



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 29, 2024

Guylene Collard, Director  
Quality Assurance  
Ansys Corporation  
2600 Ansys Drive  
Canonsburg, PA 15317

SUBJECT: ANSYS CORPORATION RESPONSES TO THE U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 99902113/2023-201, NOTICE OF VIOLATIONS AND NOTICE OF NONCONFORMANCES

Dear Ms. Collard:

Thank you for your October 10, 2023, letter (Agencywide Documents Access and Management System Accession (ADAMS) No.: ML23285A168) and February 22, 2024, confirmatory supplemental filing letter (ADAMS Accession No. ML24061A019) in response to the Notice of Violations (NOVs) and Notice of Nonconformances (NONs) that were discussed in the subject U.S. Nuclear Regulatory Commission (NRC) inspection report (IR). Based on your February 22, 2024, letter, the NRC understands that Ansys provides software as a “basic component” for use in safety-related applications when procured in combination with the optional Quality Assurance Services Agreement that Ansys offers. The NRC acknowledges that for Ansys’s customers who procured both Ansys’s software programs and the associated Quality Assurance Service Agreement, Ansys has supplied a “basic component” as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 21.3.

The NRC staff reviewed the corrective actions identified in your October 10, 2023, letter to address the NRC’s NOVs and NONs documented in IR 99902113/2023-201, and acknowledges the following Ansys positions and corrective actions:

10 CFR Part 21, “Reporting of Defects and Noncompliance”

- Ansys accepts the NRC’s observation that the reporting provisions in its 10 CFR Part 21 procedure, Quality Procedure (QP)-21, could be revised to provide greater clarity.
- Ansys is augmenting its existing procedure QP-20, “Error Notification System,” to more clearly convey Ansys’s rationale and procedure for categorizing potential errors that may not be easily identifiable, including all hidden issues, as Class 3 errors that are to be reported to customers so that the customer can make an informed judgement of their potential severity and probability.
- Ansys is revising its protocol to clarify its existing error report evaluation and

classification process and provide more context on Ansys' methodology and rationale for specifically reporting Class 3 errors.

- Ansys has implemented processes to ensure that potential deviations are analyzed and confirmed. Ansys will modify its processes to clarify that all such software deviations are reported within five days of verification.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilizing Facilities"

- Ansys's Quality Manual functions as a high-level summary that describes the nature, purpose, and relevant standards that Ansys's software products are designed to satisfy, including alignment with Appendix B to 10 CFR Part 50. The Quality Manual contains references to various QPs that provide greater detail on different topics. Adherence to these QPs is implicit in the Quality Manual's directives and widely understood by Company personnel, though Ansys intends to include more express language describing the Quality Manual relation to the QP in a future update.
- Ansys is in the process of updating and synchronizing the QP processes though using common definitions of terms and protocols and to enhance clarity and consistency across the procedure and its application.
- Ansys's Quality Manual contains high level references to the review and verification process for third-party software that is integrated into Ansys's products, but operative procedures regarding this process are specified in QP-10, "Acquisition and Integration of Third-Party Software Components." Ansys is revising the Quality Manual to more closely synchronize the manual with QP-10 and Ansys's overall compliance protocols, as well as to clarify that referenced QPs in each section need to be adhered to by Ansys staff.
- Ansys will clarify references in its QP-10, QP-44, GI-44-3 procedures to clarify these acceptance criteria for integrated third-party software. QP-10 will clarify Ansys's existing practice of testing Stories with integrated third-party software will verify the specified acceptance criteria.
- For Corrective Action Report 759, Ansys intends to incorporate a description of the containment actions intended to be taken to ensure that all third-party software included in the product's current release have been verified, as well as to address any general concerns with an evaluation of potential impact on related quality items as issues raised in CARs are investigated and solutions are implemented.
- Ansys intends to enumerate the common understanding and practice that all corrective action reports are promptly evaluated and addressed through a revision to QP-14, "Corrective and Preventive Action."

We have no further questions or comments at this time and may review the implementation of

your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained. Please contact Ms. Deanna Zhang at 301-415-1946 or via electronic mail at [Deanna.Zhang@nrc.gov](mailto:Deanna.Zhang@nrc.gov), if you have any questions or need assistance regarding this matter.

Sincerely,



Signed by Kavanagh, Kerri  
on 03/29/24

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

Docket No.: 99902113

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