Verifying and Validating Software in a Regulated Environment

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ABSTRACT

Founded in 1970, ANSYS, Inc. employs more than 3,000 professionals, and many of them are engineers' expert in fields such as finite element analysis, computational fluid dynamics, electronics, electromagnetics, and design optimization. They provide simulation software intended to bring clarity and insight to customers' most complex design challenges through fast, accurate and reliable simulation.

In order to meet some of our customers' requirements, the ANSYS, Inc. Quality System is set up to meet the requirements of International Standard ISO 9001:2008 as well as the applicable requirements of the U.S. Nuclear Regulatory Commission, Rules and Regulations, Title 10, Chapter 1, Code of Federal Regulations, Part 50, Appendix B. Supplemental requirements of NQA-1, Subpart 2.7, Quality Assurance Requirements for Computer Software are also encompassed.

The error reporting system which forms part of our quality assurance program is designed to address the requirements of Title 10, Chapter 1, Code of Federal Regulations, Part 21, titled "Reporting of Defects and Noncompliances" for commercial grade items.

ANSYS, Inc. assumes full responsibility for the quality and verification of any software components included in our products that are supplied by other organizations.

For customers who perform analyses for nuclear application, a quality assurance service was developed in to 1970's which affords customer the ability to purchase software which meets the requirements of the U.S. Nuclear Regulatory Commission, Rules and Regulations, Title 10, Chapter 1, Code of Federal Regulations, Part 50, Appendix B. We use the American Society of Mechanical Engineers (ASME) NQA-1 Standard to accomplish this.

NQA-1 is a consensus standard managed by the ASME for addressing the requirements of 10CFR50. NQA-1 reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity. The standard has been endorsed by the NRC.

Companies commit products for 10CFR50 compliance. In doing so, the processes that created the committed products must meet the requirements of 10CFR50. ANSYS, Inc. has committed numerous software products to meeting these requirements. The commitment is given to ANSYS, Inc. customers who have purchased our quality assurance service that our quality system meets 10CFR50, Appendix B and 10CFR21 as described in our Quality Assurance Service Agreement. We meet 10CFR50, Appendix B requirements by meeting the applicable requirements of NQA-1.

Because of the many definitions for design analysis software verification and validation, the subject has become contentious in nature and sometimes misused.

Verification of ANSYS Inc. software results are accomplished through formal procedures that require comparison with theoretical calculations or alternate numerical methods, not just cursory checks to see if results look "reasonable". Calculations are formally reviewed and testing results are maintained in a controlled fashion.

The verification test set consisted of over 100,000 individual test cases. Over 3000 of these tests are used in acceptance testing for all versions of the programs (each separate operating system and compiler) before we release any software for production use. A small subset (approximately 300 test problems) is formally published in the form of the ANSYS Verification Manual.

We periodically provide new releases of our products to our customers. The principal differences in new releases are error corrections, enhancements to existing features and new features to the program. Part of the verification process for any new release consists of running all applicable test cases in our verification test set at the new release of the program and comparing and analyzing results with those obtained from the previously approved release. Our acceptance criteria in evaluating these regression tests is this: any changes seen in the program output must be acceptable as improvements in the numerical algorithm or acceptable due to approved design changes in the software functionality.

Design controls take the form of review at key points in the design process. Extensive testing of all documented new features is required. Designs are reviewed during iteration meetings usually conducted every two to three weeks. Traceable documentation of the design and testing process is used to control new additions to the program. We store complete source code listings, testing results and documentation, allowing for investigative re-creation of any archived software version.

The formal verification process described has been in place since 1983, when the ANSYS program was at Revision 4.1C. All ANSYS software versions since that time, on all supported platforms, have been subject to formal verification as outlined above. This formal verification process has set the standard for engineering software quality since its inception.

The NQA-1 standard states this requirement for the manufacture of the software as:

- *"The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed."*

This requirement is met by current testing performed by our testing teams. Tests are developed to show that the software produces correct solutions for the encoded mathematical model, within defined limits, for each parameter and feature employed. These include new feature, error, regression, and verification tests. The tests are managed and documented according to ANSYS quality system procedures, work instructions, and guidelines. These problems, which verify the mathematical behaviour of our software described in our user manuals, are **defined in our quality system as "verification problems"**.

Validation of software is also required in NQA-1 standard when the computer program is used, and is stated as:

- *"The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application."*

This requirement is set for the user of the design analysis computer program, since they develop the model being analysed. However, we also try to meet this requirement for models we use in our testing. Simple verification problems that also produce valid solutions to physical problems are managed by testing teams, according to quality system procedures, and run in regression. A subset of these problems are described in our ANSYS Verification Manual and included in our verification testing package for both our mechanical and fluids products. If the customer changes these models in any way, they must show that their models produce a valid solution to the physical problem associated with their particular application to meet the above requirement. These problems provide customers

verification that our products produce correct solutions for the encoded mathematical models and also provide them examples of how to correctly use our products. These problems are **defined in our quality system as "use problems"**. Customers may also validate the solution if the described problem matches the problem they are solving.

In addition to quality standards which ANSYS, Inc. has committed to meet, various other organizations in recent years have published best practices, guidelines, and standards on software verification and validation (V&V). ANSYS, Inc. has been represented on the ASME V&V committees, but has not committed to meeting or following these best practices, guidelines, or standards. However, we believe that both our mechanical and fluids products meet most of these requirements, yet we inform our customers that they must validate their models and results.

Mechanical verification problems meet ASME V&V requirements. Fluids verification problems do not meet ASME V&V requirements. Therefore, an additional set of fluids models which meet ASME V&V requirements have been developed for fluids products. These models do not cover all features, do not follow documented quality system procedures, are not typically run as part of regression, and are not run for each new fluids product release. These fluids V&V tests are designated as **"CFD verification and validations (V&V) test problems"**. Even though these problems are not run on every release, the running of fluids regression tests (by testing teams) gives confidence that these problems will run for every release. In addition, some of these CFD V&V test problems may be passed on to the testing teams for inclusion in their test sets.

Large models which test large system applications have also been developed for both mechanical and fluids products. These models do not cover all features, do not follow documented quality system procedures, and are not typically run as part of regression. They are run with each new mechanical product release, but are not run for each new fluids product release. These larger tests are designated as **"large test problems"**. Again, the running of regression tests gives confidence that these problems will run for every release. In addition, some of these larger problems may be passed on to the testing teams for inclusion in their test sets.

SUMMARY

ANSYS, Inc. maintains an extensive suite of test cases that are run on our software prior to release. The purpose of this testing is to verify that the software performs according to documentation and to validate that it has the ability to adequately solve various engineering problems. By doing so, we meet the requirements of the NQA-1 Standard. The ANSYS Verification Manual describes a subset of this suite of test cases which meet these requirements and is intended to help customers by demonstrating proper use of our products.

Verification manual problems are selected to include a broad range of program features and analysis types. The verification manual is not intended to provide

testing coverage of all program features. Furthermore, while it is possible that one or more problems in the verification manual may assist customers with validation of a specific model and use of our software, the verification manual is not intended for software validation.

The verification manual problem input files are provided in verification testing packages which are provided as part of our Quality Assurance Services. The verification testing packages execute these problems and are intended to provide customers with a cost effective way to verify that their installation of our software is functioning properly on their hardware. Furthermore, the verification testing packages provide a link between their software installation and the testing performed by ANSYS, Inc., and demonstrate proper use of our products.