US REGULATORY OVERSIGHT OF COMMERCIAL-GRADE DEDICATION

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Agenda

- Background
- Definition
- Regulatory Requirements
- Commercial-Grade Dedication (CGD) Process
- Inspection
- Trends Associated With CGD in the Supply Chain
The overall function of a dedication program is to provide an alternate means of satisfying the requirements of 10 CFR Part 50 Appendix B with regard to procurement and acceptance of commercial-grade items (and services) for use as basic components.

It is an acceptance process.
Dedication History

Basic components supplied by entities that implement Appendix B-compliant QA programs to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

- 1970: 10CFR50, Appendix B
- 1978: 10CFR21 R0
- 1971: ANSI N45.2
- 1979: 10CFR21 R1
- 1988: NP-5652 CGID
- 1989: GL 89-02 CFI
- 1991: GL 91-05 CGID
- 1995: 10CFR21 R2
- 1996: 10CFR21 R3
- 1970-2000

- Dedication occurs after designation for use as a basic component.
- 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. CGIs do not include items when \( \geq 1 \) critical characteristic cannot be verified.
Definition

Commercial-grade dedication is a process by which a commercial-grade item (CGI) is accepted for use as a basic component. This acceptance process is undertaken to provide **reasonable assurance** that a CGI 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 (QA) program.
Regulatory Requirements

Two principal 10 CFR Part 50, Appendix B, QA criteria that are significant to the CGD process:

- Criterion VII, “Control of Purchased Material, Equipment and Services”
- Criterion III, "Design Control“
CGD Process

- **Necessary Elements**
  - Engineering Involvement
  - Documentation
  - Established Process

- **Industry Guidance**
  - EPRI 3002002982, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications Revision 1 to EPRI NP-5652 and TR-102260,” endorsed by the NRC (RG 1.164)

- **NRC Staff Position**
  - GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”
    - Conditionally endorsed EPRI NP-5652
  - GL 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs”
    - Identified weaknesses in licensee dedication programs found during inspections
Does item perform a safety function?

Is item being procured as basic component?

Document Safety Function(s) and FMEA

Select Acceptance Method(s)

Conduct Acceptance Activity

Procure item non-safety

Procure item as a basic component
What are the main steps in the CGD process?

- An acceptable dedication program consists of:
  - Technical Evaluation – identifies
    - Technical requirements
    - Quality requirements

- Acceptance Method - verifies
  - Technical and quality requirements have been met.
What is the purpose of the technical evaluation?

- Identification of critical characteristics
  - safety function and classification (active and passive)
  - PHYSICAL
    - material specification (form)
    - configuration (fit)
  - PERFORMANCE
    - pressure and temperature rating (function)
    - operation (function)
  - DEPENDABILITY (COMPUTER PROGRAMS / DIGITAL)
    - Built-in quality
    - Failure modes and management
    - reliability
- Special considerations:
  - Environmental qualification
  - Seismic qualification
- Determine acceptance criteria
- Determine acceptance methods

 oczyty Characteristics - 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.

(§ 21.3 Definitions)
Acceptance Methods

How are critical characteristics verified?

Four acceptance methods:

◦ Method 1: Special tests and inspections
◦ Method 2: Commercial-grade survey*
◦ Method 3: Source verification
◦ Method 4: Acceptable supplier/item performance record*

*Per GL 89-02 these Methods need to be used in conjunction with another Method
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).”
Inspection

- Inspection Procedure 43004, “Inspection of Commercial-Grade Dedication Programs”
  
  - Joint effort between industry and NRC

  - Basis of NQA-1a-2009 Addenda, Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services”
Breakdown of Vendor Inspection Findings

FY 2018 NONs

- Criterion V: 1
- Criterion VII: 1
- Criterion X: 1
- Criterion XI: 1
- Criterion XVII: 1
- Criterion XVI: 2
- Criterion IV: 1
- Criterion VII: 2
- Criterion XII: 3

3RD-4TH QTR FY2018 NONS

- Criterion III: 7
- Criterion XVI: 2
- Criterion XIII: 1
- Criterion XII: 1
- Criterion XI: 1
- Criterion IV: 1
- Criterion V: 1
- Criterion VII: 2
Trends Associated With CGD in the Supply Chain

- Knowledge Transfer
- Poor Technical Evaluations
  - Lack of design Requirements
  - CCs not relevant to the safety function of the item
- Ineffective Implementation of the Acceptance Methods
  - Test and Inspection are not verifying the CCs to provide reasonable assurance that the item will perform the intended safety function
  - Performing Audits instead of a Commercial-Grade Survey
  - Unjustified Sampling Plans
QUESTIONS

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