

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 supply chain. It accomplishes this through a number of activities, including: performing vendor inspections that will verify the effective implementation of the vendor's quality assurance program, establishing a strategy for vendor identification and selection criteria, and; ensuring vendor inspectors obtain necessary knowledge and skills to perform inspections. In addition, the VIP addresses interactions with nuclear consensus standards organizations, industry and external stakeholders, and international constituents.

The VIP also includes objectives and associated performance metrics to demonstrate that the overarching goals are being supported. These performance metrics will be assessed 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 describing the following:

- The objectives of the VIP, including its overarching goals that provide a link to the U.S. Nuclear Regulatory Commission's (NRC) 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 New Reactors (NRO) necessary to perform the effective oversight of vendors
- The needed infrastructure including inspection and regulatory guidance and tools such as information (e.g., quality assurance Web site), inspection planning and scheduling, and self-assessment tracking systems
- Communication and coordination activities with internal and external stakeholders

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 will be 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 being supported:

- (1) Objective Decisions are based on factual information.
- (2) Risk-informed Risk insights are considered along with other factors (such as engineering judgment) to better focus vendor and regulatory attention on issues commensurate with their importance to the NRC 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 NRO appropriately informs and involves stakeholders in the regulatory process.
- (6) Effective NRO 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 described below:

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

The vendor inspection staff will accomplish this objective by performing vendor inspections that will verify the effective implementation of the vendor's quality assurance program. The inspections will focus on verifying that vendors 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," provide a product meeting the technical and quality requirements in the procurement documents. In addition, the inspections will verify the adequate implementation of procurement and commercial-grade dedication programs as defined in Appendix B to 10 CFR Part 50 and 10 CFR Part 21, as applicable.

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

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

- Inspection findings provide sufficient detail to communicate the vendor's failure to meet commitments related to NRC 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, and acknowledgement letters are completed in a timely manner consistent the VIP metrics.
- Inspection findings are rarely rescinded if contested.

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

The vendor inspection staff will accomplish 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.

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

The vendor inspection staff will accomplish this objective by verifying that vendor inspections are conducted by qualified inspectors, that vendor inspectors-in-training make acceptable progress in their required qualifications, and that qualified vendor inspectors maintain their proficiency.

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 document describes these performance metrics.

3.0 Organization

Three NRO branches support the VIP. The vendor inspection staff conducts inspections related to 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 quality assurance programs at vendor facilities are effectively implemented and comply with applicable regulatory requirements, including 10 CFR Part 21 and the licensee-imposed requirements of Appendix B to 10 CFR Part 50. Vendor inspections may also support the Commission determination that the acceptance criteria in a combined license are met in accordance with 10 CFR 52.99 and 10 CFR 52.103(g). In addition to a vendor inspection report, the results will be documented using the Construction Inspection Program Information Management System (CIPIMS). Vendor inspections follow the procedures given in the table below, as applicable:

Procedure	Title
IP 36100	Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance
IP 37805	Engineering Design Verification Inspections
IP 43001 & IP 43003	Reactive Inspection of Nuclear Vendors
IP 43002	Routine Inspections of Nuclear Vendors
IP 43004	Inspection of Commercial-Grade Dedication Programs

5.0 Vendor Identification and Selection Methodology

The methodology for the identification and selection of vendors for inspection is considered an essential element of the VIP. Appendix A to this plan describes the strategy used by the vendor inspection staff to identify vendors supplying safety-related material, equipment, and services to

the nuclear power industry. After the vendor inspection staff establishes a list of targeted vendors, Appendix B to this plan defines the process by which the vendor inspection staff prioritizes those vendors and schedules them for inspection.

6.0 <u>Types of Inspection</u>

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

Routine Inspections

The vendor inspection staff conducts routine inspections to 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 inspection also verifies the effectiveness of the commercial-grade dedication program. Furthermore, the vendor inspection staff performs engineering design verification inspections to verify that the translation of high-level design information and performance requirements into procedures, specifications, calculations, drawings, and procurement and construction documents is consistent with the applicable NRC requirements.

Reactive Inspections

The vendor inspection staff conducts reactive inspections in response to allegations, previous inspection findings, 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 NRC 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 will evaluate the effectiveness of the vendor's QA program and procedures, as it relates to the reported problem.

7.0 Enforcement

The NRC's Enforcement Policy governs the processes and procedures for the initiation and review of violations of NRC requirements, and the NRC Enforcement Manual contains implementation guidance. The NRC's Office of Enforcement owns and issues both documents. Potential violations identified through inspection activities are processed in accordance with the NRC Enforcement Policy. The NRC's Enforcement Policy is available under ADAMS at Accession No. ML093480037 or on the NRC's public Web site at: http://www.nrc.gov/about-nrc/regulatory/ enforcement/enforce-pol.html.

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

- 10 CFR Part 21
- 10 CFR 50.5, "Deliberate Misconduct"
- 10 CFR 50.7, "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 55.55(e) (only applicable to licensees)

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

- noncited violations (NCV)
- notices of violation (NOV)
- notices of nonconformance (NON)

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. In addition, the NRC also issues NCVs and minor violations to vendors.

An NCV is a nonrecurring, nonwillful, 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 a corrective action program to address recurrence and restores compliance within a reasonable period of time. Inspectors document NCVs in the inspection report.

An NOV is the official notification of a failure to meet the NRC's regulatory requirements 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.

A minor violation is a violation that is less significant than a Severity Level IV violation, does not warrant enforcement action and is normally not documented in the inspection report. However, minor violations must be corrected.

8.0 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 following NRO divisions to ensure that adequate technical expertise is provided during vendor inspections as necessary:

- Division of Engineering
- Division of Safety Systems and Risk Assessment
- Division of Site Safety and Environmental Analysis

Technical branches within these NRO divisions 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 on vendor inspections with qualified vendor inspectors to ensure that the quality of safety-related SSCs is such that the SSCs will perform their intended safety function when installed in nuclear power plants.

In addition to the NRO divisions, the vendor inspection staff interacts with the Office of Nuclear Reactor Regulation (NRR) on issues associated with allegations. It also interacts with NRC's Region II Center for Construction Inspection staff, which provides technical support on vendor inspections as necessary.

Furthermore, the vendor inspection staff, in coordination with the NRO and NRR quality assurance branches, participates in activities associated with the following organizations:

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

Communication and Engagement with Stakeholders on Vendor Inspection Activities

The vendor inspection staff interacts with the following external organizations:

- Electric Power Research Institute (EPRI)
- International Laboratory Accreditation Cooperation (ILAC)
- Multinational Design Evaluation Programme (MDEP)
- Nuclear Energy Institute (NEI
- Nuclear Procurement Issues Committee (NUPIC)

The staff also interacts with other organizations involved with protecting the industry from counterfeit, fraudulent, and substandard items (CFSI).

Electric Power Research Institute - Joint Utility Task Group

The vendor inspection staff interacts with EPRI by attending the EPRI-Joint Utility Task Group procurement forum. During these meetings, the vendor inspection staff makes a presentation on NRC perspectives on vendor performance issues. The Joint Utility Task Group 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.

International Laboratory Accreditation Cooperation

Currently, the NRC has accepted the accreditation provided by the following domestic accrediting bodies (ABs) that are full members of ILAC as an alternative to the methods used by vendors and licensees to qualify commercial-grade calibration suppliers:

- ACLASS
- Laboratory Accreditation Bureau
- International Accreditation Service

- Perry Johnson Laboratory Accreditation
- American Association for Laboratory Accreditation
- National Voluntary Laboratory Accreditation Program

The vendor inspection staff has participated as observers in various evaluations of ABs performed by ILAC as well as evaluations of laboratories performed by the ABs. The evaluations performed by ILAC served to allow ILAC to determine the ABs' compliance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17011, "Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies" in order for the ABs to maintain their signatory status in the ILAC mutual recognition arrangement. The purpose of the evaluations performed by the ABs was to determine compliance of the laboratory's quality system with the requirements of ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

Multinational Design Evaluation Programme

MDEP is a multinational initiative to develop innovative approaches to leverage the resources and knowledge of mature, experienced national regulatory authorities that will be tasked with the regulatory review of new reactor plant designs. The Vendor Inspection Cooperation Working Group (VICWG) is one of the issue-specific working groups established under the MDEP organization. The goal of the VICWG is to identify areas of commonality and differences among the regulatory practices of member countries in the area of vendor inspection programs.

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.

Counterfeit, Fraudulent, and Substandard Items Community

The vendor inspection staff interacts with various groups related to CFSI issues such as representatives from the U.S. Department of Energy, Department of Homeland Security, National Aeronautics and Space Administration, U.S. Department of Labor, U.S. Department of Justice, U.S. Department of Transportation, and the Food and Drug Administration. During these periodic group interactions, the vendor inspection staff participates in various activities to evaluate vulnerabilities in the procurement processes of the various agencies for the introduction of CFSI and to share best practices for the prevention of CFSI in the supply chain.

The vendor inspection staff routinely reaches out to industry stakeholders through NEI, NUPIC, and EPRI to gain additional insights on CFSI issues. Periodically, it holds public workshops with the nuclear vendor community to provide information on CFSI issues and solicit industry feedback and lessons learned. Finally, the vendor inspection staff participates in Nuclear Energy Agency meetings to share CFSI information and lessons learned with foreign regulators.

9.0 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.

10.0 <u>Performance Metrics</u>

The vendor inspection staff will use evaluations and performance metrics to evaluate the success of the VIP. These metrics will be incorporated into DCIP's Operating Plan. Measurement of these metrics will allow 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

The vendor inspection staff developed a set of performance metrics associated with each of the objectives of the VIP to assess the program performance with respect to the goals described in Section 2.0 of this plan. Appendix D provides a detailed description of these performance metrics. Metrics of a more general nature are also monitored and analyzed, primarily using stakeholder feedback, to gauge the overall effectiveness of the VIP.

Each metric in Appendix D includes its definition, the criteria to determine whether it is met, and a cross-reference to those VIP goals each metric is intended to support. Stakeholder surveys to collect stakeholder feedback should be issued based on the schedule of activities during which feedback will be requested, such as vendor workshops and inspection reports (see Appendix E to this document).

11.0 Knowledge Management & Training

Knowledge Management

Knowledge management and vendor inspection staff training are critical for effectiveness of the VIP. The NRC's knowledge management process includes numerous training documents (that are defined by community of practice) as well as a SharePoint site dedicated to vendor inspector qualifications.

To support the continuing development of the VIP, the vendor inspection staff will maintain a Share Point environment (including links to other sites) 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), unique or complex inspection findings, and useful information. The vendor inspection staff will use these knowledge management systems to ensure the availability of information related to vendor inspections.

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, will ensure a continual supply of knowledgeable, well-trained, and fully qualified vendor inspectors. These steps will help to ensure that the organization is prepared for expected increases in inspection activities.

NRO-PER-105, "Qualification and Training Program," dated July 1, 2011, governs the qualifications for vendor inspectors and standardizes the initial training and qualification requirements for NRO vendor inspection staff performing inspection activities. NRO-PER-105 addresses the specific requirements derived from NRC Inspection Manual Chapter (IMC) 1245, "Qualification Program for the Office of Nuclear Reactor Regulation Programs," dated November 9, 2009, for vendor inspector qualification.

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 order to ensure that NRC staff members going through in the vendor inspector qualification process have the opportunity to obtain a reasonable level of proficiency in all of these competency areas, reasonable effort will be made to assign at least one nonqualified inspector on all domestic vendor inspections and to promote participation by junior staff in other activities directly related to the VIP (e.g., ASME code meetings, NUPIC audit observations). 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 Director of the Division of Construction Inspection and Operational Programs 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 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 Branch Chiefs have 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 Branch Chiefs 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 NRO Office Director.

Postqualification Activities

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

Postqualification 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 ongoing postqualification training to maintain and enhance their knowledge and skills. This training should include elements of both continuing and refresher training as defined in IMC 1245-03. The Branch Chiefs will review postqualification accomplishments annually and set goals for the following year to ensure that the vendor inspection staff meets the intent of IMC 1245-06 for postqualification training.

The vendor inspector's 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, Branch Chiefs will monitor inspector performance through periodic observations of inspections.

12.0 Resource Management

As a result of the development of the enhanced VIP in 2007, and within the framework of IMC 2507, "Construction Inspection Program: Vendor Inspection Program," dated October 3, 2007, the vendor inspection staff currently conducts vendor inspections to a level commensurate with the number of routine and reactive inspections specified in the NRO operating plan on a yearly basis. In turn, the overall number of vendor inspections contained in the operating plan is derived from SECY 09-0182, "Legal Constraints of Relying on Vendor Inspection Results of Foreign Regulators and the Need for Additional Resources to Achieve the Appropriate Number of NRC Vendor Inspections," dated December 14, 2009, and its associated staff requirements memorandum (SRM) (M090603), which represent the vendor inspection staff's attempt to forecast and plan for the growing need for vendor inspections, as directed by the Commission. The VIP will continue to use the NRO operating plan, in conjunction with any additional SRM, or other form of Commission or NRO 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 supply 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
- in coordination with the quality assurance branches in NRO and NRR, 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
- 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., MDEP) 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.

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

- assumptions for vendor inspections:
 - 200 hours for the team leader
 - 160 hours per team member
 - One team leader and four team members for each inspection
 - 840 hours total per inspection
- assumptions for engineering design verification inspections:
 - 350 hours for the team leader
 - 275 hours per team member
 - 2 week inspection
 - Each inspection is made up of one team leader and six team members for each inspection
 - 2,000 hours total per inspection

In general, inspection and industry interaction activities, as well as the associated infrastructure needs (e.g., revising inspection procedures, updating regulatory guides), are expected to occupy 60 to 80 percent of a vendor inspector's workload, with the balance of work consisting of

training and administrative tasks. 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 200 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 the estimated complexity and associated level of effort for each inspection, the knowledge level and current workload of each member of the inspection team, the need for technical expertise from contract or technical division sources, or both, the usefulness of the inspection as a training activity for junior inspectors, and 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 staff's workload will be 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 will ensure that vendor inspection resources are used as efficiently and effectively as possible.

13.0 Implementation Schedule and Assessment

Goal	Action	VIP Plan Section
June 2011 (complete) Improve the accessibility of the portion of the NRC's public Web site that ar relevant to vendor oversight		Appendix C
August 2011 (complete) Create a page on the public Web sit that categorizes findings and violatic from NRC vendor inspection reports		Appendix C
October 2011 (complete) Create a frequently asked questions (FAQ) page on the public Web site that includes questions received at vendor conferences and other NRC outreach meetings		Appendix C
December 2011	Create an annual electronic newsletter to be sent to interested vendors	Appendix C
April 2012	Create and manage an internal database to store vendor information and to facilitate vendor communication and selection	Appendix A
April 2012	Establish a page on the NRC public Web site that allows vendors under an Appendix B program to voluntarily provide information to the NRC	Appendix A

As described in referenced sections of the VIP Plan, the vendor inspection staff will initially perform the following actions to implement the VIP:

Goal Action		VIP Plan Section
June 2012	Issue a regulatory issue summary (RIS) to NRC applicants and licensees communicating VIP enhancements and requesting voluntary submittal of vendor information	Appendix A
November 2012	Review vendor selection pilot strategy to assess whether changes need to made to the attributes or weighting factors. At that time, it will also assess the need to revise IMC 2507 and IMC 2700 to reflect any changes.	Appendix B
December 2012	Compile a list of vendors	Appendices A & C

As described in referenced sections of the VIP Plan, the vendor inspection staff will perform the following ongoing actions:

Frequency Action		VIP Plan Section
Quarterly	Update and review vendor selection data and document selection results from in Vendor Inspection Master Schedule	Appendix B
Annually VIP Self-Assessment		All
Biennially Establish workshops on vendor oversight		Appendix C
Triennially	Assess the need to issue a RIS to NRC applicants and licensees	Appendix A

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 Committee (NUPIC) audits.

To ensure the efficient and effective use of NRC resources, the NRC has developed a methodology to select vendors for inspection (see Appendix B to the Vendor Inspection Program (VIP) Plan; ADAMS Accession No. ML112730279). Further, the NRC has also developed a strategy to enhance outreach and communications with vendors (see Appendix C to the VIP Plan; ADAMS Accession No. ML110871799). 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 (EPC) contractors
- allegations

The NRC plans to take the following actions to identify and track vendors of safety-related items and services with the goal to identify the majority of safety-related vendors:

 Issue a regulatory issue summary (RIS) to NRC applicants and licensees. <u>Target date: June 2012</u>

- The RIS will communicate recent enhancements to the NRC's outreach and communications (e.g., VIP Plan, Strategy for Enhanced Vendor Outreach and Communication, and the Strategy for Vendor Selection) and request the industry's participation in the voluntary initiative to identify vendors.
- The RIS will request the voluntary identification and submittal of information about approved safety-related suppliers and project-related approved suppliers of EPC contractors.
- The NRC will assess the need to issue a similar RIS on a triennial basis.
- Establish a page on the NRC public Web site that allows vendors under an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," to voluntarily provide information to the NRC. <u>Target date: April 2012</u>
 - The NRC will encourage registration by alerting registrants to new operating experience summaries, meeting and conference notifications, and other communications as part of the strategy to enhance vendor outreach and communications (see Appendix C; ADAMS Accession No. ML110871799).
 - The NRC will promote registration at regularly conferences attended by vendors.
- Create and manage an internal database to store vendor information and to facilitate vendor communication and selection. <u>Target date: April 2012</u>
 - The vendor inspection staff will populate the database from current methods, RIS responses, and NRC public Web site registrations.
 - The database will contain 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 e-mail address
 - scope of supply (e.g., Class I piping, electric motors)
 - comments
 - The NRC will assign a member of the vendor inspection staff to be responsible for maintaining the internal database.

CONTINUOUS IMPROVEMENT

After sufficient collection time has passed, the vendor inspection staff will track 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 a pilot strategy that the U.S. Nuclear Regulatory Commission (NRC) will use to help prioritize vendors for NRC inspection. This pilot strategy is applicable to vendors that are currently supplying safety-related material, equipment, and services to the U.S. commercial nuclear power industry. The strategy is a program tool and provides one input into the overall vendor inspection selection process. The NRC will consider the need to perform vendor inspections in response to an allegation or in response to reactive events separately, outside the scope of this strategy.

BACKGROUND

Currently, Inspection Manual Chapter (IMC) 2507, "Construction Inspection Program: Vendor Inspections," and IMC 2700, "Vendor Inspection Program," contain general guidance on selecting for NRC inspection vendors that are supplying safety-related material, equipment, and services. The strategy contained in this document expands upon the guidance in the IMCs and should help to ensure the most efficient and effective use of NRC resources allocated for vendor inspection. To ensure consistency, the vendor inspection staff will update both IMCs to reflect this strategy for vendor selection.

VENDOR SELECTION STRATEGY

As described in the accompanying strategy for vendor identification (see Appendix A to the Vendor Inspection Program Plan) the NRC will periodically solicit information from the nuclear industry on vendors that are currently supplying safety-related material, equipment and, services. The vendor inspection staff expects this process mostly to identify primary vendors (e.g., vendors that supply directly to NRC licensees). The vendor inspection staff anticipates that the majority of vendor inspections will focus on these primary vendors. As part of this strategy, NRC vendor inspectors will also collect information on key subvendors during inspections at primary vendors and through other interactions with the nuclear industry.

This prioritization strategy assesses each known vendor currently supplying safety-related material, equipment, and services to the domestic nuclear power industry by using a set of weighted predetermined attributes. Information on primary and subvendors will be tabulated in a Vendor Inspection Scoring Matrix as the information becomes available. The vendor inspection staff will then evaluate each vendor against each attribute and sum the resulting scores to generate a final score for that particular vendor.

Attributes that are associated with a positive number correspond to a perceived increased risk with respect to the potential failure of the material, equipment or services supplied by that vendor, while those with a negative number correspond to a decreased risk. The vendor inspection staff selected the assigned weighting factors based upon the relative importance of each attribute. For example, a vendor that had an NRC inspection with significant issues the previous 3 years would be scored as 1 x 3 (weighting factor) = 3 for that specific attribute. Once the vendor data are inputted and the scores obtained, the vendor inspection staff will review the prioritized list of vendors quarterly to select vendors for inspection. Vendors that receive higher overall numerical scores will receive increased consideration for an NRC vendor inspection. Although the selection of vendors for NRC inspection will primarily be based on the

Vendor Inspection Scoring Matrix, the vendor inspection staff will include other considerations in scheduling an inspection, including but not limited to the availability of the staff with the proper knowledge and expertise in the focus area of the inspection, insights from inspections performed by peer regulators (e.g., MDEP) and industry auditors (e.g., NUPIC), insights from Probabilistic Risk Assessments to the extent practicable and as available, and any conflicts with other scheduled activities at the vendor's facility.

The vendor inspection staff will document the results from the quarterly data review in a Vendor Inspection Master Schedule. It is important to note that allegations concerning vendor performance will be considered independent of this prioritization scheme and may result in a decision to perform an inspection regardless of the scoring results. The vendor inspection staff will use the following attributes to prioritize vendors in the scoring matrix:

Attribute	<u>Attribute S</u>	<u>core</u>	<u>Weighting</u> Factor	
Prior NRC inspection experience:				
Inspection within the last 3 years with no significant issues No inspection within the last 3 years Inspection within the last 3 years with significant issues	3	(-1) (0*) (1)	3	
Nuclear Procurement Issues Committee (NUPIC) results:				
Audited by NUPIC within the last 3 years with no significant Not audited by NUPIC within the last 3 years Audited by NUPIC within the last 3 years and significant is	nt issues sues	(-1) (0*) (1)	2	
Scope of supply:				
Supplier to less than four licensees Supplier to four to nine licensees Supplier to more than 10 licensees		(-1) (0*) (1)	3	
Complexity of product or service:				
Noncomplex (e.g., raw materials, limited number of parts, manufacturing steps) Somewhat complex Very complex (e.g., complex manufacturing process, mult	limited	(-1) (0*)	2	
subvendors)	ipie	(1)		
Susceptibility to counterfeiting or cyber security issues:				
Minimally susceptible (e.g., one-of-a-kind or limited-run nu specific components procured through the original equipment manufacturer)	iclear- ient	(-1*)		
Susceptible (e.g., commercial components procured throu distributors)	gh	(0)	3	
Highly susceptible (e.g. commercial electronic parts procu distributors, commercial obsolete components)	red through	(1)		

Attribute	Attribute Score	<u>Weighting</u> Factor
Industry experience with product or service (as reported under Title 10 of the Code of Federal Regulations (10 CFF Part 21, "Reporting of Defects and Noncompliance"):	<u>R)</u>	
No problems reported within the last 3 years One problem reported within the last 3 years More than one problem reported within the last 3 years	(-1*) (0) (1)	2
New or advanced technology:		
Stable or proven technology New or advanced technology	(0*) (1)	3
Oversight by other entities (e.g. American Society of Mechanical Engineers, foreign regulators):		
Extensive external oversight Some external oversight No known extensive external oversight	(-1) (0) (1*)	1
Significance to pending regulatory actions (e.g. targeted reanalyses, and acceptance criteria and licensing reviews):	eviews of inspection	<u>ns, tests,</u>
No direct significance	(-1*) (0)	3

0	· · ·	
Some indirect significance	(0)	3
Direct relation to specific commitments such as a targeted ITAAC	(1)	

* The vendor inspection staff will use this default attribute for vendors for which information is not available to score an attribute.

CONTINUOUS IMPROVEMENT

After 1 year, the vendor inspection staff will reevaluate this pilot strategy to assess whether changes need to made to the attributes or weighting factors. At that time, it will also assess the need to revise IMC 2507 and IMC 2700 to reflect any changes.

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 will serve to enhance the NRC's commitment to openness, efficiency, and clarity.

BACKGROUND

This strategy lists key areas of improvement that will 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 (<u>http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html</u>)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 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"
 - inspection procedures
 - inspection reports
 - information on commercial-grade dedication
 - presentations from past NRC workshops
 - NRC presentations at conferences attended by the NRC
- Workshops on Vendor Oversight: The NRC previously hosted two workshops on vendor oversight for new reactors. The workshops were successful and excellent examples of NRC outreach. The workshops were widely attended and generated significant dialogue with the vendor community about regulatory issues. Feedback through meeting comment forms was positive and stakeholders have requested additional workshops.

- Participation in Industry Conferences and Meetings: The staff has participated in related industry conferences and meetings such as the following:
 - Nuclear Procurement Issues Committee meetings
 - the NRC's Regulatory Information Conference
 - Electronic Power Research Institute Joint Utility Task Group meetings
 - International Laboratory Accreditation Cooperation process activities
 - Vendor Inspection Cooperation Working Group meetings, under the auspices of the Multinational Design Evaluation Program and the Nuclear Energy Agency

KEY IMPROVEMENTS

The NRC will make the following key improvements in outreach and communications:

- Improve the accessibility of the portions of the NRC's public Web site that are relevant to vendor oversight. <u>Target date: June 2011; completed June 2011</u>
 - The NRC created a link within the quick link box on the pages for new reactors and operating reactors.
- Create a page on the public Web site that categorizes findings and violations from NRC vendor inspection reports. <u>Target date: August 2011; completed August 2011</u>
 - The NRC added a page with the 18 criteria from Appendix B to 10 CFR 50 and 10 CFR 21 so that vendors can select one of the criteria or 10 CFR Part 21 requirements and have all applicable inspection reports with findings or violations in those areas listed.
- Create a frequently asked questions (FAQ) page on the public Web site that includes questions received at vendor conferences and other NRC outreach meetings. <u>Target date: October 2011; completed October 2011</u>
 - An FAQ will be useful to any vendor that was unable to attend the workshop or conference and will also provide a quick source of information and serves as a knowledge management tool. The current vendor page has slides and summaries for past NRC conferences. The vendor inspection staff makes every effort to publish questions and answers as soon as they have been adequately vetted.
- Create an annual electronic newsletter to be sent to interested vendors. <u>Target date: December 2011</u>
 - The newsletter will include recent findings, potential rulemakings, upcoming conferences, operating experience and other useful information. Stakeholders will be able to sign up for the newsletter through the NRC's Web site.
 - The newsletter will provide another source of information, in addition to the public Web site for vendors to use to be informed of current and ongoing activities at the NRC.

- Establish regular workshops on vendor oversight on biennial basis. <u>Target date for next workshop: June 2012</u>
 - The NRC will host a conference every 2 years as one key forum for communication and outreach with vendors to the nuclear industry. The vendor inspection staff will continue to use comment cards to solicit feedback and seek recommendations for improving future workshops.
- Compile a list of vendors. This is part of the parallel effort described in Appendix A to the Vendor Inspection Program Plan. <u>Target date: December 2012</u>
 - The vendor inspection staff can use the list of known vendors to solicit stakeholder interest in the NRC's outreach and communications activities. This list will state that it does not represent NRC endorsement or approval.

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. Once the change has been implemented you will be able to access the vendor Web page on NRC's public Web site by going to <u>http://www.nrc.gov</u> and then clicking on New Reactors under the Nuclear Reactors tab. You will then see a link to vendor Web page on that page.

Q. What kind of questions will I see on the new FAQ Web page?

A. The new FAQ section on the vendor Web page will list all the questions and answers that were asked at NRC conferences and workshops. It will also list questions and answers about relevant NRC regulations and inspections pertaining to vendors.

Q. How will vendors sign up for the newsletter?

A. The staff plans to create a database of e-mail addresses of vendors that wish to receive the newsletter. The staff plans to create an online link for vendors to sign up for the newsletter via the public Web site or vendors can provide their business cards at one of the NRC's conferences or workshops.

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 page 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 is the NRC planning to develop its vendor list? Is there a process to do this? A. The NRC is currently looking at considering options such as holding public meetings to develop a methodology for identifying safety-related vendors. The NRC may issue a generic communication if it deems that necessary. The vendor inspection staff also plans on advertising the new communication tools during inspections, conferences, and workshops, to obtain vendor information.

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

VENDOR INSPECTION PROGRAM PERFORMANCE METRICS

- VIP-O-1A Accomplish DCIP's [the U.S. Nuclear Regulatory Commission's Office of New Reactors Division of Construction Inspection and Operational Programs] Established Number of Inspections per Fiscal Year
- **Definition:** Accomplish DCIP's established number of inspections per fiscal year to capture a reasonable perspective of industry performance.
- **Criteria:** Expect DCIP 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 the number of NONs and NOVs to identify areas for industry improvement and take corrective actions as necessary. Corrective actions may include discussions at the vendor workshop, issuance of generic communications, and other activities.
- **Criteria:** Expect a declining trend over time.
- **Goals:** Objective, Open, Risk-Informed

VIP-O-2A Inspection Reports Are Relevant, Useful, and Written in Plain Language

Definition: Survey external and internal stakeholders to determine whether the information contained in inspection reports is relevant, useful, and written in plain language.

The NRC's quality assurance public Website provides a link to the Vendor Inspection Report Survey Form. Interested stakeholders can fill the survey and submit it electronically.

- **Criteria:** Expect stable or increasingly positive perception over time.
- **Goals:** Effective, Open, Understandable

VIP-O-2B Announcement Letters, Inspection Plans, Inspection Reports and Acknowledgment Letters Are Timely

Definition: Obtain data on the total number of announcement letters, inspection plans, inspection reports and acknowledgement letters issued within the timeliness goals stipulated in Inspection Manual Chapter 0617, "Vendor and Quality Assurance Implementation Inspection Reports," dated October 29, 2009.

- **Criteria:** Expect 90 percent of announcement letters, inspection plans, inspection reports and acknowledgement letters to be issued within the Vendor Inspection Program (VIP) timeliness goals.
- **Goals:** Effective, Open, Predictable

VIP-O-2C Inspection Results Accepted by Stakeholders

- **Definition:** Track the total number of NOVs and NONs contested by vendors.
- **Criteria:** Retract less than 20 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 completion of inspection reports resulting from reactive inspections and the timely submittal of allegation response documents.
- **Criteria:** Conduct all support within the Allegation program timeliness goals.
- Goals: Effective, Objective, Risk-Informed

VIP-O-4A Assessment of Trainee Qualifications

- **Definition:** Branch Chiefs assess inspectors in training for progress in achieving qualifications at least quarterly.
- **Criteria:** Expect 90 percent of trainees to qualify in 2 years.
- **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 E

VENDOR INSPECTION REPORT FEEDBACK FORM

Inspection Report Number: _____

Date:

- 1. Did the inspection report clearly explain the violation or nonconformance?
 - o Yes

Comments:

- **No**
- **N/A**
- 2. Was/Were the Notice of Nonconformance or Notice of Violation or both based on supported facts rather than subjective judgment?
 - YesNo

Comments:

- **N/A**
- 3. Were the technical issues described in a manner that was clearly understood?
 - YesNo

Comments:

- N/A
- 4. Was the inspection report publicly available within the agreed upon schedule?
 - o Yes

Comments:

- **No**
- **N/A**
- 5. Was the information presented in the inspection report relevant and useful?
 - \circ Yes

Comments:

- **No**
- N/A

- 6. Was the inspection report written in a clear and concise manner?
 - Yes Comments:
 No
 N/A
- 7. Please provide any comments or recommendations about the inspection report in the space below.

- 6. Was the inspection report written in a clear and concise manner?
- 7. If any, please provide any comments or recommendations about the inspection report in the space below.



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