct of the inspection.

- c. Post-inspection activities. Inspection findings/observations will be documented in accordance with IMC-0617, "Vendor and Quality Assurance Implementation Inspection Reports." Inspection issues that cannot be resolved at the time of the inspection will be documented as unresolved items in accordance with IMC-0617.

2507-07 TYPES OF INSPECTIONS

The following types of inspections are performed by the Quality and Vendor Branch. Enclosure 1 lists the inspection procedures that are applicable to the vendor inspection program as described in this manual chapter.

07.01 Routine Inspections. The inspectors will review the vendor's QA program and verify effective implementation of QA controls for activities related to the basic component being provided. The inspectors will also verify that the QA program provides controls for reporting of defects and noncompliance. For vendors performing dedication of commercial-grade items, the inspectors will verify that the facility has implemented an effective commercial-grade dedication program. In addition, the inspectors will verify the vendor's capability to assure the quality of basic components procured by licensees or applicants. Typically one inspection is conducted to verify implementation of the vendor's QA controls. Follow-up inspection are performed as necessary.

07.02 Reactive Inspections. The inspectors will verify that vendors of basic components have developed and implemented adequate procedures to evaluate and correct conditions adverse to quality. Reactive inspections are conducted in response to allegations, previous inspection findings, reports in accordance with Part 21 and/or 50.55(e), and other information sources indicating the possibility that NRC requirements are not being met. Typically one inspection is conducted to verify implementation of the vendor's QA controls. Follow-up inspections are performed as necessary.

07.03 Third-Party Audit Oversight. The NRC staff will provide oversight of third-party audit activities (e.g., Nuclear Procurement Issues Committee (NUPIC)) on a periodic basis. This includes participation in third-party audit organization meetings related to vendor

performance. The purpose of NRC oversight of third-party audit organizations is to verify the effective implementation of the audit process to ensure that the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B are satisfied. These audits are conducted twice a year by the Quality and Vendor branches.

2507-08 ENFORCEMENT ACTIONS

Potential violations identified through inspection activities will be processed in accordance with the NRC Enforcement Policy-

2507-09 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."

ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities."

70 FR 12908, "Use of the Web and ADAMS to Disseminate the Enforcement Policy, Discontinuation of NUREG-1600, and Simplification of the Official Policy Statement Title."

END

Attachments:

1. Inspection Procedures
2. Revision History for IMC 2507

ATTACHMENT 1

INSPECTION PROCEDURES

Inspection Procedure No.	Inspection Procedure Title	Procedure Applicability: Routine (R) or As Needed (N)
36100	Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance	R
37805	Engineering Design Verification Inspections	R
43002	Routine Inspections of Nuclear Vendors	R
43003	Reactive Inspections of Nuclear Vendors	N
43004	Inspection of Commercial-Grade Dedication Programs	N
43005	NRC Oversight of Third Party Organizations Implementing Quality Assurance Requirements	N

ATTACHMENT 2

Revision History for IMC 2507

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	10/03/07 CN 07-030	Initial issuance to establish guidance for 10 CFR Part 52 vendor inspections Researched commitments for 4 years and found none.	None	N/A	N/A
N/A	04/27/10 CN 10-012	Revised Manual Chapter to reference IMC 0617 on documentation of inspection reports. Clarified enforcement policy statement and referenced Inspection Procedure 43005.	None	N/A	ML100680331
N/A	ML110871798 04/25/11 CN 11-007	Revised Manual Chapter to provide guidance for translators and/or interpreters when necessary. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)).	None	N/A	N/A