



NUPIC Auditor Conference

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NRC Perspectives on Dedication

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Topics

Commercial-Grade Item (CGI) Dedication 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

CGI Dedication Process

– Dedication

- Alternate means of satisfying the applicable requirements of Appendix B with regard to procurement and acceptance of commercial-grade items (and services) for use as basic components.

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.

Technical Evaluations

- Information sources include, but not limited to:
 - Design output documents
 - Supplier technical information
 - Industry technical/operating experience
 - Failure modes and effects analyses (FMEAs)
- Complete documentation / auditable records of rationale, justifications, engineering analyses, etc.

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.

Like-for-Like CGI Replacements

- Like-for-like determination shall not be based solely on selection of commercial-grade vendors with items manufactured to meet the same industry standards as the 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-determined.

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.

Source: Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," April 9, 1991.
NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications."

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 1 - Tests/Inspections

Dedicating Entity (DE)

- Should adequately verify the CCs identified in the Technical Evaluation
- Vendors should be approved through a survey (Method 2)

Commercial Vendor (CV)

- Adequately controlled under a quality assurance (QA) program
 - Should be prescribed by procedures
 - Measuring & test equipment should be calibrated

Acceptance Methods

Method 1 - Tests/Inspections

- Sampling may be acceptable provided:
 - Documented technical basis
 - Considers lot traceability, homogeneity, complexity of item
 - If items are to be accepted by a certificate of conformance (CoC) or certified material test report (CMTR), document validity should be verified (Method 2)
 - Manufacturing process controls evaluated (Method 2)

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
- Ensure CCs to be verified are documented including the following processes:
 - Design Control
 - Procurement Control
 - Calibration
 - Inspection
 - Material Control
 - Fabrication
 - Assembly
 - Other

Acceptance Methods

Method 2 - Survey

- Acceptance based on merits of commercial vendor's quality controls
 - Documented quality program
 - Procedures
 - Practices
- Purchase orders (POs) invoke the acceptable vendor controls
- Surveys should be CC specific and item specific
- Survey teams should include technical and quality experts

Acceptance Methods

Method 2 - Survey

- 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 2 - Survey

- A CoC or CMTR may be accepted, provided:
 - Documented, verified traceability to original equipment manufacturer/vendor
 - Verification of vendor's implementation of adequate quality controls for the certified activity
 - Vendor's compliance to PO requirements is documented in the certificate
 - If distributors are included in the supply chain, their activities may need to be surveyed.

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 specific process of interest that may be associated with a specific manufacturing phase
 - Method of verification
 - Appropriate verification points

Acceptance Methods

Method 3 – Source Verification

- Document results, including the CCs for acceptance and actual results obtained during verification
- 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

- Sources of performance data should include:
 - Historical Performance (Nuclear and non-nuclear)
 - Operational performance
 - Test data
 - Historical Verification
 - Methods 1, 2, 3

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?



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