



United States Nuclear Regulatory Commission

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*Protecting People and the Environment*

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# US REGULATORY OVERSIGHT OF COMMERCIAL-GRADE DEDICATION

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KERRI KAVANAGH

CHIEF OF THE QUALITY ASSURANCE VENDOR INSPECTION BRANCH-2, OFFICE OF  
NEW REACTORS, US NUCLEAR REGULATORY COMMISSION



# Agenda

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- Background
- Definition
- Regulatory Requirements
- Commercial-Grade Dedication (CGD) Process
- Inspection
- Trends Associated With CGD in the Supply Chain





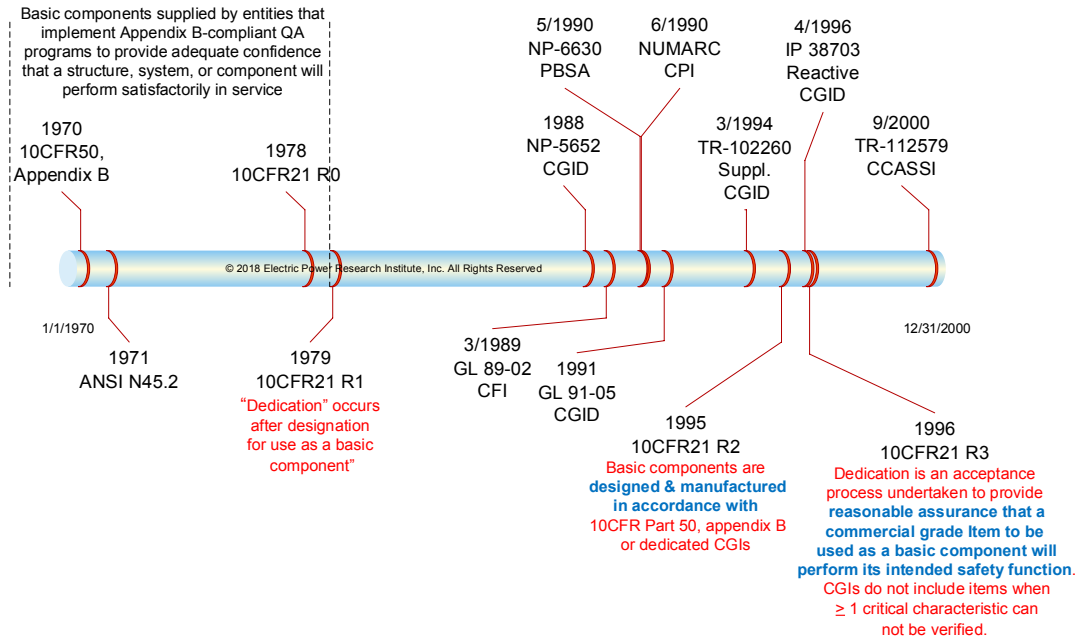
# Background

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- ❑ 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





# Definition

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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.

§ 21.3 Definitions



# Regulatory Requirements

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- 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



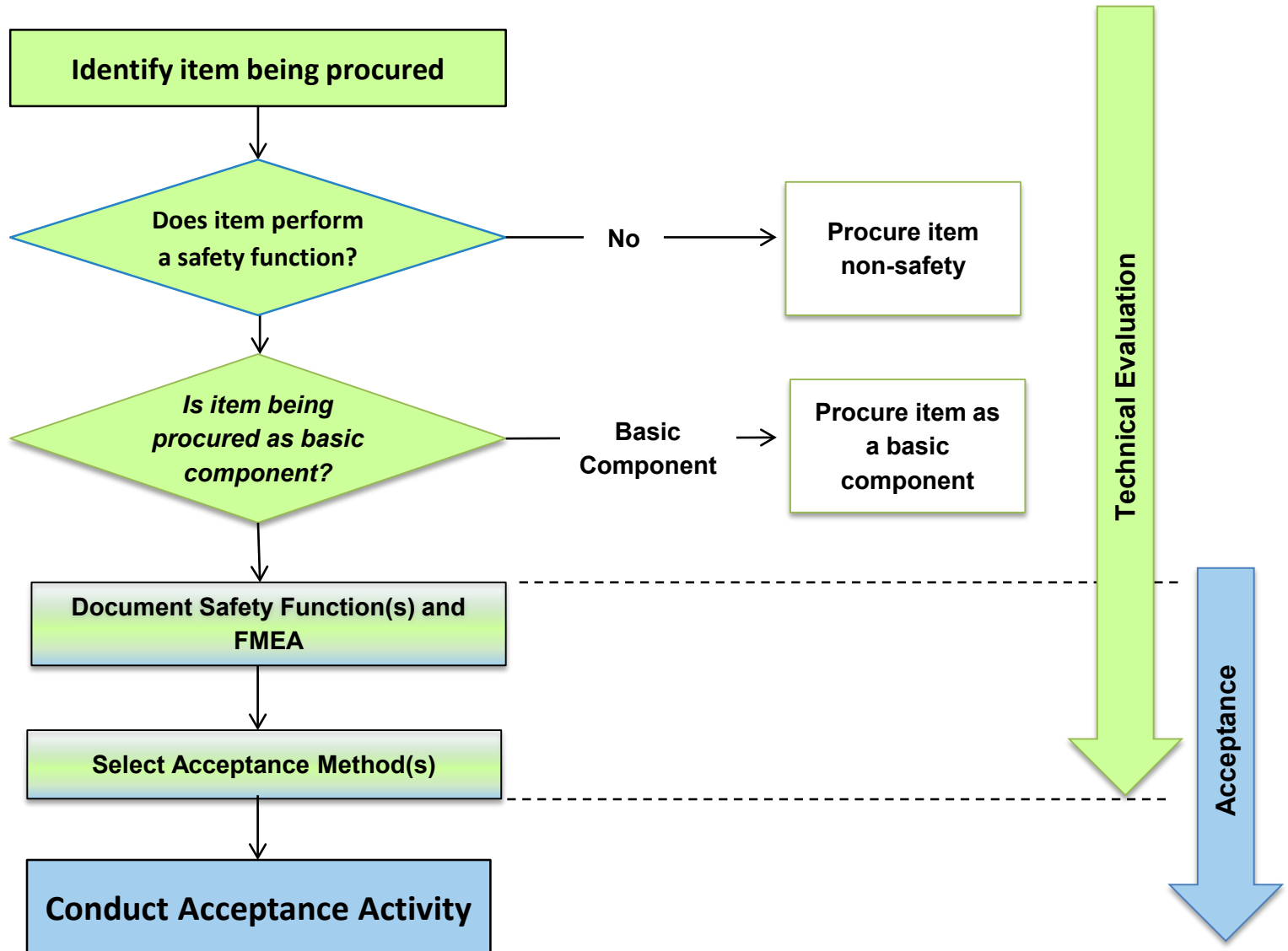
## ☐ Industry Guidance

- 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

# CGD Flow Chart







# CGD Process (cont'd)

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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.



# CGD Process

(cont'd)

## □ 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

❖ **Critical 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

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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\*

EPRI 3002002982

❖ \*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

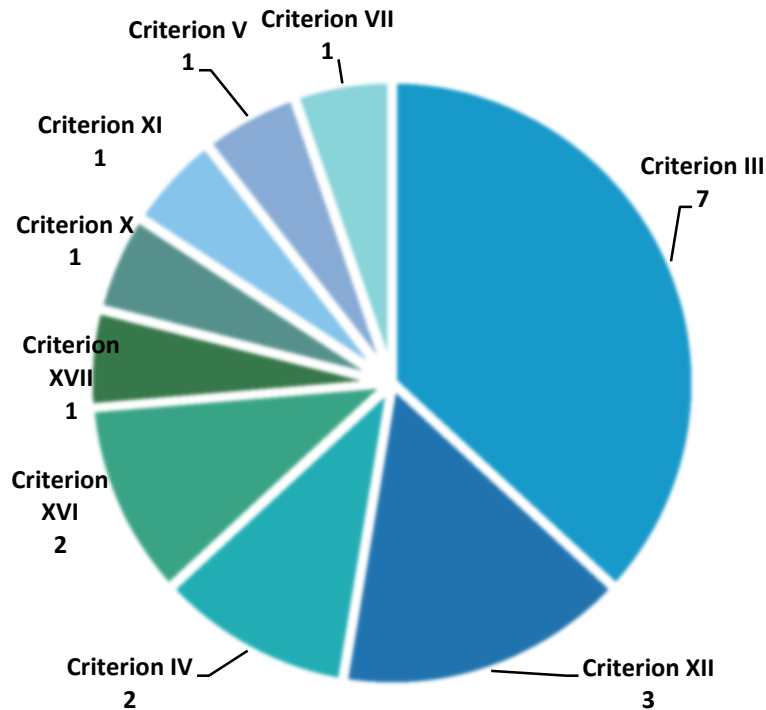
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- Inspection Procedure 43004, “Inspection of Commercial-Grade Dedication Programs”
  - Joint effort between industry and NRC
  - Basis of NQA-1a-2009 Addenda, Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services”

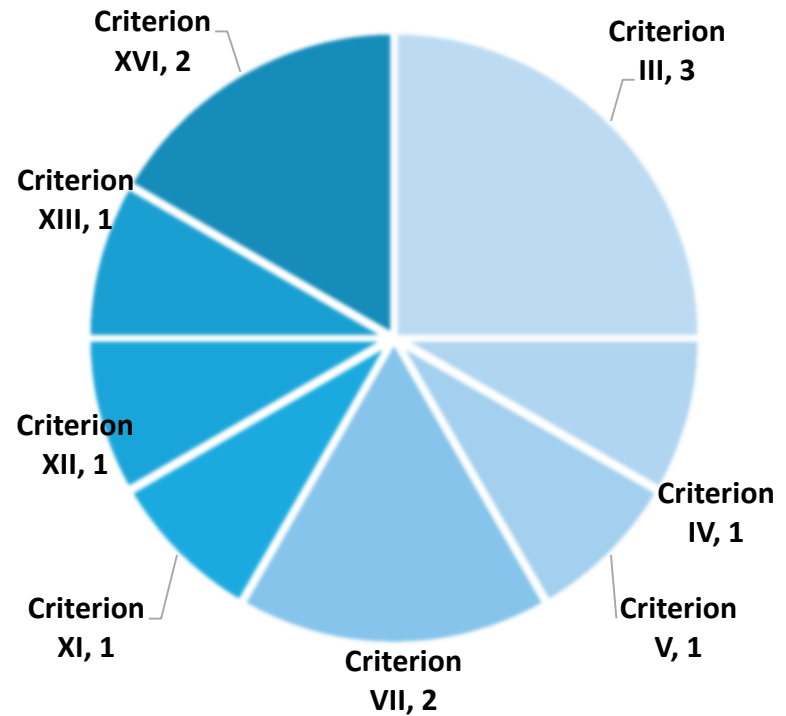


# Breakdown of Vendor Inspection Findings

**FY 2018 NONs**



**3RD-4TH QTR FY2018 NONS**





# Trends Associated With CGD in the Supply Chain

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- 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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Kerri Kavanagh

[Kerri.Kavanagh@nrc.gov](mailto:Kerri.Kavanagh@nrc.gov)

301-415-3743