U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

October 2024

Deanna Zhang
Quality Assurance & Vendor Inspection Branch
Office of Nuclear Reactor Regulation

Purpose

- Raise awareness of issues identified during recent NRC inspections of suppliers of safety-related design and analysis software
- Present recommended improvements to guidance in NQA-1 to address new technologies and processes used to develop, deploy, and maintain safety-related software

Background

- 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 and commit to adherence to NQA-1.
- NRC issued Ansys two violations against 10 CFR Part 21 and two nonconformances against Appendix B to 10 CFR Part 50.
- NRC issued Bentley one violation against 10 CFR Part 21 and one nonconformance against Appendix to 10 CFR Part 50.

NRC Inspection Observations

- One version of software exists for each software product; no differences between version of software product supplied as commercial or as safety-related.
- 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 QA program manual and implementing procedures.
- Suppliers commit to NQA-1 in the QA Program Manual but do not understand the requirements in NQA-1.

10 CFR Part 21 Program Observations

- Both suppliers did not understand 10 CFR Part 21 requirements and their 10 Part 21 implementing procedure do not align with the 10 Part 21 regulation.
- The 10 Part 21 program automatically defers 10 Part 21 evaluation responsibilities to the customer – those with a service agreement receive notification of “significant” errors.
- The 10 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 only notifies its customers of errors that it considers as non-conservative.

Recommendation of Improvements to NQA-1

- Design and analysis software suppliers have adopted new technologies and processes for software development, deployment, and maintenance.
- NQA-1, Subpart 2.7 should be improved to address new technologies processes used to develop and operate software. Examples include:
  - Use of cloud-based development, deployment, and configuration management tools (e.g., Azure DevOps, Git, Terraform).
  - Evaluation and acceptance of third-party (e.g., software tools) or open-source software and maintenance of configuration controls for these tools.
  - Use of Agile development lifecycles and parallel software development techniques.

Summary

- Recent NRC inspections of two design and analysis software suppliers found common issues with the suppliers' 10 CFR Part 21 and Appendix B to 10 CFR Part 50 QA programs.
- NRC will conduct one or two more inspections of design and analysis software suppliers and depending on the inspection results, the NRC may issue generic communications.
- NQA-1, Subpart 2.7 should be improved upon to address new technologies and processes used for software development, deployment, and maintenance.

Aaron Armstrong
Senior Reactor Operations Engineer
(301) 415-8396
Aaron.Armstrong@nrc.gov

Deanna Zhang
Senior Reactor Operations Engineer
(301) 415-1946
Deanna.Zhang@nrc.gov

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment