U.S.NRC
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THE VENDOR TIMES

NRC/NRR/DRO The Vendor Times **December 2024**

The Director's Cut

Russell Felts, Director, Division of Reactor Oversight

In fiscal year (FY) 2024, the U.S. Nuclear Regulatory Commission (NRC) vendor inspection staff performed multiple domestic and international activities. The domestic activities focused generally on performing inspections to verify that the licensees are providing effective oversight of the supply chain. The international activities focused primarily on collaborating with other regulatory bodies and presenting the NRC regulatory framework and supplier oversight to other international organizations.

The vendor inspection staff conducted a total of 21 vendor activities. The vendor inspection staff performed 17 vendor inspections and one QA implementation inspection. In addition, the vendor inspection staff observed two Nuclear Procurement Issues Corporation (NUPIC) audits and participated in a licensing audit. During these inspections and audits, the NRC evaluated the vendors' and licensees' compliance with the applicable requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The vendor inspection staff continued to maintain communication with nuclear supply chain stakeholders via the 9th NRC Workshop on Vendor Oversight, which was held on June 13, 2024, with approximately 350 attendees participating. Workshops on vendor oversight are performed biannually, and the next one is schedule for June 2026. More details can be found in page 3 of this newsletter.

The NRC vendor inspection staff participated in different international conferences related to the ASME NQA-1 international working group, Small Modular Reactors Regulators Forum and Nuclear Harmonization Meeting, International Energy Agency Technical meeting on CFSI and Committee on Nuclear Regulatory Activities Working Group on Supply Chain. In addition, the NRC vendor inspection staff performed a vendor inspection of Doosan Enerbility, Ltd, on Changwon, South Korea. More details on our international collaboration can be found in page 7 of this newsletter.

In closing, licensees and vendors need to continue ensuring there is adequate oversight of the supply chain to fulfill its vital role of ensuring the public's health and safety.

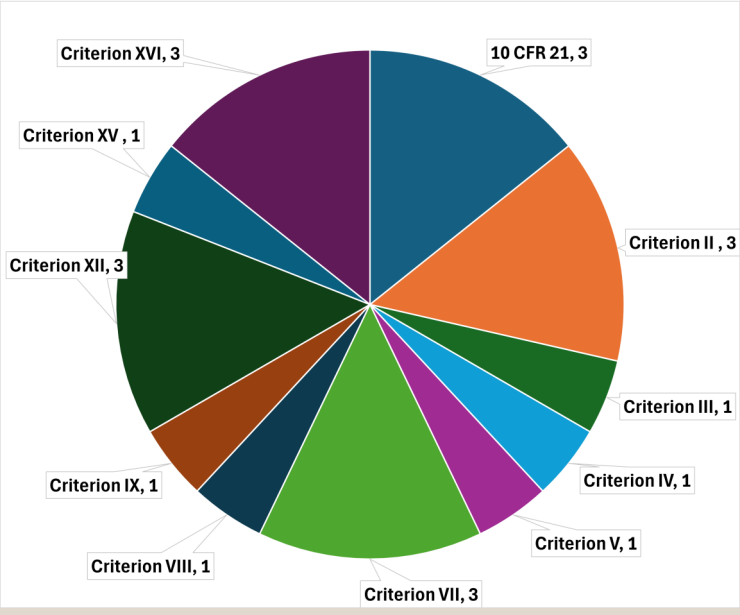
In this Issue:

2024 Vendor Inspection Activities

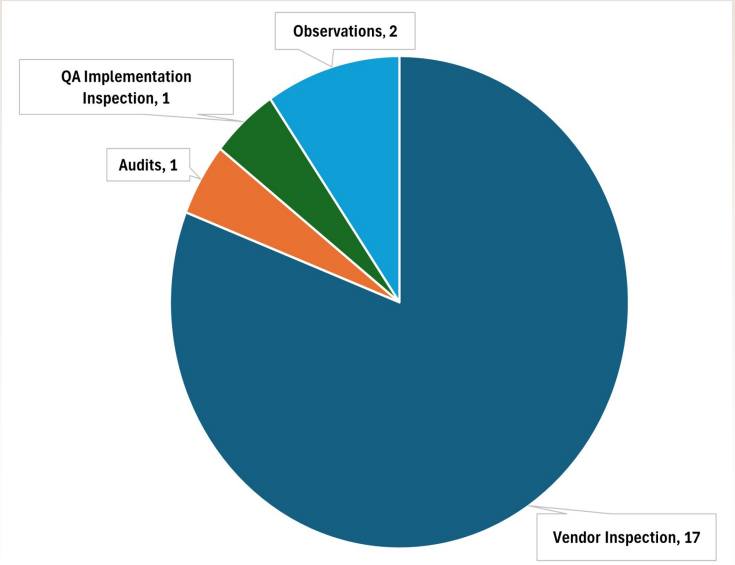
The Vendor Inspection Program Plan (VIPP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including performing vendor inspections to verify the effective implementation of the vendor's quality assurance (QA) program, establishing a strategy for vendor identification and selection criteria, and ensuring vendor inspectors obtain the necessary knowledge and skills to perform inspections. From October 1, 2023, to September 30, 2024, the vendor inspection staff completed a total of 21 vendor activities. These vendor activities cover vendor inspections, NUPIC observations, QA implementation inspections and audits. During these inspections, the NRC issued 18 nonconformances against vendors for their failure to adequately implement the applicable requirements of Appendix B to 10 CFR Part 50. In addition, the NRC issued three violations against vendors for their failure to adequately implement the requirements of 10 CFR Part 21.

The nonconformances cited against vendors fell within various criteria of Appendix B to 10 CFR Part 50, including Criterion II, "Quality Assurance Programs," Criterion III, "Design Control," Criterion IV, "Procurement Document Control, "Criterion VII, "Control of Purchased Material, Equipment, and Services," Criterion IX, "Control of Special Processes," Criterion XII, "Control of Measurement and Test Equipment," Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action." Nonconformances have different levels of significance. From the three Criterion II nonconformances, two of those involved the failure to provide training to personnel while the more significant one involved failure to establish an adequate QA program. While the NRC does not consider this to be indicative of any industry trend, the vendor inspection staff identified the failure to establish an adequate QA program in software vendors two years in a row. The VIPP contains processes to place increased focus in these areas during future vendor inspections to ensure vendors understand how to adequately implement these requirements. In addition, during future interactions with our stakeholders (e.g., industry meetings), the vendor inspection staff will continue to highlight the importance of adequately implementing their 10 CFR Part 21, and QA programs.

FY 2024 Violations and Nonconformances



FY 2024 Vendor Activities



- Dong Park, Reactor Operations Engineer

9th NRC Workshop on Vendor Oversight

On June 13, 2024, the Office of Nuclear Reactor Regulation (NRR), Division of Reactor Oversight (DRO), hosted the 9th NRC Workshop on Vendor Oversight in Baltimore, Maryland. This workshop followed the NUPIC vendor meeting to enable maximum participation by suppliers to the nuclear industry. The NRC Vendor Workshop included a keynote address by the Deputy Director, Division of Operating Reactor Licensing, Aida Rivera-Varona, as well as presentations by members of the NRC staff, NUPIC, the Electric Power Research Institute (EPRI), the American Society of Mechanical Engineers (ASME), the National Board of Boiler & Pressure Vessel Inspectors, authorized inspection agency (AIA), reactor licensees and nuclear vendors.

The Workshop on Vendor Oversight included a plenary session on such issues as the control of items under Appendix B to 10 CFR Part 50; NRC safety culture; and safety conscious work environment (SCWE) guidelines for vendors. The workshop also included afternoon panel discussions about navigating 10 CFR Part 21 and presentations of the different roles of ASME, NB, AIA, and NRC play in the oversight of ASME components.

The audience included approximately 350 attendees representing companies and organizations from 9 countries including vendors, industry groups, government regulatory agencies, and both foreign and domestic utilities. The Quality Assurance and Vendor Inspection Branch is very grateful for the support we received from NUPIC, industry partners, and other members of the NRC staff that presented!

The next Workshop on Vendor Oversight is planned for June 2026. Additional information about the 10th NRC Workshop on Vendor Oversight will be posted to the website link below, as it becomes available. Any questions or recommendations can be directed to nrc_vendor_workshop.resource@nrc.gov.

https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/vendor-oversight.html

- Michael Fitzgerald, Reactor Operations Engineer

Regulatory Issue Summary (RIS) 2024-02

On June 6, 2024, the NRC published RIS 24-02, “Required Assessment of U.S. Department of Energy Laboratories by Licensees, Applicants, and Suppliers to Verify the Effective Implementation of their Quality Assurance Programs.” The NRC issued this RIS to clarify agency’s regulatory position about the required assessment of U.S. Department of Energy (DOE) national laboratories by licensees, applicants, and vendors to verify the effective implementation of the laboratories’ QA programs.

In Section 3.2.7, “Control of Purchased Material, Equipment, and Services,” of the NRC’s safety evaluation report (SER), “Final Safety Evaluation for Technical Report NEI 11-04, ‘Quality Assurance Program Description,’ Revision 0,” dated May 9, 2013 (Agencywide Documents Access Management System (ADAMS) Accession No. ML13023A051), the NRC staff documented its regulatory position that an applicant is not required to evaluate or audit 10 CFR Part 50 and 10 CFR Part 52 licensees, Authorized Nuclear Inspection agencies, the National Institute of Standards and Technology, and other State and Federal agencies that may provide items or services to NRC licensees, as these are organizations are known to the NRC to have acceptable QA programs.

The NRC received several inquiries from nuclear industry stakeholders on whether an evaluation or audit is required for DOE national laboratories that provide basic components to the U.S. nuclear power industry. The DOE national laboratories are contractor-operated facilities owned or leased by the U.S. Federal Government and managed by third-party contractors. As such, the national laboratories are not considered Federal agencies, and the NRC staff’s regulatory position outlined in the May 2013 SER, as discussed above, does not apply to the DOE national laboratories.

When licensees, applicants, and vendors procure from a DOE national laboratory items or services that will be used in a safety-related application, they are responsible for verifying the effective implementation of the laboratory’s programmatic quality controls and other technical and regulatory requirements imposed through contractual documents, consistent with Appendix B to 10 CFR Part 50, Subpart H to 10 CFR Part 71, or Subpart G to 10 CFR Part 72, as applicable

- **Yamir Diaz-Castillo, Reactor Operations Engineer**

For more information about the NRC’s Vendor Inspection Program, please visit the NRC’s public Web site at: https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance.html. In here you will find a variety of resources, including our publicly available inspection reports, past NRC presentations made at industry meetings, past editions of this newsletter, etc.

ASME Code Edition—10 CFR 50.55a Rulemakings

The NRC routinely amends 10 CFR 50.55a to incorporate the latest acceptable editions of ASME code and the applicable RGs including the acceptable code cases. Below is a summary of the latest changes to 10 CFR 50.55a

Regulatory Guides - On July 17, 2024, the NRC published a final rule in the Federal Register (89 FR 58039) that incorporates by reference the following Regulatory Guides (RGs):

- RG 1.84, "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III," Revision 40,
- RG 1.147, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," Revision 21
- RG 1.192, "Operation and Maintenance Code Case Acceptability, ASME OM Code," Revision 5

Rulemaking - On August 30, 2024, the NRC published a final rule in the Federal Register (89 FR 70449) that incorporates by reference in 10 CFR 50.55a the 2021 Edition of the ASME BPV Code and the 2022 Edition of the ASME OM Code. On September 24, 2024, the NRC published a correction to the final rule above in the Federal Register (89 FR 77769). This publication corrected inadvertent errors in the final rule and did not result in any substantive changes to the final rule.

The next rulemaking to incorporate 2023 Edition of the ASME BPV Code and new code cases have commenced. During this rulemaking, the NRC is using a new approach intended to improve efficiency. The NRC plans to approve code cases that are non-controversial and not conditioned using the direct final rule process. The title of the direct final rule for non-controversial code cases that will not be conditioned is "Approval of American Society of Mechanical Engineers Unconditioned Code Cases." The approval of the code cases will be documented in a new RG (RG number pending). Find additional information about this Direct Rule in this website: Rule | NRC.gov.

- Yiu Law, Reactor Operations Engineer

Status of the Office of the Inspector General's Recommendations on Counterfeit, Fraudulent, and Suspect Items

The NRC staff's proposed and completed actions are documented in the following status memos to the OIG: April 11, 2022 (ADAMS Accession No. ML22077A775), September 20, 2022 (ADAMS Accession No. ML22237A227), May 26, 2023 (ADAMS Accession No. ML23122A164), December 15, 2023 (ADAMS Accession No. ML23313A144) and May 24, 2024 (ADAMS Accession No. ML24116A287). The OIG reviewed the NRC staff's proposed and completed actions and issued its analysis for each recommendation in the following status memos to the NRC staff: April 26, 2022 (ADAMS Accession No. ML22116A020), October 6, 2022 (ADAMS Accession No. ML22280A058), June 8, 2023 (ADAMS Accession No. ML23163A237), January 17, 2024 (ADAMS Accession No. ML24017A208) and July 8, 2024 (ADAMS Accession No. ML24191A371). In the July 2024 memo to the NRC staff, the OIG concluded that all recommendations related to audit report OIG-22-A-06 are now closed.

- Frankie Vega, Reactor Operations Engineer

Status of the Commercial-Grade Dedication Inspections at Licensees

The NRC vendor inspection staff continues to support the implementation of Inspection Procedure (IP) No. 71111.21N.03, “Commercial Grade Dedication.” The NRC vendor inspection staff supported the technical process and inspection implementation training for regional inspectors, including table-top scenario discussions and provides technical support as needed to the NRC inspectors implementing the inspections. NRC vendor inspection staff also support cross-regional review panels for the commercial grade dedication inspections convened before the inspection reports are issued. The NRC has completed 30 inspections as of December 2024. Though most findings identified from the first 30 inspections have been minor, there have been seven Green Non-Cited Violations (NCVs) identified.

Common issues the NRC continues to identify are:

- The lack of implementation for the control of parts and material that are signed out of the warehouse, transferred to the shop to the jobsite, and then returned to the warehouse if not used.
- The shelf-life of parts in the warehouse and the lack of controls to properly identify and update the item as needed.
- The NRC inspectors have noted a misunderstanding by some sites regarding compliance with 10 CFR Part 21 Sites reporting an event under 10 CFR Part 50.72, “Immediate notification requirements for operating nuclear power reactors,” 10 CFR Part 50.73, “Licensee event report system,” 10 CFR 73.1200, “Notification of physical security events,” and 10 CFR 73.1205, “Written follow-up reports of physical security events” can do so, however, the information provided in the 50.72, 50.73, 73.1200, and 73.1205 report must include the required information in 10 CFR Part 21 to meet the reporting requirements.
- Licensees must still evaluate for defects in accordance with 10 CFR Part 21 along with evaluating for the other reporting requirements.
- When using commercial-grade surveys as part of the commercial-grade dedication process, a commercial-grade survey report is the dedication documentation and QA record and must be retained as a permanent record for the dedicated component.
- Properly translating all design requirements into critical characteristics.

These inspections will continue through 2026, with each operating reactor site having an inspection.

- Aaron Armstrong, Sr. Reactor Operations Engineer

International Activities

As in years past, the NRC vendor inspection staff participated in a variety of international activities. Below is a summary of some of these activities and its results:

International Atomic Energy Agency (IAEA) Technical Meeting on Nuclear Security Implications of CFSI

On September 4 - 6, 2024, the NRC vendor inspection staff participated virtually in the IAEA's technical meeting on the nuclear security implications of CFSI in the nuclear supply chain. During this meeting, nuclear security experts from regulatory agencies, law enforcement, academia, and the nuclear industry, shared lessons learned and best practices to address nuclear security implications of CFSI to the supply chain. The NRC vendor inspection staff participated on a panel discussion and provided the NRC perspectives on CFSI.

ASME NQA-1 International Working Group (IWG) - Europe, Middle East, Africa (EMEA)

On February 15, 2024, and July 9, 2024, the NRC vendor inspection staff participated in the virtual meetings of the ASME NQA-1 EMEA. During the February 15, 2024 meeting, the NRC vendor inspection staff provided a presentation on Revision 6 of RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," and its endorsement of the NQA-1 2017, 2019, and 2022 standard editions. In addition, the NRC vendor inspection staff presented an overview of the NRC's regulatory framework and quality assurance regulations. During the July 9, 2024 meeting, the NRC vendor inspection staff provided a presentation on 10 CFR Part 21 and its application to licensees, applicants, and vendors. The NRC vendor inspection staff also discussed how 10 CFR Part 21 applies to non-US entities.

Committee on Nuclear Regulatory Activities (CNRA) Working Group on Supply Chain (WGSUP) Workshop

On March 5-6, 2024, the NRC vendor inspection staff participated in the second WGSUP Workshop on Nuclear Supply Chain: Assurance Today, Confidence Tomorrow, which was held at the NEA headquarters in Boulogne-Billencourt, France. The two-day workshop addressed the latest challenges related to supply chain oversight practices and potential risks that the nuclear industry needs to consider for safe and reliable nuclear operations. Recommendations developed from the workshop should be considered by regulators and industry stakeholders including licensees, nuclear suppliers and industry associations. WGSUP, as the collective regulatory representative, will prioritize certain recommendations on which it can exert influence and lead industry-wide initiatives. These recommendations aim to improve the safety, quality and efficiency of the nuclear supply chain through collaborative efforts and strategic implementation. Finally, on March 7 - 8, 2024, the NRC vendor inspection staff participated in the biannual meeting of the CNRA WGSUP. Representatives from Poland, Canada, Czech Republic, Finland, France, Hungary, United Kingdom, United Arab Emirates, Türkiye, Spain, Slovakia, Germany, Republic of Korea, IAEA, and the World Nuclear Association were in attendance.

Small Modular Reactors (SMR) Regulators Forum and Nuclear Harmonization Meeting

On April 15 - 19, 2024, the NRC vendor inspection staff participated in the meeting of the SMR regulators Forum and Nuclear Harmonization Standards Initiative Working Group (WG) 3. During this week, members of

the WG provided several presentations and held discussions on several activities being conducted by the WG. Presentations consistent of the following: (1) an update on the IAEA Activities on SMRs and an update on the European Union SMR Partnership; and (2) regulatory experience/lessons learned with SMRs in China and Japan. Each member of the WG provided a status on the SMR activities in their respective countries. Lastly, the WG discussed five proposals for future work and recognized that most of them are related to developing tools for regulators to implement different aspects of collaboration. This includes tools to address areas of regulatory difference, to support leveraging another regulator's review, to harmonize format and content of the regulatory application.

Doosan Enerbility, Ltd.'s Vendor Inspection

On May 20-24, 2024, the NRC vendor inspection staff conducted an inspection at the Doosan Enerbility, Ltd.'s (hereafter referred to as Doosan) facilities in Changwon, South Korea. The purpose of this limited scope routine inspection was to verify that Doosan's safety-related activities associated with the design, manufacturing, and testing of safety-related ASME Boiler and Pressure Vessel (B&PV) Code and non-Code items being supplied to U.S. nuclear power reactors are being effectively implemented and meet the applicable requirements of Appendix B to 10 CFR Part 50, 10 CFR Part 21, 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive waste, and Reactor-Related Greater Than Class C Waste," and the ASME B&PV Code. Doosan was selected by Westinghouse Electric Company to manufacture the lower assembly forgings of the replacement steam generators for the Surry Power Station. Doosan was also selected by NAC International to manufacture "important to safety" components related to two transportable storage canisters, and vertical concrete cask liners associated with the NAC International's MAGANASTOR spent fuel storage system for use at Three Mile Island.

As a result of this inspection, the NRC inspection team identified a potential violation against the requirements of 10 CFR 21.31, "Procurement documents," for Doosan's failure to invoke the requirements of 10 CFR Part 21 in the procurement documents for safety-related components and services.

- Yamir Diaz-Castillo, Reactor Operations Engineer

Pathways for Meeting Appendix B to 10 CFR 50

The NRC vendor inspection staff had received comments and feedback about the difficulty to implement a nuclear quality assurance program for small modular reactors and advance nuclear reactors and its effect on their supply chain. On December 5-6, 2024, the vendor inspection staff participated in the Nuclear Quality Assurance Challenges Workshop organized by the National Reactor Innovation Center (NRIC), Nuclear Energy Institute (NEI) and EPRI. Kerri Kavanagh, Branch Chief, Quality Assurance and Vendor Inspection Branch, NRC, presented the “Role of Appendix B to 10 CFR Part 50 in the NRC licensing process and pathways for meeting Appendix B” (ADAMS Accession No. ML24352A195).

The focus of the presentation was to reinforce that quality assurance is a process and it starts at initial design. The designers of the nuclear reactor plant determine the classification of the structures, systems and components (SSC) important to safety. Once SSCs are identified and classified, appropriate quality measures are applied in a graded approach consistent with their important to safety.

The NRC has several guidance documents available to designers, applicants and licensees for the classifications of SSCs important to safety of light water reactors and non-light water reactors (e.g., RG 1.26, 10 CFR 50.69, RG 1.201, RG 1.233). In addition, the NRC has the following guidance documents to meet 10 CFR Part 50, Appendix B:

1. NUREG 0800 “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” Chapter 17.5 “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants,”
2. RG 1.28 “Quality Assurance Program Criteria (Design and Construction),”
3. RG 1.33 “Quality Assurance Program Requirements (Operation).”

In conclusion, the quality assurance program can be implemented in a graded approach consistent with the SSCs important to safety. The designers, vendors, applicants or licensee determine their graded approach and how the QA measures are implemented accordingly to the SSCs impact to safety.

- Aixa Belen, Sr. Reactor Operations Engineer

Retirement of Senior Quality Assurance and Vendor Inspector Greg Galletti

Mr. Greg Galletti, Senior Reactor Operations Engineer, in the Quality Assurance & Vendor Inspection Branch, retired in January 2024, after 33 years of service with the NRC. Mr. Galletti joined the NRC in 1989 and has held various positions. Mr. Galletti started his NRC career as a human factors engineer and led the NRC's response to the Three Mile Island Action Item regarding upgrading of Emergency Operating Procedures (EOPs). Mr. Galletti's efforts were instrumental in developing closure to the TMI action items related to the EOPs and control room design reviews. As a Senior Reactor Operations Engineer in the Office of New Reactors, Mr. Galletti was assigned to lead the development of a new Vendor Inspection Program (VIP) which laid the framework for the VIPP of today. Mr. Galletti was the lead technical reviewer and inspector on high-profile, multi-year inspections of the first of the kind all-digital plant protection system, supporting design certifications.

On January 23, 2024, Mr. Galletti was awarded the NUPIC Certificate of Appreciation for Outstanding Service as the NRC's liaison to NUPIC during the January 2024 NUPIC General Membership Meeting in Clearwater, FL. Mr. Galletti served in this role for over twelve year and provided exceptional regulatory support, specially during the COVID-19 pandemic as the industry was challenged with maintaining the qualifications of suppliers of basic components. Congratulations, Greg. We miss you!!

Mr. Greg Galletti with the
NUPIC Certificate of Appreciation for Outstanding Service

Would you like to be added to the newsletter distribution or suggest topics for next year's newsletter?

We welcome useful and informative feedback on the content of this newsletter. Please contact Aixa Belen, Sr. Reactor Operations Engineer, by email at aixa.belenojeda@nrc.gov.