AUDIT REPORT

Audit of NRC's Vendor Inspection Program

OIG-10-A-20 September 28, 2010

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
INSPECTOR GENERAL

September 28, 2010

MEMORANDUM TO: R. William Borchardt
Executive Director for Operations

FROM: Stephen D. Dingbaum ***/RA/***
Assistant Inspector General for Audits

SUBJECT: AUDIT OF NRC'S VENDOR INSPECTION PROGRAM
(OIG-10-A-20)

Attached is the Office of the Inspector General's (OIG) audit report titled, *Audit of NRC's Vendor Inspection Program.*

The report presents the results of the subject audit. Agency comments provided at the August 31, 2010, exit conference and an additional meeting on September 10, 2010, have been incorporated, as appropriate, into this report.

Please provide information on actions taken or planned on each of the recommendations within 30 days of the date of this memorandum. Actions taken or planned are subject to OIG followup as stated in Management Directive 6.1.

We appreciate the cooperation extended to us by members of your staff during the audit. If you have any questions or comments about our report, please contact me at 415-5915 or RK Wild, Team Leader, Nuclear Reactor Safety Audit Team, at 415- 5948.

Attachment: As stated

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EXECUTIVE SUMMARY

BACKGROUND

The Nuclear Regulatory Commission (NRC) endeavors to protect the public health and safety and the environment by overseeing vendor compliance with NRC's regulations for assuring the integrity of domestic and global parts and services supplied to nuclear power reactors. Vendors manufacture a range of components such as fasteners, pumps, valves, and reactor vessels, as well as provide design, engineering, and construction services. While most vendors do not hold NRC licenses, they are nonetheless bound through contracts with licensees, applicants, or other vendors to comply with NRC's quality assurance regulations contained in Appendix B to Title 10, Code of Federal Regulations (10 CFR), Part 50 (Appendix B). Vendors are also required to comply with 10 CFR Part 21 (Part 21). NRC conducts reactive and routine inspections of vendors' implementation of Appendix B and Part 21 requirements.

PURPOSE

The audit objective was to assess NRC's regulatory approach for ensuring the integrity of domestic and foreign safety-related parts and services supplied to current or prospective nuclear power reactors.

RESULTS IN BRIEF

Beginning in 2007, the agency proactively enhanced its overall approach to vendor inspections and increased vendor outreach efforts. After the creation of the Office of New Reactors (NRO), two new branches were established to perform additional vendor inspections, including routine inspections. The Office of the Inspector General (OIG) has identified areas that need management attention while NRO continues its ongoing vendor inspection activities. Specifically:

- Improvements to NRO's vendor inspection planning would enhance the process NRC uses to identify and select vendors for routine inspections.
    - NRO's planning process for identifying and selecting vendors for routine inspections, and its strategy for guiding the process, is

largely an informal one. Simply identifying the number of vendors is challenging, and NRO does not know how many vendors there are or how to identify changes in the vendor universe. Furthermore, NRO's planning for selecting vendors for inspection is based on an approach that relies primarily on professional judgment. Moreover, NRO's overall strategic approach to vendor identification and selection planning is informal as indicated by NRO staff, who have varying views of the purposes of the Vendor Inspection Program and routine vendor inspections.

- NRC has an opportunity to more effectively communicate its regulatory expectations and requirements to vendors.

  - NRC relies on nuclear vendors' understanding and implementation of its regulations to assure that safety-related components will perform adequately in service, and that defects are reported. In order for vendors supplying nuclear components and services to be knowledgeable of their obligations under the regulations, NRC must effectively communicate the regulations. NRC has undertaken a number of efforts to communicate regulations to vendors, but some vendors are not aware of all obligations or NRC expectations. NRC's approach to communicating with vendors is not as effective as it could be because it does not have an outreach/ communications plan. When vendors are not knowledgeable of their obligations under NRC regulations, vendors might not report defects or otherwise fully assure that safety-related components will perform adequately in service.

- Commercial-grade dedication and Part 21 regulations and guidance could be clarified.

  - Even when vendors are aware of the applicable NRC regulations and other regulatory information, NRC could clarify its expectations and requirements for Part 21 and for the process of obtaining parts from commercial suppliers known as commercial-grade dedication. NRC presumes that adherence to its regulatory requirements on the part of licensees and vendors assures safety. However, nuclear vendors are confused about how to adequately implement Part 21 and

commercial-grade dedication due to unclear, insufficient, or conflicting guidance. Consequently, vendors might fail to implement various aspects of their programs in accordance with NRC's regulations, guidance, or expectations. Ultimately, this could lead to vendors (1) supplying parts and services to nuclear power plants that do not meet NRC regulatory requirements or quality assurance expectations, and (2) inadequately reporting defects.

- Calibration laboratory approval guidance could be clarified.

  - NRC's guidance for approving accredited commercial-grade calibration laboratories—which calibrate measuring and test equipment used by vendors to evaluate the properties of materials and parts—could be clarified. In response to a request from one of its licensees, NRC allowed a process permitting the licensee to approve calibration laboratories based on the reviews performed by accrediting bodies in lieu of an Appendix B audit or a commercial-grade survey. However, since NRC's guidance documents describing this process are disparate, vendors are confused about, and have difficulty implementing, the process. Consequently, vendors' approval of laboratories may not be in accordance with NRC's expectations, vendors may find themselves unknowingly in violation of Appendix B or NRC commercial-grade dedication requirements, and vendors could find they have used out-of-calibration equipment during the manufacturing process.

- NRC's approach to counterfeit, fraudulent, and substandard items (CFSI) could be strengthened.

  - NRC could strengthen its current approach to CFSI. Both the Federal Government and private sector have recognized the increasing prevalence of CFSI in nuclear and other industries. However, NRC's approach has been primarily reactive and based largely on the abilities of one or two individuals to monitor and evaluate the threat. This is because NRC lacks a formal strategy and plan to monitor and evaluate potential CFSI, and

consider program changes to address the issue. Consequently, the lack of any formal strategy or framework could result in reactor construction problems with major implications for public health and safety.

RECOMMENDATIONS

This report makes 10 recommendations to help NRC improve its oversight of the nuclear vendors and the parts and services they supply to nuclear power plants. A consolidated list of the recommendations appears in Section IV of this report.

AGENCY COMMENTS

On August 17, 2010, OIG provided a draft report to the Executive Director for Operations. OIG held an exit conference with the agency on August 31, 2010. During that meeting agency management provided informal comments to the draft report. Also, on September 10, 2010, OIG held an additional meeting with NRC staff to discuss the agency's informal comments to the draft report. On September 14, 2010, OIG provided the agency a revised draft report, and on September 17, 2010, the agency declined to provide any formal comments. The final report incorporates revisions made, where applicable, as a result of meetings with NRC staff.

ABBREVIATIONS AND ACRONYMS

A2LA	American Association for Laboratory Accreditation
Appendix B	Title 10 Code of Federal Regulations, Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
ASME	American Society of Mechanical Engineers
10 CFR	Title 10, Code of Federal Regulations
CFSI	counterfeit, fraudulent, and substandard items
DOD	Department of Defense
EPC	engineering, procurement, and construction
EPRI	Electric Power Research Institute
FAA	Federal Aviation Administration
FY	fiscal year
GAO	Government Accountability Office
IAEA	International Atomic Energy Agency
IMC	Inspection Manual Chapter
IP	Inspection Procedure
NRC	Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NUPIC	Nuclear Procurement Issues Committee
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
Part 21	Title 10 Code of Federal Regulations, Part 21, *Reporting of Defects and Noncompliance*
QA	Quality Assurance

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I. BACKGROUND

The Nuclear Regulatory Commission (NRC) endeavors to protect the public health and safety and the environment by overseeing vendor compliance with NRC's regulations for assuring the integrity of domestic and global parts and services supplied to nuclear power reactors. NRC directly oversees compliance by conducting reactive and routine inspections of vendors, and indirectly through licensee audits of vendors and through American Society of Mechanical Engineers (ASME) standards. Vendors manufacture a range of components such as fasteners, pumps, valves, and reactor vessels, as well as provide design, engineering, and construction services.

While most vendors do not hold NRC licenses, they are nonetheless bound through contracts with licensees, applicants, or other vendors to comply with NRC's quality assurance regulations contained in Appendix B to Title 10, Code of Federal Regulations (10 CFR), Part 50 (Appendix B). Vendors are also required to comply with 10 CFR Part 21 (Part 21).

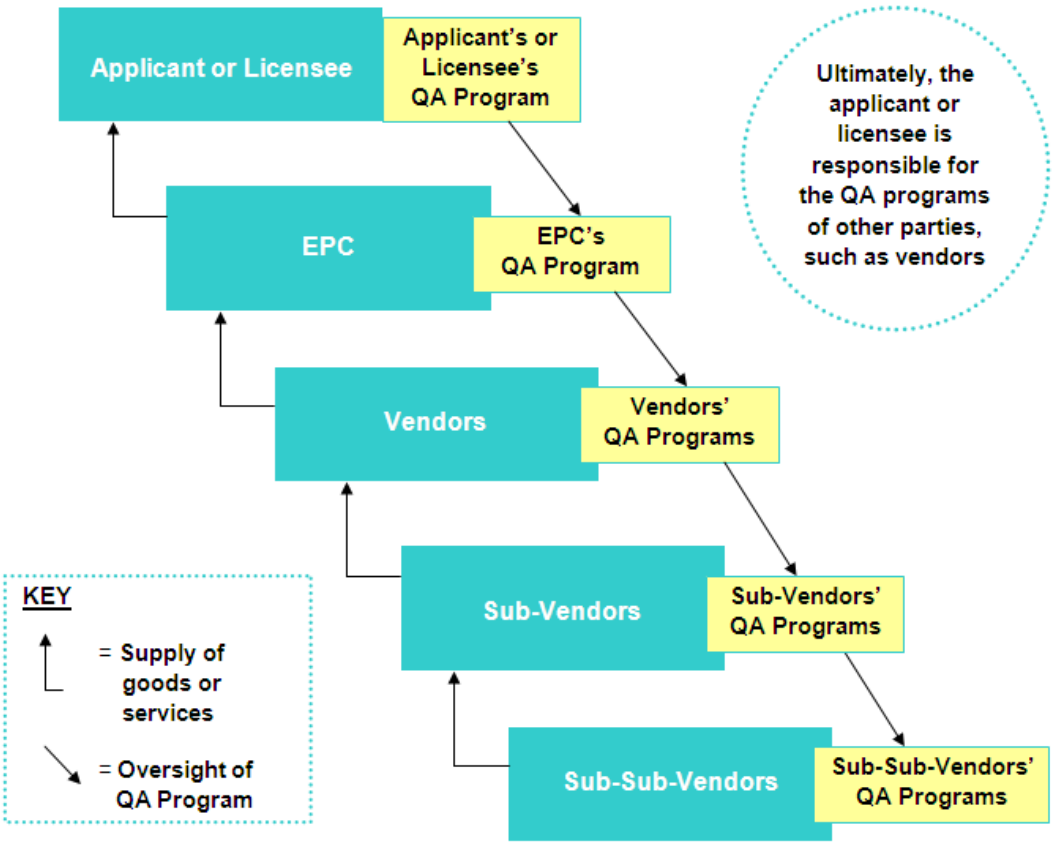
Appendix B

Appendix B requires that a quality assurance program be applied to all activities affecting structures, systems, and components of reactors that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. In particular, Appendix B requirements apply to all activities affecting the safety-related functions of those structures, systems, and components, which include the following: designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Vendors have a unique relationship with NRC through licensees given that, while the regulation requires licensees to establish and implement an Appendix B quality assurance program, it does not specifically require this of vendors. Vendors are nonetheless required to comply because this requirement is passed down from licensees to vendors through contracts.

For some new reactor projects, the applicant or licensee oversees its engineering, procurement, and construction (EPC) contractor's quality assurance program; the EPC oversees its vendors' quality assurance programs; the vendors oversee their sub-vendors' quality assurance programs; the sub-vendors oversee sub-sub-vendors' quality assurance programs; and so on, as shown in Figure 1. Likewise, operating reactor licensees oversee the quality assurance programs of their vendors, and so on. Ultimately, the applicant or licensee must ensure that applicable regulatory requirements, which are necessary to assure adequate quality, are included in the documents for procurement of material, equipment, and services, whether purchased by the applicant, or licensee, or by its vendors or sub-vendors.

Figure 1: Vendor Quality Assurance (QA) Oversight Process



Source: Office of the Inspector General (OIG) analysis and NRC documents.

Part 21

Part 21 establishes (1) procedures for reporting defects in safety-related components, and (2) a process for providing reasonable assurance that commercial off-the-shelf parts used in nuclear power plant safety-related applications will perform their intended safety function. Vendors are required to notify NRC of a defect in a basic component—also referred to as a "safety-related" component.

Vendors and their customers often acquire parts from commercial suppliers that do not produce parts specifically designed or manufactured for a nuclear safety-related application. These parts are called commercial-grade items. If a customer decides to purchase commercial-grade items, Part 21 requires the customer receiving the items to use a commercial-grade dedication process to provide reasonable assurance that these items destined for use in nuclear power plants will perform their intended safety function. Commercial-grade dedication is an acceptance process, performed under an Appendix B quality assurance program. The outcome of this process is a commercial part deemed equivalent to an item designed and manufactured under an Appendix B quality assurance program.

NRC's Vendor Inspection Programs

NRC conducts reactive and routine inspections of vendors' implementation of Appendix B and Part 21 requirements. Typically, reactive inspections are performed by NRC's Office of Nuclear Reactor Regulation (NRR), and routine inspections are performed by NRC's Office of New Reactors (NRO).

NRR inspections are generally focused on vendors supplying to the current fleet of nuclear reactors operating in the United States. The source of these reactive inspections stems from parts failures, allegations, and observed performance problems of a particular vendor, among other things. During fiscal year (FY) 2009 and the first half of FY 2010, NRR devoted 2.1 full-time equivalent staff to vendor inspection and related activities. During the period January 2009 through March 2010, NRR performed five of these reactive inspections, which resulted in findings that the vendor was not in compliance with one or more aspects of Part 21 or Appendix B.

In 2007, NRC established a routine inspection program in NRO. Like the NRR inspection program, the NRO inspection program inspects vendors' implementation of Appendix B and Part 21 and is focused on vendors who currently supply, or plan to supply, to the new generation of power reactors being developed in the United States. During FY 2009 and the first half of FY 2010, NRO devoted 23.8 full-time equivalent staff to vendor inspections, inspection program development, vendor outreach, and other related activities. During the period January 2009 through March 2010, NRO performed 16 of these routine inspections, which resulted in findings that the vendor was not in compliance with one or more aspects of Part 21 or Appendix B.

Global Market for Nuclear Parts

Vendors providing safety-related parts and services for the nuclear industry have become increasingly global over the last few decades. For example, NRC regulations require parts of the reactor coolant pressure boundary[1] to be manufactured according to the ASME Boiler and Pressure Vessel Code. The code requires those vendors manufacturing reactor coolant pressure boundary parts to have an ASME nuclear, or "N-type," certificate. According to OIG analysis of industry documents, the number of U.S. vendors maintaining an ASME N-type certificate decreased to roughly 125 in 2009 from about 500 in 1980. The number of international ASME N-type certificates has fluctuated between about 80 and 100 certificates. As of 2009, there were about 100 international firms with ASME N-type certificates.

[1] The reactor coolant pressure boundary is a primary barrier that protects the public from exposure to radiation.

II. PURPOSE

The audit objective was to assess NRC's regulatory approach for ensuring the integrity of domestic and foreign safety-related parts and services supplied to current or prospective nuclear power reactors. See the report Appendix for information on the audit scope and methodology.

III. FINDINGS

Beginning in 2007, the agency proactively enhanced its overall approach to vendor inspections and increased vendor outreach efforts. After the creation of NRO, two new branches were established to perform additional vendor inspections, including routine inspections. The staff:

- Developed program documents and inspection procedures.
- Increased NRC's outreach related to new reactor vendor activities.
- Established cooperative relationships with regulators from other countries.
- Initiated actions to evaluate counterfeit, fraudulent, and substandard items efforts within the industry.
- Held the first NRC vendor workshop.

However, OIG has identified opportunities to further improve the program at both the office and the agency level.

At the office level:

- Improvements to NRO's vendor inspection planning would enhance the process NRC uses to identify and select vendors for routine inspections.

At the agency level:

- The extent of regulations and guidance applicable to vendors is not readily apparent, and NRC has an opportunity to more effectively communicate its regulatory expectations and requirements to vendors.

- NRC could clarify its expectations and requirements for Part 21 and commercial-grade dedication.

- NRC could clarify its expectations for approving certain accredited calibration laboratories.[2]

- NRC's approach to monitoring and evaluating counterfeit, fraudulent, and substandard items in the nuclear supply chain could be strengthened.

[2] Calibration laboratories calibrate measuring and test equipment used by vendors to evaluate the properties of materials and parts.

A. Enhanced Planning Would Improve Vendor Identification and Selection

Improvements to NRO's Vendor Inspection Program planning approach would enhance the process for identifying and selecting vendors for inspections. Currently, NRO's vendor identification and selection planning process is largely informal, and faces challenges in accurately identifying the number of vendors supplying to the nuclear industry and in selecting vendors for inspection. This is because NRO does not have a management framework that includes a formalized, documented approach for identifying and selecting vendors for inspection. Consequently, NRO's implementation of the Vendor Inspection Program, including resource planning and knowledge management efforts, may be hindered. Furthermore, NRO's current, less formal approach to planning could miss vendors that should be identified for potential vendor inspections.

Importance of a Formal Approach to Planning

Government, industry, and academic studies have all emphasized the importance of a formal approach to planning. Implementing large-scale change management initiatives, such as mergers and organizational transformations, are not simple endeavors and require the concentrated efforts of both leadership and employees. As shown in Table 1, commonly accepted, formal approaches to planning include establishing an overall strategy and goals, establishing methodologies for setting priorities, identifying performance metrics, and managing resources.

Table 1: Key Elements of Program Planning

- Overall Strategy and Goals
  Establishing a strategic framework and goals for an organization is integral to effective management and planning. Agency management is responsible for developing the detailed policies, procedures, and practices to fit their agency's operations and to ensure that they are built into and are an integral part of operations.

- Methodologies for Setting Priorities
  Establishing action-oriented implementation goals and a timeline with milestones to track the organization's progress towards its goals is essential. By demonstrating progress towards these goals, the organization builds momentum and demonstrates that real progress is being made. In addition, having implementation goals and milestone dates helps pinpoint performance shortfalls and gaps and suggests midcourse corrections, including any needed adjustments to the organization's future goals and milestones.

- Identifying Performance Metrics
  Specific metrics to monitor, evaluate, and report on results allows for a feedback process to clearly identify areas for improvement. Failure to establish metrics to evaluate success and failure will result in an organization unable to clearly evaluate mission accomplishment. Furthermore, such organizations will not know which activities are succeeding or failing.

- Managing Resources and Change
  Effective agencies are also characterized by having a senior manager who has ultimate authority for, and budgetary control over, program implementation. For example, International Atomic Energy Agency (IAEA) guidance for managing program changes in nuclear utilities includes identification of a project leader and an outline of the costs, benefits, and risks involved. For significant changes, executive oversight bodies are often used to establish priorities, monitor progress, and remove barriers to change.

Source: OIG analysis based on Government Accountability Office, IAEA, and academic documents.

Planning at the program level is also important to improve successful implementation and outcomes. NRO has recognized the importance of

program-level planning for two emerging challenges, the Advanced Power Reactor Program and NRO's Pandemic Response, when it produced formal planning documents for these programs. These planning documents do not necessarily contain all of the key elements of program planning, as described above. However, each of these planning documents is adapted to the needs of the programs at their current stages of development. For example, the Advanced Power Reactor Program plan is currently focused on identifying the resource needs to stand up the program, whereas the NRO Pandemic Response plan provides office-specific, detailed guidance to be used in conjunction with NRC's Pandemic Plan.

NRO Vendor Identification and Selection Planning Process Is Largely Informal

NRO's planning process for identifying and selecting vendors for routine inspections, and its strategy for guiding the process, is largely an informal one. Simply identifying the number of vendors is challenging, and NRO does not know how many vendors there are or how to identify changes in the vendor universe. Furthermore, NRO's planning for selecting vendors for inspection is based on an informal approach that relies primarily on professional judgment. Moreover, NRO's overall strategic approach to vendor identification and selection planning is informal as indicated by NRO staff, who have varying views of the purposes of the Vendor Inspection Program and routine vendor inspections.

Vendor Identification Presents Challenges

Identifying the vendors who supply to U.S. nuclear licensees is challenging. While vendors have to meet NRC regulations for providing quality products to the nuclear industry, vendors do not have to register with or seek licensing approval from NRC. Consequently, NRO staff members do not know how many vendors there are for the purpose of selecting vendors for inspection and assessing current resource needs.

When asked how many vendors supplied safety-related items to the nuclear industry, NRO managers and staff members opined a wide numerical range of vendors, from 300 or 400 to "thousands." Lacking any formal method for acquiring this information, vendor inspection staff members attempt to gauge the number of vendors by consulting various

industry vendor lists, attending industry meetings, and reviewing licensees' vendor lists, when such lists are available. Nonetheless, none of these sources are comprehensive, which helps to explain why staff members have such wide-ranging perceptions for the number of vendors. Such differences of opinion about the number of vendors across the spectrum of staff members complicates vendor selection and resource planning.

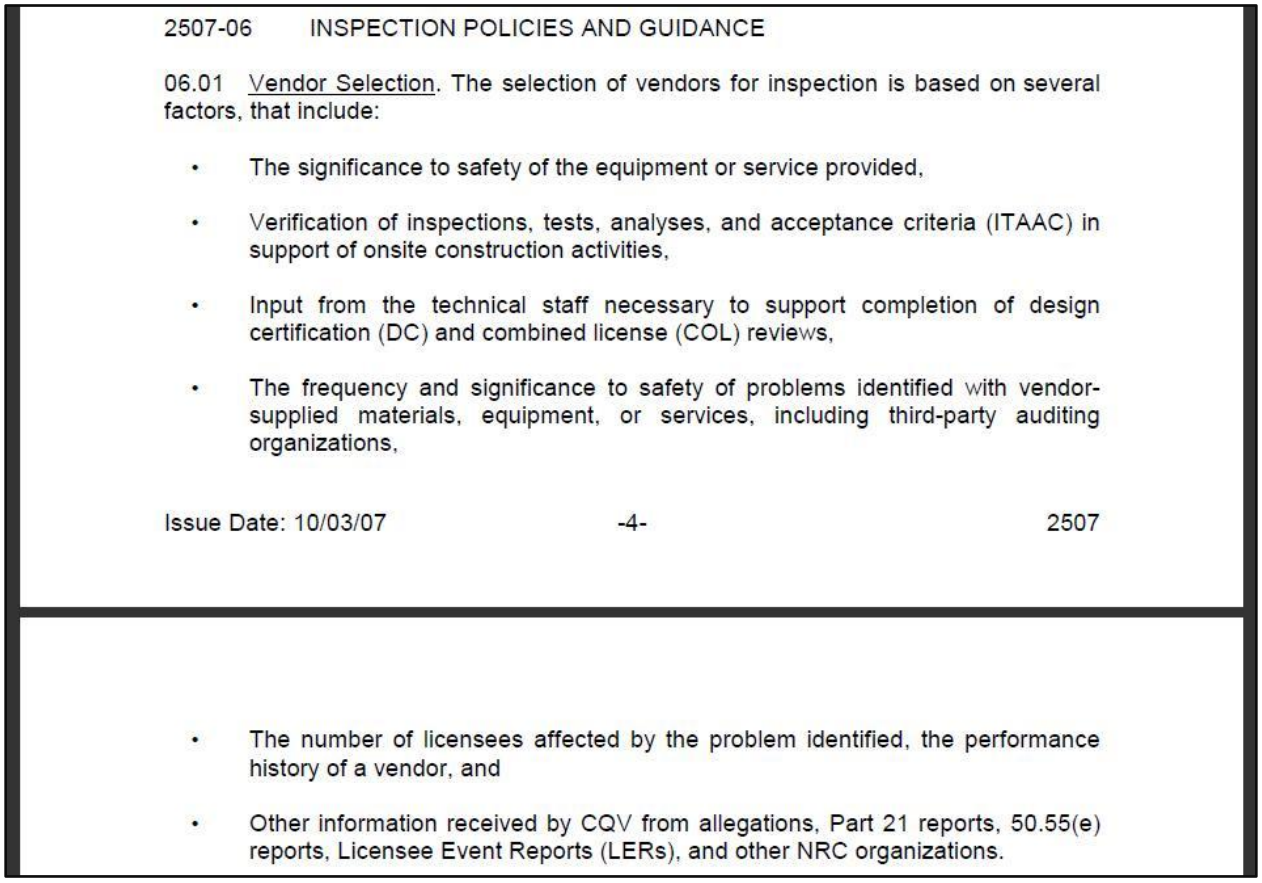
Vendor Selection Approach Relies on Professional Judgment

NRO's planning for selecting vendors for inspection is based on an informal approach that relies primarily on professional judgment. Typically, this professional judgment is exercised during brainstorming at group meetings and when individual vendor inspection staff members are solicited for suggestions based on their own experiences or knowledge. For example, one manager told OIG that people sitting down and discussing whom to inspect is the best method and that other approaches would be "unmanageable." Some NRO managers maintained that they conduct only 10 to 15 inspections per year and that, given the small number of inspections, there is no need for a more formal approach to selecting vendors for inspection. However, other NRO managers agreed, given the small number of inspections, that is all the more reason to have a more methodical vendor selection process.

A more formal, risk-based vendor selection methodology is available to agency vendor inspectors, yet most NRO inspection staff members did not appear to be aware of this methodology. In 2004, vendor inspection staff members in NRR developed a methodology for identifying and prioritizing key characteristics that would allow for a more rigorous selection of vendors for inspection by NRC. The methodology was derived from a risk-based model developed by the Federal Aviation Administration (FAA). The model included procedures for identifying and categorizing levels of risk, such as a given vendor's performance history, whether it was foreign-based or domestic, as well as the complexity of components being manufactured and whether the components would be used in safety-related systems. While this modified FAA methodology was never formally validated by NRR, some NRR staff have used it informally; however, NRO management and staff members were not using—or even familiar with—this risk-based tool for vendor selection.

A senior NRO inspector pointed to the vendor selection criteria in Inspection Manual Chapter (IMC) 2507, *Construction Inspection Program: Vendor Inspections,* as criteria by which NRO can identify vendors for inspection (see Figure 2). However, the broad-based criteria in IMC 2507 are not formally tied to a methodology that links the inspection staff members' variously-stated purposes of an inspection with the known vendor universe.

Figure 2: Broad Vendor Selection Criteria Excerpted from IMC 2507



2507-06 INSPECTION POLICIES AND GUIDANCE

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

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

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

Source: NRC Web site.

NRO Staff Have Varying Views of the Purposes of the Vendor Inspection Program

NRO's overall strategic approach to vendor identification and selection planning is informal, as indicated by NRO staff who have varying views of the purposes of the Vendor Inspection Program and routine vendor inspections. For example, one senior NRO manager told OIG that conducting routine inspections was "a required duty" that "provided value

added," while another senior NRO manager said that the main intent of the program was to ensure quality by "maintaining a global presence." Yet another staff member said that the program was intended to "maintain adequate oversight" of vendors. In no instance did NRO Vendor Inspection Program management or staff point to a commonly understood purpose of the program and the routine inspections that NRO conducts.

NRO's Vendor Inspection Program Lacks a Formalized, Documented Planning Approach

On the whole, the NRO Vendor Inspection Program conducts its activities without the benefit of a management framework that includes a formalized, documented planning approach. That is, NRO has not developed planning and guidance documents for the purpose of:

- Articulating the goals and objectives of the program and establishing metrics to guide progress towards the overall program goals.

- Identifying vendors with Appendix B quality assurance programs that supply safety-related parts and services to the nuclear industry.

- Setting risk-informed priorities for which vendors to inspect.

Program planning begins with identifying goals and objectives for the program. NRO management maintains that the vendor inspection planning approach is based on management's overall vision, and the program as it currently exists is the realization of that vision. However, management acknowledged that this vision was not formal in the sense that it was not documented. In addition, NRO management has not articulated clear goals and objectives for the purpose of conducting routine vendor inspections.

NRO does not have formal metrics and measures in place to guide the Vendor Inspection Program towards achieving its overall strategy and goals, identifying environmental changes, and determining resource needs. NRO management stated that they measure program results based on inputs received from the reactive inspection program in NRR, as well as the improved performance of some of the vendors. Given a vendor universe that ranges from a couple hundred to possibly thousands of vendors, it is unlikely that the 13 to 17 vendors that NRO inspects per

year is representative of overall vendor performance. This is especially so given the lack of any formal methodology for identifying and selecting vendors for inspection.

Program Resource Planning and Knowledge Management at Risk

Without clearly articulated goals and objectives for the program; a formalized, risk-informed documented approach to planning vendor identification and selection for inspection; or metrics for evaluating program performance, NRO's implementation of the Vendor Inspection Program, including resource planning and knowledge management efforts, may be hindered. This is especially true given changes in the new licensing environment. NRC is currently reviewing 18 combined operating license applications for a potential 27 new reactors. But this number is likely to change in the future, as is the number of potential domestic and international vendors supplying new construction efforts. NRO's current, less formal approach to planning could be missing vendors that should be identified for potential vendor inspections and may also result in expending resources to conduct information-gathering inspections of vendors rather than focus specifically on verifying the vendor's compliance with the regulations. For example, OIG observed one inspection where the vendor's organization, relationship to the licensee, and scope of work were not known. Consequently, the inspection team was faced with justifying the inspection on the basis of what they learned about that vendor's ongoing activities, rather than from specific criteria provided through a documented planning approach.

Additionally, NRO's informal, undocumented approach to identifying vendors for inspection could affect knowledge transfer efforts from more experienced inspectors to newer, less experienced staff members. Currently, Vendor Inspection Program management relies largely on a process whereby the vendor identification and selection process is communicated verbally from managers to staff members. However, transfers, promotions, and retirements have reduced the number of vendor inspection staff members who are qualified to lead inspections. Newer staff members, therefore, are coming to the Vendor Inspection Program without the same level of institutional knowledge as their predecessors. Given some of the ongoing personnel changes within NRO, a senior manager was unaware if existing NRO guidance was sufficient for newer, less experienced inspectors.

Resource planning in NRO is also at risk. Without a formalized, documented approach to identifying vendors for inspection, NRO is left to estimate the size of both the domestic and foreign vendor universe, the purpose and number of desired inspections, and the resulting resource requirements to perform those inspections. For example, in a December 2009 memorandum to the Commission, NRO asserted that "the appropriate number of inspections to be conducted annually will always be a matter of judgment." In any case, agency managers stated that "NRC is in a flat budget world" and the constrained budget has been the primary determinant in how many vendors can be inspected. Such a resource-constrained environment makes formal, documented planning even more important in the effort to identify vendors for potential inspection.

Recommendations

OIG recommends that the Executive Director for Operations:

1. Develop an NRO Vendor Inspection Program planning document that:

    a. Articulates a clear purpose for the Vendor Inspection Program.

    b. Establishes metrics to evaluate the success of the Vendor Inspection Program.

2. Develop and document a methodology to identify vendors that supply safety-related parts and services to the nuclear industry with Appendix B quality assurance programs.

3. Develop and document a risk-informed methodology to select vendors for inspection.

B. Opportunity To More Effectively Communicate Requirements

NRC relies on nuclear vendors' understanding and implementation of its regulations to assure that safety-related components will perform adequately in service, and that defects are reported. In order for vendors supplying nuclear components and services to be knowledgeable of their obligations under the regulations, NRC must effectively communicate the regulations. NRC has undertaken a number of efforts to communicate regulations to vendors, but some vendors are not aware of all obligations or NRC expectations. NRC's approach to communicating with vendors is not as effective as it could be because it does not have an outreach/ communications plan. When vendors are not knowledgeable of their obligations under NRC regulations, vendors might not report defects or otherwise fully assure that safety-related components will perform adequately in service.

Vendors' Role in the Oversight of Quality Requires Adequate Awareness of Requirements

The two primary NRC regulations regarding vendor quality assurance oversight are Appendix B and Part 21. Appendix B enumerates quality assurance criteria for components and services used in nuclear power plants. Part 21 establishes (1) procedures for reporting defects in safety-related components, and (2) a process for providing reasonable assurance that commercial parts used in nuclear power plants in safety related applications will perform their intended safety function.

NRC relies on vendors' awareness and implementation of Appendix B and Part 21 requirements to assure that safety-related systems will perform adequately in service, and that defects are reported. NRC also recognizes the importance of effectively communicating these regulations to vendors supplying safety-related nuclear components and has therefore engaged in a number of efforts to make vendors aware of their obligations. In fact, NRC recognizes this as so important, it attempts to make both vendors and licensees aware of the particular role vendors play in overseeing vendor and sub-vendor activities related to the design, manufacture, construction, and operation of safety-related systems and components.

NRC leadership and vendor inspection staff members have stressed the importance of vendors being aware of and understanding their obligations under NRC regulations. For example, while speaking at an American Nuclear Society conference, NRC's then-Chairman urged licensees, consultants, and vendors to be prepared to face the challenge of overseeing the quality and authenticity of globally manufactured components. In addition, NRC vendor inspection staff members have emphasized vendor awareness of NRC regulations and have stressed this to vendors and licensees at various nuclear industry conferences and during vendor inspections.

In addition to relying on vendors' awareness and implementation of the regulations, NRC vendor inspection staff members expect licensees to inform their vendors of NRC regulations and pass along other information that could potentially increase vendor knowledge and understanding of vendor obligations under NRC regulations. For example, a vendor inspection staff member told OIG auditors that "since licensees approve vendor programs and buy components from vendors, licensees make sure vendors receive the information."

NRC's Communication Approach

NRC has reached out to vendors to inform them of their regulatory obligations and NRC expectations, yet the agency's approach to communicating with vendors is not as effective as it could be. For each of NRC's primary methods of communicating with vendors—presentations, two vendor workshops, generic communications, the NRC Web site—OIG auditors obtained direct feedback from some vendors that indicated problems with being aware of or receiving information from the agency. Furthermore, NRC staff members are unsure of the effectiveness of the agency's outreach and communications activities.

Presentations

NRC vendor inspection staff members have given 38 presentations at no fewer than 21 nuclear industry-led meetings over the last 5 years. These presentations generally covered reporting of defects and noncompliance; quality assurance processes; commercial-grade dedication; preventing the entrance of counterfeit, fraudulent, and substandard items into the nuclear

supply chain; and NRC vendor inspection activities. These presentations were directed at vendors and licensees at various nuclear industry-related conferences and meetings.

When asked about the effectiveness of the presentations at industry-led meetings, NRC staff members could not point to any formal vendor feedback or agency analysis of effectiveness. Rather, NRC's vendor inspection staff members have simply asserted they believe these presentations are effective. For example, a senior member of the vendor inspection staff contended that they know presentations at conferences are effective because inspection staff members will inspect a vendor they have not inspected in nearly 2 decades and not find "15,000 problems." Another senior member of the vendor inspection staff said they know vendors are aware of their obligations merely because the regulations are public. However, it is difficult to claim that presentations are effective given that all vendors do not attend industry meetings, NRC does not generally know which vendors have attended all meetings, and NRC has not limited inspections to vendors who have attended industry meetings.

OIG sought feedback from vendors about the effectiveness of NRC presentations as a method of obtaining knowledge about the regulations, and noted a variety of vendor concerns. For example, one recently inspected small vendor supplying safety-related nuclear components contended it is not always able to attend these meetings given scheduling or cost constraints. Additionally, some vendors are not aware of NRC presentations at meetings and, in any case, do not always have access to all industry-related meetings. For example, while the Electric Power Research Institute (EPRI)[3] and the Nuclear Procurement Issues Committee (NUPIC)[4] periodically host conferences, vendors generally are not invited to all meetings and sometimes do not have access to industry-generated guidance related to implementing NRC regulations.

Additionally, some vendors are located outside the United States and do not always hear of these events; others, who are aware, told OIG auditors they are not always able to attend given the travel costs.

[3] EPRI is an independent, non-profit company performing research, development, and demonstration in the electricity sector for the benefit of the public.
[4] NUPIC is an organization of nuclear power utilities in the United States and overseas. On behalf of its members, NUPIC evaluates suppliers that have five or more NUPIC members as customers through joint-utility Appendix B audits.

2008 Vendor Workshop

NRC hosted a Vendor Workshop in 2008, with the purpose to:

1) Facilitate discussions on reactor construction issues.

2) Provide the opportunity for vendors to understand regulations.

3) Show how NRC evaluates vendors' implementation of NRC regulations.

The main session of the workshop was devoted to providing NRC and the nuclear industry some perspectives on implementing NRC regulations and related vendor issues (see Figure 3).

Figure 3: Presentations Covered at NRC's 2008 Vendor Workshop

Vendor Oversight Presentations
NRC Perspective on Vendor Inspection Programs
Vendor Challenges for New Reactor Construction, Industry Perspective
NRC Vendor Program and Issues
NRC International Vendor Activities
NUPIC Industry Perspective on Supplier Oversight Issues
NIAC Assessment Committee Overview
Commercial Grade Dedication Historical Perspective
Critical Characteristics and Acceptance Methods
Commercial Grade Dedication Acceptance Methods
10 CFR Part 21 Requirements and Guidance
NRC Presentation 10 CFR Part 21 Evaluations
Industry Perspective 10 CFR Part 21 Evaluations a Part 50 Licensee Perspective
Vendor Perspective Part 21 Evaluations
NRC Presentation Critical Characteristics
Industry Perspective Critical Characteristics Selection
Vendor Perspective Critical Characteristics
NRC Guidance on Sampling Process
Industry Perspective on Sampling in Commercial Grade Item Dedication
Vendor Perspective on Sampling Practices

Source: NRC Web site.

NRC attempted to notify vendors of the workshop in several ways. Vendor inspection staff members personally contacted some vendors. The agency also issued a press release and posted a notification of the workshop on its Web site. Additionally, NRC notified vendors of the workshop by requesting industry associations—such as NUPIC and the Nuclear Energy Institute—to pass the notice to vendors.

In fact, NRC relies on industry associations and licensees to pass information to vendors, but NRC is not able to verify whether this information is received by vendors. For example, a vendor who recently entered the nuclear industry indicated it was not aware of the 2008 vendor workshop. Another vendor told OIG auditors it would not have been aware of the workshop had it not recently interacted with NRC in an earlier inspection, despite the fact that it supplied to numerous licensees. A representative from a licensee and another from a vendor also told OIG auditors they do not always pass NRC information to their vendors or sub-vendors.

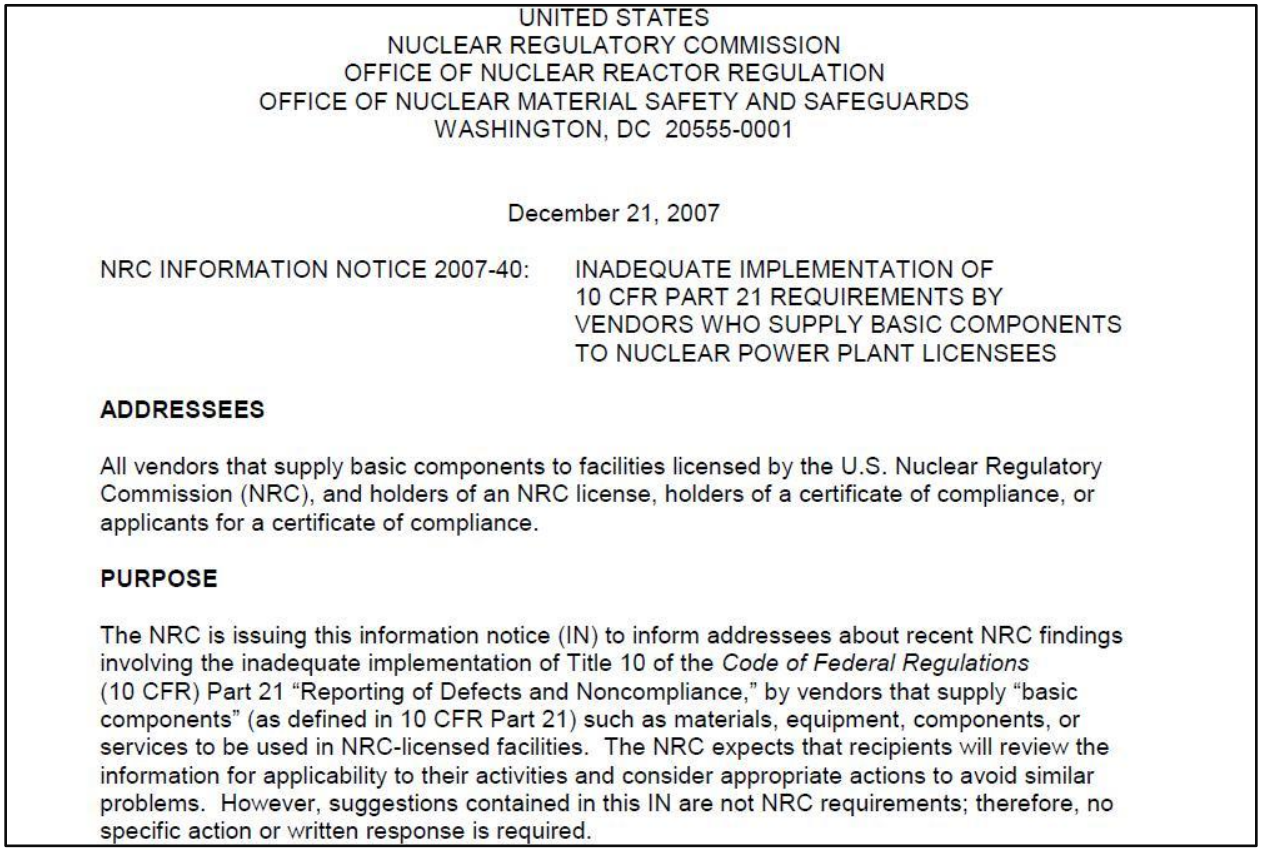
Although NRC solicited feedback from attendees, the effectiveness of NRC's efforts to notify the vendor universe about the workshop is largely unknown. NRC senior vendor inspection staff members conceded not all vendors were made aware of the 2008 workshop and NRC staff members are not sure how many vendors were actually notified. One NRO manager expressed surprise that so many vendors attended the workshop. OIG has since determined that at least 186 different vendors and utilities were represented at the 2008 workshop, which is likely a fraction of the vendors providing components and services to the nuclear industry under NRC regulations.

Generic Communications

NRC issued several generic communications to licensees regarding vendor-related quality assurance issues.[5] Moreover, in 2007, NRC issued Information Notice 2007-40 directly to vendors who supply safety-related components to facilities licensed by NRC, as seen in Figure 4.

[5] NRC strives to maintain an effective generic communications program for the purpose of communicating with the nuclear industry on generic issues. Generic communications are issued to inform the nuclear industry of issues related to safety, security, safeguards, and environmental significance.

Figure 4: Addressees and Purpose Excerpted from Information Notice 2007-40



UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

December 21, 2007

NRC INFORMATION NOTICE 2007-40: INADEQUATE IMPLEMENTATION OF 10 CFR PART 21 REQUIREMENTS BY VENDORS WHO SUPPLY BASIC COMPONENTS TO NUCLEAR POWER PLANT LICENSEES

ADDRESSEES

All vendors that supply basic components to facilities licensed by the U.S. Nuclear Regulatory Commission (NRC), and holders of an NRC license, holders of a certificate of compliance, or applicants for a certificate of compliance.

PURPOSE

The NRC is issuing this information notice (IN) to inform addressees about recent NRC findings involving the inadequate implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 "Reporting of Defects and Noncompliance," by vendors that supply "basic components" (as defined in 10 CFR Part 21) such as materials, equipment, components, or services to be used in NRC-licensed facilities. The NRC expects that recipients will review the information for applicability to their activities and consider appropriate actions to avoid similar problems. However, suggestions contained in this IN are not NRC requirements; therefore, no specific action or written response is required.

Source: NRC Web site.

The purpose of this information notice was to inform vendors of NRC findings of inadequate implementation of regulatory requirements. The information notice was sent to vendors on an NRC e-mail listserv and to other vendors listed on an industry association vendor list. Similar to outreach for the vendor workshop, while NRC vendor inspection staff members recognized the importance of making vendors aware of their obligations under the regulations, NRC relied on industry associations and licensees to pass this information to vendors, and cannot verify whether vendors received the information notice.[6]

Several vendors and workshop attendees indicated they were either not aware or did not understand the purpose of NRC generic communications. OIG auditors reviewed questions submitted at the 2008 vendor workshop,

[6] While NRC internal procedures do not require staff to track receipt of information notices, NRC relies on licensees and vendors to pass this and similar information to their suppliers.

interviewed vendors at nuclear industry meetings, and observed NRC inspections of vendors. Licensee and vendor representatives told OIG auditors that NRC efforts are mostly targeted at large vendors, and new vendors do not know how to obtain information on compliance. One licensee representative also remarked that vendors who do not have an ongoing relationship with a licensee have difficulty obtaining vendor-related information.

NRC Web Site

NRC vendor inspection staff members often direct vendors and licensees to the NRC Web site to obtain information on vendors' obligations under NRC regulations, but some vendors have trouble navigating the NRC Web site. To begin with, it is not clear from the NRC home page where a vendor unfamiliar with NRC or the Web site should begin. Vendors and an industry consultant told OIG auditors that while NRC posts valuable information on its Web site, many stakeholders are unaware of vendor-specific information on the Web site while others have difficulty navigating the site. For example, a vendor currently supplying components for the nuclear industry told OIG auditors that the NRC Web site is "tedious" and "not user friendly." This vendor also complained that while it conducts weekly searches for vendor-specific material, most of the search results point the vendor to unrelated information. Additionally, a small vendor new to the industry told OIG auditors it had difficulty navigating the NRC Web site and was unsure it was getting the most up-to-date information or recent Web pages. Moreover, an industry consultant told OIG auditors many vendors fear they might be in violation of NRC regulations because they are unable to distinguish old information from recent changes and updates on the NRC Web site.

NRC Would Benefit from a Formal, Documented Plan

NRC does not currently have—and would benefit from—a formal, documented outreach/communications plan for vendor-related activities. A formal plan would include a means for identifying the target audience and the specific messages to be communicated to vendors, measurable objectives, an implementation strategy, a means to weigh the efficiency and effectiveness of various outreach and communications methods, and a means to obtain feedback.

Decreased Vendor Ability To Assure Quality of Components and Services

When vendors are not aware of the regulations, they might not report defects or otherwise fully assure that safety-related components will perform adequately in service. Throughout OIG's audit, vendors, licensees, industry consultants, and NRC staff members expressed concerns about the nuclear industry's awareness of NRC regulations and changes in regulation, guidance from NRC, and industry-generated information related to assuring that safety-related components perform adequately in service and that defects are reported. For example, during a recent nuclear industry procurement meeting, representatives from several licensees and vendors discussed the challenges of assuring that new, current, and foreign vendors are aware of their obligations under NRC regulations.

Because NRC does not have an outreach/communications plan for vendor-related activities, it cannot fully identify and reach its target audience, or effectively plan presentations in light of varying vendor sophistication or ability to understand information. A documented plan would help NRC evaluate whether outreach activities effectively communicate intended messages, and build upon previous outreach activities by integrating feedback from vendors into an overall outreach strategy.

Recommendation

OIG recommends that the Executive Director for Operations:

4. Develop and use a vendor outreach/communications plan.

C. Commercial-Grade Dedication and Part 21 Regulations and Guidance Could Be Clarified

Even when vendors are aware of the applicable NRC regulations and other regulatory information, NRC could clarify its expectations and requirements for Part 21 and commercial-grade dedication.[7] NRC presumes that adherence to its regulatory requirements on the part of licensees and vendors assures safety. However, nuclear vendors are confused about how to adequately implement Part 21 and commercial-grade dedication due to unclear or insufficient guidance and guidance that conflicts with regulation. Consequently, vendors might fail to implement various aspects of their programs in accordance with NRC's regulations, guidance, or expectations. Ultimately, this could lead to vendors (1) supplying parts and services to nuclear power plants that do not meet NRC regulatory requirements or quality assurance expectations, and (2) inadequately reporting defects.

NRC Regulatory Requirements and Expectations for Nuclear Vendors

According to agency management, NRC presumes safety based on regulatory compliance. That is, NRC presumes that adherence to its regulatory requirements on the part of licensees and vendors assures (1) the quality of safety-related parts and services, (2) that safety-related components will perform adequately in service, and (3) that defects will be properly reported. The primary regulations applicable to nuclear vendors are Appendix B and Part 21. NRC regulatory requirements and guidance applicable to vendors covers such topics as the nuclear procurement process, including the use of commercial off-the-shelf parts and services, and the reporting of defects.

The Nuclear Procurement Process

The regulation of vendors is, in part, based on the nuclear procurement process, which is intended to assure that plants obtain quality products and services. Vendors that supply safety-related equipment or services to the nuclear industry must meet NRC's quality assurance requirements, as

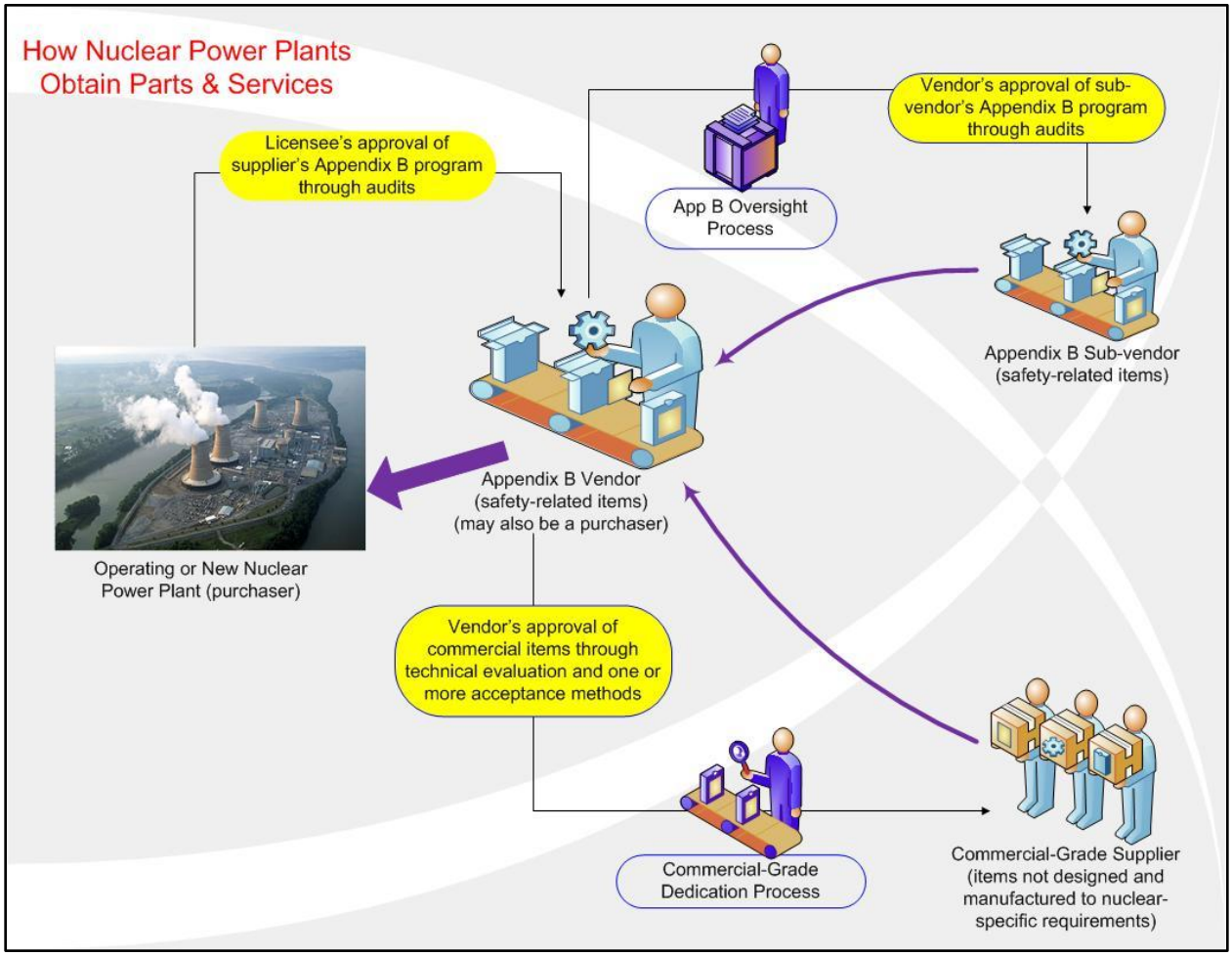
[7] If a customer decides to purchase commercial-grade items, Part 21 requires the customer receiving the items to use a commercial-grade dedication process to provide reasonable assurance that these items destined for use in nuclear power plants will perform their intended safety function.

promulgated in Appendix B.[8] Therefore, nuclear power plant safety-related structures, systems, and components must be designed and manufactured under an Appendix B quality assurance program.

Under NRC regulations, safety-related parts and services can only be procured in two ways, as shown in Figure 5. The purchaser of safety-related parts or services implementing an Appendix B quality assurance program can procure parts and services from a vendor that has been approved by the purchaser through an audit of that vendor's Appendix B quality assurance program. Alternatively, the purchaser, through its Appendix B quality assurance program, may opt to dedicate commercial-grade items provided by commercial firms using a process described in Part 21.

[8] Appendix B requires that a quality assurance program be applied to all activities affecting structures, systems, and components of reactors that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components.

Figure 5: The Nuclear Procurement Process



Source: OIG analysis and NRC documents.

Commercial-Grade Dedication

Commercial-grade dedication is an acceptance process undertaken to provide reasonable assurance that a commercial-grade item[9] to be used as a basic component[10] will perform its intended safety function. In this respect, the commercial-grade item is deemed equivalent to an item custom designed and manufactured under an Appendix B quality

[9] A commercial-grade item is a structure, system, or component that was not designed and manufactured as a basic component.

[10] A basic component is a structure, system, or component that assures the integrity of the reactor coolant pressure boundary; the capability to shut down the reactor and maintain it in a safe shutdown condition; or the capability to prevent or mitigate the consequences of accidents. It is, essentially, a safety-related component.

assurance program. NRC regulations require commercial-grade dedication to be performed under an Appendix B quality assurance program.

Commercial-grade dedication is defined in Part 21. That regulation defines a process to provide reasonable assurance that a commercial-grade item will perform its intended safety function. Specifically, Part 21 states that this assurance is achieved by identifying the critical characteristics[11] of the item and then verifying the item meets these critical characteristics through one or more of four acceptance methods.[12] EPRI, a private industry group, developed guidance for licensees to use in utilizing commercial-grade items. In Generic Letter 89-02, NRC conditionally endorsed EPRI's guidance on commercial-grade dedication.

Requirements for Reporting Defects and Posting

Nuclear licensees and vendors are required to report to NRC when a nuclear power plant safety-related component contains a defect that could create a "substantial safety hazard,"[13] and the documents relating to this reporting requirement are to be posted on the vendor's premises. NRC promulgated defect reporting requirements through Part 21. Part 21 established a process by which licensees and vendors must evaluate "deviations"[14] to determine whether they could cause a substantial safety hazard. A deviation that could cause a substantial safety hazard is a "defect." Licensees and vendors must report defects to NRC. Part 21 also prescribes that its requirements be prominently posted on the premises of any facility licensed or otherwise regulated in the United States under the Atomic Energy Act of 1954.

[11] Critical characteristics are those important design, material, and performance characteristics of a commercial-grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.
[12] Part 21 describes four methods for accepting commercial grade items: (1) inspections, tests, or analyses; (2) commercial grade surveys; (3) product inspections or witness at holdpoints at the manufacturer's facility; and (4) analysis of historical records for acceptable performance.
[13] A substantial safety hazard is a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or regulated by NRC.
[14] A deviation is a departure from the technical requirements included in a procurement document.

Vendors Are Confused About Commercial-Grade Dedication and Part 21 Regulatory Requirements

Vendors are confused about and are having difficulty implementing NRC regulations and guidance on (1) commercial-grade dedication acceptance methods and sampling, (2) Part 21 reporting requirements, and (3) Part 21 posting requirements.

Confusion Over Commercial-Grade Dedication Acceptance Methods and Sampling

Vendors are confused about NRC's commercial-grade dedication expectations and requirements. NRC vendor inspections indicate that implementation of commercial-grade dedication programs is a problem for vendors. From January 2006 through March 2010, 18 vendors were found to have deficient commercial-grade dedication programs. During an inspection, one vendor quality assurance manager referring to commercial-grade dedication said that he had "been doing this for 3 or 4 decades and [was] just now figuring out how it is supposed to work."

Vendors are specifically confused about which one, if any, of the four acceptance methods is specifically required for accepting an item from a commercial supplier. Several questions submitted by vendors to NRC during the 2008 NRC vendor workshop expressed confusion about whether one of the acceptance methods was required to be conducted as required by Part 21. Additionally, a nuclear industry consultant who regularly interacts with nuclear vendors told the OIG that many vendors ask him about this issue.

Vendors are also confused about how to conduct sampling of identical commercial items during the commercial-grade dedication process. Vendors dedicating identical items might need to destroy some of the items during testing to determine if all the items are acceptable. Because the items are destroyed, a sample must be selected, and an adequate basis for the sample must be documented. OIG witnessed one vendor's staff struggle to explain its justification in a sampling plan that called for sampling only one item per lot. Additionally, several of the questions submitted to NRC during the December 2008 NRC vendor workshop, which included presentations on commercial grade dedication and

sampling, indicated that vendors were confused about how to conduct sampling during commercial-grade dedication.

Confusion About How To Adequately Implement Part 21 Reporting Requirements

Another regulatory area that is confusing to vendors is how to adequately implement a Part 21 program. Part 21 requires vendors to evaluate deviations that could cause a substantial safety hazard or inform their customers if they are unable to perform the evaluation. If a deviation could cause a substantial safety hazard, it is considered a defect, and licensees and vendors must report defects to NRC. Of the 57 vendor inspection reports issued January 2006 through March 2010, 32 included one or more notices of violation against Part 21, indicating that the nuclear vendors' Part 21 programs had one or more deficiencies.

OIG observed firsthand how Part 21 is confusing to vendors. During four of eight vendor inspections that OIG observed,[15] NRC identified inadequacies with the vendors' Part 21 implementation procedures. One vendor quality assurance manager told the OIG that he gets "mixed signals" on Part 21. For example, with regard to Part 21 reporting, the quality assurance manager said it is hard to understand when to submit a Part 21 report. This manager explained that his company was criticized during an Appendix B audit by the customer for making a Part 21 report when it should not have, and then for not making a report when it should have.

Difficulty Implementing Part 21 Posting Requirements

Additionally, vendors are having difficulty complying with Part 21 posting requirements. Vendors must post a current copy of Part 21, Section 206 of the Energy Reorganization Act, and the vendor's procedures (or information that explains how to obtain a copy of the procedures) adopted to implement the regulation in a conspicuous position on the vendor's premises. At five of the six domestic[16] vendor inspections that OIG observed, NRC reviewed the vendors' compliance with Part 21 posting requirements. Of those five vendors, NRC found three of the vendors'

[15] Of the eight inspections OIG observed, two were followups to previous inspections that had indentified inadequacies with the vendors' implementation of Part 21.
[16] Part 21 posting requirements apply only to facilities in the United States.

attempts to comply with the posting requirements were inadequate, but NRC did not issue violations for the non-compliant postings. For example, in one instance NRC found that the vendor's Part 21 posting did not include the title of the vendor's Part 21 procedure or information on where the procedure is located. NRC inspectors chose not to issue a violation for this omission.

Issues with Regulations and Guidance Cause Confusion

Vendors are confused about commercial-grade dedication and Part 21 regulatory obligations due to unclear or insufficient guidance and guidance that conflicts with regulation. Specifically, (1) some of the industry guidance that NRC has conditionally endorsed for commercial-grade dedication acceptance methods conflicts with NRC regulations, (2) NRC has not approved any guidance for sampling for commercial-grade dedication, (3) NRC has not issued any guidance explaining a process that it considers compliant with Part 21, and (4) NRC's Web site does not clearly reflect when the Part 21 regulation has changed.

Commercial-Grade Dedication Guidance Conflicts with Regulation

Vendors are confused about whether one of the four acceptance methods for commercial-grade dedication is required because industry guidance that was conditionally endorsed by NRC conflicts with NRC regulatory requirements. According to Part 21, dedication is conducted by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser after delivery, *supplemented as necessary by one or more of the* remaining acceptance methods. However, EPRI's guidance—which was conditionally endorsed by NRC—indicates that the four acceptance methods, either individually or in combinations, is adequate. This conflicts with Part 21 because the first method (inspections, tests, or analyses) would always be performed according to Part 21, whereas EPRI's guidance says any of the four acceptance methods is suitable.

NRC Does Not Have Guidance for Sampling in Commercial-Grade Dedication

Vendors are also confused about how to conduct sampling of identical commercial parts during the commercial-grade dedication process

because NRC has not approved any guidance on sampling for commercial-grade dedication. In 1997, NRC issued draft guidance for sampling in commercial-grade dedication and, in 1999, EPRI issued its own guidance document. However, NRC has neither approved its draft guide, nor endorsed EPRI's guidance. In the absence of approved regulatory or industry guidance, NRC staff point vendors to two inspection procedures (IP)—IP 38703 and IP 43004—for guidance on sampling. These inspection procedures are written as guidance for NRC inspection staff members assessing sampling in commercial-grade dedication. The procedures are not a model for licensees or vendors to use in implementing NRC regulatory requirements.

NRC Has Not Issued Guidance Explaining Part 21 Reporting Requirements

Vendors are confused about how to implement Part 21 reporting requirements because NRC has not issued regulatory guidance describing a process that it considers compliant with the regulation. Many stakeholders have pointed to Part 21 as being one of the most complex regulations NRC has ever issued. In light of this, regulatory guidance could help vendors understand a process that NRC considers compliant with the regulation. However, NRC has not issued any guidance to help vendors implement Part 21. Recognizing that this regulation is difficult to understand, NRC has proposed a comprehensive rulemaking to revise Part 21. The rulemaking may begin in FY 2012 and could take 3 or 4 years to complete.

Part 21 Changes Are Not Clearly Indicated on the NRC Web Site

Vendors are having difficulty complying with Part 21 posting requirements because the regulations on NRC's Web site do not clearly reflect what or when changes have been made when regulations are revised, as shown in Figure 6. Compliance with the posting requirement necessitates that the vendor have the most up-to-date revision of Part 21. However, because vendors do not know where to go to get the most up-to-date version and they do not know when the regulation changed, vendors have difficulty complying with this requirement. In one example, a vendor quality assurance manager explained that NRC previously issued his company a violation for an out-of-date Part 21 posting. He said that as a result of that inspection, he revised his procedure to check the regulations

for changes every year. Even though a year had not yet elapsed since he last checked to see if the regulation had changed, he decided to check anyway, and in fact the regulation had changed. He said that if he had followed his firm's procedure, his company would have again been in violation.

Figure 6: NRC's Title 10 Web Page

Source: NRC Web site.

Vendor Confusion Might Lead To Inadequate Implementation of Appendix B and Part 21 Requirements

As a result of vendors' confusion about NRC regulatory requirements and expectations, vendors may fail to implement various aspects of their Appendix B and Part 21 programs in accordance with NRC's regulations,

guidance, or expectations. Vendors might not implement commercial-grade dedication requirements—including acceptance methods and sampling—in the manner that NRC expects or in compliance with the regulation, which could lead to substandard safety-related parts being supplied to nuclear power plants. Additionally, vendors might not be properly implementing Part 21 evaluation, reporting, and posting requirements, which could lead to (1) defects not being properly reported and (2) vendors unknowingly violating Part 21 posting requirements. If defects go unreported, it is possible that substandard safety-related parts could be supplied to, or in service at, operating nuclear power plants.

Recommendations

OIG recommends that the Executive Director for Operations:

5. Align NRC guidance and regulations to clarify acceptance methods for commercial-grade dedication.

6. Issue regulatory guidance to clarify sampling expectations for commercial-grade dedication.

7. Issue regulatory guidance describing a process that NRC considers acceptable for compliance with Part 21.

8. Clearly indicate via the NRC public Web site how and when Part 21 has changed.

D. Calibration Laboratories Approval Guidance Could Be Clarified

NRC's guidance for approving accredited commercial-grade calibration laboratories—which calibrate measuring and test equipment used by vendors to evaluate the properties of materials and parts—could be clarified. In response to a request from one of its licensees, NRC allowed a process permitting the licensee to approve calibration laboratories based on the reviews performed by accrediting bodies in lieu of an Appendix B audit or a commercial-grade survey. However, since NRC's guidance documents describing this process are disparate, vendors are confused about, and have difficulty implementing, the process. Consequently, vendors' approval of laboratories may not be in accordance with NRC's expectations, vendors may find themselves unknowingly in violation of Appendix B or NRC commercial-grade dedication requirements, and vendors could find they have used out-of-calibration equipment during the manufacturing process.

Accredited Commercial-Grade Calibration Laboratories

Calibration laboratories calibrate measuring and test equipment used by vendors to evaluate the properties of materials and parts. Under Appendix B, licensees and vendors must adequately control measuring and test equipment used on safety-related parts. In many instances, vendors send measuring and test equipment to a calibration firm for necessary calibration and adjustment. Calibration of measuring and test equipment used by vendors manufacturing safety-related parts must be procured from an Appendix B firm approved by the purchaser, or the services must undergo the commercial-grade dedication process.

In 2004, one nuclear licensee proposed an alternative process to use calibration laboratories that had been accredited by two accreditation bodies—the American Association for Laboratory Accreditation (A2LA)[17] and the National Voluntary Laboratory Accreditation Program (NVLAP)[18]—in lieu of an Appendix B audit or

[17] A2LA is a nonprofit, nongovernmental, public service, membership society that provides comprehensive services in laboratory accreditation and laboratory-related training.
[18] NVLAP is run by the National Institute of Standards and Technology. NVLAP provides third-party accreditation to testing and calibration laboratories.

commercial-grade dedication. In 2005, NRC issued a Safety Evaluation Report for this licensee approving the alternative process; however, in that report, NRC included some additional steps the utility would have to take in order to use the accredited calibration laboratories. Subsequent to the issuance of the Safety Evaluation Report, NRC has issued several letters expanding this recognition to include additional accreditation bodies in the United States. Also, NRC issued a letter clarifying that vendors could use calibration laboratories accredited by the recognized accreditation bodies, provided that vendors adhered to the additional steps stipulated in the Safety Evaluation Report.

Approving Accredited Commercial-Grade Calibration Laboratories Is Confusing

Vendors are confused about how to adequately implement the process in which NRC allows vendors to approve accredited calibration laboratories in the United States for safety-related services. For example, one vendor quality assurance manager explained that his company developed a procedure for selecting calibration suppliers based on accreditation by A2LA because "A2LA" was the latest "buzz word." However, the vendor had not adhered to the additional steps stipulated by NRC. Furthermore, OIG observed the inspection of another vendor trying to implement this process, and NRC issued a nonconformance to this vendor for approving an accredited calibration firm without performing a supplier audit, even though an audit may not have been necessary according to NRC's own guidance.

Calibration Laboratories Approval Process Guidance Is Disparate

NRC guidance explaining the process to approve accredited calibration laboratories is disparate. In addition to issuing the Safety Evaluation Report and several additional letters expanding NRC's recognition to additional accrediting bodies, NRC, in June 2006, issued a letter to NUPIC clarifying that vendors could utilize the services of the calibration laboratories accredited by the recognized accrediting bodies. NRC also described this process in the Standard Review Plan (NUREG-0800). NRC has posted most of these documents on the section of its Web site devoted to calibration services, yet the letter specifically directed at vendors—the June 2006 letter to NUPIC—is not. Having that vendor-specific letter listed with all the other correspondence explaining this

process would make it easier for vendors to understand that they may use this process to approve calibration laboratories accredited by the recognized accreditation bodies.

Furthermore, some of these NRC documents have different lists of steps that are required for implementing the process, making it difficult for vendors to know how to implement the process in the manner NRC expects. One NRO manager said that NRO and NRR staff members are reevaluating the NRC position on allowing licensees and vendors to approve accredited calibration laboratories. NRC staff are considering whether to expand this recognition to include international calibration laboratories as well as testing laboratories in the United States and overseas. One senior NRO staff person noted that accreditation bodies, such as A2LA, are better at reviewing calibration laboratories than licensees or vendors because the accreditation body staff are experts in calibration.

Vendor Confusion Might Lead To Inadequate Implementation of Appendix B and Part 21 Requirements

As a result of vendors' confusion about NRC regulatory guidance and expectations for approving certain accredited calibration laboratories, (1) vendors might not be approving accredited calibration laboratories in the manner that NRC expects, (2) vendors could find themselves unknowingly in violation of NRC regulations, and (3) vendors could later determine that they used out-of-calibration measuring and test equipment during the manufacture and assembly of safety-related parts and components or during the dedication of commercial-grade items.

Recommendation

OIG recommends that the Executive Director for Operations:

9. Develop guidance that clarifies the requirements for vendors on how to approve accredited commercial-grade calibration laboratories for safety-related applications.

E. NRC's Approach to Counterfeit, Fraudulent, and Substandard Items Could Be Strengthened

NRC could strengthen its current approach to counterfeit, fraudulent, and substandard items (CFSI). Both the Federal Government and private sector have recognized the increasing prevalence of CFSI in nuclear and other industries. However, NRC's approach has been primarily reactive and based largely on the abilities of one or two individuals to monitor and evaluate the threat. This is because NRC lacks a formal strategy and plan to monitor and evaluate potential CFSI, and consider program changes to address the CFSI issue. Consequently, the lack of any formal strategy or framework to address CFSI could result in reactor construction problems with major implications for public health and safety.

The Need To Address CFSI as a Serious Threat

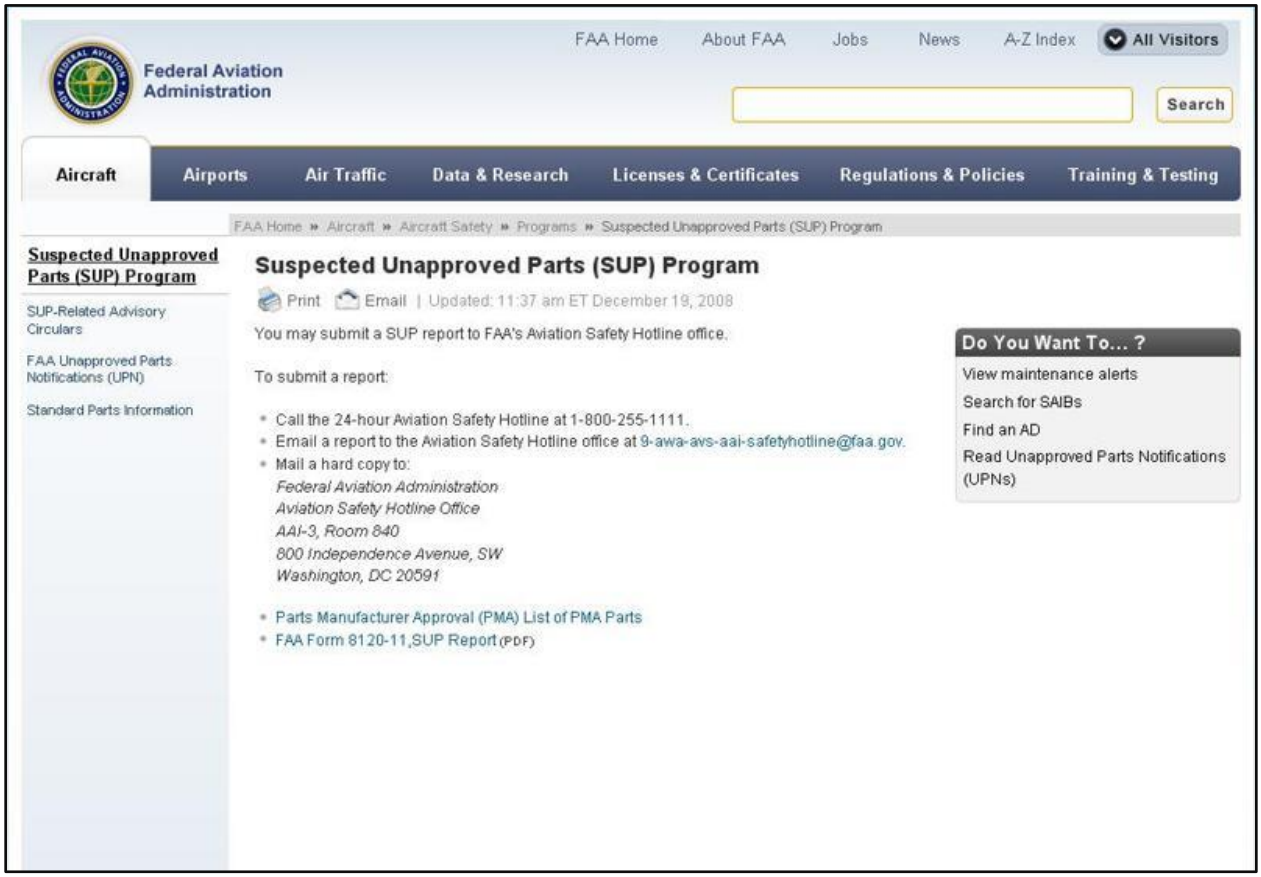
Both the Federal Government and private sector have recognized the threat of CFSI and have taken steps to address it. At the Federal level, the Department of Commerce, the Government Accountability Office (GAO), the Department of Defense (DOD), and the FAA have all determined that CFSI is a threat. NRC and the nuclear industry have also acknowledged the threat of CFSI.

The defense industry has been particularly subject to the pitfalls of CFSI. The Department of Commerce's Office of Technology Evaluation, in a 2010 report, stated that 39 percent of companies and organizations working in the defense sector encountered counterfeit electronics during a 4-year period. Moreover, the Office of Technology Evaluation found an increasing number of counterfeit incidents being detected, rising from 3,868 incidents in 2005, to 9,356 incidents in 2008. These counterfeit incidents included multiple versions of parts and components that had been qualified by DOD. The GAO also identified a number of weaknesses in the DOD supply chain, noting in a 2010 report that DOD had a limited ability to determine the extent to which counterfeit parts exist in its supply chain. As a result of the GAO report, DOD agreed to improve its ability to prevent, detect, report, and dispose of counterfeit parts.

For the civilian aviation industry, the FAA implemented a program in 1995 to address suspected unapproved parts. The FAA program's purpose is to identify unapproved parts related to the aircraft industry and to remove them from the aviation system. According to the FAA, the program

extends into the wider aviation community. FAA officials have stated that there are many parts suppliers, distributors, owners/operators, and legal enforcement authorities who do not understand the importance of installing only approved aircraft parts. To combat this, the FAA holds seminars with the aviation community and has a Web site and hotline to facilitate rapid receipt and analysis of complaints about suspected parts (see Figure 7). As a result of the increase of public awareness of the suspected unapproved parts program, the FAA has reported a significant increase in notifications and investigations. The FAA has asserted that the only way to keep CFSI out of aircraft is for *the entire industry* to proactively identify and ensure such items are removed from the supply chain.

Figure 7: FAA Web Site for Reporting Suspected Unapproved Parts



Source: FAA Web site.

The nuclear industry has also reported concerns with the integrity of the nuclear supply chain. EPRI published a report in late 2009 that noted an increase in CFSI activity worldwide. The report further noted that there

have been at least six separate instances of counterfeit parts getting into the nuclear industry supply chain, though as far as is known, none of them were safety-related.

Given the global nature of the nuclear supply chain, some agency Commission members have also spotlighted CFSI in public speeches. In 2007, NRC's then-Chairman expressed concerns that the close scrutiny that regulatory agencies can bring to bear on major manufacturers to assure that quality components are produced does not always apply with the same intensity to the sub-vendors that supply parts and materials to the manufacturers. The Chairman stated that it was of great concern that substandard or counterfeit components could find their way into a commercial nuclear reactor. The Chairman returned to the issue of CFSI in 2008, and proposed that foreign regulatory counterparts set up a formal system of sharing data about CFSI. One of NRC's previous Commissioners also emphasized the issue of CFSI, declaring that concerns were neither academic nor hypothetical and that NRC has previously identified counterfeit and deficient parts and continues to seek better ways of monitoring the increasing globalization of the nuclear supply chain through international collaborations.

Emphasizing the threat of CFSI to the nuclear industry, NRC published an information notice in 2008 that provided specific examples of CFSI that had gotten into the nuclear industry's supply chain. This included some counterfeit valves that were discovered in 2007 in systems that were not safety-related, but provided cooling to the main electric generator at a boiling water reactor plant. Another example showed how the Consumer Product Safety Commission issued a recall of counterfeit Square D circuit breakers that had been manufactured overseas (see Figure 8). The breakers had been purchased for use by three licensees, one of whom discovered that the breakers were counterfeit.

Figure 8: A Counterfeit Square D Circuit Breaker

Sources: NRC and Consumer Product Safety Commission.

Ultimately, the threat posed by CFSI to the nuclear industry is that of a faulty component being installed in a safety-related system. The failure of safety-related components could affect a reactor's operations, reducing the margin of safety and resulting in operating conditions of degraded safety and quality.

NRC's Overall Approach to CFSI Is Largely Reactive

NRC's overall approach to CFSI appears not to match the significance of the potential threat and is primarily reactive in nature. Despite concerns with CFSI in other industries dating back to the mid-1990s, NRC's attention was not significantly drawn towards CFSI until relatively recently. NRC and EPRI staff members said that there had not been substantive concerns regarding CFSI activity at NRC for nearly 20 years until spurred by the former Chairman's 2007 speech. One senior program manager stated that the industry was "taken by surprise" by the Chairman's speech, as CFSI had not been thought to have been much of a problem since NRC last addressed it in the late 1980s with a generic communication sent to licensees.

Since NRC's renewed interest, the agency's approach to combating CFSI has been based largely on the abilities of a few individuals in NRR and NRO to monitor and evaluate the threat. NRC managers stated that staff members addressing CFSI are doing so on an informal basis as their

other duties allowed and, at present, only about 15 percent of one full-time equivalent staff member is being dedicated to addressing CFSI issues. To NRR's and NRO's credit, these staff members are evaluating component defect reports for CFSI-related items. However, these staff members also acknowledged that there are no clear procedures for whom to contact in the event potential CFSI was uncovered at a vendor. Moreover, when asked if current inspection procedures included criteria for identifying CFSI, a senior inspector said that it probably would not.

Outside of the NRO- and NRR-designated staff members for CFSI, other staff members are generally not involved in CFSI monitoring and evaluation. For example, Vendor Inspection Program staff members are either unaware of the agency's CFSI efforts or have varying interpretations of where CFSI fits into vendor inspections. Some NRO inspectors felt that identifying and evaluating CFSI-related issues was outside their area of responsibility. Other inspectors said that overall direction from managers was unclear and staff members were using their own judgment to informally evaluate potential CFSI. Nonetheless, one NRC executive expressed belief that the vendor inspections as carried out will identify potential CFSI. During the eight vendor inspections that OIG attended, auditors observed only one inspector informally reviewing a vendor's facilities for conditions that may contribute to future CFSI. Furthermore, when asked if the current inspection process would catch CFSI, a senior inspector stated that it probably would not.

NRC's CFSI Approach Lacks a Formal Strategy and Plan

NRC's approach to CFSI appears to be largely reactive because the agency does not have a formal strategy and plan to monitor and evaluate potential CFSI, and consider program changes to address the CFSI issue. NRC managers acknowledged that they could not provide many details about the agency's approach to CFSI issues. NRC also does not have a standing working group or other centralized body to address CFSI issues, although it does have a largely-incomplete draft CFSI charter for such a group. This document is very preliminary and currently provides no details beyond a statement establishing the intent to create mechanisms for notification and coordination across NRC program offices. However, there is no specific plan or strategy for communicating CFSI issues.

NRC Might Be Missing Opportunities To Identify CFSI Early

NRC might be missing opportunities to identify CFSI in a less reactive and more proactive manner. CFSI is an evolving threat that poses serious potential risks to the nuclear industry. Without a formal strategy or framework to address CFSI, NRC could fail to identify CFSI issues in a timely fashion, with the potential for counterfeit or fraudulent components being installed in safety-related reactor systems. Additionally, a lack of a formal strategy hampers NRC's ability to identify resource needs and allocations to address CFSI and impairs agency knowledge management efforts to address it. Furthermore, if CFSI were to make it into a safety-related system in a nuclear power plant, it could degrade the ability of the system to perform its safety function, which could reduce the protection of public health and safety.

Recommendation

OIG recommends that the Executive Director for Operations:

10. Develop and implement a formal agencywide strategy and plan in order to monitor and evaluate CFSI.

IV. CONSOLIDATED LIST OF RECOMMENDATIONS

` OIG recommends that the Executive Director for Operations:

1. Develop an NRO Vendor Inspection Program planning document that:

    a. Articulates a clear purpose for the Vendor Inspection Program.

    b. Establishes metrics to evaluate the success of the Vendor Inspection Program.

2. Develop and document a methodology to identify vendors that supply safety-related parts and services to the nuclear industry with Appendix B quality assurance programs.

3. Develop and document a risk-informed methodology to select vendors for inspection.

4. Develop and use a vendor outreach/communications plan.

5. Align NRC guidance and regulations to clarify acceptance methods for commercial-grade dedication.

6. Issue regulatory guidance to clarify sampling expectations for commercial-grade dedication.

7. Issue regulatory guidance describing a process that NRC considers acceptable for compliance with Part 21.

8. Clearly indicate via the NRC public Web site how and when Part 21 has changed.

9. Develop guidance that clarifies the requirements for vendors on how to approve accredited commercial-grade calibration laboratories for safety-related applications.

10. Develop and implement a formal agencywide strategy and plan in order to monitor and evaluate CFSI.

V. AGENCY COMMENTS

On August 17, 2010, OIG provided a draft report to the Executive Director for Operations. OIG held an exit conference with the agency on August 31, 2010. During that meeting agency management provided informal comments to the draft report. Also, on September 10, 2010, OIG held an additional meeting with NRC staff to discuss the agency's informal comments to the draft report. On September 14, 2010, OIG provided the agency a revised draft report, and on September 17, 2010, the agency declined to provide any formal comments. The final report incorporates revisions made, where applicable, as a result of meetings with NRC staff.

Appendix

SCOPE AND METHODOLOGY

The audit objective was to assess NRC's regulatory approach for ensuring the integrity of domestic and global parts and services supplied to nuclear power reactors. To address the audit objective, OIG observed eight vendor quality assurance inspections, which include NRC's review of vendor's compliance with both Part 21 and Appendix B criteria; attended one NUPIC vendor audit; observed industry training courses for vendor quality assurance; and attended several industry meetings and two NRC vendor workshops. OIG discussed vendor issues with applicable vendor managers or consultants at each of the eight vendor inspections, and at all of the industry meetings and training courses attended. OIG also reviewed NRC regulations and guidance, and interviewed NRC staff members and industry officials. Additionally, OIG identified and reviewed vendor quality assurance inspection-related reports and memoranda, reviewed nuclear industry vendor standards and guidance, and analyzed NRC vendor quality assurance inspection reports dating back to 2006. Key documents reviewed include:

- Energy Reorganization Act of 1974, Section 206.
- 10 CFR Part 21, *Reporting of Defects and Noncompliance*.
- 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*.
- NUREG-0302, Rev 1, *Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance.*
- NUREG-1055, *Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress.*
- Inspection Manual Chapter 2507, *Construction Inspection Program: Vendor Inspections.*
- Inspection Manual Chapter 0614, *Documenting 10 CFR 52 Construction Audit Activities.*

- Inspection Manual Chapter 0617, *Vendor and Quality Assurance Implementation Inspection Reports.*
- Inspection Procedure 36100, *Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance.*
- Inspection Procedure 38703, *Commercial Grade Dedication Programs.*
- Inspection Procedure 43002, *Routine Inspections of Nuclear Vendors.*
- Inspection Procedure 43003, *Reactive Inspections of Nuclear Vendors*.
- Inspection Procedure 43004, *Inspection of Commercial Grade Dedication Programs.*
- Inspection Procedure 43005, *NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements.*
- Management Directive 8.18, *NRC Generic Communications Program*.
- NRC information notices.
- NRC generic letters.
- Agency office instructions.
- Vendor QA inspection plans and reports.
- SECY papers.
- NRC vendor presentations.
- Commissioners' speeches and NRC press releases.
- Nuclear industry vendor guidance documents.
- GAO reports.
- Academic management publications.

Auditors conducted 46 interviews with agency and industry employees, including NRC managers and staff members at headquarters, and members of the nuclear industry. OIG conducted this audit at NRC headquarters, and selected licensee and vendor locations in the United States, France, and Japan.

We conducted this performance audit, from October 2009 through August 2010, in accordance with generally accepted Government auditing standards. Those standards require that the audit is planned and performed with the objective of obtaining sufficient, appropriate evidence to provide a reasonable basis for any findings and conclusions based on the stated audit objective. OIG believes that the evidence obtained provides a reasonable basis for the report findings and conclusions based on the audit objectives. Internal controls related to the audit objective were reviewed and analyzed. Throughout the audit, auditors were aware of the possibility or existence of fraud, waste, or misuse in the program.

Major contributors to this report were Sherri Miotla, Team Leader; R.K. Wild, Team Leader; Kevin Nietmann, Senior Technical Advisor; Michael Zeitler, Audit Manager; Timothy Wilson, Senior Management Analyst; Levar S. Cole, Senior Management Analyst; Vidya Sathyamoorthy, Student Management Analyst; and Diane Furstenau, Student Management Analyst.