



VOGTLE September 2012

2012 VENDOR WORKSHOP HIGHLIGHTS



NRC Vendor Workshop 2012

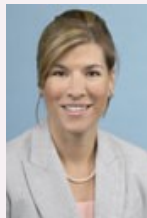
On June 28, 2012, the Office of New Reactors hosted the third U.S. Nuclear Regulatory Commission (NRC) Workshop on Vendor Oversight for New Reactor Construction in Baltimore, MD. The workshop included presentations by members of the NRC staff, the Nuclear Procurement Issues Committee (NUPIC), the American Society of Mechanical Engineers (ASME), the Nuclear Energy Institute (NEI), the Electric Power Research Institute (EPRI), and three nuclear vendors. Participants of the workshop discussed various topics, such as vendor oversight for new reactors, upcoming proposed changes to 10 CFR Part 21 "Reporting of Defects and Noncompliance", safety culture, the use of international calibration laboratories, current activities of the counterfeit, fraudulent, or suspect items (CFSI) team, the use of commercial-grade dedication in safety-related applications, software quality assurance, supplier oversight implementation, non-power reactor vendor oversight, and vendor insights on licensee, NUPIC, and NRC oversight. For more information on the NRC 2012 vendor workshop, please visit the NRC's public Web site at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html>.

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The Director's Cut



Laura Dudes, Director of Division of Construction Inspection and Operational Programs

The Office of New Reactors (NRO) completed the first year of operations under the new Vendor Inspection Program (VIP) Plan. Additionally, the NRC made changes within the Office of Nuclear Reactor Regulation (NRR) and NRO is now leading the vendor inspection center of expertise. These activities include performing routine and reactive vendor inspections and

quality assurance (QA) inspections for the commercial nuclear power industry, including both new and operating reactors. Based on the agency's restructuring and follow-

ing the guidance in the VIP, we conducted inspections of vendors performing design verification and qualification testing for the AP1000 construction activities. NRO also performed vendor inspections of key vendors supporting the operating reactor fleet and responded to several operating events related to vendor activities. In 2013, NRO will continue to perform inspections to verify that design requirements are preserved and effectively translated through the design, procurement, and manufacturing process, and that safety related goods and services meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance". Maintaining a strong safety culture and keeping the focus on quality throughout the supply chain is a responsibility that everyone shares to ensure a safe construction and operation of these new facilities. Please find more information

about safety culture on page 3 of this newsletter or on the Web at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0500/>. Please find more information on the vendor center of excellence on page 2 of this newsletter or on the Web at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/coe.html>.



James Luehman, Deputy Director of Division of Construction Inspection and Operational Programs

Counterfeit, Fraudulent, and Suspect Items Updates

The NRC staff has been working to implement the 19 recommendations the agency identified as a part of its agencywide strategy plan to address issues of counterfeit, fraudulent, and suspect items (CFSI) in today's nuclear power industry. Since SECY-11-0154, "An Agencywide Approach to Counterfeit, Fraudulent, and Suspect Items," was issued in October 2011, the NRC staff has managed to complete many internal and external recommendations. Completed recommendations included utilizing the established outreach relationships with the U.S. Department of Homeland Security and other Government agencies, recently issuing an NRC information notice on available CFSI training modules, completing CFSI training for NRC inspectors, and conducting quarterly public meetings. In addition, the NRC continues to make progress in updating 10 CFR Part 21 regulations, incorporating CFSI into the NRC operating and construction experience program for information sharing, and updating current NRC inspection procedures to include CFSI language. The NRC staff also has been evaluating the need for a pilot program to inspect current operating reactors' procurement programs.



Intellectual Property Rights Coordination Center PR Center Director Lev Kubiak (left) and NRC Office of Investigations Director Cheryl L. McCrary (right)

In recent news, the NRC became the 21st partner agency with the National Intellectual Property Rights Coordination Center (IPR), which is a part of the U.S. Department of Homeland Security's immigration and customs enforcement. The partnership outlines the collaborative investigative efforts and cooperation protocols the two agencies will share on counterfeit, fraudulent, and suspect parts and equipment used in nuclear power plants and devices using nuclear materials.

"This important interagency partnership will play a critical role in the NRC's formal, proactive efforts to address the potential threat that counterfeit parts pose to the global supply chain, which will reduce vulnerabilities as they relate to NRC-regulated activities," said Cheryl McCrary, Director of the NRC's Office of Investigations. "This partnership initiative will enhance the fight against wrongdoing in support of the NRC's safety and security mission."

The NRC staff has been actively involved with the voluntary CFSI initiatives and the agency challenges the industry to increase collaboration efforts to prevent CFSI in the nuclear power industry. More details about the NRC and IPR partnership can be found at <http://www.nrc.gov/reading-rm/doc-collections/news/2012/>.

Vendor Center of Expertise

What is the vendor center of expertise (COE)? The vendor COE, located within the NRO, leads and performs routine and reactive vendor inspections and quality assurance inspections for the commercial nuclear power industry, including new and operating reactors. By combining the NRO and NRR vendor inspection programs into one COE, the agency can further enhance its environment for knowledge management for the vendor inspection staff and provide the junior staff better access to senior staff for mentoring and on-the-job training so they can grow in their areas of expertise. Specific responsibilities of the vendor COE include performing reactive inspections in response to the following: (1) operating experience, (2) reports of defects and noncompliance made in accordance with 10 CFR Part 21, (3) allegations, and (4) inspections to verify the effective implementation of vendor quality-assurance programs in the nuclear power reactor industry. More information on the vendor COE can be found at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/coe.html>.

Hot Off the Press! The Vendor Inspection Plan Updates



Vendor inspectors at the Mangiarotti facility in Monfalcone, Italy

NRO recently achieved important milestones in its efforts toward implementing strategies from the Vendor Inspection Program Plan (VIP). NRO staff completed 90 percent of the strategies for vendor outreach and communications to enhance the NRC's commitment to openness, efficiency, and clarity with its stakeholders. The completed strategies consist of reconstructing the NRC's public Web site for vendor oversight. Changes to the website include categorizing findings and violations from NRC vendor inspection reports, providing the latest information on vendor oversight conferences, and adding a frequently asked questions page. Moving forward, the NRO staff plans to release a regulatory issue summary and a vendor registration web page to identify vendors of safety-related parts and services for new and operating nuclear power plants. This approach will enable the NRC to effectively identify and plan its inspection efforts and outreach activities with vendors. The NRO staff will be requesting voluntary participation in these future initiatives to enhance vendor outreach and communications. For more information on VIP activities, please visit the NRC's public Web site at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>.

NEW NEWS ON 10 CFR PART 21

The NRC took a big step toward clarifying Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance". On December 5, 2012, the NRC published the draft regulatory basis for 10 CFR Part 21. The following is the introduction chapter of the draft regulatory basis:

"The recommendations in this regulatory basis, if pursued, would simplify and clarify the rule language in Part 21, provide consolidated regulatory guidance, and would enhance regulatory stability and predictability for the entities to which Part 21 applies."

The publication of this document represents a major milestone in the NRC's plan, as outlined in Commission Paper SECY-11-0135, "Staff Plans To Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the *Code of Federal Regulations* Part 21, 'Reporting of Defects and Noncompliance,'" which the staff issued on September 29, 2011. The draft regulatory basis details 22 technical areas for improvement and four administrative changes. The 22 areas for improvement are split into the two main subjects of 10 CFR Part 21: evaluating and reporting, and commercial-grade dedication. The document gives the NRC's analysis of the problems in each area, and it offers potential solutions, while examining the pros and cons of each. Some of the highlights of the document include a plan to publish NRC-endorsed guidance on evaluating and reporting, as well as improvements to the commercial-grade dedication process.

In response to the NRC's early efforts, the Electric Power Research Institute (EPRI) started work on a revision to EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," which was originally issued June 1988. The NRC's draft regulatory basis describes the staff's approach to potentially endorsing a revised EPRI guide.

The NRC decided to publish a draft version of the regulatory basis with early stakeholder involvement in mind. According to Vic Hall, the NRC's 10 CFR Part 21 subject matter expert:



"We wanted to make sure that all of our stakeholders had a chance to weigh-in, and help clarify Part 21. This is a rare opportunity to change an important rule that affects not just licensees, but nuclear suppliers all over the world. We can make some much needed changes to Part 21, and finally clear up these key regulatory processes. Putting the regulatory basis out as a draft will allow everyone to comment on the areas that need clarifying, and will make the rulemaking process run more efficiently. I think we've done a great job advertising this effort, and I feel really confident that we're going to get a lot of quality input from our stakeholders. The end result is going to be a much improved 10 CFR Part 21."

The NRC has scheduled a public meeting on January 24, 2013, at headquarters in Rockville, MD, to discuss the draft regulatory basis. The meeting is scheduled to be a workshop format, in which the NRC can work with stakeholders on the technical details in the document.

The 10 CFR Part 21 draft regulatory basis provides details about the public meeting and other information on this effort at the following link: <http://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML12248A200>. To get involved and receive the latest updates on the 10 CFR Part 21 rulemaking, subscribe to the 10 CFR Part 21 updates and join more than 1,600 interested parties. Sign up by clicking on "Subscribe to Page Updates" at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/>.

Vendor's Approach on Safety Culture

In March 2011, the NRC approved the Safety Culture Policy Statement. This policy statement provides the NRC's expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. Because safety and security are the primary pillars of the NRC's regulatory mission, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of the Safety Culture Policy Statement. The policy statement applies to all licensees, holders of quality assurance program approvals, vendors and suppliers of safety related components, and applicants for a license. For vendors, you and all of your employees should keep the safety function of your products in mind when making decisions during all of the procurement, manufacturing and testing stages associated with your product. This includes procedure adherence to assure key steps or processes are properly completed, the use of the corrective action and 10 CFR Part 21 reporting processes to assure issues that could impact the performance of your products are identified, appropriately resolved and reported, and keeping the ultimate impact on safety function in mind when making decisions at all levels. During NRC inspections, the staff focuses on how you assure your products will be able to meet the demands of operation in both normal and accident conditions. To improve the safety culture at vendor sites, the Safety Culture Policy Statement contains a list of personal and organizational traits that are present in a positive safety culture environment for your review. More details about Safety Culture Policy Statement can be found at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0500/>.



What's Hot in the Vendor World!

Use of accreditation provided by International Laboratory Accreditation Cooperation

Calibration laboratories that provide safety-related calibration services, similar to other safety-related suppliers, need to have a quality assurance program (QAP) that meets the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Licensees and suppliers of nuclear components may procure commercial-grade calibration services from a calibration laboratory that does not have a QAP that meets the requirements of Appendix B to 10 CFR Part 50, however; the calibration services must be dedicated in accordance with the licensee's or supplier's commercial-grade dedication program.

The NRC recognizes that most suppliers of calibration services do not have a QAP that meets the requirements of Appendix B to 10 CFR Part 50. As such, the NRC has allowed that for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by any of the U.S. domestic accreditation services provided by a domestic accrediting body, as accredited by ILAC, are acceptable in place of a commercial-grade survey as part of the commercial-grade dedication process when all of the requirements described in the Arizona Public Service Company safety evaluation report (SER) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML052710224) are met. The NRC expanded this guidance to include the use of domestically accredited calibration laboratories by suppliers and subsuppliers in a letter from the agency to Ms. Sherry Grier, Nuclear Procurement Issues Committee (NUPIC) Chairman, dated June 6, 2006 (ADAMS Accession No. ML061580350). It is important to note that NRC's recognition of the ILAC accreditation process is only limited to U.S. domestic calibration service suppliers, not to international calibration suppliers. In addition, ILAC's accreditation shall not be used as the sole basis for qualifying safety-related calibration services.

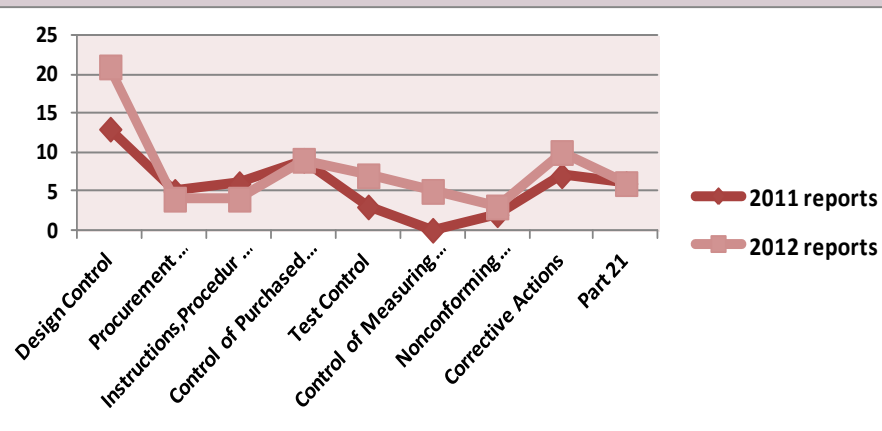


In February 2009, the NRC received a request from an international supplier to evaluate the acceptance of international accrediting bodies belonging to ILAC as third-party accreditation for commercial-grade calibration services. Similar to the U.S, most international calibration service suppliers do not have a QAP that meets the requirements of Appendix B to 10 CFR Part 50. In addition, most of these international calibration suppliers do not allow their customers to perform any kind of direct oversight; hence making the performance of commercial-grade surveys very difficult. As such, the NRC is currently awaiting an industry proposal from the Nuclear Energy Institute to expand the acceptability of third-party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC.

2012 Inspection Finding Statistics

The chart below represents a comparison of findings encountered during NRC vendor and QA implementation inspections in 2011 to 2012. The agency continues to identify issues with the implementation of effective commercial-grade item dedication programs as part of design control activities. These findings are consistent with the scope of our NRC inspections over the past year that focused on design control and equipment qualification testing activities. The NRC encourages all vendors to visit the agency's Web site to review the specific details of these findings and to make adjustments if your quality program reflects those specific issues.

See next year's newsletter for more great statistics!



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We welcome useful and informative feedback on the contents of this newsletter. If you would like to suggest topics, please contact Shavon Edmonds from the Electrical Vendor Branch at 301-415-6773 or email at shavon.edmonds@nrc.gov.