NRC INSPECTION MANUAL

IQVB

INSPECTION MANUAL CHAPTER 2507

VENDOR INSPECTIONS

VENDOR INSPECTIONS

TABLE OF CONTENTS

| 2507-01 | PURPOSE | 1 |
|---|--|--------|
| 2507-02 | OBJECTIVES | 1 |
| 2507-03 | DEFINITIONS | 1 |
| 2507-04 04.01 04.02 04.03 | RESPONSIBILITIES AND AUTHORITIES Director, Office of Nuclear Reactor Regulation (NRR) Director, Division of Reactor Oversight (DRO) Chief, Quality Assurance and Vendor Inspection Branch (IQVB) | 4 4 |
| 2507-05 | DISCUSSION | 4 |
| 2507-06 06.01 06.02 06.03 06.04 06.05 06.06 06.07 2507-07 07.01 07.02 07.03 07.04 | INSPECTION POLICIES AND GUIDANCE Vendor Selection Inspection Emphasis Inspection Plans Development of Generic Communications Inspection Contractor Support Inspection Language Services General Inspection Process TYPES OF INSPECTIONS Routine Inspections Reactive Inspections Third-Party Audit Oversight Witnessing Unsafe Conditions | |
| 2507-08 | ENFORCEMENT ACTIONS | 10 |
| 2507-09 | REFERENCES | 10 |
| Attachment | t 1: Inspection Procedures | Att1-1 |
| Attachment | t 2: Revision History for IMC 2507 | Att2-1 |

2507-01 PURPOSE

- 01.01 To establish the inspection program for vendors providing safety-related materials, equipment, and services to the domestic commercial nuclear industry.
- 01.02 To provide requirements and guidance to U.S. Nuclear Regulatory Commission (NRC) inspectors for conducting inspections at vendor facilities.

2507-02 OBJECTIVES

- 02.01 To verify effective implementation of vendor quality assurance (QA) programs as a means of assuring the quality of materials, equipment, and services supplied to the domestic 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 and 10 CFR Part 50.55(e) as applicable.
- 02.04 To conduct inspections at vendor facilities to help support the Commission's determination that the acceptance criteria in a combined license (COL) 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) are accomplished in a timely manner.
- 02.07 To verify that vendors have programs in place to assure that fraudulently marketed basic components are identified and removed from the nuclear supply chain, 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's operating experience program of instances involving substandard, suspected counterfeit, or fraudulently marketed basic components and to gather information in order to provide timely information to licensees and other users.

2507-03 DEFINITIONS

- 03.01 Allegation. See Definition in Management Directive 8.8.
- 03.02 <u>Announced Inspection</u>. The vendor or any member of the 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 telephone call followed by written communication informing any member of the vendor organization that an inspection may or will take place at a specific time or date.

Issue Date: 12/20/19 1 2507

- 03.03 <u>Apparent violation</u>. A situation or circumstance that does not appear to meet NRC requirements and for which the NRC staff has not made a final enforcement determination.
- 03.04 <u>Applicant</u>. A person or entity applying for an early site permit, standard design certification, standard design approval, construction permit, COL or manufacturing license subject to the requirements of 10 CFR Part 50 or 10 CFR Part 52.
- 03.05 Basic Component. See Definition in 10 CFR Part 21.
- 03.06 <u>Combined License.</u> A combined construction permit and operating license with conditions for a nuclear power facility issued under Subpart C of 10 CFR Part 52.
- 03.07 <u>Conclusion</u>. As used in this chapter, an assessment of a vendor program or process based on observations or findings.
- 03.08 <u>Counterfeit or Fraudulently Marketed Items</u>. 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.
- 03.09 <u>Defect</u>. See Definition in 10 CFR Part 21.
- 03.10 Deviation. See Definition in 10 CFR Part 21.
- 03.11 <u>Draft Inspection Report</u>. Any version of the inspection report before its official issuance.
- 03.12 <u>Escalated Enforcement Action</u>. A Notice of Violation for any Severity Level I, II, or III violation (or problem), or a civil penalty or order based on a violation.
- 03.13 <u>Finding</u>. As used in this chapter, an observation of a vendor not meeting a requirement that has been described with objective evidence and assessed for significance.
- 03.14 <u>Inspection</u>. The examination and assessment of any vendor activity to determine its effectiveness, to ensure safety, and/or to determine compliance.
- 03.15 <u>Inspection Document</u>. Any material obtained or developed during an inspection that is considered to be an NRC record (see below).
- 03.16 <u>Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)</u>. 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, as amended, and the Commission's rules and regulations.
- 03.17 <u>ITAAC Family</u>. A grouping of ITAAC that are related through similar construction processes, resulting products, and general inspection attributes.
- 03.18 ITAAC Finding. An inspection finding that is material to the ITAAC acceptance criteria.
- 03.19 <u>Licensee</u>. The holder of an NRC license, construction permit, or <u>COL</u>. The provisions listed as applicable to "licensees" in this chapter are also applicable to vendors and applicants for an NRC license.

Issue Date: 12/20/19 2 2507

- 03.20 <u>Minor Violation</u>. A violation that is less significant than a Severity Level IV violation, not the subject of formal enforcement action, and not usually described in inspection reports. However, minor violations must be corrected.
- 03.21 <u>Non-Cited Violation (NCV)</u>. A violation which satisfies the criteria in the NRC Enforcement Policy that allows the staff to exercise discretion and refrain from issuing a 10 CFR Part 2.201 Notice of Violation.
- 03.22 Noncompliance. A violation, non-cited violation, or nonconformance.
- 03.23 <u>Nonconformance</u>. A vendor failure to meet contractual requirements related to NRC-regulated activities (e.g., Appendix B to 10 CFR Part 50), where the NRC has not placed the requirement directly on the vendor.
- 03.24 <u>Notice of Nonconformance (NON)</u>. A formal written notice that sets forth one or more nonconformances to contract requirements.
- 03.25 <u>Notice of Violation (NOV)</u>. A formal written citation in accordance with 10 CFR Part 2.201 that sets forth one or more violations of a legally binding regulatory requirement.
- 03.26 Observation. A fact; any detail noted during an inspection.
- 03.27 <u>Quality Assurance Manual</u>. A compilation of quality assurance documents that define the QA 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.
- 03.28 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, etc.), 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.
- 03.29 <u>Record</u>. Any written, electronic, or photographic record under legal NRC control that documents the policy or activities of the NRC or an NRC licensee (see also the definition of Record in 10 CFR Part 9).
- 03.30 <u>Regulatory Commitment</u>. An explicit statement to take a specific action agreed to or volunteered by a licensee, where the statement has been submitted in writing on the docket to the NRC. This may include a commitment in the licensee's application, a response to a NOV, etc.
- 03.31 <u>Requirement</u>. A legally binding obligation such as a statute, regulation, license condition, technical specification, or order.
- 03.32 <u>Routine Vendor Inspection</u>. An inspection performed to verify the vendor documented QA program is in conformance with Appendix B to 10 CFR Part 50, and other applicable requirements, and to verify effective implementation of a facility's QA program used to supply basic components to the nuclear industry.

Issue Date: 12/20/19 3 2507

- 03.33 <u>Team Inspection</u>. An inspection with two or more inspectors.
- 03.34 <u>Unannounced Inspection</u>. 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. <u>Unannounced inspections could be routine or reactive</u>.
- 03.35 <u>Unresolved Item (URI)</u>. An issue about which more information is required to determine if it is acceptable, if it is a finding, or if it constitutes a deviation or violation. Such a matter may require additional information from the vendor or cannot be resolved without additional guidance, clarification, or interpretation of the existing guidance.
- 03.36 <u>Vendor</u>. For the purposes of this manual chapter, any company or organization that provides basic components such as material, equipment, components, or services to a vendor, licensee, or applicant 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). Vendors may include suppliers of basic components or third party commercial-grade dedicating entities.
- 03.37 <u>Violation</u>. 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.
- 03.38 <u>Willfulness</u>. An attitude towards noncompliance with requirements that ranges from careless disregard to a deliberate intent to violate or falsify.

2507-04 RESPONSIBILITIES AND AUTHORITIES

- 04.01 <u>Director, Office of Nuclear Reactor Regulation (NRR)</u>. Provides overall direction for the NRC's vendor inspection program.
- 04.02 Director, Division of Reactor Oversight (DRO).
 - 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.
- 04.03 Chief, Quality Assurance and Vendor Inspection Branch (IQVB) is responsible for:
 - a. Development, implementation, and assessment of the vendor inspection program.

2507-05 DISCUSSION

IQVB is responsible for implementing the construction and operational vendor inspection program at facilities where basic components are designed, manufactured, or stored. Routine

and reactive inspections are conducted to verify that vendor QA programs are implemented and comply with the applicable regulatory requirements of Appendix B to 10 CFR Part 50, 10 CFR Part 21, 10 CFR 50.55(e), and other industry applicable standards (e.g., the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code and the Institute of Electrical and Electronic Engineers (IEEE) Standards).

This manual chapter provides NRC guidance for inspection and assessment of vendor QA programs, detailed design and manufacturing activities, and 10 CFR Part 21 implementation in support of operating reactors and new reactor licensing, as well as 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 material, equipment, and services supplied to the commercial nuclear industry.
- Inspections to assess whether the vendor QA programs address specific processes such as commercial-grade dedication practices, vendor/sub-vendor 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 or 10 CFR 50.55(e) as applicable.
- Inspections to assess whether the vendor QA program implementation during design, fabrication, and testing of basic components supports ITAAC-related activities such as inspection of offsite fabrication, modular construction techniques, equipment qualification, and fabrication of long-lead components. These inspections are tools to obtain information that will be used to support the Commission's determination that the ITAAC acceptance criteria in a combined license are met in accordance with 10 CFR 52.99 and 10 CFR 52.103(g).
- 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 marked basic components.

2507-06 INSPECTION POLICIES AND GUIDANCE

06.01 <u>Vendor Selection</u>. The selection of vendors for inspection is based on several factors that include:

- The significance to safety of the equipment or service provided,
- Vendors manufacturing major plant modifications, (i.e., replacement of steam generators and reactor vessel heads, new fuel design, etc.)
- Verification of ITAAC in support of onsite construction activities,

- Input from the technical staff necessary to support completion of design certification and 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 from allegations, 10 CFR Part 21 reports, 10 CFR Part 50.55(e) 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.

Refer to the Vendor Inspection Program Plan for additional guidance on the process used for the selection of vendors for inspection.

06.02 <u>Inspection Emphasis</u>. Inspection emphasis is placed on implementation of the processes employed by vendors during the design, fabrication, and testing of basic components. The inspectors will verify through sampling that the vendor's quality processes meet the applicable industry codes, standards, and regulatory requirements.

Vendor inspections will also follow-up on reported problems and design activities, examination of the implementation of licensee and vendor procurement programs, and the licensee's interface and action in response to vendor information. The intent of the inspections is to ensure that the vendor or the licensee has determined the root cause of problems. The inspections also determine that suitable corrective action is being or has been developed, design packages are technically accurate, and licensees are receiving vendor information and using it appropriately. Inspection of certain programmatic aspects of vendor and licensee programs is appropriate to the extent necessary to ensure that procedures are in place to identify, evaluate, and act on potential or identified problems, action is taken to prevent recurrence, and adequate control of other activities, such as design, is exercised.

In addition to verifying the implementation of the Appendix B to 10 CFR Part 50 criteria described above, vendor inspections will include the review of the vendor's implementation of 10 CFR Part 21 or 10 CFR Part 50.55(e) procedures, industry applicable standards (e.g., ASME B&PV Code and IEEE standards) 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 <u>Inspection Plans</u>. 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 <u>Development of Generic Communications</u>. <u>IQVB</u> will prepare input to the NRR 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 <u>Inspection Contractor Support</u>. 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 <u>Inspection Language Services</u>. Translators and/or interpreters will be used as necessary to ensure that the use 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's 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 U.S. Embassy or the Interpreting Division of Language Services of the U.S. 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 <u>General Inspection Process</u>. For each inspection, the NRC inspection team should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. The inspection procedures listed in Attachment 1 provide more specific guidance for onsite inspection activities.
 - a. <u>Pre-inspection activities</u>. To facilitate management of inspection resource allocations and tracking of inspection activities, the lead inspector should develop a facility-specific inspection plan 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, inspection procedures, 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., 10 CFR Part 50.73 reports, 10 CFR Part 21 notifications) reported by the vendor.

Note: Inspections of vendors performing activities associated with ITAAC are coordinated with Region II. Inspections of licensee activities are coordinated with the NRR Project Manager and appropriate Regional Divisions of Reactor Project and Reactor Safety. Engagement of international regulators should be coordinated through the NRR Multinational Design Evaluation Program (MDEP) or International Programs contact.

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 meeting, the lead inspector should brief his/her supervisor on the preliminary inspection findings.

Note: 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 be present during the conduct of the inspection.

As stated in Section 06.02 above, inspection emphasis is placed on the implementation of the processes employed by vendors during the design, fabrication, and testing of basic components. To execute this concept, an inspector should apply performance-based inspection techniques. These techniques place emphasis on observing the vendor performing activities related to the design, fabrication or testing of basic components. The inspector's discussions with vendor personnel, and document reviews should be used to support the observations.

When the inspector identifies issues during a performance based inspection, emphasis should be focused on identifying: 1) the root cause of the problem; 2) if the problem is limited or widespread (extent of condition); 3) if the initiator is due to procedures, work controls, training or other programmatic controls; 4) whether the vendor's quality program has previously identified and addressed the issue and; 5) the potential impact to purchasers (operating nuclear power plants and/or those under construction). The documents relating to the performance of the activity should be reviewed prior to

observing the activity. Inspection through direct observation provides reasonable assurance that quality has been achieved in the vendor's activities.

The application of performance-based inspection techniques may include some of the following examples. If an inspector identifies an inadequate procedure that may affect the performance of an activity, then the inspector should then verify if there was a direct impact on the activity. If an inspector identifies a gauge that is out of calibration, then the inspector should determine if the vendor has assessed if the gauge has been in use since that date and whether the gauge is outside of allowed tolerances. If an inspector identifies that the vendor did not verify all critical characteristics during the dedication of an item, then the inspector should evaluate how failing to determine the safety-related function affects that item.

In some cases, the activity to be inspected may not be in process at the time of inspection. Therefore, the inspector must perform an evaluation of the vendor's quality controls without the benefit of direct observation of the activity. The inspector may employ alternative methods that include: 1) discussions with cognizant vendor management and/or personnel; 2) review of pertinent documentation of activities; 3) requests for demonstrations of vendor fabrication or testing activities and; 4) observing initial set-up preparations for upcoming work activities. As previously discussed, the preferred method of inspection is direct observation of vendor activities; however, inspectors need to be flexible and complete the necessary inspection goals. The inspector may still be able to assess the vendor's level of quality applied to safety-related equipment.

Guidance on determining the significance of a finding is provided in Inspection Manual Chapter (IMC) 0617, "Vendor and Quality Assurance Implementation Inspection Reports."

c. <u>Post-inspection activities</u>. Inspection findings/observations will be documented in accordance with IMC 0617. Inspection issues that cannot be resolved at the time of the inspection will be documented as unresolved items in accordance with IMC 0617. Inspection findings, unresolved items, or pertinent information that could affect ITAAC closure should be documented in accordance with IMC 0617. The Vendor Inspection Program Plan provides additional guidance on the process used by IQVB for communicating with Region II's Construction Inspection staff and the affected licensees on inspection findings that could affect ITAAC closure.

In accordance with the guidance in IMC 0617, the lead inspector should convene a findings review panel prior to the inspection report being issued to evaluate potential findings and to ensure that the findings are consistently dispositioned across the Vendor Inspection COE.

2507-07 TYPES OF INSPECTIONS

The following types of inspections are performed by IQVB. Attachment 1 lists the inspection procedures that are applicable to the vendor inspection program as described in this manual chapter.

- 07.01 <u>Routine Inspections</u>. 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 inspections are performed as necessary. Routine inspections could be unannounced inspections.
- 07.02 <u>Reactive Inspections</u>. 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 10 CFR Part 21 and/or 10 CFR 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. Reactive inspections could be unannounced inspections.
- 07.03 Third-Party Audit Oversight. The NRC staff will provide oversight of third-party audit activities (e.g., Nuclear Procurement Issues Corporation (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 to 10 CFR Part 50 are satisfied. These audits are conducted approximately twice a year by IQVB. The NRC staff will also engage with NUPIC regarding significant inspection findings that are indicative of inadequate NUPIC oversight. Further regulatory actions will be evaluated on a case by case basis.
- 07.04 <u>Witnessing Unsafe Conditions.</u> During all inspections the inspector is expected to make every reasonable attempt to stop work practices that are unsafe or could lead to an unsafe situation.

2507-08 ENFORCEMENT ACTIONS

Potential violations and nonconformances identified through inspection activities will be processed in accordance with the NRC's 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."

Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction),"

Issue Date: 12/20/19 10 2507

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."

Vendor Inspection Program Plan (available on the Vendor QA Inspections page of the NRC's Public Web site)

IMC 0617, "Vendor and Quality Assurance Implementation Inspection Reports."

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) |
|--|--|--|
| 35007 | Quality Assurance Program Implementation During Construction and Pre-Construction Activities | Ν |
| 35017 | Quality Assurance Implementation Inspection | N |
| 35034 | Design Certification Testing Inspection | N |
| 35710 | Quality Assurance Inspection of Software Used in Nuclear Applications | N |
| 36100 | Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Nonconformance | R |
| 36100.01 Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction | | N |
| 37804 | Aircraft Impact Assessment | N |
| 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 | Ν |
| Inspection of Implementation of Mitigation Strategies Order Regarding the Use of National Safer Response Centers | | R |
| 65001 | Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (TAAC) Work | |
| Protection of Safeguards Information by Design Certification Applicants and Vendors | | R |

ATTACHMENT 2

Revision History for IMC 2507

| 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 | 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. | 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. | N/A | ML100680331 |
| C1 | 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)). | N/A | N/A |
| C2 | ML13247A725 10/03/2013 CN 13-024 | Revised Manual Chapter to provide guidance on the vendor selection process. The requirements have been moved from IMC 2700, "Vendor Inspection Program," and incorporated into this version of IMC 2507, "Vendor Inspections." Upon issuance of this version of IMC 2507, IMC 2700 will be deleted. Update to the vendor selection process is in response to OIG audit (OIG-10-A-02 (ML103020267)). | N/A | ML13247A726 |
| C3 | | Updated the responsibilities and authorities for the Vendor Inspection COE with respect to how the vendor inspection programs inform ITAAC in response to OIG audit (OIG-12-A-16 (ML12194A434)). | | |

| 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 | ML18099A114 05/16/18 CN 18-013 | The purpose of this revision is to include the latest vendor reorganization, major plant modifications as a factor for vendor selection and remove the reference to ASME NQA-1-1994 and replace it with RG 1.28. Staff from the technical lead branch for this procedure has evaluated the document for continued applicability and have addressed previously identified change requests in the IMCIP update database. (non-public) | N/A | ML18099A112 |
| N/A | ML19337C706 12/20/19 CN 19-041 | Revised Manual Chapter to reflect the new organization based on the merger of NRR and NRO, added several inspection procedures to Attachment 1, and made some editorial changes. | N/A | N/A |