

Observations from NRC Vendor Inspections of Suppliers of Safety-Related Design and Analysis Software

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Purpose

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- Raise awareness of issues identified during recent NRC inspections of suppliers of safety-related design and analysis software.
- Present recommendations on application of NUPIC's audit checklist for audits of these suppliers.



Background

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- NRC conducted inspections of Ansys and Bentley Systems in June 2023 and August 2024, respectively.
- NRC's first time inspecting both suppliers.
- Ansys and Bentley Systems supply their products to the commercial industry as well as to the nuclear power industry.
- Based on the results of the inspection, NRC issued Ansys two violations against 10 CFR Part 21 and two nonconformances against Appendix B to 10 CFR Part 50.
- The NRC has similar preliminary findings for Bentley Systems; the NRC's inspection report will be issued at the end of this month.



NRC Inspection Observations

- ❑ One version of software exists for each software product; no differences between software product supplied as commercial or as safety-related (i.e., 10 CFR Part 21 and Appendix B to 10 CFR Part 50 apply).
- ❑ Add-on service agreements distinguish the software as commercial or “safety-related.”
- ❑ Bentley Systems has additional documentation for software that is supplied as “safety-related.”
- ❑ Design and development activities for the software do not align with the documented Quality Assurance (QA) Program Manual and implementing procedures.



10 CFR Part 21 Program Observations

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- ▣ Both suppliers did not understand 10 CFR Part 21 requirements and their 10 CFR Part 21 implementing procedure does not align with the 10 Part 21 regulation.
- ▣ The 10 CFR Part 21 program automatically defers the evaluation responsibilities to the customer - those with a service agreement receive notification of “significant” errors.
- ▣ The 10 CFR Part 21 program does not require customers to be notified of all errors:
 - Ansys only notifies its customers on errors that appear to provide a correct solution when it is not.
 - Bentley Systems only notifies its customers of errors that it considers as non-conservative.



Observations of Application of NUPIC Audit Checklist to Software Suppliers

- Design and analysis software suppliers have unique processes different from traditional manufacturing facilities.
- Application of the NUPIC audit checklist for these suppliers should be tailored to the design, development, and testing processes and software terminologies. Examples include application of:
 - Nonconformance program: Ansys and Bentley Systems view nonconformances as deviations from process, and not software errors, defects, or anomalies.
 - Corrective actions program: Ansys and Bentley Systems do not apply terminologies in their QA procedures (e.g., conditions adverse to quality or significant conditions adverse to quality) to the software development activities.
- **Audits should be performed on the development environment and activities; not just the documentation.**



Summary

- Recent NRC inspections of two design and analysis software suppliers found common issues with the implementation of the suppliers' 10 CFR Part 21 and Appendix B to 10 CFR Part 50 QA programs.
- NRC plans to conduct one or two more inspections of design and analysis software suppliers and depending on the inspection results, the NRC may issue generic communications.
- Software suppliers have unique implementations of 10 CFR Part 21 and Appendix B to 10 CFR Part 50 QA programs; therefore, it is recommended that NUPIC adapt its audit checklist and audit processes to accommodate the uniqueness of each software supplier in the NUPIC suppliers' list.



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