

May 26, 2011

MEMORANDUM TO: Stephen D. Dingbaum
Assistant Inspector General for Audits

FROM: Michael R. Johnson, Director *S. Flanders for /RA/*
Office of New Reactors

SUBJECT: STATUS OF RECOMMENDATIONS AND STAFF RESPONSE TO
THE OFFICE OF THE INSPECTOR GENERAL'S AUDIT OF THE
U.S. NUCLEAR REGULATORY COMMISSION'S VENDOR
INSPECTION PROGRAM (OIG-10-A-20)

This memorandum provides the U.S. Nuclear Regulatory Commission (NRC) staff's updates for all 10 recommendations from the Office of the Inspector General's (OIG's) audit OIG-10-A-20, "Audit of NRC's Vendor Inspection Program," dated September 28, 2010. The staff received OIG's analysis and status of recommendations, dated January 11, 2011. OIG provided this analysis in response to the staff's memorandum, dated October 30, 2010, which outlined planned actions and target dates for completion. The staff believes that the updated planned actions for the remaining unresolved Recommendations 1 and 9 are responsive to OIG's analysis. The staff has also completed actions for Recommendations 4 and 8.

Recommendation 1:

Develop an Office of New Reactors (NRO) Vendor Inspection Program planning document that:

- a. Articulates a clear purpose for the Vendor Inspection Program; and
- b. Establishes metrics to evaluate the success of the Vendor Inspection Program.

Agency response dated October 30, 2010:

The staff agrees with the essence of the recommendation, namely that NRO articulate a clear purpose and establish metrics.

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Inspection Manual Chapter (IMC) 2507 "Construction Inspection Program: Vendor Inspections," dated April 27, 2010, describes the purpose and objectives for the vendor inspection program. It establishes the vendor inspection program for vendors providing safety-related materials, equipment, and services in support of new reactor construction and provides the requirements and guidance to the NRC inspectors for conducting inspections at vendor facilities. IMC 2507 lists eight objectives, which provide the purpose of the program and can be used to evaluate its success.

The vendor inspection program could benefit from updating IMC 2507 to more clearly articulate the program's purpose. Based on the updated objectives, NRO will enhance the office-level metrics in its operating plan to evaluate the program's success.

Planned actions: NRO will update IMC 2507. The current IMC already provides basic guidance in this area and is suitable for use while the staff is drafting an update.

Target date for completion: October 28, 2011.

The Fiscal Year (FY) 2012 Operating Plan will incorporate enhanced metrics.

Target date for completion: Submittal of FY 2012 Operating Plan (estimated November 2011).

OIG analysis dated January 11, 2011:

The proposed corrective action does not address the intent of OIG's recommendation. The OIG recommendation is to develop a planning document that includes, at a minimum, some key program planning elements. As noted in the audit report, "an operating plan should include establishing an overall strategy and goals, establishing methodologies for setting priorities, identifying performance metrics, and managing resources." A document as important and multifaceted as an office operating plan is not a good fit for an existing inspection manual chapter, which has a different purpose altogether.

Similarly, program-level metrics are likely better co-located in a program planning document rather than in an office-level operating plan. In this way, vendor inspection program stakeholders can observe obvious linkages between the program goals and objectives and the desired outcomes as measured by program-level metrics.

The OIG report provided examples of planning documents from other NRO programs that may serve as models for NRO's routine vendor inspection program. This recommendation will be considered resolved when the agency provides updated information regarding the development of an NRO Vendor Inspection Program planning document as described above.

Status: Unresolved.

Update:

Actions taken and planned: NRO will author a planning document that will include key program planning elements. The plan will establish an overall strategy, goals, and methodologies for setting priorities, identifying performance metrics, and managing resources. NRO will include program-level metrics in this program planning document.

NRO has held planning meetings and management briefings for the development of such a program planning document. NRO plans to incorporate the elements of its actions in response to OIG's recommendations into the program plan. For example, the methodologies for identifying vendors and selecting vendors for inspection and the strategy for outreach and communications will be included in the program plan. Enclosure 1 to this memorandum provides a draft outline of the vendor inspection program plan.

The NRC's practice is to locate official administrative and inspection program statements of policy in IMCs. Therefore, the staff will consider the program plan as a tool to develop and improve its fundamental organizational tools (i.e. IMCs, or office instructions).

Target date for completion: Issue program plan by December 30, 2011.

Recommendation 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.

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

The staff will document and implement a methodology to identify vendors that supply safety-related parts and services to the nuclear industry, providing the staff with an additional tool for selecting vendors for routine inspections and for communication and outreach activities.

Planned actions: NRO will coordinate with the Office of Nuclear Reactor Regulation (NRR) and regional offices to develop a methodology to identify vendors that supply safety-related parts and services to the nuclear industry. This methodology may include issuing generic communications to NRC licensees to request copies of licensee approved suppliers lists. The staff can later consider the need to expand or update the database of safety-related vendors as appropriate.

Target date for completion: October 28, 2011.

OIG analysis dated January 11, 2011:

The proposed action meets the intent of the recommendation. As noted above, the staff will develop a methodology to identify vendors that supply safety-related parts and services to the nuclear industry. This recommendation will be closed when OIG receives the vendor identification methodology and assesses its effectiveness and implementation.

Status: Resolved.

Update:

Actions taken and planned: NRO continues to develop its methodology to identify vendors that supply safety-related parts and service to the nuclear industry. NRO will coordinate this effort with NRR and regional offices. The staff contacted licensees and vendors and solicited interest

and feedback during industry meetings. Industry response and cooperation have been predominantly positive. Enclosure 1 to this memorandum provides a draft strategy document for the methodology.

Target date for completion: Unchanged—Issue methodology by October 28, 2011.

Recommendation 3:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation to enhance the selection of vendors. The staff currently uses the criteria in IMC 2507 as a basis for selecting safety significant vendors for inspection. NRO has targeted a wide array of vendors currently performing activities related to new reactor construction using this process.

Planned actions: NRO will coordinate with NRR to revise its IMCs to enhance existing guidance on the selection of vendors for routine inspections as appropriate. The staff will include consideration of the risk significance of vendor activities as an element in the guidance.

Target date for completion: October 28, 2011.

OIG analysis dated January 11, 2011:

The staff's proposed action—to enhance existing guidance to include vendor selection criteria and risk-informed methodologies—meets the intent of the recommendation. This recommendation will be closed when OIG receives the updated guidance and determines that it includes a risk-informed methodology to select vendors for inspection.

Status: Resolved.

Update:

Actions taken and planned: NRO continues to develop a risk-based methodology to select vendors for inspection. NRO will coordinate this effort with NRR.

Target date for completion: Unchanged—Issue revised guidance by October 28, 2011.

Recommendation 4:

Develop and use a vendor outreach/communications plan.

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

As noted in the OIG report and in SECY-07-0105, "Enhancement to the Vendor Inspection Program Within the Office of New Reactors," dated June 27, 2007, the staff has increased its

presence at conferences related to new reactor activities and has held two workshops on vendor oversight for new reactor construction. NRO considers the workshops conducted to date to be very successful events and excellent examples of NRC outreach. The workshops were widely attended, and each one generated significant dialogue with the vendor community about regulatory issues. The staff answered more than 300 questions from workshop participants and posted formal responses on the NRC Web site. Feedback to the staff in the form of meeting comment forms has been positive, and stakeholders are requesting additional workshops. While the staff continues to believe that it is implementing a robust and effective program of outreach and communications, preparation of a formal plan may provide an opportunity for more strategic focus and coordination.

Planned actions: NRO will coordinate with NRR to develop a vendor outreach/communications plan to enhance communications with current and prospective vendors and other stakeholders. This plan can incorporate the methodology prepared under Recommendation 2 to identify vendors and expand outreach efforts. This document will model NRO's current outreach successes, identify new opportunities as applicable, and map out a strategy going forward.

Target date for completion: Completed—April 28, 2011.

OIG analysis dated January 11, 2011:

The proposed action meets the intent of the recommendation. OIG agrees that developing and implementing a formal outreach/communications plan may provide an opportunity for more strategic focus and coordination of vendor outreach efforts. More specifically, such a plan could help NRO verify the degree to which outreach efforts are effective and successful, as well as validate NRO's belief that it is implementing a robust and effective program of outreach and communications.

This recommendation will be closed pending receipt of (1) a vendor outreach/communications plan that OIG verifies includes 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; and (2) OIG receipt of staffs evidence of use, such as NRO analysis of outreach activities and incorporation of this analysis and vendor feedback into planned outreach efforts.

Status: Resolved.

Update:

Actions taken: NRO coordinated with NRR to develop a strategy for enhanced vendor outreach and communications. The strategy was approved by division management and is being implemented. The current revision of the strategy (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110871799) is included as Enclosure 3 to this memorandum and will be incorporated into the program planning document discussed in Recommendation 1.

While the strategy for enhanced vendor outreach and communications will remain a living document within the program plan, the staff believes it has completed actions related to this recommendation.

Recommendation 5:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

Since 2007, the staff has recognized the need for clarified regulations and guidance regarding requirements under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," which include commercial-grade dedication. The staff has issued information notices and initiated vendor outreach efforts such as the NRC vendor workshops. However, rulemaking would provide a more holistic and effective solution. NRO staff began preliminary rulemaking activities as noted in an internal memorandum "User Need Memorandum Requesting Rulemaking to Revise 10 CFR Part 21 and 10 CFR 50.55(e)" dated December 10, 2009 (ADAMS Accession No. ML093090033). While revising 10 CFR Part 21 as part of the potential rulemaking, the staff will consider the NRC's other regulations (e.g., 10 CFR Parts 50, 70, 71, 72) when addressing basic components and commercial-grade item dedication. When preparing the various regulatory guidance documents, the staff will consider existing industry guidance and the appropriateness of its use.

Planned actions: NRO will coordinate with NRR and the Office of Nuclear Material Safety and Safeguards (NMSS) to author a Commission paper recommending options to clarify the requirements of 10 CFR Part 21. The paper will address the need and priority for rulemaking, guidance (i.e., regulatory guide), and outreach efforts.

Target date for completion: September 30, 2011. This action may be adjusted to add insights from OIG's ongoing audit of NRR's implementation of 10 CFR Part 21 as appropriate. In the interim, the staff will consider the need for agency guidance as appropriate.

OIG analysis dated January 11, 2011:

The proposed action partially meets the intent of the recommendation. While developing a Commission paper with options for clarifying 10 CFR Part 21 requirements is an important initial step towards completion of the recommendation, the steps taken after the Commission paper is developed are also important. This recommendation will be closed when OIG receives the Commission paper, and determines that the next steps—to include implementation of those actions necessary to align the guidance and the regulation to clarify acceptance methods for commercial-grade dedication—has been performed.

Status: Resolved.

Update:

Actions taken and planned: The staff has been actively pursuing efforts to develop a holistic solution to 10 CFR Part 21 and associated issues, including commercial-grade dedication. This has included internal discussions, management briefings, formation of the Part 21 Focus Group, and presentations at industry meetings and the 2011 Regulatory Information Conference.

NRO has led three meetings of a Part 21 Focus Group. These meetings have served to develop the problem statements and paths forward to the technical issues. The group has helped solidify the staff's positions on a proposed rulemaking and has been essential to interoffice coordination. The group also developed a SharePoint site to share documents and collaborate on the development of the Commission paper and the subsequent regulatory basis for rulemaking.

NRO and NRR have worked together following OIG's issuance of audit report OIG-11-A-08 "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," to incorporate relevant recommendations into the Commission paper. While the additional recommendations regarding 10 CFR Part 21 add complexity to the rulemaking, the staff is targeting its original completion date for the Commission paper.

Target date for completion: Unchanged—Issue Commission paper by September 30, 2011.

Recommendation 6:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

As noted above for Recommendation 5, the staff recognizes the need for appropriate guidance for sampling for commercial-grade dedication.

Planned actions: As noted above, NRO will coordinate with NRR and NMSS to author a Commission paper recommending options to clarify the requirements of 10 CFR Part 21. The paper will address the need and priority for rulemaking, guidance (i.e., regulatory guide), and outreach efforts.

Target date for completion: September 30, 2011. This action may be adjusted to add insights from OIG's ongoing audit of NRR's implementation of 10 CFR Part 21 as appropriate. In the interim, the staff will consider the need for agency guidance as appropriate.

OIG analysis dated January 11, 2011:

The proposed action partially meets the intent of the recommendation. OIG concurs with the staff determination that rulemaking would provide an effective solution to the need to align regulations and guidance on commercial grade dedication and the plan to develop a Commission paper with options for clarifying 10 CFR Part 21 requirements, including regulatory guidance. The staff noted that it will consider the need for regulatory guidance in the interim as

appropriate; however, the staff gave no target completion date for this effort. Such consideration will be an ongoing effort, and OIG encourages the staff to establish a timeframe within which to undertake that consideration. This recommendation will be closed when OIG receives the Commission paper, and determines that the next steps—to include implementation of the actions necessary to clarify sampling expectations for commercial-grade dedication—have been performed.

Status: Resolved.

Update:

Actions taken and planned: As noted above for Recommendation 5, the staff is moving forward with the Commission paper for rulemaking on the topics associated with 10 CFR Part 21, including the sampling expectation for commercial-grade dedication. The Part 21 Focus Group discussed the topic of sampling in detail during a meeting on May 19, 2011.

Regarding OIG's encouragement to establish a timeframe for consideration of interim regulatory guidance, the staff agrees that this should be an ongoing effort. NRO will coordinate with NRR to consider the need for any interim regulatory guidance. However, issuance of regulatory guidance concurrent with rulemaking will be the most effective way to communicate the staff's overall expectations on all items related to 10 CFR Part 21. The staff expects to have a clear timeline for rulemaking following issuance of its Commission paper on 10 CFR Part 21.

Target date for completion: Unchanged—Issue Commission paper by September 30, 2011.

Recommendation 7:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

As noted above for Recommendations 5 and 6, the staff recognizes that 10 CFR Part 21 rulemaking and clear regulatory guidance are necessary.

Planned actions: As noted above, NRO will coordinate with NRR and NMSS to author a Commission paper recommending options to clarify the requirements of 10 CFR Part 21. The paper will address the need and priority for rulemaking, guidance (i.e., regulatory guide), and outreach efforts.

Target date for completion: September 30, 2011. This action may be adjusted to add insights from OIG's ongoing audit of NRR's implementation of 10 CFR Part 21 as appropriate. In the interim, the staff will consider the need for agency guidance as appropriate.

OIG analysis dated January 11, 2011:

The proposed action partially meets the intent of the recommendation. While developing a Commission paper with options for clarifying 10 CFR Part 21 requirements, including regulatory guidance, is an important initial step towards completion of the recommendation, the steps taken after the Commission paper is developed are also important. This recommendation will be closed when OIG receives the Commission paper, and determines that the next steps—to include implementation of the actions necessary to describe a process that NRC considers acceptable for compliance with Part 21—have been performed.

Status: Resolved.

Update:

Actions taken and planned: As noted above for Recommendation 5, the staff is moving forward with the Commission paper for rulemaking on the topics associated with 10 CFR Part 21, including the description of a process it considers acceptable for compliance with 10 CFR Part 21. The staff considers “evaluating and reporting” to be paramount to the clarification of 10 CFR Part 21. This has been the central topic of two of the staff’s meetings of the Part 21 Focus Group and will be a central issue in the Commission paper.

Target date for completion: Unchanged—Issue Commission paper by September 30, 2011.

Recommendation 8:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

The NRC Web site includes the regulations in 10 CFR. The bottom of each regulation, including 10 CFR Part 21, lists the relevant *Federal Register* notices through which the NRC published changes to the regulation. NRO currently maintains a Web site with its inspection reports, generic communications, presentations given, and other vendor-related information.

Planned actions: NRO will provide a link on its Web site directly to 10 CFR Part 21 and a statement showing the last date of update.

Target date for completion: Completed—February 28, 2011.

OIG analysis dated January 11, 2011:

The proposed action meets the intent of the recommendation. This recommendation will be closed after OIG reviews the staff’s proposed changes to the Web site.

Status: Resolved.

Update:

Actions taken: NRO updated its Web site and implemented a subscription service for updates to the 10 CFR Part 21 regulations.

The following pages provide links directly to 10 CFR Part 21 and notes the date of the regulation's last update:

- The phrase "(Last updated December 1, 2009)" was added to the page entitled "Regulations, Standard Review Plan, SECY Paper, and NUREG-1055 Regarding Quality Assurance for New Reactors," as noted as Figure 1 in Enclosure 4 of this memorandum: <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-regs.html>
- The phrase, "10 CFR Part 21 was last updated on December 1, 2009," was added to the page entitled "Vendor Quality Assurance (QA) Inspections," as noted as Figure 2 in Enclosure 4 of this memorandum: <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>

The NRC's 10 CFR Part 21 page includes a "Subscribe to Updates" button as noted as Figure 3 in Enclosure 4 of this memorandum. This service provides an e-mail update to subscribers when the regulation is updated: <http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/>

The staff believes that it has completed actions related to this recommendation.

Recommendation 9:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

As noted above for Recommendations 5, 6, and 7, the staff recognizes that 10 CFR Part 21 rulemaking and clear regulatory guidance are necessary.

Planned actions: As noted above, NRO will coordinate with NRR and NMSS to author a Commission paper recommending options to clarify the requirements of 10 CFR Part 21. The paper will address the need and priority for rulemaking, guidance (i.e., regulatory guide), and outreach efforts.

Target date for completion: September 30, 2011. This action may be adjusted to add insights from OIG's ongoing audit of NRR's implementation of 10 CFR Part 21 as appropriate. In the interim, the staff will consider the need for agency guidance as appropriate.

OIG analysis dated January 11, 2011:

The proposed corrective action does not address the intent of OIG's recommendation. The process established to approve accredited commercial-grade calibration laboratories is entirely created by guidance documents; it is an alternative to practice outlined in regulation. Starting rulemaking for 10 CFR Part 21 with a Commission paper will not clarify the guidance-based requirements for approving accredited commercial-grade calibration laboratories. This recommendation will be considered resolved when the agency outlines the specific actions it will take to develop guidance that clarifies the requirements for vendors on how to approve accredited commercial-grade calibration laboratories for safety-related applications.

Status: Unresolved.

Update:

Actions taken and planned: NRO, in coordination with NRR and NMSS, expects to author a safety evaluation report (SER) to clarify the requirements for vendors on how to approve accredited commercial-grade calibration laboratories for safety-related applications in response to an industry submittal. NRO will then issue generic communications to industry indicating that the submittal and SER are available.

The staff has been extensively involved with industry groups to develop a complete process that can be fully endorsed by the NRC. On March 31, 2011, NRO and NRR staff met with representatives from the Nuclear Energy Institute, the Nuclear Procurement Issues Committee (NUPIC), the National Institute of Standards and Technology (NIST), and the International Laboratory Accreditation Cooperation at NIST Headquarters in Gaithersburg, MD. The meeting provided a consensus path forward that includes an industry submittal, such as a topical report for NRC review and approval, on the use of commercial calibration and testing laboratories. The nuclear industry is taking actions to include the use of testing and international laboratories in the scope of its submittal.

The staff is closely following industry's developments. In the interest of providing contemporary guidance that is not immediately superseded, the staff will work with industry to develop solutions to the outstanding technical issues before guidance is issued. The staff expects industry to submit a topical report on the use of commercial calibration and testing laboratories. The staff will then issue an SER, followed by generic communications to provide this information to licensees and vendors. In addition, the staff will include this information in the development of the Commission paper and the subsequent regulatory basis for 10 CFR Part 21 rulemaking and associated guidance.

Target date for completion: The staff anticipates an industry submittal by August 31, 2011, and will then issue an SER and generic communications within 6 months.

Recommendation 10:

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

Agency response dated October 30, 2010:

The staff agrees with the recommendation.

Planned actions: NRO will coordinate with the Office of Investigations, Office of Nuclear Security and Incident Response, NRR, NMSS, and regional offices to develop a formal agencywide strategy to monitor and evaluate Counterfeit, Fraudulent, and Suspect Items (CFSI).

Target date for completion: October 28, 2011.

OIG analysis dated January 11, 2011:

The proposed action meets the intent of the recommendation. This recommendation will be closed when OIG receives the formal agencywide strategy and plan, and determines it contains the elements necessary to monitor and evaluate CFSI.

Status: Resolved.

Update:

Actions taken and planned: In late December 2010, the staff began an agencywide approach to address the threat of CFSI. The staff is working with both internal and external stakeholders to assess the current status and develop an effective path forward.

The staff established the following four working groups to engage offices potentially affected by CFSI:

1. Working Group on Supply Chain Oversight
2. Working Group on Communications
3. Working Group on Response Protocols
4. Working Group on Malicious Products (including cyber security)

This effort is consistent with similar ongoing initiatives within the U.S. Government. The staff is actively participating on Federal working groups to share CFSI-related information, anti-counterfeiting practices, proper Federal response protocols, knowledge, and resources. The staff has begun similar outreach activities with the U.S. Department of Energy, the Electric Power Research Institute, and NUPIC. The staff has also made CFSI presentations to the international community and is continuing its outreach activities.

The staff is leveraging these diverse activities to develop its formal agencywide strategy and plan to monitor and evaluate CFSI. Enclosure 5 to this memorandum provides the CFSI Response Community meeting minutes from February 3, 2011, and March 2, 2011.

S. Dingbaum

- 13 -

Target date for completion: Unchanged—Issue strategy by October 30, 2011.

Enclosures:

As stated

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
SECY
EDO

Target date for completion: Unchanged—Issue strategy by October 30, 2011.

Enclosures:
As stated

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
SECY
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Memo to Steven D. Dingbaum from Michael R, Johnson dated May 26, 2011

**SUBJECT: STATUS OF RECOMMENDATIONS AND STAFF RESPONSE TO
THE OFFICE OF THE INSPECTOR GENERAL'S AUDIT OF THE
NUCLEAR REGULATORY COMMISSION'S VENDOR INSPECTION
PROGRAM (OIG-10-A-20)**

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OFFICE OF NEW REACTORS VENDOR INSPECTION PROGRAM PLAN OUTLINE

I. Purpose of the VIP Plan

The purpose of the Vendor Inspection Program (VIP) Plan is to establish an overall strategy, including goals, methodologies for setting priorities, performance metrics, and resource management strategies for VIP activities necessary to provide reasonable assurance that licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain for new reactor licensing and construction. Key parts of the plan include describing:

- the goals and objectives of the VIP,
- the organization, staffing, and training and qualification of NRC staff necessary to perform the oversight of vendors,
- the needed infrastructure including inspection and regulatory guidance and tools such as information (quality assurance website), inspection planning and scheduling, and self-assessment tracking systems,
- the communication and coordination activities with internal and external stakeholders.

II. Goals/Objective of the VIP

This section will clearly articulate the goals and objectives of the VIP.

III. Organization

This section will describe of the organization of both vendor branches.

IV. Scope of Activities

This section will describe the current activities performed by both of the vendor branches.

V. Vendor Identification and Selection Methodologies

This section will describe of the methodology to identify vendors that supply safety-related parts and services as well as describe the risk-informed methodology to select vendors for inspection.

VI. Types of Inspection

This section will describe of the types of inspections that the vendor branches perform.

VII. Enforcement

This section will provide a detailed description of the enforcement process as it is applicable to vendors.

VIII. Coordination Activities/Industry Interactions

This section will describe our current activities, internal communications (e.g., Office of Nuclear Reactor Regulation) and stakeholder interactions. Specifically, this section will describe our relationship with American Society of Mechanical Engineers, Nuclear Procurement Issues Committee, Electric Power Research Institute Joint Utility Task Group, Institute of Electrical and Electronics Engineers, Multinational Design Evaluation Program, Nuclear Energy Institute, International Laboratory Accreditation Cooperation, and organizations the Counterfeit, Fraudulent, and Suspect Items community interfaces with.

IX. Outreach/Communication Plan

This section will describe the current plans/actions to establish and communicate the staff's strategy for improved outreach communications to the vendors and suppliers.

X. Performance Metrics

This section will provide a description of the metrics established to evaluate the success and effectiveness of the VIP.

XI. Knowledge Management/Training

This section will describe plans for the transfer of knowledge between the senior and most experienced members of both branches to the newer less experienced inspectors as well as the training and qualification requirements.

XII. Resource Management

This section will describe the basic assumptions for resource planning and our plan for effectively managing our inspection resources.

XIII. References

This section will be included as necessary.

METHODOLOGY TO IDENTIFY SUPPLIERS OF SAFETY-RELATED PARTS AND SERVICES STRATEGY DOCUMENT

Supplier List Goal

- Safety-related suppliers to new and operating reactors

Plan to Identify Suppliers

- Utilize existing sources
 - Title 10 of the *Code of Federal Regulations* Part 21 reports
 - Interactions with industry and standards organizations such as Nuclear Issues Procurement Committee (NUPIC), Nuclear Industry Assessment Committee (NIAC), and the American Society of Mechanical Engineers
 - Communications with Engineering, Procurement, and Construction contractors
- Regulatory Issue Summary (RIS) requesting voluntary submittal of applicants' and licensees' approved suppliers
- Voluntary supplier registration on the Nuclear Regulatory Commission public website
 - Reach out to NUPIC and NIAC and other industry venues to promote
 - Incentives
 - Newsletter
 - Part 21 and Construction/Operating Experience information
 - Inspection guidance
 - Meeting and conference invitations

STRATEGY FOR ENHANCED VENDOR OUTREACH AND COMMUNICATIONS

PURPOSE

The purpose of this document is to establish and communicate the Office of New Reactors (NRO) vendor branches' strategy to enhance outreach and communications with vendors for new reactor construction.

AUDIENCE

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

As part of a parallel effort, the NRO vendor branches are developing a list of vendors to be used for future outreach activities.

BACKGROUND

This strategy lists key improvement areas that will enhance current staff efforts in this area and identifies key trending data to be collected to measure the effectiveness of these enhancements. Preparation of a formal plan will also provide an opportunity for more strategic focus and coordination, consistent with the Office of the Inspector General's audit of the NRC vendor inspection program (OIG-10-A-20).

CURRENT COMMUNICATIONS AND OUTREACH TOOLS

- **Public Website:** The vendor branches' public website gives vendors a venue to obtain useful information on many topics, including:
 - Key regulations, such as Appendix B to the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, and 10 CFR Part 21
 - Inspection procedures
 - Inspection reports
 - Information on commercial-grade dedication
 - Presentations from past NRC workshops
 - NRC presentations from conferences attended by the NRC
- **Workshops on Vendor Oversight:** The NRC hosted two workshops on vendor oversight for new reactor oversight. The workshops were successful and excellent examples of NRC outreach. The workshops were widely attended and generated significant dialogue with the vendor community about regulatory issues. Feedback through meeting comment forms was positive and stakeholders have requested additional workshops.

- Participation in industry conferences and meetings including:
 - The Nuclear Procurement Issues Committee meetings
 - American Society of Mechanical Engineers codes and consensus standards development process
 - NRC's Regulatory Information Conference
 - Electronic Power Research Institute Joint Utility Task Group meetings
 - Institute of Electrical and Electronics Engineers consensus standards development process
 - International Laboratory Accreditation Cooperation process activities
 - Vendor Inspection Cooperation Working Group under the auspices of the Multinational Design Evaluation Program and the Nuclear Energy Agency.

KEY IMPROVEMENTS

- Improve the accessibility of the portions of the NRC's public website relevant to vendor oversight. Target date: June 2011
 - The NRC plans to create a link within the quick link box on the New Reactors page and the Operating Reactors page.
- Create a page on the public website that categorizes findings and violations from NRC vendor inspection reports. Target date: August 2011
 - A page with the 18 criteria of 10 CFR 50 Appendix B and 10 CFR 21 will be added so that vendors will be able to select one of the criteria or Part 21 and all applicable inspection reports with findings or violations in those areas will be listed.
- Create a Frequently Asked Questions (FAQ) page on the public website which would include questions received from vendor conferences and other NRC outreach meetings. Target date: October 2011
 - A FAQ will be useful to any vendor that was unable to attend as well as provide a quick information source of knowledge management tool. The current vendor page has slides and summaries for past NRC conferences which could be included. It should be noted that the vendor branches make every effort to publish questions and answers as soon as they have been adequately vetted.
- Create an annual electronic newsletter to be sent to interested vendors. Target date: December 2011
 - Include recent findings, potential rulemakings, upcoming conferences, operating experience and other useful information. Stakeholders would be able to sign up through the NRC's website.
 - A newsletter would provide another source of information in addition to the public website for vendors to utilize to be informed of current and ongoing activities at the NRC.

- Establish regular workshops on vendor oversight on biennial basis.
Target date for next workshop: June 2012
 - Host a conference every two years as one key forum for communication and outreach with vendors to the nuclear industry. Continue to solicit feedback and seek recommendations for improving future workshops through comment cards.
- Compile list of vendors. This is part of a parallel effort which will be described in the NRO vendor inspection program plan. Target date: December 2012
 - List of known vendors can be used to solicit stakeholder interest in the NRC's outreach and communications activities. This list will state that it does not represent NRC endorsement or approval.

CONTINUOUS IMPROVEMENT

The vendor branches will use the following tools to track the improved efficiency and effectiveness of its outreach and communications activities:

- Usefulness of Information Shared
 - Feedback forms from vendor workshops will include specific questions to obtain feedback on usefulness of information shared. Feedback will be used to enhance future workshops.
 - Website will include electronic feedback mechanism to obtain feedback on usefulness of information on the site. Feedback will be used to enhance the website as appropriate.
- Stakeholder interest and participation
 - The number of attendees at the conferences will be used to measure the level of interest and success of the conference.
 - Feedback forms from vendor workshops will be used to gauge stakeholder interest.
- Revisit and revise this strategy as necessary.
 - This strategy will be incorporated into the NRO vendor inspection program plan.
 - This strategy is a living document and should be updated and modified to suit the changing needs of NRO's vendor branches.

STRATEGY Q'S & A'S

Q. How can I access the NRC's webpage for Quality Assurance and Vendor Oversight?

A. Once the change has been implemented, you will be able to access the vendor webpage on NRC's public website by going to www.nrc.gov and then clicking on the New Reactors page under the Nuclear Reactors tab. You will then be able to see a link to vendor webpage on that page.

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

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

Q. How will vendors sign-up for the newsletter?

A. We plan on creating a database of interested vendor e-mail addresses that will receive the newsletter. We plan to create an online link for vendors to sign-up via the public website or they could always drop a business card at one of our conferences or workshops.

Q. Will there be any additional burden on the industry?

A. No. Our goal is to provide additional tools for the industry to utilize to be more cognizant of current NRC regulations. Vendors will be able to use our public webpage more efficiently to learn about current events and upcoming conferences and NRC workshops.

Q. Will the NRC consider other options for outreach and communications that may be proposed by the industry and the public?

A. We are constantly striving for ways to improve our communications with the public and will consider other options that will be beneficial.

Q. How is the NRC planning on developing its vendor list? Is there a process to do this?

A. We are currently looking at options such as holding public meetings to develop a methodology to identify safety-related vendors. The NRC may issue a generic communication if it deems necessary. We also plan on advertising the new communication tools during inspections, conferences, and workshops, to obtain vendor information.

Q. How are we planning to improve tracking and trending?

A. We plan on tracking and trending the questions we receive at our conferences and FAQ page to gauge the most common issues and concerns that vendors have. We will be able to use this information to concentrate our efforts in clarifying the hot topic issues. We also plan on tracking and trending the vendors that attend our conferences and workshops. This will help us track industry interest in the topics being presented and inform our planning for future activities.

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Index | Site Map | FAQ | Facility Info | Reading Rm | New | Help | Glossary | Contact Us BrowseAloud 


U.S. NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

About NRC
Nuclear Reactors
Nuclear Materials
Radioactive Waste
Nuclear Security
Public Meetings & Involvement

Quality Assurance for New Reactors

Regulations, Standard Review Plan, SECY Paper, and NUREG-1055

Safety Evaluation Reports Concerning Revised Basis for QA Programs

QA Inspections for New Reactor Licensing

Vendor QA Inspections

Nuclear Procurement Issues Committee (NUPIC) and Industry Interactions

Workshops on Vendor Oversight for New Reactor Construction

Home > Nuclear Reactors > New Reactors > Regulatory Oversight > Quality Assurance > Regulations, Standard Review Plan, SECY Paper, and NUREG-1055

Regulations, Standard Review Plan, SECY Paper, and NUREG-1055 Regarding Quality Assurance for New Reactors

The "Quality Assurance Criteria for Nuclear Plants and Fuel Reprocessing Plants," set forth in Appendix B to Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), must be implemented for activities affecting safety-related plant equipment. Licensees are also required to develop, and control changes to, their quality assurance (QA) programs, as stated in 10 CFR 50.54(a)(1). In addition, 10 CFR 50.34(b)(6)(ii) requires that a licensee's description of its QA program for a nuclear power plant must include a discussion of how the applicable requirements of Appendix B will be satisfied. For detail, see the following topics on this page:

- [Code of Federal Regulations](#)
- [Standard Review Plan \(NUREG-0800\)](#)
- [SECY Paper](#)
- [NUREG-1055](#)

ADDITION

Code of Federal Regulations

Part	Subject
Appendix A to 10 CFR Part 50	General Design Criteria
Appendix B to 10 CFR Part 50	Main QA Regulation
10 CFR Part 21	Reporting of Defects and Noncompliance (Last updated December 1, 2009)
10 CFR 50.4(b)(7)	Written Communications - Quality Assurance Related Submittals
10 CFR 50.34(b)(6)(ii)	QA Program Description
10 CFR 50.34(f)(3)(ii) and 10 CFR 50.34(f)(3)(iii)	Requirements Related to the Incident at Three Mile Island (TMI) (I.F.1 and I.F.2)
10 CFR 50.36(c)(5)	Administrative Controls

FIGURE 1: Addition to “Regulations, Standard Review Plan, SECY Paper, and NUREG-1055 Regarding Quality Assurance for New Reactors” page

Index | Site Map | FAQ | Facility Info | Reading Rm | New | Help | Glossary | Contact Us BrowseAloud  Search


U.S. NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

About NRC
Nuclear Reactors
Nuclear Materials
Radioactive Waste
Nuclear Security
Public Meetings & Involvement

Quality Assurance for New Reactors

[Regulations, Standard Review Plan, SECY Paper, and NUREG-1055](#)

[Safety Evaluation Reports Concerning Revised Basis for QA Programs](#)

[QA Inspections for New Reactor Licensing](#)

[Vendor QA Inspections](#)

[Nuclear Procurement Issues Committee \(NUPIC\) and Industry Interactions](#)

[Workshops on Vendor Oversight for New Reactor Construction](#)

Home > Nuclear Reactors > New Reactors > Regulatory Oversight > Quality Assurance > Vendor QA Inspections

Vendor Quality Assurance (QA) Inspections

In a *Federal Register* notice (50 FR 47716) issued on November 20, 1985, the U.S. Nuclear Regulatory Commission (NRC) announced a minor revision to its Enforcement Policy to describe how the policy applies to vendors that supply products or services to the nuclear industry for ultimate use in NRC-licensed facilities or activities. That revision reflected a Commission decision to support increased focus on NRC inspection and oversight of industry vendor activities. In addition, the NRC expanded various sections of the enforcement policy, including the purpose section and supplements, to encompass vendor activities and add references to the Notice of Nonconformance to vendors.

ADDITION

The NRC Enforcement Policy is applicable to non-licensees, including contractors and subcontractors, applicants or holders of NRC approvals (e.g., certificates of compliance, early site permits, standard design certificates, quality assurance program approval) and employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation.

Vendor inspections are conducted at vendor shops principally to examine whether the vendor has been complying with [Appendix B](#) to Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), as required by procurement contracts with licensees. Notices of Nonconformances or Notices of Violations are issued to vendors for failures to meet quality commitments or the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," respectively. 10 CFR Part 21 was last updated on December 1, 2009.

For additional information, see the following related pages:

- NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants," May 1984
- NRO SECY Paper on Enhancements to the Vendor Inspection Program for New Reactors
- NRO SECY Paper on Legal Constraints of Relying on Vendor Inspection Results of Foreign Regulators and the Need for Additional Resources to Achieve the Appropriate Number of NRC Vendor
- Inspection Procedures
- Generic Letters
- Information Notices
- Regulatory Information Summaries
- Commercial-Grade Dedication
- NUREG-0302, Revision 1 (10 CFR Part 21)
- Inspection Reports

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 Thursday, January 27, 2011

FIGURE 2: Addition to “Vendor Quality Assurance Inspections” page

Index | Site Map | FAQ | Facility Info | Reading Rm | New | Help | Glossary | Contact Us BrowseAloud 

*Protecting People and the Environment*

About NRC Nuclear Reactors Nuclear Materials Radioactive Waste Nuclear Security Public Meetings & Involvement

Home > [Electronic Reading Room](#) > [Document Collections](#) > [NRC Regulations \(10 CFR\)](#) > [PART 21--REPORTING OF DEFECTS AND NONCOMPLIANCE](#)

 Subscribe to Updates

PART 21--REPORTING OF DEFECTS AND NONCOMPLIANCE

[Full Text Version](#) (43.95 KB)

General Provisions

Sec.

- [21.1 Purpose.](#)
- [21.2 Scope.](#)
- [21.3 Definitions.](#)
- [21.4 Interpretations.](#)
- [21.5 Communications.](#)
- [21.6 Posting requirements.](#)
- [21.7 Exemptions.](#)
- [21.8 Information collection requirements: OMB approval.](#)

Notification

- [21.21 Notification of failure to comply or existence of a defect and its evaluation.](#)

Procurement Documents

- [21.31 Procurement documents.](#)

Inspections, Records

- [21.41 Inspections.](#)
- [21.51 Maintenance and inspection of records.](#)

Enforcement

- [21.61 Failure to notify.](#)
- [21.62 Criminal penalties.](#)

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Source: 42 FR 28893, June 6, 1977, unless otherwise noted.

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Monday, January 24, 2011

ADDITION

FIGURE 3: Button for subscription service for “PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE” page

MEETING MINUTES
CFSI RESPONSE COMMUNITY

- Meeting: Counterfeit, Fraudulent, and Suspect Item (CFSI) Steering Committee
- Date: February 3, 2011
- Subject: Initial meeting with the CFSI Steering Committee:
Discuss the task's mission statement, provide a progress report, discuss the implementation strategy, provide project milestones, determine steering committee meeting frequencies, and solicit feedback.
- Members: NMSS, NRO, NRR, NSIR, OE, OGC, OI
- Attendees: James Biggins (OGC), Andy Campbell (OE), Scott Langdon (OI), John Tappert (NRO), Craig Erlanger (NSIR), Rick Rasmussen (NRO)
- Presenter(s): Dan Pasquale (CQVB): "Project/Progress"
- Discussion: 1) The steering committee reviewed, discussed and approved the mission statement as presented. The statement reads:
- "To coordinate the diverse staff resources within the agency to improve the agencies abilities to respond to challenges associated with counterfeit, fraudulent, and suspect items. This effort shall include agency-wide assessments of the following key areas: 1.) supply chain oversight, 2.) communications (both internal and external), and 3.) Agency response protocols."
- 2) The steering committee reviewed, discussed and approved using three key Working Groups. The three groups are:
- I. Working Group on Supply Chain Oversight (including exploring the relationship between security & sabotage)
 - II. Working Group on Communications (including how CFSI information should be shared)
 - III. Working Group on Response Protocol (including how the various organizations need to inter-act)
- Milestones: The steering committee approved the following milestones and their corresponding dates.
- 1) Begin Working Group sessions: **06Jan11**
 - 2) CFSI Stakeholder Meeting: **June 2011** (tentative)
 - 3) Summary/Conclusion: **July 2011** (tentative)
 - 4) Present to Steering Committee: **August 2011**
 - 5) Obtain Steering Committee alignment for final recommendations: **September 2011** (tentative)
 - 6) EDO Commitment: **24OCT11**

MEETING MINUTES
CFSI RESPONSE COMMUNITY

Next Meeting: The steering committee requested that monthly updates to apprise them of the project's progress and any issues raised by the working groups.

Feedback: The following comments were received from members of the Steering Committee regarding the information presented during the meeting:

- 1) Conclusions and/or recommendations from this effort should clearly reference a regulatory basis (or lack of) in order to facilitate effective communications, both internal and external. (OGC)
- 2) Outcomes from discussions associated with the various topics must include considerations for implementation at both the licensee level and at the supplier level. (OE)
- 3) A plan must be developed to engage the multiple external stakeholders, including the FSME & NMSS communities along with the commercial power licensees and suppliers. (OE)
- 4) NSIR committed resources at the working group level to facilitate discussions with various other federal agencies to support discussions related to cyber-security. (NSIR)
- 5) The working groups should, during the course of working this task, proceed with the goal of submitting the SECY paper and making a presentation to the commissioners, at the forefront of their efforts to facilitate meeting the proposed timeline. The groups may be well served by keeping an on-going draft or outline of the final product, and update them as progress is realized. (OE)

Summary: On Thursday February 3, the Counterfeit, Fraudulent, and Suspect Items (CFSI) steering committee approved the mission statement and implementation plan for an Agency-wide assessment of the NRC's handling of CFSI. This effort is in support of commitments made by the division to implement OIG recommendations associated with Finding #10 to OIG audit number OIG-10-A-20.

MEETING MINUTES
CFSI RESPONSE COMMUNITY

- Meeting: Counterfeit, Fraudulent, and Suspect Item (CFSI) Steering Committee
- Date: March 2, 2011 - Wednesday
- Subject: Monthly meeting of the CFSI Steering Committee including the following topics:
Report on task progress, present challenges facing the working groups and to discuss future business.
- Members: NMSS, NRO, NRR, NSIR, OE, OGC, OI
- Attendees: Andy Campbell (OE), Scott Langdon (OI), John Tappert (NRO), Rich Correia (NSIR), Michael Tschiltz (NMSS)
- Rick Rasmussen (NRO), Dan Pasquale (NRO), Marty Murphy (NRR), Jeff Jacobson (NRO), Eugene Huang (NRO), Garrett Newman (NRO), Kirby Scales (NRR)
- Presentations: “Implementation of the CFSI Working Groups” - Rick Rasmussen (NRO)
“Introduction to the CFSI Knowledge Management Center” - Dan Pasquale (NRO)
- Discussions: After the formal presentations, discussions transpired in the following topics:
- 1) Rich Correia informed the Steering Committee that from hence forth, Craig Erlanger would replace him on the CFSI Steering Committee as the representative from NSIR.
 - 2) The CFSI team requested Steering Committee clarification on the scope of the team’s activities. Historically, the scope has always been limited to items manufactured with intent to financially profit from the gain, but recent discussions appear to suggest that the scope may be expanding to include items manufactured with intent to do harm to the facility. The Steering Committee unanimously agreed that for the purpose of this project, a fourth Working Group should be established to consider CFSI manufactured with a malicious intent in mind. Cyber Security should be considered as an activity under this new group.
 - 3) Members of the steering committee offered their support and assistance to furthering the progress of the project by asking the Working Group Leaders to consider what the steering committee members can be doing to assist them in accomplishing their tasks.
- Milestones: There were no new milestones or due dates established at this meeting.
- Next Meeting: The steering committee agreed to set the next meeting of the CFSI Steering Committee Meeting for the first week in April, 2011.

MEETING MINUTES
CFSI RESPONSE COMMUNITY

Feedback: The following comments were received from members of the Steering Committee regarding the information presented during the meeting:

- 6) The feedback from the “Implementation of the CFSI Working Groups” presentation was positive. The flow charts provided were clear, concise and well presented. (OI)
- 7) The presentation on “Introduction to the CFSI Knowledge Management Center” was well done and easily followed. Rich Correia agreed to have NSIR review the site content for information that may be sensitive, and to share additional information deemed suitable for the KMC. (NSIR)

Summary: On Wednesday March 2, the Counterfeit, Fraudulent, and Suspect Items (CFSI) Steering Committee met with the CFSI Working Group leads for their monthly progress report. The Steering Committee instructed the Project Lead to institute a fourth Working Group to include inventory manufactured with a malicious intent. Presentations on “Implementation of the CFSI Working Groups” and “Introduction to the CFSI Knowledge Management Center” were given by members of NRO/DCIP. This effort is in support of commitments made by the division to implement OIG recommendations associated with Finding #10 to OIG audit number OIG-10-A-20.