

October 30, 2024

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, DC 20555-0001

Kerri Kavanagh  
Chief, Quality Assurance Vendor Inspection Branch  
Division of Nuclear Reactor Oversight  
Office of Nuclear Reactor Regulation

SUBJECT: Response to Vendor Inspection Report

REFERENCE: Vendor Inspection Report No. 99902127/2024-201, Notice of Violation, and Notice of Nonconformance

Dear Ms. Kavanagh,

Bentley Systems, Inc. ("Bentley") received notification from the Nuclear Regulatory Commission ("NRC") on September 30, 2024, of Vendor Inspection Report No. 99902127/2024-201, Notice of Violation ("NOV"), and Notice of Nonconformance ("NON"). The report identified one violation and one nonconformance. This letter constitutes Bentley's response to the NOV and NON.

Bentley's Quality Assurance Program ("QA Program") is defined in its Quality Assurance Policy Manual ("QAPM") and the Quality Assurance Procedures Manual ("QAP"). The QA Program was developed based on the requirements of 10CFR50 Appendix B, 10CFR Part 21, and ASME NQA-1 to support Bentley's engineering simulation software users operating in the nuclear industry. Bentley provides an optional Quality Assurance & Reporting ("QA&R") subscription for its AutoPIPE and STAAD.Pro software. This subscription is suited for users employing these software programs for nuclear safety-related applications, where compliance with stringent regulatory standards is necessary. Many users in nuclear and non-nuclear industries who are not subject to NRC regulations use AutoPIPE and STAAD.Pro without the QA&R subscription. Over the past 24 years, Bentley's QA Program has regularly been audited by subscribers of the QA&R Service, including NUPIC, NIAC, and various DOE facilities. These audits found the program satisfactory.

To document and control the violation and nonconformance identified by the NRC, Bentley has issued Corrective Action Reports ("CAR"). Bentley issued CAR 24-013, 24-014, 24-015, 24-016, and 24-017 during the inspection and CAR 24-018 the week following the inspection. Further details regarding these actions are provided below.

IE09  
Q004  
NRR

**Response to Notice of Violation (99902127/2024-201-01)**

Bentley accepts that its quality assurance procedures do not adequately explain the process for the evaluation of deviations and the identification of defects associated with substantial safety hazards per 10CFR Part 21. However, we would like to clarify that we review all software errors (deviations) and, during the discovery process, evaluate the potential impact of the errors on our users' models. Only errors of critical severity have the potential to lead to a substantial safety hazard should they be left uncorrected. These errors are reported to our users within five days of discovery. We provide as much information as possible to help our users determine if the error could lead to a substantial safety hazard, assisting them with their evaluation on request. Additionally, critical and high severity errors are communicated to our QA&R subscribers via monthly error reports and are published in the product ReadMe and Bentley Communities site for our users.

Bentley is in the process of updating the QAPM and QAP and will incorporate applicable requirements from 10CFR Part 21 to provide greater clarity of our processes. The following is a summary of the key updates Bentley is planning to make:

- Bentley will update QAP 9.5 to align with the terminology defined in 10CFR 21.3, including definitions for *deviation*, *defect*, *discovery*, and *evaluation*. We will also clarify the discovery, evaluation, and notification process for defects according to 10CFR 21.21.
- Bentley will update QAP 5.4 to align with the terminology defined in 10CFR 21.3, including definitions for *deviation*, *defect*, *discovery*, and *evaluation*. We will also further clarify the software error severity definitions and criteria for severity classification of errors as low, medium, high, and critical. This will clarify why only critical severity errors have the potential to create a substantial safety hazard should they be left uncorrected.
- Bentley has created CAR 24-018 to review potentially incorrect severity assignments for software errors, including errors 1427565 ("Self-weight distribution for quadrilateral plates") and 1221514 ("Wind load panel formation affected by support nodes"), found during the inspection.
- QAPM Section 16 and QAP 9.1 will be revised to document a new process for handling the evaluation of critical severity errors as nonconformances. In response to the NRC's inspection findings, Bentley now includes a summary of the evaluation performed during the discovery process in the critical error notification to help users assess the problem in their own models. We plan to develop a checklist to aid the documentation of the evaluation process and discovery.
- The following statement in QAPM Section 15, related to evaluation and notification, will be removed:

*Note: Since Bentley does not have direct control over the use of its applications software, Bentley is unable to determine whether there is an actual safety hazard due to a specific critical software error. It is the client's responsibility to notify all regulatory organizations of any safety hazard that is discovered.*

We will further clarify the policy for evaluation of deviations that we determine to be critical through our discovery.

**Response to Notice of Nonconformance (99902127/2024-201-02)**

The NRC noted five issues in the NON. Bentley accepts that its quality assurance procedures do not adequately explain the process in sufficient detail and there were a few issues identified with the implementation of the QA Program. The software development and testing activities have evolved over the past few years with the implementation of improved automation, workflow, and configuration control systems. While Bentley does have detailed instructions that govern the use of these systems, these instructions will now be incorporated into the appropriate quality assurance procedures. The quality assurance procedures related to software development, testing, and configuration control activities will be updated to provide more detailed instructions.

Bentley is in the process of updating the QAPM and QAP to incorporate all applicable requirements from 10CFR50 Appendix B and 10CFR Part 21. The following is a summary of the updates Bentley is planning to make:

- Bentley will provide more detailed instructions on software development, review, and configuration management activities. This will be incorporated into QAP 2.0, QAP 3.2, QAP 3.3, QAP 3.7, QAP 5.1, and QAP 5.2.
- Bentley will update QAP 5.4 to align with the terminology defined in 10CFR 21.3, including definitions for *deviation*, *defect*, *discovery*, and *evaluation*. We will also further clarify the software error severity definitions and criteria for severity classification of errors as low, medium, high, and critical. This will clarify why only critical severity errors have the potential to create a substantial safety hazard should they be left uncorrected.
- Bentley will update the software tool evaluation process and the acceptance criteria will be clarified in an update to QAP 6.4.
- QAPM Section 16 and QAP 9.1 will be revised to document a new process for handling the evaluation of critical severity errors as nonconformances. In response to the NRC's inspection findings, Bentley now includes a summary of the evaluation performed during the discovery process in the critical error notification to help users assess the problem in their own models. We plan to develop a checklist to aid the documentation of the evaluation process and discovery.
- To strengthen the internal audit program, a comprehensive internal audit checklist will be created that covers the quality assurance procedures and the applicable 10CFR50 Appendix B criteria. Moreover, Bentley will ensure that internal audits that cover all aspects of the QA Program are performed at least once a year. We plan to add an appendix to QAP to map procedures to the 18 criteria of 10CFR50 Appendix B. Bentley may, from time to time, involve a certified external auditor to audit the QA Program including the QAPM and QAP.

Bentley expects to complete the actions described above by June 2025. We look forward to further guidance from the NRC on the implementation of quality assurance programs as it applies to software suppliers. Bentley is committed to further advancing its QA Program in recognition of any communications the NRC issues regarding this matter.

Sincerely,



Joshua Taylor  
Vice President, Structural Engineering  
Bentley Systems, Inc.