

Vendor Newsletter

10 CFR Part 21

The U.S. Nuclear Regulatory Commission (NRC) recently achieved an important milestone in its efforts toward clarifying Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance". The NRC staff issued Commission Paper SECY-11-0135, "Staff Plans To Develop the Regulatory Basis for Clarifying the Requirements in 10 CFR Part 21, Reporting of Defects and Noncompliance on September 29, 2011. This paper informs the Commission of the staff's plan to develop the regulatory basis to clarify Part 21.

The paper describes the background of Part 21, including the compliance challenges that the regulation has posed. It outlines the staff's basis for undertaking rulemaking and lists the long-term goals, up to potential issuance of a final rule in 2014. Finally, the paper proposes 25 areas for improvement, which fall into three categories: evaluating and reporting, commercial-grade dedication, and administrative changes.

The staff has been active in soliciting early stakeholder feedback and will continue to seek your help in improving Part 21. The 10 CFR Part 21 SECY paper is available at the following link: <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0135scy.pdf>. To get involved and receive the latest updates on Part 21 rulemaking, sign up by clicking on "Subscribe to Page Updates" at: <http://www.nrc.gov/reading-rm/doc-collections/cfr/part021>.

The Directors' Cut

We are pleased to present the inaugural issue of the Vendor Times.

With the onset of the New Year, the Nuclear Regulatory Commission (NRC) is prepared to provide regulatory oversight of the AP1000 construction activities as the industry moves forward on the first licenses to construct and operate a new nuclear power plant. With new construction, there will be an increase in the procurement of goods and services necessary to support this activity. These activities must be conducted in a manner that ensures 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 10 CFR Part 21. The safe construction and operation of these new facilities requires the commitment of everyone in the supply chain to focus on quality and to maintain a strong safety culture.

Counterfeit, Fraudulent, and Suspect Items (CFSI)

The NRC staff recently issued SECY-11-0154 "An Agencywide Approach to Counterfeit, Fraudulent, and Suspect Items" on October 28, 2011. This paper informs the Commission of the staffs' plans to identify and implement proactive strategies to detect and prevent the intrusion of counterfeit, fraudulent, and suspect items (CFSI) into equipment, components, systems, and structures regulated by the NRC. The paper describes the historical background of CFSI and discusses the staffs' assessment of the current regulations, guidance, and licensee procurement processes associated with preventing the intrusion of CFSI into NRC regulated activities. The staff assembled an internal task force comprised of representatives from the various offices potentially affected by the CFSI issue. As part of this effort, four working groups

were formed to assess activities and potential vulnerabilities in the specific areas of supply chain oversight, response protocols, communications, and cyber security supply chain oversight.

As a result of the activities of the working groups, the staff identified 24 issues for improvement and 19 planned recommendations, which are listed in more detail in the working groups' final report, "Staff Review of Counterfeit, Fraudulent, and Suspect Items (CFSI)" dated November 18, 2011 (Agency Document Access and Management System (ADAMS) Accession Number ML112130293). The working groups' final report contains a more detailed description of the agencywide strategy and plan, implementation goals, and impacted offices. The CFSI SECY Paper is available on the NRC public web site and at <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0154scy.pdf> for more exciting details.

Vendor Inspection Program

The vendor inspection program (VIP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including performing vendor inspections that will verify the effective implementation of the vendor's quality assurance (QA) program, establishing a strategy for vendor identification and selection criteria, and ensuring that vendor inspectors continually obtain the necessary knowledge and skills for performing inspections. Additionally, the VIP addresses interactions with nuclear consensus standards organizations, industry and external stakeholders, and international constituents. The VIP's objectives and implementation strategy are contained in the recently issued Vendor Inspection Program Plan that is available in ADAMS (ADAMS Accession No. ML112450113). For 2011, the NRC vendor inspection branches conducted a total of 18 vendor inspections and 6 QA implementation inspections. The discussion below highlights some of the inspection efforts in 2011.

Most Significant Inspection of 2011

In July 2011, staff conducted our first engineering design verification inspection at Westinghouse Electric Company. The objectives of this inspection were to assess the implementation of Westinghouse's processes for transferring the design requirements contained in the design certification document into detailed engineering, procurement, and construction documents. Based on the results of this inspection, the NRC concluded that Westinghouse was properly controlling the design approved in the Design Certification Document (DCD). However, the inspection team identified three examples where the detailed design did not meet the requirements contained in the DCD. These issues are documented in the inspection report (IR) and should be addressed in Westinghouse's response. The Westinghouse IR is available at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/inspreports/2011/>. Stay tuned for more of these inspections in the near future.

2011 Inspection Finding Statistics

The chart below represents the increase in findings encountered during our vendor and QA implementation inspections from 2010 to 2011. We continue to identify issues with the implementation of effective commercial-grade item dedication programs as part of design control activities. Although, we have seen a reduction in findings related to the implementation of the requirements in 10 CFR Part 21. See next year's newsletter for more great statistics!

Updated Inspection Procedures and Guidance Documents of 2011

The NRC updated the following guidance documents applicable to vendor and QA implementation inspections:

- IP 36100 Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance
- IP 37805 Engineering Design Verification Inspections
- IP 43002 Routine Inspections of Nuclear Vendors
- IP 43003 Reactive Inspections of Nuclear Vendors
- IP 43004 Inspection of Commercial-Grade Dedication Programs
- IP 43005 NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements
- IN 2011-19 Licensee Event Reports Containing Information Pertaining to Defects in Basic Components
- IN 2011-01 Commercial-Grade Dedication Issues Identified During NRC Inspections

Software Dedication

The dedication of commercial software products that are being used in safety-related applications has been a focus area for industry and the NRC. Subpart 2.7 of American Society of Mechanical Engineers Standard (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," contains the QA requirements for software, but fails to give guidance on the dedication of software components. Other standards, such as Electric Power Research Institute (EPRI) NP-5652, "Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," issued June 1988, and EPRI TR-06439, "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Related Applications," issued October 1996, form a basis for accepting commercial grade computer software, however, these documents lack guidance on the dedication of software components.

Currently, new guidance documents for software dedication are being developed by EPRI's technical advisory group (TAG) and ASME's NQA-1 QA subcommittee for commercially procured software. The next edition of the NQA-1 standard should include "new" nonmandatory guidance related to the dedication of commercially procured design analysis software. Also, the EPRI TAG, made up of members of the Nuclear Procurement Issues Committee, Joint Utility Task Group, and Nuclear Information Technology Strategic Leadership is developing a separate dedication guidance document for acceptance of commercial-grade computer codes for use as a basic component in safety-related activities. The EPRI TAG is working with the NRC's QA task force and plans to submit the EPRI guidance document to the NRC for review and acceptance as a Nuclear Energy Institute document submittal. Stay tuned for more information on software dedication activities!

Upcoming Vendor Events

NRO/DCIP will host the third Workshop on Vendor Oversight for New Reactor Construction on Thursday, June 28, 2012, in Baltimore, MD. This workshop brings together numerous attendees, including members of the public, licensees, applicants, vendors, suppliers of basic components, industry organizations, and the NRC staff. The workshop allows the NRC to provide information and training to the industry on specific topics related to issues identified by the staff during routine vendor inspection and interaction activities. The workshop will begin at

8 a.m. and will continue until approximately 5:30 p.m. Topics will include upcoming changes to 10 CFR Part 21, the use of international calibration laboratories, and the use of commercial-grade dedication in safety-related applications. Any stakeholders with feedback related to the planning and coordination of the vendor workshop or anyone who would like to suggest a topic or volunteer as a speaker for the workshop are encouraged to contact Marlayna Vaaler at marlayna.vaaler@nrc.gov.

Enclosure:

1. Vendor Newsletter (PDF)

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ADAMS Accession No.: ML11326A078 (pkg)

*concurring via email

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