



ANSYS, Inc.  
Southpointe  
2600 ANSYS Drive  
Canonsburg, PA 15317

T: 724.746.3304  
F: 724.514.9494

[www.ansys.com](http://www.ansys.com)

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

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

Subject: Docket No. 99902113, Report No. 2023-201; ANSYS, Inc. Reply to Nuclear Regulatory Commission September 7, 2023, Notice of Violations and Notice of Nonconformances

Dear Branch Chief Kavanagh,

Ansys, Inc. (“Ansys” or “the Company”) has received and reviewed the Nuclear Regulatory Commission’s (“NRC” or “the Commission”) September 7, 2023, correspondence enclosing the Commission’s Notice of Violation, Notice of Nonconformance, and Inspection Report No. 99902113/2023-201 (“the Notice”). Ansys appreciates the NRC’s constructive engagement on the issues raised in the Notice, particularly in light of the NRC’s important role ensuring the safety and security of the U.S. nuclear industry.

As discussed in more detail below, Ansys provides engineering simulation software to customers operating in the nuclear industry as well as many other advanced industries. Ansys’s engineering simulation software is an analysis solution; it is not used to monitor, control, or operate nuclear facilities. Ansys’s software enables Ansys customers to simulate and analyze engineering phenomena, including those associated with the design, analysis, and construction of physical systems found in nuclear facilities. Ansys’s software products are produced and sold as commercial grade software products. For customers that have been licensed by the NRC and that procured a specific, limited subset of Ansys software products, Ansys offers separate, optional Quality Assurance Services for purchase. Those optional Quality Assurance Services give customers audit access, error reports, verification testing packages, and technical support.<sup>1</sup>

<sup>1</sup> While Ansys provides engineering simulation software used in the nuclear industry, Ansys does not perform actual design or analyses of nuclear systems, structures, or components. Nor does Ansys produce systems, structures, and components used in nuclear power plants. Ansys software can be used to simulate a wide array of situations and phenomena, depending on the individualized and fact-specific data and taskings that Ansys customers input into their copy of the software. However, Ansys does not have access to—and is not provided—the design and materials information pertaining to systems, structures, and components necessary to



Ansys routinely reports and makes available to its customers the small number of software deviations in its software products that, if undetected or uncorrected, could potentially (depending on how a customer used that software) result in a defect as defined by the NRC. To date, this process has been effective, as Ansys not been informed of nor independently learned of the existence of an unreported or uncorrected deviation in an Ansys software product that resulted or could have resulted in a substantial safety hazard for a nuclear facility. Ansys appreciates the trust of its customers who use Ansys software to simulate conditions at their facilities to help advance their safety goals and obligations.

Ansys welcomes and values the NRC's engagement and technical insights and studied the NRC's findings closely. Ansys has already begun addressing these findings, including by opening corrective action reports for each item cited in the Notice and developing focused updates to Ansys' policies and procedures for identifying and correcting conditions potentially adverse to quality. These steps are described in more detail below. Ansys intends to use this constructive dialogue with the NRC to further develop and clarify the Company's adherence to strict quality standards and best practices and looks forward to continuing to be a proud provider of engineering simulation software to the nuclear industry.

## I. Background

Founded in 1970 and headquartered in Canonsburg, Pennsylvania, Ansys develops and globally markets engineering simulation software and services widely used by engineers, designers, researchers and students across a broad spectrum of industries and academia, including high-tech, aerospace and defense, automotive, nuclear and non-nuclear energy, industrial equipment, materials and chemicals, consumer products, healthcare, and construction. Ansys develops open and flexible solutions to enable users across the design conception, final-stage testing, validation, and deployment phases to analyze designs on-premise and/or via the cloud with a common solutions platform for fast, efficient, reliable, and cost-effective product development. Ansys distributes its suite of simulation technologies through direct sales offices in select locations and a global network of independent resellers and distributors. Ansys software offers customers a tool to simulate the operation of complex systems under customer-specified hypothetical conditions, which may assist them in evaluating their design specifications and safety protocols.

The Company is following the NRC's guidance as it further enhances its existing policies and procedures as described below. The implementation process first entails drafting and adopting written modifications to existing Company documents. This process will also include educating affected Company personnel tasked with administering these changes on the impact of

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independently evaluate whether a potential "defect" exists (an evaluation hinging in key part on whether a deviation could create a substantial safety hazard or contribute to the exceeding of a safety limit). Rather, it is the Company's customers who evaluate systems, structures, and components for any potential safety-related defects that might result from the deviations Ansys reports. As noted in this reply, to date Ansys has not been informed by a customer of any defect resulting from any reported or discovered deviation in Ansys software, but should Ansys become aware of a defect in a system, structure, or component attributable to an Ansys software deviation that has not been reported to the Commission by its customer, Ansys will bring the matter to the NRC's attention. As noted later in Ansys's response, Ansys is revising its quality procedure to make its reporting practices (including timing) clearer.



these modifications through communications and training modules, evaluating and adopting any necessary modifications to the Company's tooling and infrastructure, and verification of effective adoption through audits or other intensive internal reviews. The Company intends to implement the modifications discussed below on a rolling basis and anticipates implementing the first of these modifications by end of the first quarter of 2024 and the remainder by the end of that calendar year.

## II. The Company's Policies, Procedures, and Practices Relating to 10 C.F.R. Part 21

While the Company is a provider of commercial grade software products that support a broad set of commercial applications, Ansys strives to maintain a quality system that meets business needs in the varied industries and use cases in which the Company's simulation software is deployed. In the case of sales to nuclear industry customers that purchase the Company's optional Quality Assurance Services, Ansys provides additional audit access, error reports, verification testing packages, and technical support services to those customers. Ansys contracts with customers who procure Quality Assurance Services to maintain a quality system that is consistent with the standards enumerated at Appendix B to 10 CFR Part 50 and that enables the Company's customers to address the Commission's regulations enumerated at 10 CFR Part 21.

Ansys continuously looks for ways to improve aspects and clarify the scope of the Company's standard operating procedures to achieve optimal results for the Company's customers. To that end, we are pleased to provide a summary of the steps we have initiated since receiving the NRC's Notice, as well as an explanation of the manner in which Ansys has applied the terms "Class 1," "Class 2," and "Class 3" in the context of simulation software deviations the Company has either detected itself or has had brought to its attention by its user community. Ansys believes these improvements and explanations address the findings in the NRC's outlined Notice, and Ansys looks forward to continuing dialog with the NRC to further enhance how software deviations in commercial grade software products like Ansys's can effectively be reported to provide meaningful information to nuclear industry customers.

Ansys's optional Quality Assurance Services can be purchased separately at a customer's discretion. The steps Ansys takes to deliver the Quality Assurance Services are described in Ansys's Quality Manual and implemented in Ansys Quality Procedures ("QP").<sup>2</sup> The services include, among other things, providing customers with quality assurance information and support aligned with Appendix B to 10 CFR Part 50. Included within those services is active, affirmative customer notification when errors within the covered Ansys software that are not obvious or easily identified are recorded and verified so that the customer can assess whether the reported deviation did or could have caused a defect that could lead to a substantial safety hazard.

The Company believes that certain of the findings in the Notice are the result of the Company not having clear explanations in its policies regarding its classifications of errors even

<sup>2</sup> NRC staff previously reviewed the Company's Quality Manual and QPs in connection with the routine inspection that is referenced in the Notice. Ansys's Quality Manual and QPs are business sensitive documents containing proprietary and confidential information. To the extent necessary to inform the Commission's review, the Company is able to separately provide additional copies of these documents upon request.



though its practices are in line with the Commission's guidance. The below discussion provides more detail concerning Company practices and plans for additional clarification of policies.<sup>3</sup>

Ansys evaluates all potential deviations it detects or receives. When Ansys personnel evaluate a potential error involving the Company's software, they are directed to categorize the error based, in part, on whether the issue manifests in a plainly observable or potentially latent manner. For example, QP-20 (Error Notification System) defines a Class 1 error as "[a]n error that causes the program to fail by terminating abnormally before the execution is complete," and a Class 2 error as "[o]bvious errors in output, such as unwarranted error messages, errors in graphic displays, or those that produce observable invalid results" that would not constitute Class 1 or Class 3 errors. "Class 3 Error" is defined as "a Program error which allows the Program execution to complete and yield results that may be wrong but are not easily identifiable as incorrect." Wherever an error may not be "easily identifiable," (i.e., potentially latent) Company personnel categorize the issue as a Class 3 error and initiate the proper reporting procedure. Given that Class 1 and 2 errors would result in the software not being able to be used for simulation purposes, these errors by definition could not "create a substantial safety hazard" as they would need to be corrected before the software could be used. Rather, Ansys's policies focus on identifying and reporting errors that are not, by their nature, already called out and plainly observable to users.<sup>4</sup> Once reported or detected potential Class 3 deviations are verified, they are reported affirmatively to customers who purchase the Quality Assurance Services and otherwise are available to all other customers through a dedicated Ansys customer web portal.

Ansys personnel review error reports and delineate between errors that could conceivably fall under Class 3 as compared to another category, and in practice are trained to re-classify Class 2 and Class 1 errors as Class 3 upon application of certain evaluation criteria. Ansys is augmenting its existing policies to clarify these procedures in greater detail and better reflect steps that personnel already take in practice to review and recategorize. Ansys is revising this QP 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

<sup>3</sup> Ansys accepts the NRC's observation that the reporting provisions in QP-21 ("10 CFR 21 Reporting Responsibilities") could be revised to provide greater clarity. In the passage cited in Enclosure 1 to the Notice, QP-21 averred that Ansys did not know precisely how customers might have used Ansys software, and so the ultimate responsibility for evaluating the severity of defects rested with a licensee customer. Ansys wishes to clarify that, where Ansys identifies any Class 3 error in a product covered by a QA services agreement, it promptly reports that Class 3 error to customers with an active QA services agreement in accordance with the Company's standing reporting procedures. See QP-21, § 2 ("Ansys Inc. informs all licensees with QA service agreements of Class 3 Errors (hidden issues) according to (QP-20) Error Notification System."). In a hypothetical instance where Ansys becomes aware a customer has not notified the NRC of a potential safety hazard, including those arising from any deviation found in Ansys software, Ansys would report that information promptly to the NRC. "However, if we have actual knowledge that notification has already been made to the USNRC [by an Ansys customer,] then ANSYS, Inc. notification to the USNRC is not required." See QP-21, § 6. Ansys is reviewing and revising this QP and cross-referenced QPs for clarity and consistency in light of the NRC's comments.

<sup>4</sup> Unlike hardware components that could present a latent defect that threatens the safety of a facility or machinery, or software that operates a nuclear power plant and whose malfunction could lead to misoperation, Class 1 errors in Ansys's simulation software are characterized by an inability to run the software that is plainly obvious to the user. If simulation software crashes, the simulation ends—a fact that is immediately obvious to the user. Class 2 errors would by definition similarly produce obvious errors in output that would alert the user to a potential issue involving the software.



reported (and are in practice reported) to customers so that the customer can make an informed judgment of their potential severity and reportability, informed by their more specific insights into their plant's design and operation.

The Notice also referenced QP-21's adoption of Class 3 errors as the threshold for customer reporting and indicated that the procedure should have included a requirement to report to customers "any [unspecified in the Notice] departures from technical requirements included in a procurement document," as well as "non-class 3 errors." Ansys is in the process of establishing a revised and more detailed protocol that clarifies the Company's existing error report evaluation and classification process, which will add context for the Company's methodology and rationale for specifically reporting Class 3 errors.

Ansys's delineation of three classes of software errors (i.e., "deviations") is an effort by the Company to determine and prioritize analysis and reporting of deviations relating to the software based on multiple factors, including whether the latency of the deviation might make it more difficult for a customer to detect. Importantly, issues initially identified as Class 1 or Class 2 may be reported to customers based on an individualized evaluation of the facts. Ansys takes steps to recategorize errors where warranted, including by upgrading issues to Class 3 and reporting them to customers accordingly.

This approach is an effective mechanism to more efficiently evaluate a wide range of potential issues inherent in the operation of software and to triage them for prompt review and resolution—especially considering that overreporting carries the additional risk of potentially obscuring errors that are more important to highlight. Reporting true Class 1 or Class 2 errors (i.e., those which are not properly reclassified as Class 3) would, in simple terms, report to customers deviations of which they are already plainly aware. In these cases, the customer is thus already enabled to perform the analysis imposed on the customer by NRC regulations as to whether those deviations led to or could lead to a defect in the system, structure, or component of concern.

Ansys recognizes that, for some nuclear industry customers (i.e., those who purchase the Quality Assurance Services), early reporting of deviations (i.e., within five days) can be important, given that the customers will need to determine whether a defect in a system, structure, or component could exist as a consequence of that deviation. In addition to those potential deviations Ansys discovers on its own, the Company receives customer and user reports of potential deviations. Not all of those potential deviations turn out to be actual deviations, however. For example, reported potential deviations could be the result of user error, input error, or have other benign explanations. With this context, Ansys has implemented processes to ensure that potential deviations are analyzed and confirmed to ensure that they are fully understood and that false positives are screened out. This is a multi-phase process that exists at Ansys to ensure that the information Ansys provides to customers is accurate, complete, and meaningful. Accordingly, Ansys will modify its processes to clarify that all such software deviations are reported within five days of verification.



### III. The Company's Policies, Procedures, and Practices Relating to Appendix B to 10 C.F.R. Part 50

Ansys has crafted and developed procedures for implementing its Quality Manual with careful attention to assisting its customers in the nuclear industry with meeting NRC regulations standards, including Appendix B to 10 CFR Part 50. The Company consistently looks for ways to strengthen these policies and procedures relating to product quality, a commitment the Company makes across all industries in which Ansys software is deployed, and welcomes opportunities to engage in constructive dialogue with affected stakeholders. The Company also trains Ansys personnel to adhere to best practices in the exercise of their duties under these procedures, some of which may not be expressly described in Company documents. To this end, the Company welcomes the opportunity to describe and clarify certain aspects of its policies, procedures, and practices in greater detail, as well as the iterative process by which the Company intends to augment its procedures to reflect existing practices.

As a threshold matter, the Ansys Quality Manual functions as a high-level summary that describes the nature, purpose, and relevant standards that the Company's software products are designed to satisfy, including alignment with Appendix B to 10 CFR Part 50. The Quality Manual also provides a structural overview of Company personnel with shared responsibilities for ensuring that the Company's products meet these standards as well as the protocols by which these standards are enforced. The Quality Manual also contains many references to various QPs that provide greater detail on different topics, but the Quality Manual itself is not intended to serve as a standalone, step-by-step or comprehensive protocol regarding the Company's quality system. Adherence to these QPs is implicit in the Quality Manual's directives and widely understood by Company personnel, though the Company intends to include more express language describing the Quality Manual's relationship to the QP in a coming update.

Ansys employs an Agile software development methodology that involves regular team interactions and prototyping to develop and refine requirements or specifications and acceptance criteria that will be verified through testing. These team interactions involve the product owner or designee, software developers, testers and product documentation writers. As the code is developed, suitable test cases are designed by testers in collaboration with the software developers to verify acceptance criteria. How the software operates from the perspective of the user is captured in product documentation through collaboration between software developers and documentation writers.

A "Charter Document" is created per major release or for a sequence of major releases. It sets out the highest-level deliverables required in the release. The highest-level requirements are referred to as Initiatives, Epics and Features and are broken down into User Stories. User Stories are the lowest level of requirements and constitute the design specification. More detailed design documents may optionally be attached to user story artifacts. The code is developed in response to a User Story.

Traceability between design specification and corresponding requirements is managed between User Stories and the Features through these hierarchical links, and between the code and the design by linking code changes to Stories as outlined in QP-44, § 7.3 (Ansys Software



Development Lifecycle Process Definition). In addition, all changes to the baseline product design must be expressly approved by Company personnel and documented. With this in mind, the Quality Manual and corresponding QPs are crafted to reflect Appendix B criteria.<sup>5</sup>

While Company personnel are well-equipped to administer these traceability procedures, Ansys is currently in the process of updating and synchronizing these QP processes through using common definitions of key terms and protocols to enhance clarity and consistency across the procedure and its application. In particular, these amendments will clarify the scope of what information constitutes design specifications and requirements, as well as how those terms specifically relate to the Company's existing traceability protocols. In addition, QP-1 will be updated to require acceptance criteria to be captured along with requirements in Features or Stories. The Company's use of an Agile software development methodology can at times lead to innovation and cultivation of best practices through regular team interactions as opposed to top-down implementation of one-size-fits-all written protocols. The Company nonetheless understands the importance of maintaining written procedures that reflect existing methods and best practices, and is therefore amending its QP accordingly.

The Quality Manual similarly contains high-level references to the review and verification process for third-party software that is integrated into the Company's products in certain cases, but operative procedures regarding this process are specified in QP-10 (Acquisition and Integration of Third-Party Software Components). As a matter of practice, the Company utilizes a common set of criteria when incorporating third-party software into Ansys products pursuant to QP-10 that may not be explicitly referenced in the underlying documentation. These criteria include, for example, the use of open source software that has certain approved license types, review of security vulnerabilities, and approval of vendors or platforms from which the software is acquired.

The Company is revising the Quality Manual to more closely synchronize it with QP-10 and the Company's overall compliance protocols, as well as to clarify that referenced QPs in each section need to be adhered to by Ansys staff. The Company will adopt similar clarifying references in its QP (QP-10, QP-44, GL-44-3) to clarify these acceptance criteria for integrated third party software. In addition, QP-10 will clarify the Company's existing practice that testing of Stories with integrated third party software will verify the specified acceptance criteria.

Ansys is dedicated to appropriately addressing matters relating to the quality of its software in all use cases, and is committed to administering a quality assurance program that reflects this objective. QP-14 (Corrective and Preventive Actions) outlines the steps required to correct deficiencies or nonconformities and address problems requiring preventive action. Company personnel are directed to promptly evaluate and address all corrective action reports, and in practice do so to the greatest extent practicable. The Company intends to enumerate this common understanding in QP-14. The Company also intends to include more express guidance on the scope of "conditions adverse to quality" in QP-14, as well as additional guidance on use of containment actions and evaluation of additional quality-related considerations. In particular,

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<sup>5</sup> While these standards are often more straightforward in application to hardware or physical products, the Company's Quality Manual and QP seek to apply the nature and intent of these provisions to the Company's engineering simulation software to the greatest extent practicable.



in light of events involving Corrective Action Report (“CAR”) 759, the Company intends to incorporate a description of the containment actions intended to be taken to ensure that all third party software included in that product’s current releases 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.

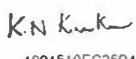
#### IV. Conclusion

Ansys recognizes the nature and importance of the NRC’s objectives relating to ensuring the safety of key nuclear facilities and assets. Ansys is dedicated to maintaining stringent quality and safety standards related to the use of the Company’s general purpose commercial simulation software by customers in all industries and contexts, including in the instances outlined in the NRC’s Notice and more broadly. Ansys will continue to review and adopt improvements to its policies and procedures to enhance their clarity and their utility in engagements with customers and stakeholders regulated by the NRC.

Thank you for your attention to this reply. Should you have any questions or wish to discuss the contents of this reply, please do not hesitate to contact the undersigned at [redacted] and [redacted]. For any such communication, please also copy the Company’s senior legal counsel Bradford E. Biegon at [redacted] as well as Ansys’s outside counsel Jones Day at gyeargin@jonesday.com and sschouten@jonesday.com.

DocuSigned by:  
  
B703B882AFBF425

Guylene Collard  
Director of Quality Assurance  
Quality System Management Representative  
Ansys France SAS

DocuSigned by:  
  
1991510EC25B4C2

Kiran Kumar K.N.  
Senior Director, Research and Development  
Ansys, Inc.

