
NRC Update

NUPIC General Membership Meeting

January 22-23, 2024

Clearwater, FL



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Office of Nuclear Reactor Regulation



Recent & Upcoming NRC Inspections

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Recent:

- ❑ Namco
- ❑ ILAC Observation (Brazil)
- ❑ Thermo Fisher
- ❑ Henry Pratt Company
- ❑ Rosemount (NUPIC Observation)
- ❑ Hanna Cylinders

Upcoming:

- ❑ KHNP - Safeguards Information
- ❑ Consolidated Power Supply
- ❑ Westinghouse Columbia Fuel Cycle Facility
- ❑ NuScale Standard Design Approval Application QA Implementation

FY24 has QA Implementation and Protection of SGI Inspections planned, in addition to routine Vendor QA Inspections.



NRC Vendor Inspections & Findings

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- Part 21 Violations:
 - Section 21.21(a)(1) - Thermo Fisher
 - Failed to evaluate a deviation to identify defects associated with substantial safety hazards as soon as practicable.
- Appendix B Nonconformances:
 - Criterion IV, “Procurement Document Control,” and Criterion VII, “Control of Purchased Material, Equipment, and Services” - Henry Pratt Company
 - Did not invoke the applicable regulatory, technical, and quality requirements in the procurement documents for safety-related components and services.
 - Did not perform an assessment of suppliers to verify the adequacy of their quality controls.
 - Criterion XVI, “Corrective Action” - Namco
 - Failed to promptly identify and correct conditions adverse to quality.
- Unresolved Item (URI):
 - 10 CFR 21.51(a)(1) - Henry Pratt Company



VIP Plan - 2023 Annual Self-Assessment

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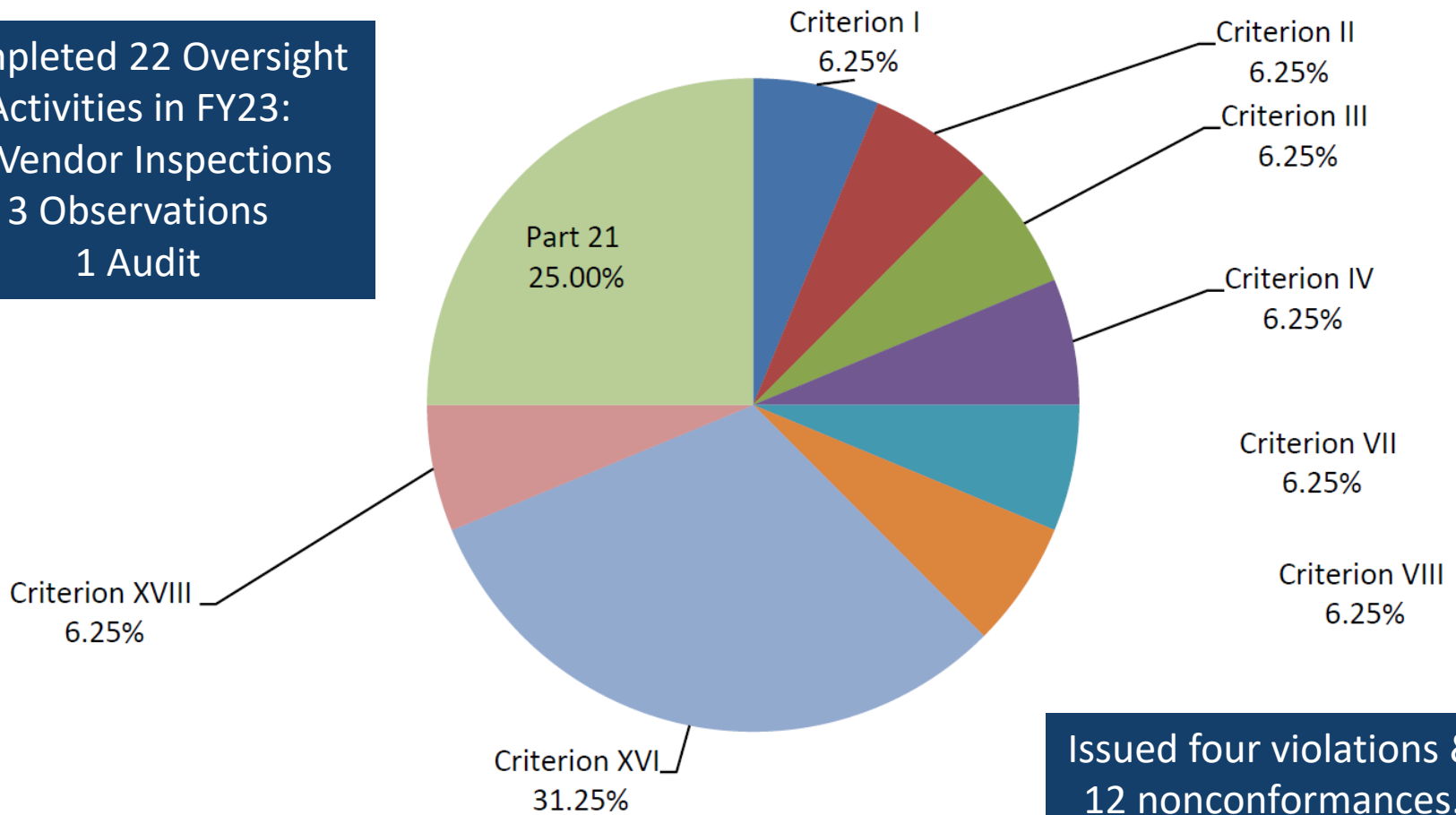
- IQVB's Vendor Inspection Program (VIP) plan establishes an overall approach, including goals, priorities, performance metrics, and resources management strategies.
- Annual Self-Assessment
 - 2023 Self-Assessment was published in November 2023 (ML23290A222)
- VIP Plan and Annual Self-Assessments are available on the NRC's website.
 - <https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/vendor-insp/vendor-insp-prog-plan.html>



VIP Plan - 2023 Annual Self-Assessment

FY2023 Violations & Nonconformances

Completed 22 Oversight Activities in FY23:
18 Vendor Inspections
3 Observations
1 Audit



Issued four violations & 12 nonconformances.



Mistras Services

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- NRC inspection performed on March 6-10, 2023.
- Evaluated nondestructive examination services provided for safety-related equipment.
 - ▣ Inspection Report (ML23151A458)
 - ▣ Resulting enforcement actions included:
 - Two Violations (SL IV) for Part 21 Notifications
 - One Nonconformance against Criteria I
- Department of Justice (DOJ) Prosecution of Mistras Personnel
 - ▣ On October 18, 2023, DOJ issued a press release announcing that two men pled guilty for their roles in creating false calibration certificates in a matter within the jurisdiction of the NRC.
 - Both helped create and transmit final testing reports to the owners of the plants which, among other things, contained calibration certificates for the equipment used.
 - Both created numerous false calibration certificates for AE testing equipment, and 15 of these false certificates were sent a total of 29 times to nuclear plant owners as part of final testing reports required by the NRC. The falsified calibration certificates were discovered in 2021 during an NUPIC audit.
 - Both are scheduled to be sentenced on Jan. 25, 2024. Each faces a maximum penalty of five years in prison.



Mistras Services

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- Office of Investigation Report 1-2022-003 (ML23340A106)
 - Resulting enforcement action - 1 apparent violation to:
 - 10 CFR 50.5(a)(2), “Deliberate misconduct”
 - Criterion XVII, “Quality Assurance Records”
 - Criterion XII, “Control of Measuring and Test Equipment”
- Mistras has requested Alternative Dispute Resolution



ANSYS Vendor Inspection

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- Vendor Inspection performed June 26-30, 2023.
 - Evaluated software development and support services provided for safety-related services.
 - Inspection Report documents (ML23237B258):
 - Inadequate Part 21 procedures and actions related to notification to the Commission and Purchasers.
 - Company failed to establish a quality assurance program that met the applicable provisions of Appendix B to 10 CFR Part 50. Specifically, procedures failed to document the policies, procedures, and instructions of a quality assurance program which complies with Appendix B.
 - Resulting enforcement actions included:
 - Two Violations (SL IV) for Part 21 Notifications
 - Two Nonconformances against Criteria II & XVI
 - NRC received a response from ANSYS on October 10, 2023 (ML23285A168), in which ANSYS stated that they are a “provider of commercial grade software products” and does not accept any responsibility for Part 21 reporting.
- NUPIC led a team of nuclear industry organizations in a meeting with ANSYS on November 17, 2023.
 - NRC is awaiting a revised response from ANSYS.



NRC Observation During the Rosemount Audit

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- Two NRC inspectors observed NUPIC's audit of Rosemount from December 4-8, 2023.
 - Members of the audit team did not appear to be knowledgeable in the areas being audited.
 - Some members of the audit team appeared to lack a questioning attitude.
 - NUPIC auditors did not identify the issue with independence of internal audits until suggested by the NRC staff.
 - Auditors covering areas of their own work during internal audits.
 - Auditors auditing areas where they have direct responsibility.



Regulatory Guide (RG) 1.28

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- RG 1.28 Revision 6 was published on September 7, 2023 (ML23177A002)
 - Endorses Part I & II requirements in NQA-1-2017, NQA-1-2019, and NQA-1-2022 subject regulatory positions.
 - Majority of regulatory positions from Revision 5 still applicable in Revision 6.
 - New regulatory positions:
 - Direct users to use Revision 1 of NEI 14-05A
 - Subpart 2.2 - "Etching should not be used on nickel alloys, weld areas, or sensitized areas of stainless steel."
 - Subpart 5.5 - "When the referenced or invoked code or standard becomes superseded or canceled, licensees or applicants need to submit their proposed alternative for NRC review and approval, as appropriate, for continued use of the code or standard or a proposed alternative."



Draft RIS - Required Assessment of DOE Labs

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- Developed a Regulatory Issue Summary (RIS) to clarify the agency's regulatory position on the required assessment of U.S. Department of Energy Laboratories by licensees, applicants, and suppliers.
- 60 days public comment period closed on December 5, 2023.
 - ▣ No comments received.
- Currently working to issue the RIS by Spring 2024.



9th Vendor Workshop on Vendor Oversight

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- The workshops provide an open forum for exchanging information regarding oversight of the supply of components, and materials to both new and operating nuclear power plants.
- Scheduled for Thursday June 13, 2024, in Baltimore, MD.
- Currently coordinating presentation topics and presenters with NUPIC/industry. If you have any feedback or suggestions, please contact Michael Fitzgerald.

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