



**Department of
Energy/Environmental
Management Quality Assurance
Corporate Board Meeting**

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NRC Perspectives on Dedication

**Paul Prescott
NRR/DE/EQVB**



Commercial-Grade Item (CGI) Dedication Process

Topics

- Commercial Grade Dedication : Achieving Safety Through a Quality Process

- Attributes of Process
- Oversight of Process

- Technical Evaluations

- Critical Characteristics
- Like-For-Like CGI Replacements
- Equivalency Evaluations

- Acceptance Methods

- Method 1 – Special Test & Inspections
- Method 2 – Commercial- Grade Survey
- Method 3 – Source Verification
- Method 4 – Acceptable Supplier/Item Performance

CGD: Achieving Safety Through a Quality Process

- Engineering Involvement
- Documentation
- Established Process

CGD: Achieving Safety Through a Quality Process

- Inspection Procedures
- Inspector Qualification
- NRC Oversight

CGD: Achieving Safety Through a Quality Process

- Generic Communications
 - Endorsement of Industry Guidance
 - Website
- NRC/Stakeholder Interaction
 - Workshops
 - NUPIC (Nuclear Procurement Issues Comm.)
 - EPRI (Electric Power Research Institute)
 - NQA-1 (American Society of Mechanical Engineers (ASME))

CGI Dedication Process

Dedication

- 10 CFR 21.3, “Definitions”
 - 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 an 10CFR50, Appendix B QA Program.

CGI Dedication Process

- An acceptable dedication program consists of:
 - Technical Evaluation - identifies
 - Technical requirements
 - Quality requirements
 - Acceptance Method - verifies
 - Technical and quality requirements have been met.

Technical Evaluations

- Identify item's safety function, classification, performance requirements, and service conditions.
- Identify **critical characteristics**, including acceptance criteria.
- Identify dedication methods for verification of acceptance criteria.

Critical Characteristics (CCs)

- 10 CFR 21.3, “Definitions”
 - Important design, material, and performance characteristics of a CGI (or service) that, once verified, will provide reasonable assurance that the item (or service) will perform its intended safety function.

Critical Characteristics (CCs)

- Basis for Selection of CCs
 - Design, material, performance characteristics
 - Active/passive safety-related functions.
 - Safety/non-safety interfaces.
 - Changes in design, material, or manufacturing process.
 - Number and nature of CCs are based on safety function, application requirements, FMEA, and performance requirements.
 - Seismic and environmental qualification should be treated as critical characteristics to be verified.

Like-for-Like CGI Replacements

- Like-for-like criteria:
 - Item was purchased at the same time and from the same supplier, **or**
 - User verifies that no changes in the design, materials, or manufacturing process have occurred since procurement of original item.
- If dedicating entity can demonstrate that replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-established.
- CCs must still be verified.

Equivalency Evaluations

Equivalency evaluation: A technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended safety functions.

Equivalency Evaluations

- Equivalency evaluations shall be documented and include the following:
 - Identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item;
 - Evaluation of the change(s);
 - Confirmation that the change(s) do not adversely affect the current design or safety function of the item.
- Equivalency evaluations are not to be used as the sole basis to accept a commercial-grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

Acceptance Methods

Relation to Appendix B of 10 CFR Part 50

- Criterion VII - Control of Purchased Material, Equipment, and Services

“Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection (Method 2), objective evidence of quality furnished by the contractor or subcontractor (Method 4), inspection at the contractor or subcontractor source (Method 3), and examination of products upon delivery (Method 1).”

Acceptance Methods

Method 1 - Tests/Inspections

Inspections*

- Receipt
- Installation
- Post Installation
- Document Review

Tests*

- Pre-Installation
 - Bench
 - Aging
 - Destructive
 - Non-Destructive
- Post Installation
 - Post Maintenance Test
 - Surveillance/Test Procedure

*Critical Characteristics (CCs)

Acceptance Methods

Method 2 - Survey

- Should be used in combination with one or more of the other acceptance methods to collect objective evidence necessary to ensure acceptable historical item performance
- Acceptance based on merits of commercial vendor's quality controls
 - Documented quality program
 - Procedures
 - Practices
- Purchase orders (POs) invoke the acceptable vendor controls

Acceptance Methods

Method 2 - Survey

- Surveys should be CC specific and item specific
- Survey documentation should include identification of:
 - Item the surveyed vendor is supplying
 - Item's CCs the vendor is expected to control
 - Programmatic controls to be applied
 - Description of activities performed
 - Survey results/conclusion

Acceptance Methods

Method 3 – Source Verification

- Source verification involves direct observation to confirm the item's CCs are satisfactorily controlled by the CV
- Involves witnessing quality-related activities before releasing the item from the vendor or test facility
- Verifies supplier controls when those controls are not documented in a commercial quality program or procedures

Acceptance Methods

Method 3 – Source Verification

- Source verification should be conducted and controlled using a source verification plan that identifies:
 - A process of interest that may be associated with a manufacturing phase
 - Method of verification
 - Appropriate verification points
 - Document results, including the CCs for acceptance
 - Deficiencies observed should be corrected by the vendor before shipping
 - Final item acceptance should be completed by receipt inspection

Acceptance Methods

Method 4 – Acceptable Supplier/ Item Performance Record

- Acceptance of one or more CCs based upon a confidence in the supplied item's performance
- Item performance could be based on historical verification, acceptable quality control of CCs (as confirmed periodically by survey) or other acceptance methods

Acceptance Methods

Method 4 – Acceptable Supplier/ Item Performance Record

- Performance record should provide data that is directly applicable to the item's CCs for acceptance and its plant-specific, safety-related application
- This method should be used in combination with one or more of the other acceptance methods to collect objective evidence necessary to ensure acceptable historical performance

Questions or Comments?



Paul Prescott

Paul.Prescott@nrc.gov