VC Summers 2 & 3 – Construction Site 2014

THE VENDOR TIMES

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U.S.NRC
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Protecting People and the Environment

The Directors Cut

MICHAEL CHEOK, Director of Division of Construction Inspection and Operational Programs

2014 was an active year for the U.S. Nuclear Regulatory Commission's (NRC's) vendor inspection program (VIP). We completed 37 vendor inspections with findings in the areas of commercial grade dedication (CGD), evaluating and reporting consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 ("Reporting of Defects and Noncompliance") and 10 CFR Part 50 ("Domestic Licensing of Production and Utilization Facilities") Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"). The results of these inspections identify some continuing challenges with vendor performance and licensee oversight of the supply chain.

In the current environment, many vendors provide services and plant components to customers in multiple countries and many of these vendors operate from outside the United States. In the past year alone, we performed inspections at four international vendors. For efficiency and to leverage the resources and talents of our regulatory peers in other countries, we continued to actively participate in bilateral and multilateral interactions with our international counterparts to help enhance our vendor oversight. For example, the NRC VIP staff actively participated in several Multinational Design Evaluation Program (MDEP) activities including the AP1000 working group which focuses on various AP1000 equipment issues, and the vendor inspection cooperation working group which facilitates the sharing of vendor inspection information. In July, the NRC led a team of inspectors from several countries in the first MDEP multinational inspection of a facility in France. Also, the staff has continued to develop the framework for interactions with the Chinese regulator (National Nuclear Safety Administration) regarding AP1000 plant commissioning activities at the Sanmen site in China to share insights on AP1000 construction, testing and component manufacturing activities.

ANDREA VALENTIN, Deputy Director of Division of Construction Inspection and Operational Programs

An ongoing priority of the VIP is to communicate issues and to share NRC expectations with the vendor community. In June, we conducted a widely-attended and successful workshop on vendor oversight. ***Directors Cut continued on page 2***

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In all, 467 people from 14 countries participated, including those representing vendors, industry groups, government regulatory agencies, and electric utilities. More details on this workshop are provided in the next article.

During 2014, the NRC VIP staff formed a working group to evaluate lessons learned from our previous inspections. This group has made several recommendations to enhance the effectiveness and efficiency of the vendor inspection program. We will discuss these recommendations with our internal and external stakeholders in early 2015, and after taking into account comments and suggestions, we plan to begin the implementation of the plan soon thereafter.

In closing, the NRC is encouraged to see that progress has been made by the nuclear industry in the design, procurement, and manufacturing processes so that safety related goods and services meet our regulatory requirements. However, licensees and vendors need to continue to be diligent in their emphasis on a robust safety culture and on the continued implementation of proper supplier oversight. Vendors and the nuclear industry play an important role in enhancing the regulatory process and in ensuring public safety.

2014 Workshop on Vendor Oversight

The fourth biennial NRC Workshop on Vendor Oversight was held on June 12, 2014 in Portland, OR. The NRC Vendor Workshop included a keynote address by Commissioner Svinicki, as well as presentations by members of the NRC staff and representatives from the following:

⇒ the Nuclear Energy Institute (NEI)

⇒ the Electric Power Research Institute (EPRI)

⇒ the Korean Institute of Nuclear Safety

⇒ the Korea Hydro & Nuclear Power Co., Ltd

⇒ two new reactor licensees

⇒ six nuclear vendors

Over 400 attendees from 14 countries participated in this workshop. The workshop brought together members of the public, licensees, applicants, vendors, suppliers of basic components, and industry organizations for discussions on important topics such as vendor oversight; 10 CFR Part 21 rulemaking activities; international calibration laboratories; activities in Counterfeit, Fraudulent, or Suspect Items; commercial grade dedication in safety-related applications; software quality assurance; and supplier oversight implementation.

Through interactions during the workshop, participants developed the following key messages:

⇒ Rigorous vendor oversight is crucial to maintaining the integrity of the global supply chain and nuclear safety.

⇒ A robust and positive safety culture promotes quality in the global supply chain.

⇒ Comprehension and compliance with codes, standards, and quality requirements form a foundation to the work being carried out.

⇒ Vigilance is the key in preventing the entry of counterfeit, fraudulent, and suspect items into the global supply chain.

⇒ The licensee is ultimately responsible for quality.

NRC Participation in MDEP/ VICWG Inspection

From July 7–11, 2014, NRO vendor inspectors led a team of inspectors representing France, the United Kingdom, and the United States in performing the first MDEP multinational inspection at Valinox Nuclear in Montbard, France. Multinational inspections consist of multiple regulators performing inspections to a set of common quality standards. Valinox Nuclear's primary product line is steam generator tubes for the nuclear industry. The purpose of the inspection was to assess Valinox's compliance with the quality assurance/quality management (QA/QM) criteria described in the MDEP VICWG Technical Report, TR-VICWG-03, "Common QA/QM Criteria for Multinational Vendor Inspection," Revision 1, dated January 20, 2014, and MDEP Protocol, VICWG-01, "Witnessed Joint and Multinational Vendor Inspection Protocol," Revision 2, dated March 20, 2014, respectively. The inspection also offered the inspectors an opportunity to pilot the VICWG draft documents to gain valuable insights into the effectiveness of application of the common QA/QM criteria to vendor inspections performed by a multinational inspection team. During this inspection, the inspection team evaluated implementation of Valinox's quality assurance program with respect to the 15 specific criteria described in TR-VICWG-03. The NRC issued a vendor inspection report which is available at h tt p ://ww w.n rc.go v/r eact o rs/n ew -react o rs/o ver sight /q u alit y -ass u ra n ce/ ven d o r -in sp /in sp -rep o rts/ 201 4/ or Agencywide Documents Access and Management System Accession No. ML14217A535. At the conclusion of the inspection, the team reviewed the process and identified positive points as well as some areas for improvement. Overall, the team concluded that the MDEP multinational inspection format worked well and provided useful results for all of the participants. The inspection was considered a valuable cooperative exercise by all of the member-nations involved, and based on the success of the Valinox inspection; the VICWG will likely continue performing multinational inspections.

REGULATORY ISSUE SUMMARY 2014-07

Enhancements to the Vendor Inspection Plan

The NRC is populating an internal database of contractors, vendors (C/Vs) and supplier's information in support of the Vendor Inspection Program Plan, and is seeking more comprehensive information on C/Vs and suppliers. The NRC issued Regulatory Issue Summary (RIS) 2014-07 on May 5, 2014, which requested all holders of an operating license, construction permit, early site permit, combined license or design certification to collect data concerning C/Vs and suppliers of basic components and safety-related services to operating and new power reactors, to voluntarily submit the data to the NRC. The data collected included contact information for the C/Vs and suppliers, as well as their scope of supply (i.e., valves, pumps, electric motors, parts, design services, etc.).

10 CFR Part 21 Update

In 2014, the NRC's Office of New Reactors (NRO) staff continued engaging its external stakeholders in the 10 CFR Part 21 clarification effort. In June, the staff presented an update on the Part 21 rulemaking effort at the biennial NRC Workshop on Vendor Oversight. The staff was particularly active with outreach in August when it delivered presentations on the Part 21 rulemaking effort at the EPRI
Joint Utility Task Group Procurement Forum and the American Nuclear Society Utility Working Conference and Vendor Technology Expo in Florida.

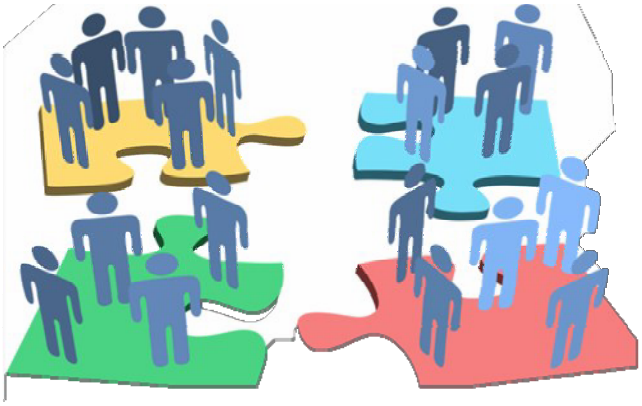
In support of the staff's efforts, NEI made three submittals on behalf of industry to provide guidance on evaluating and reporting and on commercial grade dedication as they relate to Part 21. NEI submitted the following:

1) NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 0
2) NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (see article on next page)
3) EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260."

The NRC staff is currently reviewing these submittals for potential endorsement as industry guidance for implementing the 10 CFR Part 21 regulations.

The NRO staff has also worked closely with its internal stakeholders on the Part 21 rulemaking effort by collaborating with the NRC Office of Nuclear Material Safety and Safeguards to address Part 21 policy issues as they impact fuel fabrication facilities. Kerri Kavanagh, Branch Chief of the Quality Assurance Vendor Inspection Branch, provided the following update on the current status of the 10 CFR Part 21 rulemaking efforts:

> ***"The Agency has had extensive interactions with its stakeholders. As such, we are diligently attempting to incorporate all stakeholder feedback. We are currently working with our Office of the General Counsel, to expeditiously resolve comments and issue Revision 1 of the draft regulatory basis."***



FOR MORE INFORMATION

For the latest information related to 10 CFR Part 21 clarification and rulemaking, go to the NRC Web site, at the following link:
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Draft Regulatory Guide 1305: Acceptance of Commercial-Grade Design and Analysis Computer Programs

The NRC staff continues to publish guidance to promote understanding and adherence to existing regulatory requirements. Earlier this year, NEI submitted Revision 1 of EPRI 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications," for staff review and approval. EPRI 1025243 describes a dedication methodology specifically for commercial grade design and analysis computer programs. NEI requested NRC evaluation of the EPRI 1025243 CGD method, which follows the method provided in EPRI NP-5652, for acceptability in meeting regulatory requirements. Revision 1 of EPRI 1025243 is currently available for free on the EPRI Web site (h tt p :/ /E PRI.co m).

Draft regulatory guide (DG) 1305, "Design and Analysis Computer Program Commercial-Grade Dedication Requirements," has been developed to communicate commercial-grade dedication methods considered acceptable in meeting specific requirements for acceptance of commercial grade design and analysis computer programs (software). DG 1305 is near completion and is expected to be available for public comment in 2015. The draft guide will be posted in the Power Reactors (Division 1) section of the NRC Web site at h tt p ://ww w. n rc.gov/r ead in g -rm/d o c -colle ctio n s/r eg -gu id es /p o wer -reac to rs/d ra ft -in d ex.h tml . After resolution of public comments, the NRC expects to develop a final regulatory guide, which would be presented for public comment. Public comments during the current draft guide period present the optimal opportunity for exchange of information, resolution of con- cerns, and incorporation of alternatives.

NRC's Recognition of the International Laboratory Accreditation Cooperation

By letter dated August 28, 2014, NEI submitted Revision 1 of NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to the NRC staff for review and endorsement. NEI 14-05 provides an approach for licensees and suppliers of basic components to use laboratory accreditation by accreditation bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (the ILAC accreditation process). This process can be used in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

The staff's evaluation report documenting the review and acceptance of this submittal will provide the conditions that must be met to use this recognition in lieu of performing commercial grade surveys for procurement of commercial calibration and testing services. The NRC's endorsement of NEI 14-05 will expand the agency's recognition of the ILAC accreditation process first documented in a staff evaluation report on an Arizona Public Service request (Agencywide Documents Access and Management System Accession No. ML052710224). The NRC's earlier recognition was limited to laboratory calibration services accredited by specific U.S. ABs.

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We welcome useful and informative feed back on the contents of this newsletter.

If you would like to suggest topics for the newsletter, please contact Ashley Thomas, Quality Assurance Vendor Inspection Branch, by telephone at 301-415-6638 or by e-mail at Ashley.Thomas@nrc.gov.