U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

Vendor Inspection Program Plan

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1.0 Vendor Inspection Program Overview

The Vendor Inspection Program (VIP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the nuclear supply chain. It accomplishes this through limited scope, targeted inspections of vendor quality assurance (QA) programs, communicating relevant vendor information to stakeholders, and supporting allegation response activities. Vendor inspections are planned using a strategy for vendor identification and selection which samples the effectiveness of the domestic and international nuclear supply chains for the current fleet and new reactor construction. To effectively implement vendor inspections, the vendor inspectors maintain the necessary knowledge and skills to perform inspections. Communication of vendor-related information is achieved through interaction with nuclear consensus standards organizations, vendors, industry supply chain organizations, international constituents, and other external stakeholders. The VIP serves as a mechanism to address vendor-related allegations received by the U.S. Nuclear Regulatory Commission (NRC) by providing technical support and/or vendor inspections for such allegations.

The VIP includes objectives and associated performance metrics to demonstrate that overarching goals are being met. These performance metrics are assessed annually to ensure successful implementation and continuous improvement of the VIP.

The purpose of the VIP Plan is to establish an overall approach, including goals, priorities, performance metrics, and resource management strategies for VIP activities. Key parts of the plan include:

- The objectives of the VIP, including its overarching goals that provide a link to the NRC's statutory mission of protecting public health and safety, promoting the common defense and security, and protecting the environment.

- The organization, staffing, training, and qualification of the vendor inspection staff in the NRC's Office of Nuclear Reactor Regulation (NRR) necessary to perform effective oversight of vendors.

- The necessary infrastructure, including inspection and regulatory guidance and tools (e.g., QA web site, inspection planning and scheduling, and self-assessment tracking systems).

- Communication and coordination activities with internal and external stakeholders.

- Technical and managerial support for vendor-related allegations.

2.0 Objectives of the Vendor Inspection Program

The VIP establishes specific objectives derived from six overarching goals that provide a nexus to the NRC's statutory mission of protecting public health and safety, promoting the common defense and security, and protecting the environment. The VIP is communicated both internally within the NRC and externally with industry stakeholders to ensure full integration of the program. Performance metrics have been established for each VIP objective to demonstrate that the following overarching goals are met:

(1) Objective - Decisions are based on factual information.

(2) Risk-informed - Risk insights are considered along with other factors (such as engineering judgment and management discretion) to better focus vendor and regulatory attention on issues commensurate with their importance to the NRC's mission.

(3) Understandable - The process and its results are clear and written in plain English.

(4) Predictable - More than one individual can follow the same defined process and arrive at the same conclusion in a consistent manner (e.g., repeatable).

(5) Open - NRC appropriately informs and involves stakeholders in the regulatory process.

(6) Effective - NRC's actions are of high quality, efficient, timely, and realistic, to enable the safe operation and construction of nuclear power plants.

The vendor inspection staff is responsible for implementing the VIP and ensuring that the objectives of the VIP are met. The objectives of the VIP are:

VIP-O-1 Verify that applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the nuclear supply chain for both operating reactors and new reactor design and construction activities through a strategic sample of vendor inspections.

The vendor inspection staff accomplishes this objective by performing vendor inspections that verify the effective implementation of the vendor's QA program. The inspections focus on verifying that vendors are supplying basic components in accordance with the requirements of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," as passed down by licensees and applicants in the procurement documents.

VIP-O-2 Effectively communicate with internal and external stakeholders.

The vendor inspection staff accomplishes this objective through confirmation of the following:

- Inspection nonconformances and/or violations provide sufficient detail to communicate whether the vendor is meeting commitments related to NRC-regulated activities and provide a direct link to the requirements that were not met.

- Inspection reports are written in plain language.

- Announcement letters, inspection plans, inspection reports, requests for information, acknowledgment letters, and other correspondence are completed in a timely manner consistent with the VIP metrics.

- Inspection nonconformances and/or violations are rarely rescinded if contested.

VIP-O-3 Perform timely and adequate allegation follow up and closure.

The vendor inspection staff accomplishes this objective by providing the necessary technical support to make sure that allegations are closed in a timely manner consistent with the NRC's metrics, in coordination with the Office of Enforcement (OE), Headquarters Allegation Review Team, as discussed in Appendix E, "Vendor Inspection Program Performance Metrics," of this plan.

VIP-O-4 Ensure that vendor inspectors have the necessary knowledge and skills to successfully implement the VIP.

The vendor inspection staff accomplishes this objective by verifying that vendor inspections are conducted by qualified inspectors, vendor inspectors-in-training make acceptable progress in their required qualifications, and qualified vendor inspectors maintain their proficiency. In addition, management provides appropriate oversight of on-going inspections and inspection reports.

The vendor inspection staff developed a set of performance metrics associated with each of the objectives of the VIP to assess program performance with respect to the goals listed above. Section 10.0 of this plan describes these performance metrics.

3.0 Organization

The vendor inspection staff conducts inspections related to the requirements in Appendix B to 10 CFR Part 50 and 10 CFR Part 21 at suppliers that provide design, fabrication, and engineering services (including commercial-grade dedication) for nuclear components. In addition, the vendor inspection staff provides technical support for regional inspections, special projects, programs, and policy activities. The vendor inspection staff coordinates inspection activities and, as necessary, requests additional support from other NRC offices, technical divisions, regions, branches or contractors.

4.0 Scope of Activities

The vendor inspection staff conducts vendor inspections to verify that QA programs at vendor facilities are being effectively implemented and comply with the applicable regulatory requirements, including 10 CFR Part 21 and the licensee-imposed requirements of Appendix B to 10 CFR Part 50. These inspections also verify that component design requirements imposed on the vendors by their customers have been met, including as applicable, requirements associated with the environmental and seismic qualification of equipment. Vendor inspections may also support the Commission's determination that the acceptance criteria in a combined license are met in accordance with 10 CFR Part 52.99, "Inspection During Construction," and 10 CFR Part 52.103(g). Also, using Inspection Procedure (IP) 37805, "Engineering Design Verification Inspections," dated April 8, 2020, the NRC has conducted vendor inspections to review the development of the detailed design for new reactor designs licensed under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Vendor inspections follow the procedures given in the table below, as applicable, and are governed by Inspection Manual Chapter (IMC) 2507, "Vendor Inspections."

Inspection Procedure (IP)	Title
IP 35007	Quality Assurance Program Implementation During Construction and Pre-Construction Activities
IP 35017	Quality Assurance Implementation Inspection
IP 35034	Design Certification Testing Inspection
IP 35710	Quality Assurance Inspection of Software Used in Nuclear Applications
IP 36100	Inspection of 10 CFR Parts 21 and Programs for Reporting Defects and Noncompliance
IP 36100.01	Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction
IP 37804	Aircraft Impact Assessment
IP 37805	Engineering Design Verification Inspections
IP 43002	Routine Inspections of Nuclear Vendors
IP 43003	Reactive Inspection of Nuclear Vendors
IP 43004	Inspection of Commercial-Grade Dedication Programs
IP 43005	NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements
IP 43006	Inspection of Implementation of Mitigation Strategies Order Regarding the Use of National Safer Response Centers
IP 65001	Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Related Work
IP 81811	Protection of Safeguards Information by Design Certification Applicants and Vendors

5.0 Vendor Inspection Program

The NRC performs routine and reactive vendor inspections and QA implementation inspections for the commercial nuclear power industry including new and operating reactors via the Quality Assurance Vendor and Inspection Branch (IQVB). IQVB also reviews changes to vendor and licensee's QA programs pursuant to 10 CFR Part 50.4(b)(7) or 10 CFR Part 50.54(a), respectively. IQVB is responsible for performing reactive inspections in response to operating experience, reports of defects and noncompliance made in accordance with 10 CFR Part 21 or allegations, and conducting routine inspections to verify the effective implementation of vendor QA programs in order to assure the quality of materials, equipment, and services supplied to the commercial nuclear power reactor industry.

6.0 Vendor Identification and Selection Methodology

The identification and selection of vendors for inspection is based on several factors that include:

- The significance ot safety of the equipment or service provided.
- Vendors manufacturing major plant modifications (i.e., replacement 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 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.
- Other information received by IQVB from allegations, 10 CFR Part 21 reports, 10 CFR Part 50.55(e), “Evaluation of Defects and Failures to Comply Associated with a Substantial Safety Hazard” reports, Licensee Event Reports, and other NRC organizations.

The methodology for the identification and selection of vendors for inspection is considered an essential element of the VIP. More detailed information on how IQVB identifies and selects vendors for inspection can be found in Appendix A, “Strategy for Vendor Identification,” Appendix B, “Strategy for Vendor Selection,” and Appendix F, “Major Plant Modification Criteria,” to this plan. Specifcally, Appendix A describes the strategy used to identify vendors supplying safety-related material, equipment, and services to the nuclear power industry. Appendix B defines the process by which those vendors are prioritized and scheduled for inspection, and Appendix F provides the criteria to determine when a plant change should be considered a major plant modification for enhanced vendor oversight.

7.0 Types of Inspection

Vendor inspections are classified into two broad categories: routine inspections and reactive inspections.

Routine Inspections

Routine inspections verify that vendors supplying basic components in accordance with the requirements in Appendix B to 10 CFR Part 50 and 10 CFR Part 21 provide a product meeting the technical and quality requirements in the procurement documents, including industry codes, standards, and applicable regulatory requirements. Routine inspections focus on observing the vendor’s activities during the design, fabrication, and testing of basic components. In addition, the inspection verifies that the vendor implements controls for reporting defects and noncompliance in accordance with 10 CFR Part 21 requirements. For vendors performing

dedication of commercial-grade items, the inspections also verify the effectiveness of the commercial-grade dedication program. Furthermore, the vendor inspection staff performs QA implementation and engineering design verification inspections to verify that the translation of high-level design information and performance requirements into procedures, specifications, calculations, drawings, procurement, and construction documents is consistent with the applicable regulatory requirements. For vendors that hold safeguards information (SGI), including applicants for design certification, the vendor inspection staff performs triennial inspections of SGI information protection per IP 81811 in accordance with 10 CFR Part 73.22, "Protection of Safeguards Information: Specific Requirements."

Reactive Inspections

Reactive inspections are conducted in response to allegations, previous inspection nonconformances and/or violations, reports submitted in accordance with 10 CFR Part 21 or 10 CFR 50.55(e), or other information indicating the possibility that vendors are not meeting regulatory requirements. Reactive inspections verify that vendors of basic components have developed and implemented adequate procedures and controls to evaluate and correct conditions adverse to quality. In response to allegations, the vendor inspection staff conducts reactive inspections to verify the validity of any declaration, statement, or assertion of impropriety or inadequacy associated with NRC-regulated activities involving a vendor-supplied product or service. During these inspections, the vendor inspection staff evaluates the effectiveness of the vendor's QA program and procedures, as it relates to the reported problem.

The vendor inspection staff also supports regional requests in response to events at licensee facilities. Inspections of vendors have been conducted in support of regional reactive inspections where the focus has been on the failure of safety-related systems, structures, or components.

When the vendor inspection staff receives information that questions a vendor's ability to provide quality components, the following criteria are used to determine the need to perform a reactive versus a routine inspection:

- Involved loss of a safety function at an operating reactor site where a vendor issue was identified as a root cause.
- Involved a major deficiency in design or dedication involving potential generic safety implications.
- Led to a significant issue that affected/could affect closure of ITAAC.
- Involved counterfeit, fraudulent, or suspect items that caused or could have caused a failure of a safety system.
- Involved a fabrication or construction deficiency involving potential generic implications.
- Involved a major deficiency in the design, function, or traceability of a critical digital asset.
- Involved repetitive and frequent failures of components provided by a specific vendor (i.e. as evident by regulatory notifications).

- Involved a reported defect that failed to provide an appropriate technical evaluation to address the scope of the identified concern.

Routine and reactive inspections can be announced or unannounced. For announced inspections, 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. For unannounced inspections, the vendor or any member of the vendor organization is not notified by the inspector or any member of the NRC staff until the inspectors arrive at the vendor's facility or at the site where the inspection is to be conducted.

8.0 Enforcement

The NRC's Enforcement Policy governs the processes and procedures for the initiation and review of nonconformances and/or violations of NRC requirements, and the NRC Enforcement Manual contains implementation guidance. The NRC's OE issues both documents. Potential violations identified through inspection activities are processed in accordance with the NRC's Enforcement Policy. The NRC's Enforcement Policy is located on the NRC's public website at: https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. NRR's Office Instruction NRR COM-104, Revision 2, "NRR Interfaces with the Office of Enforcement," provides information on the interface between NRR and OE.

Vendors supplying basic components to the nuclear power industry are subject to the following regulations:

- 10 CFR Part 21
- 10 CFR 50.5 and 10 CFR 52.4, "Deliberate Misconduct"
- 10 CFR 50.7 and 10 CFR 52.5, "Employee Protection"

In addition, applicants and licensees contractually impose the following regulations, as applicable, on their vendors:

- Appendix B to 10 CFR Part 50
- 10 CFR 50.55a, "Codes and Standards"
- 10 CFR 50.55(e)
- 10 CFR 73.54, "Protection of Digital Computer and Communication Systems and Networks"

For vendors that hold SGI, the following apply:

- 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements"
- 10 CFR 73.22
- NRC Order No. EA-07-231, "Order Imposing Safeguards Information Protection Requirements and Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information," dated September 12, 2007 (applicable to addressed design certification applicants)

A vendor that fails to comply with the above regulations is subject to the following enforcement actions:

- non-cited violations (NCVs)
- notices of violation (NOVs)
- notices of nonconformance (NONs)

The NRC issues NONs and NOVs to vendors for failures to meet the requirements of Appendix B to 10 CFR Part 50 or 10 CFR Part 21, respectively. Failure to meet an NRC Order, applicable to that vendor, would also be an NOV. In addition, the NRC also issues NCVs to vendors. When applicable, the NRC may also issue an Unresolved Item (URI). URIs are for issues which more information is required to determine if it is acceptable, if it is a finding, or if it constitutes a deviation or violation. These issues may require additional information from the vendor or cannot be resolved without additional guidance, clarification, or interpretation of the existing guidance.

Vendors' NONs and NOVs are assessed annually to identify industry weaknesses and are communicated through the VIP's Strategy for Enhanced Vendor Outreach and Communications. The target audience for this strategy includes licensees, license or design certification applicants, and vendors. The strategy also includes hosting workshops on vendor oversight every two years, which are widely attended and generate significant dialogue with the vendor community about technical and regulatory issues. Additionally, the vendor inspection staff will hold virtual town hall meetings the years following the biennial workshop, or as necessary, to engage with external stakeholders to discuss any current issues of importance to the nuclear industry, and to provide guidance and clarification, as necessary. The goal of the virtual town hall meeting is to keep the external stakeholders informed on activities related to vendor inspection, quality assurance, etc. The number of virtual town hall meetings will depend on the number of significant topics or issues as well as the availability of NRC resources.

An NCV is a nonrecurring, non-willful, Severity Level IV violation dispositioned under the traditional enforcement process that is not subject to formal enforcement action if the vendor places the violation in its corrective action program to address recurrence and restores compliance within a reasonable period of time. Inspectors document NCVs in the inspection report, but the NRC does not request a response from the vendor regarding the noncompliance.

An NOV is the official notification of a failure to meet the NRC's regulatory requirements (e.g., 10 CFR Part 21) while an NON is the official notification to a vendor of a failure to meet contract requirements related to NRC activities (e.g., Appendix B to 10 CFR Part 50) where the NRC has not placed requirements directly on the vendor. For NOVs and NONs, the NRC requests the vendor to respond to the issue and (1) discuss the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and results achieved; (3) the corrective steps that will be taken to avoid further noncompliance; and (4) the date when the corrective actions will be completed.

9.0 Coordination Activities and Industry Interactions

The vendor inspection staff communicates both internally within the NRC and externally with industry stakeholders as described below.

Communication within the NRC on Vendor Inspection Activities

The vendor inspection staff interacts with the technical branches within NRR divisions that provide technical expertise in civil, mechanical, electrical, instrumentation and control, geotechnical, and chemical and materials engineering for all structures, systems, and

components (SSCs) for new and operating nuclear power reactors manufactured and procured through licensee engineering procurement contracts. These technical experts participate in vendor inspections with qualified vendor inspectors to ensure that the quality of safety-related SSCs is such that there is reasonable assurance that the SSCs will perform their intended safety function when installed in nuclear power plants.

The vendor inspection staff also interacts with OE on issues associated with allegations and with the NRC's Region II staff to coordinate the agency's resources necessary to support inspections of targeted and non-targeted ITAAC-related activities at vendors manufacturing safety-related components and modular assemblies for new reactor construction. Coordination includes effectively communicating any nonconformances and/or violations identified at the vendor facility. Inspection samples of ITAAC-related activities, as well as any relevant nonconformances and/or violations, are documented in the inspection reports. Appendix D of this plan provides the strategy used by the vendor inspection staff for coordinating vendor inspections with the appropriate Region II staff.

In addition, as part of the vendor inspection staff's effort to enhance communications, when potential nonconformances and/or violations at vendor inspections affect an operating reactor(s), the vendor inspection staff will include the applicable NRR Project Managers on the inspection report distribution.

Furthermore, the vendor inspection staff participates in activities associated with the following organizations:

- American Nuclear Society (ANS)
- American Society of Mechanical Engineers (ASME)
- Institute of Electrical and Electronics Engineers (IEEE)

Communication and Engagement with Stakeholders on Vendor Inspection Activities

The vendor inspection staff interacts with the following external organizations:

- Electric Power Research Institute (EPRI)
- Committee on Nuclear Regulatory Activities (CNRA)
- Nuclear Energy Institute (NEI)
- Nuclear Procurement Issues Corporation (NUPIC)
- Nuclear Utility Group on Equipment Qualification (NUGEQ)

Electric Power Research Institute - Joint Utility Task Group

The vendor inspection staff interacts with EPRI by attending the EPRI-Joint Utility Task Group (JUTG) procurement forum. During these meetings, the vendor inspection staff makes a presentation on NRC perspectives on vendor performance issues. The EPRI JUTG provides a forum for utility procurement personnel to candidly exchange information and to work together to address common industry issues related to the procurement of materials and services.

Committee on Nuclear Regulatory Activities

CNRA is an international committee made up of senior representatives from regulatory bodies. It was created in 1989 to guide the NEA program concerning the regulation, licensing and inspection of nuclear installations with regard to safety. The CNRA's main tasks are to: (1) exchange information and experience among regulatory organizations; (2) review developments which could affect regulatory requirements; and (3) review current practices and operating experiences.

The Working Group on Supply Chain (WGSUP) provides a mechanism for nuclear safety regulators and technical support organizations (TSOs) to share their knowledge in making policy and licensing decisions related to the supply chain. The WGSUP seeks to facilitate an active and timely exchange of commendable practices as well as lessons learned to help regulators perform these functions more effectively and efficiently. Although the focus of the group is on those portions of the supply chain used to support the construction and operation of power reactors, the WGSUP may draw on lessons learned from other areas if they are relevant to safety.

The vendor inspection staff participates in vendor inspections led by foreign regulatory authorities to provide additional insights relative to the effectiveness of licensee (both foreign and domestic) oversight of these international vendors.

Nuclear Energy Institute

The vendor inspection staff occasionally interfaces with NEI to discuss mutual items of interest (i.e., commercial-grade dedication, 10 CFR Part 21 implementation, procurement, software dedication, and vendor oversight). These interactions ensure that the agency and industry concerns are both addressed during the development of vendor and supplier guidance documents. In addition, the staff has endorsed several NEI documents related to quality and vendor oversight which can be found on the NRC’s QA web site.

Nuclear Procurement Issues Corporation

The vendor inspection staff routinely observes NUPIC joint utility audits in order to verify the effectiveness of the NUPIC audit.

The typical NUPIC audit scope is to determine the overall acceptability and verify the effective implementation of a vendor’s QA requirements through use of the NUPIC audit checklist, which is structured in accordance with the requirements of Appendix B to 10 CFR Part 50, ASME NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications,” and 10 CFR Part 21. While observing the audit, the NRC inspectors sample and review audit checklist evaluation areas, observe NUPIC’s review of the implementation of the vendor’s QA program, and evaluate the adequacy of NUPIC’s process for documenting audit findings in the associated trip report. The vendor inspection staff continuously interacts with NUPIC auditors during the NUPIC audit observation. If the vendor inspection staff observes any potential violations of regulations during the audit and the NUPIC auditors fail to act on the issue, the vendor inspection staff will bring the issue to the attention of the NUPIC utility lead auditor for resolution. The results of the NUPIC observation are documented in a publicly available trip report.

The vendor inspection staff observes approximately two NUPIC audits a year. In September 2012, the vendor inspection staff evaluated the NRC’s oversight of NUPIC to make sure the

interactions meet current regulatory standards and the process is appropriately holding licensees accountable for their oversight of vendors. The results from that evaluation concluded that the vendor inspection staff's current interactions with NUPIC (1) are effectively communicating regulatory concerns/initiatives and industry issues between organizations and has served as a catalyst for several NUPIC process improvements, and (2) provide valuable insights into vendor performance issues used as a key parameter in the NRC's criteria for selecting vendors for inspection. However, in order to improve the NRC's oversight of the NUPIC audits, the vendor inspection staff will supplement the current biannual observations of NUPIC audits with observations of limited scope audits (LSAs). An LSA is a supplemental audit scheduled outside the normal NUPIC audit frequency focused at specific performance deficiencies.

NUPIC, in conjunction with NEI, formed an industry team, consisting of licensees and suppliers, to monitor activities by the International Laboratory Accreditation Cooperation (ILAC) as they relate to industry's use of the ILAC accreditation process in lieu of performing a commercial-grade survey as part of commercial-grade dedication process. NUPIC plays a central role in the continued oversight activities, and a NUPIC member leads or participates in the observations of peer evaluations of an Accrediting Body and the associated assessments of calibration and testing laboratories to verify that the ILAC accreditation process continues to be implemented consistent with ILAC's requirements and procedures.

Up to three times per year, the vendor inspection staff participates in NUPIC meetings during which the vendor inspection staff provides an update on on-going NRC vendor inspection activities and shares the results of recent NRR NUPIC audit observations. The NRC plans to continue its oversight of the NUPIC process in order to further enhance the NUPIC joint utility audit program and increase the alignment between NUPIC and the agency regarding the conduct of vendor inspections.

Nuclear Utility Group on Equipment Qualification (NUGEQ)

The vendor inspection staff routinely attends the annual NUGEQ meetings and has made presentations and participated in discussions on a wide range of topics that involve equipment qualification from a vendor perspective. Among the topics presented at recent meetings were: maintaining qualification for commercially dedicated equipment; reverse engineering; design verification versus qualification; and challenges in qualifying first-of-a-kind equipment. The vendor staff has also presented summaries of EQ issues identified during recent vendor inspections.

10.0 Communication and Outreach

Licensees and applicants are ultimately responsible for the safety of the facilities licensed by the NRC. As such, they must ensure that their vendors understand and effectively implement the applicable regulations. The vendor inspection staff's efforts to improve communication and outreach with these stakeholders enhances the NRC's commitment to openness, efficiency, and clarity. The vendor inspection staff developed the Strategy for Enhanced Vendor Outreach and Communications (see Appendix C to this plan). The purpose of this strategy is to establish and communicate the NRC's plan to enhance outreach and communications with vendors supplying materials, equipment and services for both operating and new reactors. The vendor inspection staff will update this strategy as necessary as part of the annual VIP self-assessment process.

Additionally, in order to better facilitate communication and outreach activities with stakeholders, the NRC established the following goals for announcement letters, inspection plans, inspection reports, and acknowledgment letters:

(1) Notification of Inspection: 30 calendar days before the start of the inspection unless the inspection is unannounced. Notification can be made either by email, phone, or in person. In cases where the need for the inspection arises (i.e., allegation, testing schedule, and/or specific vendor activity) less than 35 days before the inspection start date, issue the Announcement Letter within five calendar days of being notified of the need for the inspection. In cases where the need for the inspection arises less than five calendar days, issue the Announcement Letter prior to inspection.

    Applicants, and/or vendors should not be notified of the NRC's plans to perform an inspection at the applicant, and/or vendor's facility prior to 60 days before the start date of the inspection, except in limited cases (e.g., international inspections, etc.) as previously discussed with and approved by the IQVB Branch Chief.

(2) Inspection Plans: Seven calendar days before the start of the inspection. In cases where the need for the inspection arises (i.e., allegation, testing schedule, and/or specific vendor activity) less than seven calendar days before the inspection start date, issue the inspection plan prior to the inspection. Inspections plans are for the inspection team only and are not made public or shared with the vendors being inspected (Note: inspection plans are non-public).

(3) Inspection Reports: 45 calendar days after the exit meeting, extended until the next business day if the 45 days end on a weekend or holiday.

(4) Acknowledgment Letters: 30 calendar days after the vendor's last communication is entered into Agencywide Documents Access Management System (ADAMS).

Additional Methods of Communication Regarding Vendor Issues

When issues are identified regarding materials or services supplied by a vendor to a specific licensee, the vendor inspection staff should consider adding the appropriate NRR Project Manager, Resident Inspectors, and/or licensee contacts to the inspection report distribution list. Additionally, the vendor inspection staff may notify licensees about specific vendor-related issues via direct written correspondence or generic communications. If significant weaknesses in oversight are observed, the NRC staff may choose to engage directly with the lead licensee on a case by case basis.

11.0 Performance Metrics

The vendor inspection staff uses performance metrics to evaluate the success of the VIP. Measurement of these metrics allows the vendor inspection staff to do the following:

- Identify performance issues and determine their significance
- Adjust resources to focus on significant performance issues
- Take necessary regulatory actions for significant performance issues
- Effectively communicate inspection results to stakeholders
- Make program improvements based on stakeholder feedback and lessons learned

Appendix E, attached to this document, provides a detailed description of the performance metrics associated with the goals described in Section 2.0 of this plan.

Each metric in Appendix E includes its definition, the criteria to determine whether it is met, and a cross-reference to the VIP goals that the metric is intended to support.

12.0 Knowledge Management & Training

Knowledge Management

Knowledge management and vendor inspector training are critical for effectiveness of the VIP. The NRC's knowledge management process includes several training documents (that are defined by community of practice) and SharePoint sites dedicated to vendor inspector qualification and continuing training.

To support the continuing development of the VIP, the vendor inspection staff also maintains a SharePoint site to share information on the various activities performed in the VIP, including 10 CFR Part 21 issues, the issues of other organizations (e.g., NUPIC, ASME), and unique or complex inspection findings. The vendor inspection staff uses these knowledge management systems to ensure the availability of information related to vendor inspections. The IQVB Branch Chief and senior staff actively participate in the mentoring of new staff in support of the vendor inspection and technical reviewer qualification programs.

Vendor Inspector Training and Qualification Activities

As a part of the overall VIP, active involvement by vendor inspection staff members at all experience levels is critical. Specifically, training and qualification monitoring by senior staff, combined with a cohesive system of knowledge transfer from experienced vendor inspection staff to trainees, ensures a continual cadre of knowledgeable, well-trained, and fully qualified vendor inspectors. Appendix C-8, "Vendor Inspector Technical Proficiency Training and Qualification Journal," of NRC's IMC 1245, "Qualification Program for New and Operating Reactor Programs," contains the training and qualification requirements for NRR vendor inspection staff performing inspection activities.

Competency Areas

Vendor inspector qualification requires the completion of numerous activities. Each activity is designed for the inspector to learn information or a skill that will be important to performing as a vendor inspector. Completion of all qualification training and activities (including those for basic-level general proficiency, and technical proficiency-level) demonstrates that an individual possesses the knowledge necessary to become a successful vendor inspector. Full vendor inspector qualification indicates that the individual has completed all required training and qualification activities. Vendor inspector qualification allows an individual to independently perform the full scope of inspection-related activities with routine oversight and supervision.

In general, nonqualified inspectors will receive specific tasks to accomplish during these activities, but they will have an experienced inspector assigned as a mentor to provide guidance on the necessary tasks as well as to assist with any questions or concerns related to the activity. In this manner, junior inspectors will gain knowledge from senior staff, meaningfully participate in the VIP, and fulfill their on-the-job training requirements.

Methods for Completing Qualification

In accordance with IMC 1245, previous work experience and training may be accepted as evidence that an individual already possesses the required knowledge or skills achieved by completing parts of the vendor inspection qualification program. The Division of Reactor Oversight (DRO) Director has the authority to accept previous experience and training as an alternate method for meeting the requirements. Justification for accepting previous experience and training to meet program requirements must be determined by the IQVB Branch Chief and documented in the individual's qualification journal. In accordance with IMC 1245, an individual who was previously qualified as an NRC inspector must complete the additional specific training and qualification requirements for vendor inspection specified in Appendix C-8 to IMC 1245. Inspectors need not repeat previous equivalent training requirements, and the qualification journal will indicate credit for previous similar training. A fully qualified inspector is not required to complete another qualification board for vendor inspector qualification.

The IQVB Branch Chief has the flexibility to determine when an employee is ready for an oral qualification board. For example, this determination can be done by conducting a mock oral qualification examination or by an interview. The IQVB Branch Chief will confirm that all qualification requirements have been met and will convene a qualification board to examine the employee's regulatory knowledge, skills, and ability to perform the functions independently. If an employee passes a board and then completes a different position-specific qualification, that employee shall only be tested on the requirements of the subsequent position-specific qualification program. Successfully completing a qualification board will ensure that the inspector understands the role of the agency, the inspection program, and the inspector's responsibilities. Final vendor inspector qualification is provided through certification by the NRR Office Director.

Post-qualification Activities

Qualified vendor inspectors maintain their qualification as required in Appendix D-1 to IMC 1245. Appendix D-1 defines the requirements for post-qualification and refresher training for qualified vendor inspectors.

Post-qualification training is defined as the training received after qualification to supplement or enhance the professional development of the vendor inspection staff. All qualified vendor inspectors are required to participate in on-going post-qualification training to maintain and enhance their knowledge and skills. This training includes elements of both continuing and refresher training as defined in IMC 1245-03. Continuing training includes Vendor Inspector group training conducted at least three times per fiscal year that concentrates on core competencies and lessons learned.

The IQVB Branch Chief and other office management will evaluate the need for additional continuing and refresher training necessary to meet the requirements of Appendix D-1 to IMC 1245, as necessary. Additionally, the IQVB Branch Chief will monitor inspector performance through periodic observations of inspections.

13.0 Resource Management

As a result of the development of the enhanced VIP in 2007, and within the framework of IMC 2507, the vendor inspection staff conducts vendor inspections to a level commensurate with the number of routine and reactive inspections specified in the NRR operating plan on a yearly

basis. The VIP continues to use the NRR operating plan, in conjunction with any additional SRMs, or other form of Commission or NRR management direction, to plan and manage resources for the conduct of vendor inspection activities.

In terms of resource management, the objective of the VIP is to ensure that the NRC has an adequate number of knowledgeable, well-trained, and qualified vendor inspectors to meet the forecasted workload of vendor inspections. The vendor inspection staff supports this objective by:

- providing timely training and qualification for vendor inspectors;

- periodically looking ahead to anticipate the upcoming workload in terms of planned and potential unplanned or reactive inspections;

- routinely assessing policy and key technical issues that may have an impact on the VIP;

- establishing relationships between the vendor inspection staff and various outside organizations (e.g., NUPIC, ASME, NEI) such that routine interactions can be undertaken as efficiently as possible with maximum results; and

- ensuring that the composition of the vendor inspection team represents the best combination of senior vendor inspectors, technical experts, and vendor inspectors-in-training available, given the nature of the vendor to be inspected, including the leverage of contract resources and technical expertise from other divisions, as necessary.

In addition, the vendor inspection staff gains insights from inspections performed by peer regulators (e.g., CNRA) and industry auditors (e.g., NUPIC) to help inform the prioritization of vendor inspection resources. These insights are another input into the selection process for vendor inspections which also considers other items, including but not limited to the safety significance of the component or service, operational and construction experience (domestic and foreign), construction inspection program insights, and licensee and applicant procurement plans.

NRR currently makes the following resource assumptions about vendor inspection activities in order to support appropriate resource loading for the VIP:

- assumptions for typical vendor inspections (including preparation and documentation):

  – 200 hours for the team leader
  – 120 hours per team member
  – one team leader and three team members for each inspection
  – 560 hours total per inspection

- assumptions for typical engineering design verification inspections (including preparation and documentation):
  – 350 hours for the team leader
  – 275 hours per team member
  – 2 week inspection
  – each inspection is made up of one team leader and five to eight members for each inspection

– 2,000 hours total per inspection

For the majority of the inspection procedures executed by the vendor inspection branches, the resources related to direct inspection effort for each team member are estimated to be between 40 and 80 hours, depending on the complexity of the activity being inspected and the scope of the inspection.

The vendor inspection staff assembles inspection teams based on: (1) the estimated complexity and associated level of effort for each inspection; (2) the knowledge level and current workload of each member of the inspection team; (3) the need for technical expertise from contract or technical division sources, or both; (4) the usefulness of the inspection as a training activity for junior inspectors; and (5) the potential burden placed upon the vendor from having a larger inspection team. By taking all of these factors into consideration, the vendor inspection branches are able to assemble the most effective teams available, while also providing for training opportunities and continued learning.

The vendor inspection staff's workload is periodically assessed to ensure that the appropriate level of resource loading is being applied to each vendor inspector, commensurate with his or her experience level, special interests, unique qualifications, and other factors. This ensures that vendor inspection resources are used as efficiently and effectively as possible.

14.0 Implementation Schedule and Assessment

As described in referenced sections of the VIP Plan, the vendor inspection staff performs the following on-goingongoing actions:

Frequency	Action	VIP Plan Section
On-going	Manage an internal database to store vendor information and to facilitate vendor communication and selection	Appendix A
On-going	Maintain a list of vendors	Appendices A & C
Quarterly	Review vendor selection data and update, as necessary	Appendix B
Annually	VIP Self-Assessment	All
Annually	Provide an electronic newsletter to be sent to interested vendors	Appendix C
Biennially	Establish workshops on vendor oversight	Appendix C
Biennially or as necessary	Host town hall meetings with stakeholders	Appendix C

SUBJECT: Vendor Inspection Program Plan Revision 27 DATED AUGUST 31, 2022

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APPENDIX A

STRATEGY FOR VENDOR IDENTIFICATION

PURPOSE

The purpose of this document is to establish and communicate the U.S. Nuclear Regulatory Commission's (NRC's) strategy for identifying vendors of safety-related parts and services for new and operating nuclear power plants. Application of the strategy will result in a listing of vendors that will enable the NRC to identify and plan its inspection and outreach activities.

BACKGROUND

Licensees and applicants are responsible for the safety of facilities licensed by the NRC. As such, they are responsible for ensuring that their vendors meet applicable regulations and requirements (both technical and quality) in purchase documents. In order to ensure that licensees are meeting the regulatory requirements in this area, the NRC inspects vendors to evaluate their conformance with technical and quality requirements. The NRC also performs direct oversight of licensees by observing Nuclear Procurement Issues Corporation (NUPIC) audits.

To ensure the efficient and effective use of NRC resources, the NRC has developed a methodology to select vendors for inspection and a strategy to enhance outreach and communications with vendors (see Appendix B, "Strategy for Vendor Selection," and Appendix C, "Strategy for Enhanced Vendor Outreach and Communications," to this document). This vendor identification strategy will support those efforts.

VENDOR IDENTIFICATION STRATEGY

Currently, the NRC obtains information about vendors from the following sources:

- reports under Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation" 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors"; and 10 CFR 50.73 reports, "Licensee Event Report System"

- interaction with industry and standards organizations such as NUPIC, the Nuclear Industry Assessment Committee, and the American Society of Mechanical Engineers

- formal and informal communication with licensees, applicants, and engineering, procurement, and construction contractors

- allegations

- approved supplier lists of licensees and vendors

The vendor inspection staff manages an internal database to store vendor information and facilitate vendor communication and selection.

– The vendor inspection staff populates the database from the above-mentioned sources.

– The database contains the following information for each vendor (this list may be expanded to support the vendor selection methodology):

  - name
  - address
  - telephone number
  - point of contact (e.g., Quality Assurance Manager) and email address
  - scope of supply (e.g., Class I piping, electric motors)
  - comments

CONTINUOUS IMPROVEMENT

The vendor inspection staff tracks the effectiveness of its vendor identification and outreach activities by considering the usefulness of the information gathered. The vendor inspection staff will consider the strategy's effect on inspection planning and vendor outreach and revisit and revise this strategy, as necessary. This strategy is a living document and as such the vendor inspection staff will update and modify it to suit the changing needs of the NRC and at a minimum, it will be reviewed on an annual basis.

APPENDIX B

STRATEGY FOR VENDOR SELECTION

PURPOSE

The purpose of this document is to describe the risk-informed Vendor Inspection Program (VIP) strategy that the Quality Assurance and Vendor Inspection Branch (IQVB) uses to help prioritize vendors for inspection by the U.S. Nuclear Regulatory Commission (NRC) staff. This strategy is applicable to vendors that are currently supplying safety-related material, equipment, and services to the U.S. nuclear power industry. The strategy is a program assessment tool that establishes the basis for the vendor selection process and ensures the integrity of the nuclear supply chain for basic components.

BACKGROUND

Inspection Manual Chapter (IMC) 2507, "Construction Inspection Program: Vendor Inspections," contains general staff guidance on selecting vendors that are supplying safety-related material, equipment, and services for NRC inspection. The strategy contained in this document expands upon the guidance in the IMC and helps to ensure an efficient and effective use of NRC resources allocated for vendor inspection.

VENDOR SELECTION STRATEGY

As described in the "Strategy for Vendor Identification," (Appendix A of the VIP Plan), the vendor inspection staff maintains an internal database to store vendor information and facilitate vendor communication to assist with the vendor selection strategy. The VIP provides guidance for effective oversight of the nuclear supply chain by way of fixed and qualitative factors. Fixed factors are the objectives of the VIP activities which dictate the overarching goals of the NRC's statutory mission of protecting public health and safety, promoting the common defense and security, and protecting the environment. Qualitative factors are those elements related to VIP activities which verify that reactor applicants and licensees are fulfilling their regulatory obligations with respect to ensuring the integrity of the supply chain. The qualitative factors are administered and evaluated by the Vendor Strategists. The Vendor Strategists collect data, detailed below, and present the findings to IQVB management for making a final determination on vendor inspection selection. Management discretion will be responsible for the majority of the vendors selected (about 75%), while the remaining (about 25%) will be based on the Vendor Strategists' recommendations.

MANAGEMENT DISCRETION

Management discretion considerations in selecting the vendors to be inspected include, but are not limited to: safety culture issues, susceptibility to counterfeiting or cybersecurity issues, targeted reviews of inspections, tests, analyses, and acceptance criteria (ITAAC), fabrication of major plant modifications, Regional management input on potential vendor issues, and risk insights to the extent practicable.

Management discretion considerations also include reactive inspections. Reactive inspections are conducted in response to allegations, previous inspection findings, reports in accordance with 10 CFR Part 21, "Reporting of Defects and Noncompliance" and/or 10 CFR 50.55(e), and other information sources potentially indicating that NRC requirements are not being met. The need to perform reactive vendor inspections is determined outside the scope of this strategy.

Fixed factors that the Vendor Strategists prepare for management review when applying discretion include, but are not limited to:

- Inadequate/questionable response to previous NRC inspection findings in the response letter
- Susceptibility to counterfeiting or cybersecurity issues
- Reviews of targeted ITAAC*
- Current or past allegations
- Safety Conscious Work Environment (SCWE), safety culture issues, open chilling effect letters
- Confirmatory orders
- Major plant modifications, input and request from regional management
- Issues with 10 CFR Part 21
- International interest (Multinational Design Evaluation Programme/Vendor Inspection Cooperation Group (MDEP/VICWG))

* Targeted ITAAC represent those that provide the highest value of inspection optimization of NRC resource and inspection planning, while providing reasonable assurance that a significant construction flaw will not go undetected.

VENDOR STRATEGISTS

The IQVB Branch Chief assigns Vendor Strategists to conduct on-going VIP Plan activities to assess vendors for proposed selection. The Vendor Strategists are responsible for management of the internal database (Appendix A of the VIP Plan) and the use of qualitative risk-informed research to assess and select vendors for potential vendor inspection. Before the vendor evaluation and selection process, the Vendor Strategists will gather information related to vendors from various sources which include but are not limited to: (1) representative leads from technical review groups (TRGs), Allegations Team, the Electric Power Research Institute (EPRI) Joint Utility Task Group (JUTG), the American Society of Mechanical Engineers (ASME), Nuclear Procurement Issues Corporation (NUPIC), the Nuclear Energy Institute (NEI) and others (See Figure 1 below, “Organization Chart”); (2) list of non-selected vendors from previous vendor planning meetings; and (3) findings review panel (FRP) recommendations made by vendor inspection team leads. As part of the research targeting process, the Vendor Strategists will review and evaluate qualitative factors that include, but are not limited to:

- Safety significance of the item/component/service
- Frequency of safety significance of problems identified (number of licensees affected/performance history of vendor)
- Results from past inspections
- Information received from TRGs, Licensee Event Reports and other NRC organizations
- Information received from NUPIC, JUTG and/or other exterior organizations
- Vendor Quality Assurance (QA) Program Strength:
  a. History (vendor inspection findings, Notice of Violations (NOVs) and Notice of Nonconformances (NONs), corrective action response history, 10 CFR Part 21 notifications, NUPIC findings, Operational Experience (OpE) e-mails, industry issues, etc.)
  b. Production Dynamics Indicators (QA program changes, first time nuclear supplier, ASME Certificate Holder, foreign supplier, etc.)

- Product Impact:

a. Level of Technology (Complexity of manufacturing process, reverse engineering, new products (e.g., first-of-a-kind), new manufacturing process (example – additive manufacturing), new/emerging technology)
b. Component System Criticality (ranking of safety-related and ASME pressure retaining/safety-related and non-ASME components, risk-significance, etc.)

The Vendor Strategists will document the researched vendor information for each vendor assessed in a tabular format to support inspection significance and associated risk (high probability and high consequence).

Here is an example of a tabular target research vendor information:

Vendor	Scope	NRC Inspection & Findings	NUPIC Audit & Findings	Part 21 Reports	Industry Issues	Product Impact	Recommendation
ACME Electric Company 5454 St. Charles Avenue, Washington DC 20012	ASME QSC manufacturer of ferrous and non-ferrous welding material including utilization of unqualified source materials	None	None	None	None	Low complexity Low Risk-significance	Management Discretion

Target Research Information:

1. ACME Electric Company is an Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” supplier with an ASME Quality System Certificate supplying safety-related and ASME certified welding materials throughout the commercial nuclear industry
2. No prior NRC inspection, hence, no history of previous NONs or NOVs
3. Since no prior NRC inspection, no history of corrective action response history
4. No 10 CFR Part 21 issued by the vendor nor by a licensee
5. No NUPIC audits have been conducted at either of the above locations, since ACME Electric Company is not listed on NUPIC’s database as an approved vendor
6. No industry issues
7. Low complexity of manufacturing process
8. Safety-related and ASME product that may be used for fabrication of pressure retaining components
9. Risk-significance of weld wires and electrodes is very low (safety-related low safety significant)
10. ACME Electric Company may have been independently audited by utilities or by ASME Certificate Holders.

VENDOR SELECTION DETERMINATION

During the vendor inspection planning meeting, the Vendor Strategists will present to the IQVB Branch Chief the researched vendor information and provide justification as to why a particular vendor is selected and proposed for vendor inspection. The IQVB Branch Chief will use the Vendor Strategists' information and apply management discretion to make an informed decision as to which vendors will be selected and assigned to the vendor inspection master schedule. The non-selected vendors will be documented and maintained by the Vendor Strategists for potential future selection and recommendations.

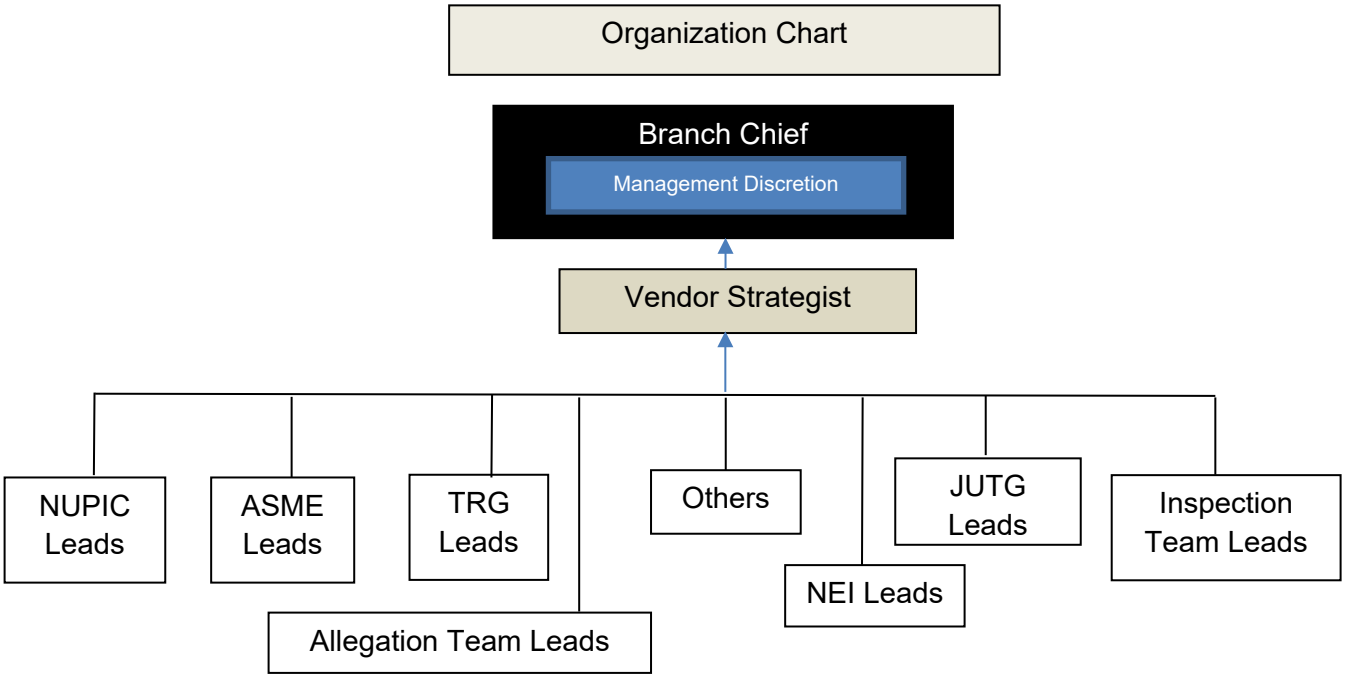

FIGURE 1

CONTINUOUS IMPROVEMENT

The vendor inspection staff continually evaluates this strategy to assess whether changes need to be made to the decision factors. The vendor selection strategy will be reviewed on an annual basis prior to a vendor inspection planning meeting and updated in accordance with Appendix A, "Strategy for Vendor Identification." This strategy was last updated in May 2020.

APPENDIX C

STRATEGY FOR ENHANCED VENDOR OUTREACH AND COMMUNICATIONS

PURPOSE

The purpose of this document is to establish and communicate the U.S. Nuclear Regulatory Commission's (NRC's) strategy to enhance outreach and communications with vendors supplying safety-related parts and services.

AUDIENCE

The target audience for this strategy includes licensees, license or design certification applicants, and vendors. Licensees and applicants are ultimately responsible for the safety of the facilities licensed by the NRC. As such, they must ensure that their vendors understand and implement applicable regulations. The vendor inspection staff's efforts to improve outreach and communications with these stakeholders serves to enhance the NRC's commitment to openness, efficiency, and clarity.

BACKGROUND

This strategy lists key areas of improvement that enhance current vendor inspection staff efforts in communication and outreach and identifies key trending data to be collected to measure the effectiveness of these enhancements. The preparation of a formal plan also provided the staff an opportunity for more strategic focus and coordination.

CURRENT COMMUNICATIONS AND OUTREACH TOOLS

The NRC currently uses the following communications and outreach tools:

- Public web Site: The vendor inspection public web site (http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html) gives vendors a venue to obtain useful information on many topics, including the following:
  - key regulations, such as Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance"
  - inspection procedures
  - inspection reports
  - information on commercial-grade dedication
  - presentations from past NRC workshops and town hall meetings
  - NRC presentations at conferences attended by the NRC

- Workshops on Vendor Oversight: The NRC continues to host workshops on vendor oversight. The workshops continue to be successful and are excellent examples of NRC outreach. The workshops are widely attended and always generate significant dialogue with the vendor community about regulatory issues. Feedback through meeting comment forms is positive and stakeholders have requested additional workshops.

- Virtual Town Hall Meetings: The NRC will hold virtual town hall meetings the years following the biennial workshop, or as necessary, to engage with external stakeholders to discuss any current issues of importance to the nuclear industry, and to provide guidance and clarification, as necessary. The goal of the virtual town hall meeting is to keep the external stakeholders informed on activities related to vendor inspection, quality assurance, etc. The number of virtual town hall meetings will depend on the number of significant topics or issues as well as the availability of NRC resources.

- Participation in industry conferences and meetings: The vendor inspection staff continues to participate in related industry conferences and meetings such as the following:

  - American Society of Mechanical Engineers
  - Nuclear Utility Group on Equipment Qualification
  - Nuclear Procurement Issues Committee meetings
  - NRC's Regulatory Information Conference
  - Electric Power Research Institute Joint Utility Task Group meetings
  - International Laboratory Accreditation Cooperation process activities
  - Working Group on Supply Chain meetings, under the auspices of the Committee on Nuclear Regulatory Activities and the Nuclear Energy Agency
  - SMR Regulators' Forum
  - Nuclear Oversight Conference

KEY IMPROVEMENTS

The NRC implemented the following key improvements in outreach and communications:

- Improved the accessibility of the portions of the NRC's public web site that are relevant to vendor oversight.

  - The NRC created a link within the quick link box on the pages for new reactors and operating reactors.

- Created a page on the public web site that categorizes nonconformances and violations from NRC vendor inspection reports.

  - The NRC added a page with the 18 criteria from Appendix B to 10 CFR Part 50 and 10 CFR Part 21 so that vendors can select one of the criteria or 10 CFR Part 21 requirements and have all applicable inspection reports with nonconformances and violations in those areas listed.

- Created a frequently asked questions (FAQ) page on the public web site that includes questions received at vendor conferences and other NRC outreach meetings.

  - The FAQ provides a quick source of information and serves as a knowledge management tool.

- Provide an annual electronic newsletter for vendors.

  - The newsletter includes recent nonconformances and/or violations, potential rulemakings, upcoming conferences, operating experience and other useful

information. Stakeholders can sign up for the newsletter through the NRC's web site.

  - An NRC network announcement is issued when the yearly newsletter is posted.

- Continue biennial workshops on vendor oversight.

  - The NRC will continue to host a workshop every 2 years as one key forum for communication and outreach with vendors. The vendor inspection staff will continue to use comment cards to solicit feedback and seek recommendations for improving future workshops.

CONTINUOUS IMPROVEMENT

The vendor inspection staff will track the improved efficiency and effectiveness of its outreach and communications activities by assessing the usefulness of the information shared. Feedback forms from vendor workshops will include specific questions to obtain feedback on the usefulness of information shared. The vendor inspection staff will use the feedback to enhance future workshops.

To evaluate stakeholder interest and participation, the vendor inspection staff will use the number of attendees at the conferences to measure the level of interest and success of the conference. The vendor inspection staff will use feedback forms from vendor workshops to gauge stakeholder interest.

The vendor inspection staff will revisit and revise this strategy as necessary, and at a minimum, it will be reviewed on an annual basis. This strategy is a living document, and the staff will update and modify it to suit the changing needs of the NRC.

STRATEGY QUESTIONS AND ANSWERS

Q. *How can I access the NRC's web page for quality assurance and vendor oversight?*
A. You can access the vendor web page on NRC's public web site by going to http://www.nrc.gov and then clicking on New Reactors under the Nuclear Reactors tab. You will then see a link to "Quality Assurance for New Reactors" on that page.

Q. *What kind of questions will I see on the FAQ web page?*
A. The FAQ section on the vendor web page lists common questions and answers that presented at NRC conferences and workshops. It also lists questions and answers about relevant NRC regulations and inspections pertaining to vendors.

Q. *How do vendors sign up for the newsletter?*
A. To sign up to receive the vendor newsletter or to suggest future topics, please visit our Vendor Newsletter public web page.

Q. *Will there be any additional burden on the industry?*
A. No. The NRC's goal is to provide additional tools for the industry to use to be more cognizant of current NRC regulations. Vendors will be able to use the agency's public web site more efficiently to learn about current events and upcoming conferences and NRC workshops.

Q. *Will the NRC consider other options for outreach and communications that may be proposed by the industry and the public?*
A. The NRC constantly looks for ways to improve its communications with the public and will consider other options that will be beneficial.

Q. How *does the NRC plan to improve tracking and trending?*
A. The NRC plans to track and trend the questions received at its conferences and through its FAQs page to gauge the most common issues and concerns that vendors have. The vendor inspection staff will use this information to concentrate its efforts in identifying those issues that are hot topics. The vendor inspection staff plans to track and trend the vendors that attend NRC conferences and workshops. This will help the agency track industry interest in the topics being presented and inform its planning for future activities.

APPENDIX D

STRATEGY FOR COORDINATING VENDOR INSPECTIONS

PURPOSE

The purpose of this Appendix is to document how the U.S. Nuclear Regulatory Commission's (NRC's) strategy for coordinating resources between the Office of Nuclear Reactor Regulation (NRR) and the Regional Offices to support NRC's Regional staff to support the (1) inspections, testing, analyses, and acceptance criteria (ITAAC) - related inspections of vendors manufacturing safety-related components and modular assemblies for new reactor construction, and (2) major digital instrumentation and controls (I&C) modifications approved under the Digital I&C Interim Staff Guidance (ISG)-06, Revision 2, Alternate Review Process (ARP) . Application of the strategy will result in the effective and efficient coordination of the agency's inspection resources allocated in the ITAAC and major digital I&C modification oversight process that will enable the NRC to facilitate the ITAAC closure process and development activities for safety-related digital I&C systems, respectively.

BACKGROUND

The NRC staff conducts inspections to review the licensee's construction activities as the licensee completes the applicable ITAACs. Guidance for these inspections is contained in Inspection Manual Chapter (IMC) 2503, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) Related Work." The Region II staff is primarily responsible for implementing the ITAAC inspection program. For major safety-related digital I&C system modifications reviewed under the digital I&C ISG-06, ARP, the NRC staff conducts inspections to verify licensee oversight of vendor development activities for safety-related digital I&C systems in accordance with the activities described in the licensee's vendor oversight plan (VOP). Guidance for these inspections is contained in IMC 2515, "Light Water Reactor Inspection Program Operations Phase," Appendix C, "Special and Infrequently Performed Inspections," which identifies Inspection Procedure (IP) 52003, "Digital Instrumentation and Control Modification Inspection." Staff from the NRC Region responsible for the plant undergoing the major digital I&C system modification leads these VOP implementation inspections with support from NRC Headquarter technical staff.

The NRC staff also conducts routine and reactive inspections to examine whether vendors of safety-related components or services have complied with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," as required under vendor procurement contracts with applicants or licensees. Guidance for these inspections is contained in IMC 2507, "Construction Inspection Program: Vendor Inspections." The NRR vendor inspection staff is responsible for implementing the vendor inspection program.

Currently, IMC 2507 contains general guidance for conducting NRC inspections of vendors supplying safety-related components and modular assemblies. The strategy contained in this Appendix expands upon the guidance in IMC 2507 and should help ensure the most efficient and effective coordination of NRC's resources.

VENDOR INSPECTION COORDINATION STRATEGY

The following steps will be implemented to ensure that vendor inspections associated with (1) new reactor construction are properly coordinated with appropriate Region II staff and (2) major safety-related digital I&C system modifications are properly coordinated with appropriate Regional and Headquarter staff:

a. The vendor inspection staff consistently updates its vendor inspection schedule based on the information collected through communications with:
    i. new reactor licensees and their engineering and procurement contractors; as well as the review of a list of recommended inspections of ITAAC-related safety-related components including modular assemblies fabricated at vendor sites provided by Region II staff; and
    ii. operating reactor licensees who have or intend to submit license amendment requests for safety-related digital I&C systems and their vendors responsible for developing these systems.

b. When a vendor's scope of supply includes ITAAC-related items, the vendor inspection staff will coordinate the inspection plan and request inspection support from Region II staff.

c. When planning for a vendor inspection of a safety-related digital I&C system that has been or is in the process of being reviewed under the ISG-06, ARP, the vendor inspection staff will coordinate the inspection plan and request inspection support from NRR I&C staff, and as applicable, inform the appropriate regional staff to provide the opportunity to observe or participate on the vendor inspection.

d. The NRR vendor inspection schedule is currently published on the vendor inspection SharePoint site.

e. Bi-Weekly vendor inspection schedule calls are conducted between the NRR vendor inspection and Region II inspection branch chiefs to discuss vendor inspections and resources for construction activities associated with Vogtle Electric Generating Plant Units 3 and 4.

    Topics of discussion during these meetings include but are not limited to:

    1. Update on any changes to the vendor inspection schedule, and coordination of Region II inspection resources.
    2. Update on confirmed Region II construction inspection resources.
    3. Discussion on any vendor issues identified onsite by the NRC resident inspectors Region II construction inspectors, or generic issues identified by the vendor inspection staff.
    4. Discussion on any identified ITAAC-related vendor inspection activities.
    5. Review of action items.

f. ITAAC-related inspections at facilities that are not controlled by the licensee shall be planned in coordination with the vendor inspection staff to ensure that the inspection is properly staffed and includes at least one qualified vendor inspector. These inspections will be licensee inspections, will be led by Region II, and will be conducted in accordance

with IMC 2503. Enforcement actions will be taken against the specific licensee as applicable.

g. Sample-based ITAAC inspection

While the scope of the NRC's inspection program is comprehensive, 100% inspection is neither necessary nor efficient when evaluating a vendor's performance. For this reason, NRC historically has relied on a sample-based inspection program.

For the AP1000 reactor design, between 10-15% of vendor-related ITAACs will likely be verified at the vendor facilities. The vendor inspection and Region II staff will interact with licensees and their agent(s) as applicable to determine which type test or qualification ITAAC will be inspected based upon testing at a vendor location. The vendor inspection staff in coordination with Region II staff will inspect a representative sample of these testing activities at a broad range of test vendor locations to verify programmatic quality controls associated with key test or qualification attributes are adequately implemented, the methodology used is sound, and that the same methodology is implemented for other ITAAC-related structures, systems, and components. The results of the vendor inspection, as described in the inspection report will support future closure verification of ITAAC.

i. Inspection Consolidation of Safety-Related Digital I&C System Development Activities:

The inspections of safety-related digital I&C system development activities will be consolidated based on the development phase. The vendor inspection staff should coordinate with NRR I&C technical staff to identify the appropriate vendor inspection timeline for the various phases of safety-related digital I&C development phases. Consideration should be given to which vendor activities require direct observation versus those that are documentation reviews. In general, an inspection should be conducted for earlier phases of the system development lifecycle (e.g., requirements and design phase) and one conducted for vendor testing activities (i.e., factory acceptance tests). The results of the vendor inspection, as described in the inspection report will support regional inspection activities conducted using IP 52003.

NEXT STEP

For each subsequent Reactor Design Center, a similar evaluation process will be conducted if modular construction is utilized.

APPENDIX E

VENDOR INSPECTION PROGRAM PERFORMANCE METRICS

VIP-O-1A **Accomplish DRO's (the U.S. Nuclear Regulatory Commission's Office of Nuclear Reactor Regulation, Division of Reactor Oversight) Established Number of Inspections per Fiscal Year**

Definition: Accomplish DRO's established number of inspections per fiscal year to capture a reasonable perspective of industry performance.

Criteria: Expect DRO to perform the required number of inspections established at the beginning of the fiscal year.

Goals: Effective, Open

VIP-O-1B **Completion of Annual Assessment of the Number of NOVs (Notices of violations) and NONs (Notices of Nonconformance)**

Definition: Perform an annual assessment of NONs and NOVs to identify generic industry issues and take corrective actions, as necessary. Corrective actions may include discussions at the vendor workshop, issuance of generic communications, and other activities.

Criteria: Expect industry attendance at vendor workshops and industry outreach meetings and through generic communications.

Goals: Objective, Open, Risk-Informed

VIP-O-2A **Obtain Feedback from Vendors After the Vendor Inspection**

Definition: The Branch Chief will solicit feedback from vendors on such aspects as the immediate inspection effort, vendor oversight, or NRC requirements and guidance.

Criteria: Expect stable or increasingly positive perception over time.

Goals: Effective, Open, Understandable

VIP-O-2B **Notification of Inspection**

Definition: Obtain data on the total number of inspections that were notified to the vendor within the timeliness goals stipulated in Section 10 of the Vendor Inspection Program (VIP) plan.

Criteria: Expect 90 percent of inspections to be announced to the vendor within the VIP's timeliness goals.

Goals: Effective, Open, Predictable

VIP-O-2C Inspection Plans are Timely

Definition: Obtain data on the total number of inspection plans issued within the timeliness goals stipulated in Section 10 of the VIP plan.

Criteria: Expect 90 percent of inspection plans to be issued within the VIP's timeliness goals.

Goals: Effective, Open, Predictable

VIP-O-2D Inspection Reports are Timely

Definition: Obtain data on the total number of inspection reports issued within the timeliness goals stipulated in Section 10 of the VIP plan and Inspection Manual Chapter 0617, "Vendor and Quality Assurance Implementation Inspection Reports," dated February 2020.

Criteria: Expect 90 percent of inspection reports to be issued within the VIP's timeliness goals.

Goals: Effective, Open, Collaborative, Predictable

VIP-O-2E Acknowledgment Letters Are Timely

Definition: Obtain data on the total number of acknowledgment letters issued within the timeliness goals stipulated in Section 10 of the VIP plan.

Criteria: Expect 90 percent of acknowledgment letters to be issued within the VIP's timeliness goals.

Goals: Effective, Open, Predictable

VIP-O-2F Inspection Results Accepted by Stakeholders

Definition: Track the total number of NOVs and NONs contested by vendors.

Criteria: Retract less than 10 percent of NOVs and NONs because they are successfully contested by the stakeholders.

Goals: Effective, Objective, Open, Predictable

VIP-O-3 Allegation Support

Definition: Achieve the timely submittal of allegation response documents.

Criteria: Conduct all support within the Allegation program timeliness goals. Support includes, but is not limited to, providing input for Allegation Review Board (ARB) materials, attending ARBs, providing input to Requests for Information, participating in phone calls with the Concerned Individual(s), providing input for closure and response after closure letters, etc.

Goals: Effective, Objective, Risk-Informed

VIP-O-4A Assessment of Trainee Qualifications

Definition: The Branch Chief assess inspectors-in-training for progress in achieving qualifications at least three times per fiscal year.

Criteria: Expect 90 percent of trainees to qualify in 2 years from the start date.

Goals: Effective, Predictable, Understandable

VIP-O-4B Assessment of Inspector Proficiency

Definition: Maintain proficiency for all qualified inspectors.

Criteria: Maintain annual proficiency for all qualified inspectors in accordance with the guidance set forth by the VIP for refresher and continuing training.

Goals: Effective, Predictable, Understandable

APPENDIX F

MAJOR PLANT MODIFICATIONS CRITERIA

Quality Assurance Vendor Inspection Branch (IQVB) staff worked with staff from the Division of Inspection and Regional Support and Division of Engineering from the Office of Nuclear Reactor Regulation (NRR), and the Regions to develop criteria to determine when a proposed plant modification in operating reactors should be considered a major modification for enhanced supplier oversight. The criteria encompass licensee's plant modifications regardless of the outcome of the 10 CFR 50.59, "Changes, Tests, and Experiments," analysis which include:

1. Modifications for the installation of replacement steam generators, reactor vessel heads, control rod drive mechanisms, etc.

2. Modifications for the implementation of non-measurement uncertainty recapture power uprates;

3. Modifications to install digital instrumentation and control systems, devices, or features in accordance with an NRC-approved topical report;

4. Modifications to install a component, device, or design feature pursuant to an NRC Order or compliance backfit;

5. Implementation of new fuel design campaigns at operating reactors; or

6. Modifications to install a component, device, or design feature to perform a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.

IQVB staff seeks input from the Regions on an annual basis to identify major plant modifications at nuclear power plants that may highlight potential vendors for inspection.