

Dedication of Commercial Grade Design and Analysis Software

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KEYWORDS

QUALITY, COMMERCIAL-GRADE, DEDICATION, DESIGN AND ANALYSIS, REGULATED

ABSTRACT

Software used in design and analyses of nuclear plants in U.S. are subject to the regulations of the U.S. These are published under the U.S. Nuclear Regulatory Commission's, Rules and Regulations, Title 10, Chapter 1, Code of Federal Regulations. Computer programs with a functional safety classification of safety-related and are purchased as commercial items, they should be procured as commercial grade and dedicated for use as a basic component. In the past, most organizations supporting nuclear power plants have accepted design analyses computer programs in accordance with their software quality assurance programs.

Quality processes known as software verification and validation were typically used as qualifications for of commercial grade software in many software quality assurance programs. Many believed that commercial grade dedication was not an option for complex items such as computer programs. Although discussed in terms of plant structures, systems, and components in 10CFR21 the Nuclear Regulatory Commission (NRC) concluded that design and analysis software could meet the definition of a commercial-grade item in the U.S. NRC Safety Evaluation Report (SER) of Topical Report TR-106439.

They noted that existing software quality assurance practices that rely on verification and validation alone may not be sufficient to accept commercial-grade computer programs for use in safety-related applications. The NRC emphasized that commercially produced computer programs used for safety-related design and analysis are considered to be safety-related, and safety-related items must be either designed and manufactured in accordance with a quality assurance program that meets the requirements of 10CFR50, Appendix B or dedicated for use in a safety-related application in accordance with requirements of 10CFR21.

The NRC also noted that when the computer program is dedicated, the acceptance process should be documented in the form of a commercial-grade item dedication

evaluation. Important elements of a commercial-grade item dedication evaluation include:

- Identification of the safety functions of the items being dedicated
- A failure modes and effects analysis (FMEA) for the items being dedicated that postulates failure modes and/or mechanisms of the items that could affect its ability to perform its safety-related functions
- Identification of critical characteristics of the item that can be verified to obtain reasonable assurance that the item is capable of performing its intended safety-related functions and will not succumb to the failure modes identified in the FMEA
- Establishing acceptance criteria for each critical characteristic that will be verified
- Identification of the acceptance methods and activities that will be used to verify each critical characteristic
- Documenting the technical evaluation and results of the acceptance activities

Although verification and validation typically involve comprehensive testing and examination of the computer program, current verification and validation documentation may not always identify specific functions of the computer program as they may relate to the safety-related functions of structures, systems and components (SSC) or impact design analysis activities. In addition, verification and validation may not include an FMEA or other documented means of identifying critical characteristics. Although commercial-grade item dedication technical evaluations for computer programs may incorporate verification and validation activities, the technical evaluation should address each of the elements noted above.

NQA-1 Part II, Subpart 2.7, paragraph 302, definition of the dedication process for design and analysis software includes the following three criteria:

- Identification of the capabilities and limitations for intended use as critical characteristics
- Utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations
- Instructions for use (e.g., a user's manual) within the limits of the dedicated capabilities. The dedication process shall be documented, and the performance of the actions necessary to accept the computer program shall be reviewed and approved. The resulting documentation and associated computer programs(s) shall establish the current baseline

These criteria can be addressed through implementing the commercial grade dedication process defined by NQA-1 Part II, Subpart 2.14. The identification of the capabilities and limitations for intended use should be addressed during the selection of the set of performance critical characteristics. Test plans and test cases required to

demonstrate those capabilities within the limitations should be exercised through special tests and surveys. Instructions for use within the limits of the capabilities should be identified through the selection of the physical or performance critical characteristic associated with a user's manual, online help, or other methods to assist the user in the proper operation of the computer program within the limits of the dedication.

Dedication is an acceptance process. For computer programs the acceptance process is the process of verifying critical characteristics identified for the computer program using one or more of the four defined acceptance methods. These are:

- Method 1: Special Test(s), Inspection(s) and/or Analyses
- Method 2: Commercial Grade Survey of the Supplier
- Method 3: Source Verification
- Method 4: Acceptable Supplier Item or Service Performance Record

The use of commercial grade dedication as an acceptance process is not intended to validate the suitability of design. Selection of the software and suitability of its design and established before initiating the commercial grade dedication acceptance process. Subject matter experts are typically responsible for selecting the software for use and establishing the design. The amount and level of detail of design and qualification information available impacts the types of dedication acceptance methods used as well as the direction in which test are targeted.

Depending on the critical characteristics selected and the dedication method, the purchaser's procurement documents for the computer program may need to include the following:

- A detail description of the computer program name, title, release, version, or other descriptive identifiers
- Technical specification requirements related to the computer program application
- The media or process used to provide the computer program to the purchaser
- Identification of the supplier's QA program applicable to the computer program's development and support
- Identification of the documentation to be provided with the computer program
- Special shipping, storage, and handling requirements for media and any precautionary controls related to consideration of temperature, humidity, electromagnetic interference, etc. to be identified by the supplier
- Right of access for performing surveys or surveillances

- Need for the supplier to provide error reporting or technical support

Documentation of the commercial grade computer program or service dedication process shall be traceable to the computer program or services and should contain the following types of documents, depending on the applicable dedication method:

- Dedication plans or procedures, including the essential elements of the dedication process
 - scope and objectives for the dedication process
 - requirements document for computer program or service dedication
 - plans for a configuration management process for computer program or service dedication, including planned regression test requirements and expected results
 - computer program V&V methodology
- Commercial grade item or service procurement documents
- Technical evaluations
 - computer program requirements, summary, and review
 - documentation referenced during the technical evaluation
- Critical characteristic identification and acceptance criteria
- Test plan(s), test specifications, test report(s) or results, inspection reports, analysis reports
 - review of test coverage
 - evaluation of test results –validation
- Commercial grade survey reports
- Source verification reports
- Historical performance information (e.g., availability and use of user experience)
- Dedication report containing sufficient data to accept the item or service