
NRC Update

PeARTS - Procurement engineering And Related Topics Symposium

January 23-25, 2024

Clearwater, FL



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Topics

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- Updated on Mistras Services Inspection and Investigation
- NRC Vendor Inspection Results Update
- Updates on Draft Regulatory Information Summary, Draft Regulatory Guide (RG) 1415 and Draft RG 1416
- NRC position on ASME Code Case N-883

- Questions



Mistras Services Findings Update

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- Vendor Inspection performed 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
- 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”



NRC Vendor Inspection Results Update

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Since the August 2023 meeting, the NRC has completed and issued reports for 7 vendor inspections:

- ▣ Fluor, Greenville, SC
- ▣ ANSYS, Canonsburg, PA
- ▣ Velan Inc., Montreal, Canada
- ▣ Westinghouse Electric Company (WEC), Cranberry Township
- ▣ Namco Controls, Elizabethtown, NC
- ▣ Thermo Fisher Scientific, Oakwood Village, OH
- ▣ Henry Pratt Company, Kimball, TN



NRC Vendor Inspection Results Update

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Vendor Inspections completed, but inspection reports not issued:

- ▣ Hanna Cylinders, Pleasant Prairie, WI



NRC Vendor Inspection Results Update

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There were 7 findings of significance identified during the above inspections:

- Criterion II, “Quality Assurance Program”
- 10 CFR 21.21(a)(1), “Notification of failure to comply or existence of a defect and its evaluation”
- 10 CFR 21.21(b), “Notification of failure to comply or existence of a defect and its evaluation”
- Criterion VII, “Control of Purchased Material, Equipment, and Services”
- Criterion V,
- Criterion XV
- Criterion XVI, “Corrective Action”
- Criterion IV and Criterion VII
- Part 21 URI



NRC Vendor Inspection Results Update

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Ansys Corporation Inspection Report 99902113/2023-201:

- Criterion II, “Quality Assurance Program”
 - Ansys’ Quality Manual and its referenced documents do not include provisions for ensuring that measures are established to assure that applicable regulatory requirements and the design basis for those Ansys products that Appendix B to 10 CFR Part 50 applies to are correctly translated into specifications. The Ansys’ Quality Manual and referenced procedures do not provide consistent definitions of what constitutes design specifications or requirements. Ansys’ Quality Manual and referenced procedures do not have provisions to establish controls for traceability from specifications and requirements to software design and code. Details for this example are provided in Section 3 of this inspection report.
 - Ansys’ Quality Manual does not include provisions for establishing measures for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components and establishment of provisions to assure that purchased material, equipment, and services conform to the procurement documents, when applied to the use of third-party software. Third party software includes open source and freeware software integrated into Ansys products. Details of this example are provided in Sections 3 and 4 of this inspection report.
 - Ansys’ Quality Manual does not include provisions for ensuring activities affecting quality are prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and are accomplished in accordance with these instructions, procedures, or drawings. Ansys’ Quality Manual references specific policies, procedures, and work instructions, but does not specify the adherence to these documents for accomplishing specific requirements within the Quality Manual. In addition, instructions, procedures, or drawings do not specify appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Examples are provided in the Section 3 of this inspection report.
 - Ansys’ Quality Manual and its referenced procedures do not include requirements for the prompt identification and resolution of conditions adverse to quality. Specifically, Ansys’ Quality Manual and procedure QP-14, “Corrective and Preventive Actions,” Revision 12, do not specify that conditions adverse to quality must be promptly identified and corrected.



NRC Vendor Inspection Results Update

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Ansys Corporation Inspection Report 99902113/2023-201:

- 10 CFR) Part 21.21(a)(1), “Notification of failure to comply or existence of a defect and its evaluation,”
 - Ansys failed to adopt appropriate procedures to evaluate deviations and failures to comply and identify defects as soon as practicable.
 - Ansys’ implementing procedure for 10 CFR Part 21 only requires reporting of Class 3 errors to purchasers of its products in lieu of reporting any departures from technical requirements included in a procurement document, per the definition of a deviation in 10 CFR 21.3. As a result, Ansys failed to perform an adequate evaluation of a deviation in its products to determine a defect exists, or notify Ansys’ customers of all deviations (e.g., non-class 3 errors) so that they may evaluate the deviations, pursuant to § 21.21(a).
 - Ansys failed to inform its customers or purchasers within five working days of determining that Ansys does not have the capability to perform an evaluation of a deviation to determine if a defect exists. Specifically, Class 3 error reports 2022-013, 2022-016, 2022-108, and 2023-059, were sent to Ansys’ customers 21 to 65 days from Ansys’ classification of these errors as Class 3..



NRC Vendor Inspection Results Update

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Ansys Corporation

Inspection Report 99902113/2023-201:

- Criterion XVI, “Corrective Action”
 - Ansys failed to correct conditions adverse to quality. Ansys closed Corrective Action Reports (CAR) 742, and implemented corrective actions in CAR 759, without adequately correcting the conditions adverse to quality identified in these CARs.



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 Vendor Inspection Results Update

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Namco Controls

Inspection Report 99901470/2023-201:

- Namco failed to promptly identify and correct conditions adverse to quality. Specifically, no corrective actions were implemented by Namco to address two of the four findings in the 2016 NRC inspection report No. 99901470/2016-202, dated August 29, 2016 (ADAMS Accession No. ML16238A509). As a result, the NRC inspection team identified the following examples of the reoccurrence of issues identified in the August 2016 inspection
- Namco failed to provide objective evidence that nonconforming items dispositioned as “re-work” were re-inspected to original specification requirements, as required by Namco Standard Procedure 60-0004 “Processing Nonconforming Material, Parts, Components and Services”. This issue was previously identified as part of NON 99901470/2016-202-02.
- Namco failed to ensure that for mandatory hold points specified in procedures, the work did not proceed beyond such hold points until the required inspections were complete. This issue was previously identified as part of NON 99901470/2016-202- 04.



NRC Vendor Inspection Results Update

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Henry Pratt Company LLC, Kimball, TN.
Inspection Report 99902116/2023-201:

- Criterion IV, “Procurement Document Control,” and Criterion VII, “Control of Purchased Material, Equipment, and Services”
 - HPCO failed to assess the effectiveness of the control of quality by contractors and subcontractors. HPCO did not invoke the applicable requirements in the procurement documents for paint used for protective coating on the safety-related valves, for the procurement of water testing services to ensure the water meets the chemistry requirements used in hydrostatic testing and cleaning of the safety-related valves.
 - HPCO did not perform an assessment of the paint supplier and the water testing suppliers to verify the adequate implementation of their quality controls associated with the manufacturing of the paint and the supply of water testing services.



NRC Vendor Inspection Results Update

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Henry Pratt Company LLC, Kimball, TN.
Inspection Report 99902116/2023-201:

- HPCO staff informed the NRC inspection team that relocation of its operations from Aurora, IL, to Kimball, TN, was completed in September 2022 and most of its quality assurance (QA) records are in a storage facility. It would require a considerable amount of time to determine if the Part 21 evaluations for the last five years were retained at the record storage facility. HPCO started its search for the objective evidence necessary to demonstrate that it had retained the 10 CFR Part 21 evaluations as required, however, at the conclusion of the inspection, HPCO had not completed its investigation.
- The NRC inspection team concluded that more information is required to determine if a violation of the requirements of 10 CFR 21.51(a)(1) has occurred. Therefore, the NRC inspection team identified this issue as Unresolved Item (URI) 99902116/2023-201-02, pending HPCO's investigation on whether it had appropriately retained Part 21 evaluations for the last five years.



Draft RIS 20XX-XX– Required Assessment of DOE Labs Public Comment Period

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- The NRC staff 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.
- Docket Number: NRC-2023-0058 (ML22080A051)
 - Document Citation: 88 FR 69555
 - Comments were due by December 5, 2023.
 - Currently working to issue document within the next few months.



Draft RG 1415 – DEDICATION OF COMMERCIAL-GRADE ITEMS FOR USE IN NUCLEAR POWER PLANTS

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- RG 1.28 Revision 6 was published on Sept. 7, 2023. (ML23177A002)
 - Endorses Part I & II requirements included in NQA-1-2017, NQA-1-2019, and NQA-1-2022 subject to exceptions:
 - Audit Participation Requirement
 - Laboratory Calibration and Testing Services – Controls & Conditions
 - Lifetime and Nonpermanent Records
 - Managing Quality Assurance Records in Electronic Media
 - Internal and External Audits
 - QA Requirements for Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Facilities
 - QA Requirements for Installation, Inspection, Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities



Draft RG 1416 – title goes here

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ASME Code Case N-883 Update

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- ❑ What is the purpose of a Code Case?
 - To clarify the intent of existing requirements.
 - To allow early implementation of an approved Code revision.
 - To provide, when there is an urgent need, rules for materials or construction not covered by existing Code rules.
- ❑ Status: The NRC is working with a task group from Section III, Subgroup General Requirements (SGGR), to address issues that a future licensee would need to use the code case.



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.
- Since the NRC performs a limited number of vendor inspections each year, the vendor workshop also allows the NRC to provide regulatory perspective to the industry on specific topics related to issues identified by the staff during routine vendor inspections.
- Scheduled for Thursday June 13, 2024 in Baltimore, MD.
- Currently coordinating presentation topics and presenters with NUPIC. If you have any feedback, please contact Michael Fitzgerald.
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