

Commercial Dedication, A Manufacturer's Perspective

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History

The U.S. Nuclear Regulatory Commission defines a basic component as an item designed and manufactured under a quality assurance program such as ASME NQA-1 that complies with 10 CFR Part 50, Appendix B, or a commercial grade item which has successfully completed a dedication process. A commercial grade item is defined as an item that is not subject to design or specification requirements that are unique to nuclear facilities or activities; is used in applications other than nuclear facilities or activities; and is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description. Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

Before the Three Mile Island Unit 2 accident, nuclear plants typically procured equipment for safety-related systems from suppliers with an approved 10 CFR Part 50, Appendix B quality assurance program. After the Three Mile Island Unit 2 accident, the nuclear equipment market went into decline and many of the vendors supplying basic components

eliminated their nuclear QA programs. Since that time, Utilities in the U.S. have been forced to find alternate suppliers for safety-related equipment and components. Commercial Grade Dedication was introduced as a method for Utilities to procure replacement parts for safety components that were no longer available from the manufacturer.

ANSI N18.7-1976 was the first standard to specifically address commercial items. ANSI N18.7-1976 stated that replacement parts may be procured as commercial items but the purchaser must exercise care to assure equivalent performance. This placed the risk on the purchaser to ensure the commercial item would perform its intended safety function.

10CFR21, issued in June 1977, provided instructions for reporting defects and non-compliances of basic components that could create substantial safety hazards. This requirement applied to all parties in the procurement process including suppliers of commercial grade items. As many of the commercial grade item suppliers were not accustomed to supplying equipment to the nuclear industry, they rejected orders with this requirement. The October 1978 revision to 10CFR21 exempted suppliers of commercial grade items from the reporting responsibilities while still requiring the purchasers to cover the commercial grade items in their 10CFR50, Appendix B quality assurance program.

NRC inspections of Licensee commercial grade dedications initiated in the mid 1980s revealed problems with the execution of dedication activities.

Industry guidance EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)" was issued in June 1988 and provided guidance for procuring and using commercial grade items. This was followed in March 1994 with EPRI TR-102260 "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items."

In November 1993, NRC issued IP 38703 "Commercial Grade Dedication" to address the most difficult Dedication issues.

The NRC has endorsed ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facility Applications" as an acceptable method for complying with the pertinent quality requirements of 10CFR50, Appendix B. ASME NQA-1, subpart 2.14 "Quality Assurance Requirements for Commercial Grade Items and Services" provides guidance for commercial grade dedication.

The U.S. Nuclear Regulatory Agency (NRC), the Department of Energy (DOE) and the Electric Power Institute (EPRI), and various other Agencies and Societies have published numerous additional documents providing guidance and instructions for commercial dedication.

Ultimately, it is the responsibility of the Licensees to ensure that commercial grade items comply with 10CFR50, Appendix B.

Qualification vs. Dedication

The table below provides the general steps required for qualification of equipment and components compared to the steps for commercial dedication. Both processes start and end similarly. The execution and implementation step vary significantly.

<u>FULL QUALIFICATION</u>	<u>COMMERCIAL DEDICATION</u>
<p>1) A technical evaluation is performed to develop the technical and quality procurement requirements and to ensure the item will satisfactorily meet the intended design conditions.</p> <p>2) Determine if the part performs a safety function.</p> <p>-----</p>	<p>1) A technical evaluation is performed to develop the technical and quality procurement requirements and to ensure the item will satisfactorily meet the intended design conditions.</p> <p>2) Determine if the part performs a safety function.</p> <p>-----</p>
<p>3) A qualification plan is prepared based on the equipment specification. The qualification plan consists of an equipment performance evaluation to demonstrate that the equipment will perform its specified safety function. The required elements include aging considerations, qualified life, margin, maintenance requirements and acceptance criteria.</p> <p>3) Qualification methods with consideration to potential malfunctions that would degrade the required function defined in the design specification are specified.</p> <p>-----</p>	<p>3) Confirm part meets definition of a commercial grade item.</p> <p>4) Complete a technical evaluation which includes determination of safety function, failure modes and effects analysis.</p> <p>5) Write commercial dedication plan identifying critical characteristics and acceptance criteria.</p> <p>6) Select method of acceptance</p> <p>-----</p> <p>7) Execute dedication plan.</p>

4) Execute qualification plan.	
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Inconsistent Interpretations

A significant issue with commercial grade dedication is the inconsistent interpretation of the requirements for defining critical characteristics of commercial grade items. Further, there is the potential for inconsistent acceptance criteria that ensure the critical characteristics are met for commercial grade items. A dramatic example is the comparison of a qualified safety related chiller with various levels of commercial dedication.

As detailed in Mr. Mark Hemrick’s paper presented at the 27th Nuclear Air Cleaning Conference titled “Qualification & Testing of Nuclear Safety Related Chilled Water Units”, each component in a Safety Related Chiller needs to be qualified and the system performance was verified by testing. Testing and/or analysis were performed on all components of the chiller including the motors, compressors, evaporator, condensers, controls and instrumentation. Further, the evaporator and condensers were fabricated to the requirements of ASME Section III Code. The motors provide an example of the component qualifications used for the chiller components. Each motor type was qualified per IEEE 323 & 334 and required seismic and environmental qualifications, including motorette testing to validate the insulation, high temperature exposure, mechanical stress exposure, cold shock, moisture exposure, voltage checks, thermal aging of a prototype motor, mechanical aging, routine performance testing, radiation exposure, seismic testing, HELB simulation, post accident endurance testing to confirm that the motors are capable of surviving a representative design basis event (DBE), and remain functional for a specified time period after a DBE at any time within the motor’s design life. All other critical components within the chiller were analyzed and tested in a similar fashion to ensure the unit would perform as required.

Alternately, commercially available chillers are being proposed for safety related applications using commercial grade dedication. The critical characteristics identified for these chillers vary and could be limited to the verification of the function, performance, pressure retaining materials. Acceptance criteria includes the verification of these critical characteristics and may include a seismic shake test. The commercial grade dedication may not go to the function or performance of the critical components of the chiller. If the purchaser accepts the critical characteristics and the acceptance criteria for the chiller, the commercial dedication is deemed acceptable.

The above example is an extreme case. However, it should not be discounted as there are many similar examples. A primary factor driving the increased use of commercial

dedication is cost. The cost differential between qualification and commercial dedication can be 10 times or more due to the additional analysis and testing.

Why this is an issue for manufacturers

In most cases, procurement of safety related components and systems are competitively bid and the cost to the purchaser is important. The best, most robust design may never make it to the fabrication floor due to the design, manufacturing and testing costs. A manufacturer's success is dependent upon the manufacturer providing their customers with the best value that meets their customer's specifications.

Commercial dedication meets the requirements of the applicable codes and standards. However, all commercial dedications are not created equal. If less onerous commercial dedication approaches are acceptable, it can be argued that the codes and standards could be revised to reflect the acceptable level. A "de facto" variation in the interpretation of the codes and standards is not good for the nuclear industry.

The potential inconsistencies for manufacturers under a dedication scheme could harm our industry. Suppliers could reduce the dedication activities to reduce costs and provide attractive lead times, potentially at the cost of quality. Since the approval of the dedication plans is the responsibility of the Utilities some of these less burdensome dedication plans could be approved because there are more and more inexperienced engineers reviewing the plans. This creates an unfair advantage to those suppliers with weak dedication activities and also increases the risk to the renaissance of nuclear power in the United States.

Commercial dedication leaves many unanswered questions. The NRC and EPRI have significant guidance documents on commercial dedication but the inconsistencies continue. Manufacturers that truly understand the requirements may price themselves out of the market.

Legal Perspective

Ultimately the Utility or Licensee is responsible for ensuring 10 CFR Part 50, Appendix B is satisfied. Under certain circumstances a Licensee may be able to place reasonable reliance upon a supplier to provide a commercial grade item that is equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program.

A supplier of basic components who has an ASME NQA-1 quality assurance program in place can be reasonably relied upon by the Licensee to provide an acceptable product meeting the safety requirements. This is not to say that the Licensee may turn a blind eye to the actions of these suppliers, but rather, the supplier is committed to meeting the nuclear industry requirements. A supplier of basic components accepts the risks of non-compliance under 10 CFR 21 which specifies civil and criminal liability for non-compliance.

A Licensee may not be able to place the same reasonable reliance on a supplier without an ASME NQA-1 quality assurance program or third party dedicator. Suppliers of commercial grade items may be exempted from civil and criminal liability under 10 CFR 21 for non-compliance. Further, these suppliers may not have the required expertise to properly define the critical characteristics or acceptance criteria for basic components. As such, the Licensee may need to perform a critical evaluation of critical attributes and acceptance criteria to ensure 10 CFR Part 50, Appendix B compliance. Further, the Licensee may need to perform audits to ensure compliance to the dedication plan. Failure to provide this additional oversight may increase the risk to the Licensee.

Bibliography

- 10 CFR Part 50, Appendix B
- ASME NQA-1
- 10 CFR 21
- Qualification of Mechanical Equipment Used in Nuclear Power Plants - ASME Standard QME-1-2007
- ASME Code AG-1
- Commercial Grade dedication: Historical Perspective - Richard McIntyre, NRC Workshop on Vendor Oversight for New Reactor Construction