

NRC INSPECTION MANUAL

RVIB

MANUAL CHAPTER 2700

VENDOR INSPECTION PROGRAM

2700-01 PURPOSE

To establish general requirements for the review and inspection by the Vendor Inspection Branch (VIB) of nuclear steam system suppliers (NSSSSs), architect engineering (AE) firms, suppliers of products and/or services, independent testing laboratories performing equipment qualification tests, and holders of NRC licenses (construction permit holders and operating licenses) in vendor-related areas.

2700-02 OBJECTIVES

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

02.02 To determine that vendors are complying with applicable NRC and industry requirements, that licensees/applicants are adequately overseeing vendors, and that sufficient interfaces exist between licensees/applicants and vendors.

02.03 To determine that licensees and/or vendors have effectively implemented a commercial grade dedication program for safety-related parts.

02.04 To assure that licensees and construction permit holders are implementing their responsibility for the adequacy of vendor products for service in nuclear plants commensurate with their safety importance.

02.05 To inform industry/vendors 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.

02.06 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.

02.07 To inform other Federal agencies of appropriate matters involving substandard vendor products.

02.08 To assure that licensees/applicants programs and their vendors, as applicable, have an effective system for reporting defects under 10 CFR Part 21, 10 CFR Part 50.73, and 10 CFR Part 50.55(e).

02.09 To assure that follow-up and resolution of allegations, Part 21 reports, and licensee event reports (LERs) assigned to the VIB are accomplished in a timely manner.

02.10 To provide technical assistance to other NRC offices or government agencies.

2700-03 DEFINITIONS

03.01 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.

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

03.03 Nonconformance. Any vendor inspection result determined to not comply with applicable commitments made to a licensee. Specific industry codes and standards, company quality assurance (QA) manual sections, or operating procedures established to address licensee requirements are examples of commitments that may be cited when identifying nonconformances.

03.04 Potential Enforcement Finding. An apparent violation of a specific regulatory requirement or a deviation from specific commitment by a licensee. A potential enforcement finding (PEF) is generally identified in VIB inspection reports or licensees, in which case, the PEF supporting information and a recommended course of action are forwarded to the appropriate regional office for disposition and enforcement determination.

03.05 Violation. Any inspection result determined to be in violation of Federal regulations (such as 10 CFR Part 21) that are applicable to the organization being inspected.

03.06 Vendor. Any supplier of products such as material, equipment, components, or services to be used in an NRC-licensed facility or activity. In certain cases the supplier may be an NRC licensee (e.g., a nuclear fuel fabricator) or the product may have NRC certificates (e.g., a transportation cask).

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

03.08 Programmatic Inspection. Inspections performed to verify that a licensee's or a vendor's documented QA program is in conformance with 10 CFR Part 50, Appendix B, and other applicable

requirements and that the licensee's programs are being effectively implemented.

03.09 Announced Inspection. The licensee/vendor or any member of the licensee/vendor organization is notified by the 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 (from home, office, or motel) 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.

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

2700-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of Nuclear Reactor Regulation

- a. Overall direction of program development.
- b. Overall direction of the assessment of implementation of the established vendor inspection program.

04.02 Director, Division of Reactor Inspection and Safeguards

- a. Administration and control of vendor inspection program development, revision, and implementation.
- b. Administration and control of the assessment and effectiveness of the vendor program.

04.03 Chief, Vendor Inspection Branch

- a. Development of the vendor inspection program.
- b. Implementation of the vendor inspection program.
- c. Assessment of the vendor inspection program.

04.04 Vendor Inspection Branch. The Vendor Inspection Branch is responsible for implementation of the vendor inspection program at vendor-owned, and vendor-operated facilities and at sites where vendor-supplied components are used or stored. In addition, the VIB may also inspect certain licensee activities.

The VIB, as well as the regions, inspects the interface between licensees and vendors and licensee procurement activities as a means of evaluating the licensee's performance with respect to oversight and control of vendor-related activities. The licensee/vendor interface inspection will review the licensee's program for receiving service information on purchased items from vendors and how that information is being distributed, evaluated, and acted upon.

The VIB provides assistance to other branches in NRR in resolving technical issues by commenting on appropriate enforcement action and by conducting inspections. The VIB also comments on escalated enforcement actions with respect to the licensee's equipment qualification program. The VIB also provides technical assistance to the Office of Investigation (OI) on matters relating to vendor activities.

The VIB notifies the appropriate Regional office and NRR Project Manager upon identification of a plant specific problem that may require prompt followup by Regional and/or licensee personnel.

2700-05 BASIC REQUIREMENTS

05.01 To determine the adequacy of the licensee's/vendor's QA program and its implementation relative to 10 CFR Part 50, Appendix B, and other applicable industry standards and codes.

05.02 To determine the adequacy of the licensee's/vendor's procedure and its implementation relative to the requirements of 10 CFR Part 21.

05.03 To determine whether the licensee/vendor is appropriately utilizing industry codes and standards, e.g., the ASME Boiler and Pressure Vessel Code and IEEE Standards.

2700-06 GENERAL POLICIES

06.01 Vendor Selection. The selection of vendors for inspection is based on the significance to safety of the equipment or services provided, the frequency and significance to safety of problems identified with vendor-supplied equipment or services, the number of licensees affected by the problem identified, the performance history of a vendor, and other information received by VIB from allegations, Part 21 reports, LERs, and other NRC organizations.

06.02 Licensee Selection. The selection of licensees for inspection is based on periodic vendor program review requests from the regions, the frequency and significance to safety of potential vendor interface issues identified through inspections at vendor facilities, and potential procurement problems. Licensee selection is coordinated with the applicable regional office and the NRR projects staff utilizing the Master Inspection Plan (MIP) process.

06.03 Inspection Emphasis. Vendor inspection emphasis is primarily related to 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. The principal thrust of the inspection is to review the technical aspects of vendor activities and program implementation. However, the VIB effort does not replace the licensee's responsibility to perform thorough and adequate inspections of their vendors/suppliers.

06.04 Inspection Plans. Inspection plans are required for all inspections. The lead inspector is responsible for preparation of the inspection plan. Inspection plans are approved by the appropriate section chief and inspection team members before the inspection in accordance with the MIP (when applicable). The extent and detail of the inspection plan varies with the type, length, and complexity of each inspection. Inspections of licensee activities are coordinated with the NRR Project Manager and appropriate Regional Divisions of Reactor Projects and Reactor Safety.

06.05 Coordination With Headquarters Organizations. Coordination for evaluation and follow-up of reported operating events is maintained through participation in the morning conference call between the Vendor Inspection Branch (VIB), the Generic Communications Branch (GCB), the Events Assessment Branch (EAB), and the Office for Analysis and Evaluation of Operational Data (AEOD). The items discussed are events reported in the morning report and notifications made in accordance with 10 CFR 50.72 (Immediate notification requirements for operating nuclear power reactors).

In addition, the VIB is routinely assigned responsibility for resolution of issues identified by Part 21 reports and allegations. The VIB frequently participates in the NRR Allegation Review Board to review allegations involving vendor issues and to plan or approve the course of action.

Many inspections result in findings that are related to counterfeit or fraudulently supplied materials or services and implied suspicion of internal wrongdoing. These matters are referred to and coordinated with the NRC OI.

06.06 Coordination With Other Federal Agencies. Coordination with other Federal agencies is necessary when VIB inspections and reviews identify vendor-supplied products that do not meet the required standard or the product is suspected of being misrepresented and there is information that suggests that the vendor has supplied products directly to other Federal agencies (such as DOD, DOE, or NASA) or to industries regulated by other Federal agencies. Also, through interagency coordination, the VIB staff attempts to obtain similar vendor information from other agencies that may affect the nuclear industry.

06.07 Development of Bulletins, Information Notices, and Generic Letters. Development of bulletins, information notices and generic letters to alert the nuclear industry and others of vendor-related product/service deficiencies is the responsibility of the VIB. VIB prepares and coordinates these generic communications with OI, Office of the General Council (OGC), the Regions, and other NRR

technical branches as appropriate and then forwards the document to the Division of Operational Events Assessment (DOEA) for review and issue.

06.08 Support to Regions Including Contractor Support. The VIB provides inspection support to the Regions by assisting in inspections of vendors and/or licensees or by providing contract consultants.

2700-07 TYPES OF INSPECTIONS

The following types of inspections are performed by the Vendor Inspection Branch. Appendix A lists all the inspection procedures that are applicable to the vendor inspection program as described in this manual chapter.

07.01 Service Organization Inspection. The inspection of AE firms and NSSSs addresses identified problem areas and interfaces with licensees regarding procurement of equipment, outage activities, and modifications for plants. Inspection of companies that supply technical services to an NSSS, an AE firm, or an Engineering Service Organization (ESO) is performed on a similar basis. Inspection of licensees that supply engineering services to other utilities may be performed by the VIB in conjunction with the regional office in which the licensee is located and other NRR branches. The inspection of an NSSS, an AE firm, or an ESO will normally entail a detailed review of design activities and the results of those activities by a multidiscipline team of technical specialists.

When an inspection of an AE firm, an NSSS, or an ESO is conducted, in addition to the detailed review of design activities, the effectiveness of implementation of the following should generally be determined:

- a. Vendor conformance with purchase requirements when supplying products or services for use in licensed facilities;
- b. Vendor conformance with 10 CFR Part 21 requirements;
- c. Vendor conformance with other NRC rules and regulations imposed directly or indirectly through licensee requirements;
- d. The means of notifying customers of deviations or defects in the vendor's products or services; and,
- e. Vendor control and evaluation of sub-vendor activities.

07.02 Component/Material Service Supplier Inspection. Deficiencies in the design, fabrication, or testing or other deficiencies in equipment with varying degrees of safety significance and generic impact result in reports from external sources (i.e., morning report items and Part 21, Part 50.55(e), and Part 50.72 reports) or from inspections and reviews conducted by the VIB or other NRC organizational elements. Some of these items will require inspection at the vendor's facilities to determine the scope

of the problem and to ensure that appropriate corrective action is taken. These inspections are usually reactive.

The inspection of component/material suppliers should generally include evaluation of the effectiveness of implementation of the following:

- a. Vendor conformance with purchase requirements when supplying products or services for use in licensed facilities;
- b. Vendor conformance with 10 CFR Part 21 requirements;
- c. Vendor conformance with other Commission rules and regulations imposed directly or indirectly through licensee requirements;
- d. The means of notifying customers of deviations or defects in the vendor's products or services; and
- e. Vendor control and evaluation of sub-vendor activities.

07.03 Nuclear Power Plant Inspections. The vendor inspection program includes conduct of inspections of licensed nuclear facilities. These inspections generally include evaluation of the effectiveness of implementation of:

- a. Actions taken by the licensee when notified by vendors of defects in products;
- b. Actions taken by the licensee on matters identified by the NRC through bulletins, information notices, and generic letters, and matters involving vendors and their procurement activities, or dedication program activities;
- c. Actions taken by the licensee on vendor recommendations for operation and maintenance of equipment;
- d. Procurement and dedication programs for safety-related items and for commercial-grade products that are subsequently upgraded for safety-related application;
- e. Implementation of Commission rules and regulations imposed directly or indirectly through licensee requirements and commitments; and
- f. Implementation of Commission regulations in 10 CFR Part 21 requiring deviations to be identified, evaluated, and reported, as appropriate.

2700-08 INSPECTION REPORTS

08.01 Reports of vendors inspected will be issued by the Vendor Inspection Branch as required by MC-0610. In addition to the standard distribution, copies of vendor inspection reports will also be provided to the Office of Enforcement, the NRR Division of Engineering Technology, the NRR Division of Systems Technology, the Office of Nuclear Material Safety and Safeguards (NMSS), and other

NRC organizations, as appropriate. Reports that identify Level III violation(s) or potential enforcement finding(s) in accordance with the Enforcement Manual will also be distributed to the Office of Enforcement and require coordination with the Office of the Executive Director for Operations. Severity Level III violations are to be signed by the Division Director.

08.02 Reports on licensees inspected by the Vendor Inspection Branch will be issued in accordance with the requirements of MC-0610 and:

- a. The reports will be approved by the Chief, Vendor Inspection Branch. The Director, DRIS will concur in the transmittal letter.
- b. A report number will be obtained using the NRR report numbering sequence.
- c. The reports will be reviewed and approved by the appropriate regional office.
- d. The reports will be transmitted to the licensee by the applicable NRR Projects Division Director with copies to the applicable Regional Administrator.
- f. The reports will identify potential enforcement findings in accordance with the NRC Enforcement Policy. Enforcement items identified during the course of a VIB inspection will be coordinated with the appropriate Regional office. VIB will provide support for the closure of these items as appropriate.
- g. A memorandum will be prepared by the VIB for signature of the Director, DRIS, to the Director, Reactor Projects of the appropriate regional office, recommending the enforcement action to be taken, including a draft Notice of Violation and associated recommended severity level(s).
- h. A memorandum will be provided by the VIB to the NRR projects staff and the appropriate Region with input for the Systematic Assessment of Licensee Performance (SALP) report for the areas inspected.
- i. Reports concerning wrongdoing are to be transmitted to OI for review and will be withheld pending OI approval to release.
- j. The VIB provides the appropriate Region with a listing of inspection procedure(s) which were completed or partially completed during the inspection.

08.03 The VIB is responsible for providing the manuscript for publication of NUREG-0040 (the White Book), which is published quarterly. The White Book contains copies of the VIB inspection reports that are made public in the quarter for which it is issued. A selected list of pertinent bulletins and information notices is also included.

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