Verifier and Validating Software in a Regulated Environment

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

The ANSYS, Inc. Quality System is set up to meet the requirements of the International Organization for Standardization (ISO) ISO 9001:2008 as well as the applicable requirements of the U.S. Nuclear Regulatory Commission’s, Rules and Regulations in Title 10, Chapter 1, Code of Federal Regulations, Appendix B to 10 CFR Part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants” and Title 10, Chapter 1, Code of Federal Regulations, Part 21, titled "Reporting of Defects and Noncompliances" for reporting and dedication of commercial grade items. ANSYS, Inc. assumes full responsibility for the quality and verification of any software components included in our products that are supplied to other organizations.

For customers who perform analyses for nuclear application, a quality assurance service was developed in the 1970’s which affords customers the ability to purchase software that meets the requirements of the U.S. Nuclear Regulatory Commission (NRC). We use the American Society of Mechanical Engineers (ASME) NQA-1 Standard to accomplish this.

ASME NQA-1 is a consensus standard managed by the ASME for addressing the requirements of Appendix B to 10CFR Part 50. ASME
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 to safety of the item or activity. The ASME NQA-1-2008 Standard, including the ASME NQA-1-1a-2009 Addenda, has been endorsed by the NRC.

Companies commit products for Appendix B to 10CFR50 compliance. In doing so, the processes that created the committed products must meet the requirements for Appendix B to 10CFR50. ANSYS, Inc. has committed numerous software products to meeting these requirements. The commitment is given to customers who have purchased our quality assurance service that our quality system meets Appendix B to 10CFR Part 50, and 10CFR Part 21 as described in our Quality Assurance Service Agreement.

Because of the many definitions for design analysis software verification and validation, the subject has become contentious in nature and sometimes misused. Verification of software results is 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 ANSYS, Inc. verification test set consists of tens of thousands of individual test cases. Thousands of these tests are used in acceptance testing for all versions of the programs (each separate operating system and compiler) before release of any software for production use. A small subset (approximately 900 test problems) is formally published in the form of a Verification Manual. These tests are small in size to allow users a fast and easy way to show that the software is producing the same results as those produced on our installation.

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, acceptable as improvement to the implemented physical models accuracy, or acceptable due to approved design changes in the software functionality. Regression testing is defined by ASME NQA-1-2015 as selective retesting to detect errors introduced during modification of the computer program or to verify that the modified computer program still meets its specified requirements.

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.

ASME NQA-1-2015, Requirement 3, Section 401, “Use of Computer Programs,” states that the acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:

(a) "The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solution for the applied mathematical model within defined limits for each parameter employed."

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

Verification requirements are met by testing. 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 tests include new feature, error, regression, and verification tests. The tests are managed and documented according to 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 requirements are set by the user of the design analysis computer program, since the user develops the geometry and defines the parameters for the analysis. However, we also try to meet this requirement using published examples of physical problems. Simple verification problems that also produce valid solutions to physical
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problems are managed by testing teams according to quality system procedures and run in regression testing. A subset of these problems are described in our Verification Manual and are included in our verification testing package for both our mechanical and fluids products. If the customer changes the geometry or parameters, then they are responsible for showing that their analysis produces a valid solution to the physical problem associated with their particular application.

These supplied 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". Because of problem size requirements, use problems are small in size to allow users a fast and easy way to show that the software is producing the same results as those produced on our installation. Because of this constraint, some physics simulations; (i.e., computational fluid dynamics (CFD)) may not be as robust as the user may wish to demonstrate proper use of the software.

Mechanical verification problems meet the intent of “Guide for Verification and Validation in Computational Solid Mechanics”, ASME V&V 10 -2006. Fluids verification problems meet ASME verification requirements. Fluids validation tests meet the intent of “Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer”, ASME V&V 20 – 2009. These additional set of CFD software product validation tests are designated as "CFD validations contained in our EKM validation database". The CFD validation test set contains more than 300 tests, which are selectively run in addition to our other testing.

In addition to quality standards, various other organizations—such as the European Research Community on Flow, Turbulence, and Combustion (ERCOFTAC); the European Thematic Network for Quality and Trust in the Industrial Application of CFD (QNET-CFD); the Organisation for Economic Cooperation and Development/Nuclear Energy Agency/Committee on Safety of Nuclear Installations CFD working groups; and the American Society of Mechanical Engineers (ASME)—have published best practices, guidelines, benchmarks and standards on software verification and validation (V&V). We believe that, with proper use, both our mechanical and fluids products meet these standards, yet we inform our customers that they must validate their results. A good example of such a validation has been published by the United States Nuclear Regulatory Commission in NUREG-2152
“Computational Fluid Dynamics Best Practice Guidelines for Dry Cask Applications”.

We maintain an extensive suite of test cases which 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 demonstrate that it has the ability to adequately solve various engineering problems. By doing so, we meet the testing requirements of the regulations and quality standards we have committed to.

Our Verification Manual describes a subset of these test cases called “use problems” and is intended to help customers by demonstrating proper use of our products. Verification Manual test cases are selected to include a broad range of program features and analysis types. While it is possible that one or more use problems in the verification manual may assist customers with validation of a specific geometry and use of our software, the verification manual test cases are not intended for software validation.

The verification testing package, provided as a testing service, executes the verification manual test cases and is intended to provide customers with a cost effective way to verify that their installation of our software is functioning properly on their hardware. The verification testing package provides a link between software installation and the testing performed by ANSYS, Inc., and demonstrates proper use of our products.
REFERENCES


