

Significance of Historical Changes to 10CFR21

Impact on Commercial Grade Dedication

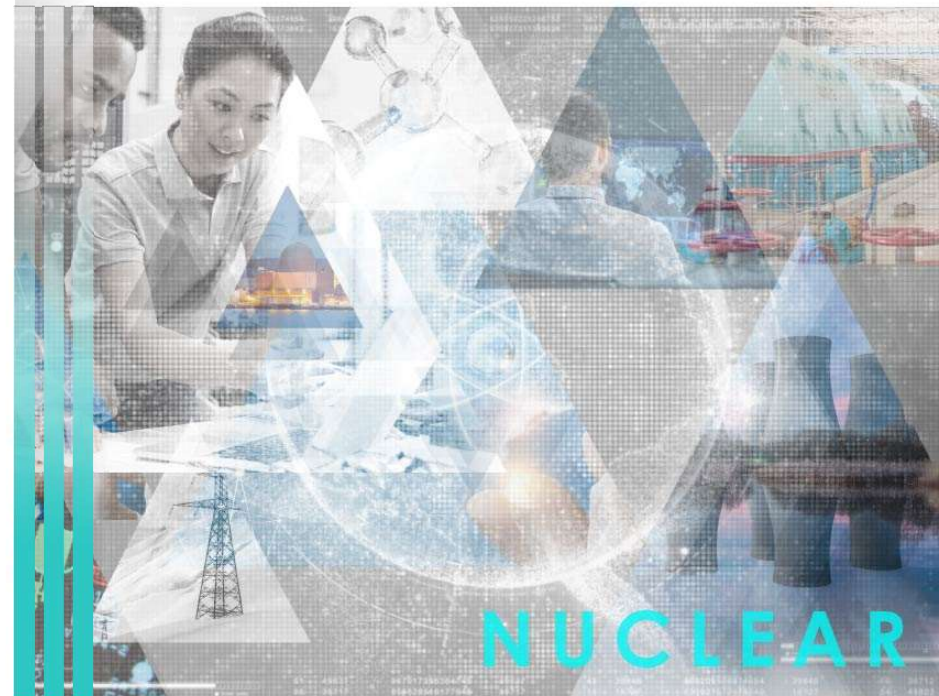
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Regulatory changes impacting commercial grade dedication

- The term “dedication” (in the context of nuclear procurement) was first introduced in U.S. regulation 10CFR, Part 21, “Reporting of Defects and Noncompliance”
- The meaning of commercial grade dedication, and requirements that apply to commercial grade dedication changed over time

1978 – 10CFR, Part 21 becomes law

- Intent of the regulation was to ensure that **when suppliers of basic components** detected defects or noncompliance impacting basic components they provided, the **suppliers would report the defects or noncompliance to NRC and to impacted customers**
- The term “dedication” is not included
 - At the time 10CFR21 was written, all safety-related items were purchased as basic components from suppliers with nuclear quality assurance (QA) programs

1979 – 10CFR, Part 21 is revised

- The 1979 revision recognizes that some safety-related items are not purchased as basic components from suppliers with nuclear QA programs
- The terms “commercial grade item” and “dedication” are introduced
- **“Dedication”** of a commercial grade item occurs after receipt when that item is designated for use as a basic component
 - In the original context, “dedication” was essentially the point in time when a licensee accepted an item for use as a basic component.

1979 – 10CFR, Part 21 is revised (continued)

- "Commercial grade item" means an Item that is:
 - (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 of this chapter and
 - (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 of this chapter and
 - (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog)

- In effect, a commercial grade item is a standard, well-made commercial item used in similar but non-nuclear applications and perhaps proven to be reliable in those applications.



1980's – Concerns identified about licensee “dedication”

- NRC inspections indicated that acceptance activities used by licensees were inadequate to accept commercial grade items for use in safety-related applications
- NRC issued an Advance Notice of Proposed Rulemaking (SECY-90-057, withdrawn September 1995)
- Instead, Licensees and EPRI worked together to develop a process for commercial grade item dedication that would ensure acceptance activities were adequate

1988 – EPRI Publishes NP-5652

- Process for accepting commercial grade items by establishing reasonable assurance they can perform their safety function(s)
- Introduced new definitions
 - “**Critical Characteristics**” - Identifiable and measurable attributes/ variables of a commercial grade item, which once selected to be verified, **provide reasonable assurance that the item received is the item specified**.
 - “**Dedication**” - The **point in time** after which a commercial grade item is accepted for a safety-related application and deficiency reporting becomes the responsibility of the party performing the acceptance.
- All U.S. nuclear utilities implemented NP-5652 by July, 1992 as part of the Comprehensive Procurement Initiative (NUMARC 90-13)

1995, 10CFR, Part 21 is revised

- The following phrase was added to establish dedication as **not only a point in time, but also a method** of establishing a commercial grade item as a basic component when the supplier did not control it under a nuclear QA program
 - “Basic components are designed and manufactured in accordance with 10CFR50, Appendix B or dedicated commercial grade items”

1996, 10CFR, Part 21 is revised

- Significant revision to 10CFR21
- Added information about “how” to dedicate in the definitions, establishing new requirements
- **Basic Components** are items designed and manufactured under a quality assurance program complying with 10CFR Part 50, appendix B, or commercial grade items which have successfully completed the dedication process.
 - Significance: recognizes there are two methods of bringing a basic component to market: (1) control using traditional 10CFR50, Appendix B quality activities and (2) successful commercial grade dedication

1996, 10CFR, Part 21 is revised

- **Dedicating entity.** When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the **manufacturer of the item, a third-party dedicating entity, or the licensee itself.** The dedicating entity, pursuant to §21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.
 - *Significance – recognizes that any entity with a 10CFR50, Appendix B-compliant QA program could perform dedication and therefore accept responsibility for reporting defects and failures to comply*

1996, 10CFR, Part 21 is revised

- **Commercial grade item.** (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component.
- **Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected** (i.e., one or more critical characteristics of the item cannot be verified).
 - Significance: **Increased the scope of items that are eligible for dedication in commercial nuclear power generation facilities. Particularly important for replacement of items that are obsolete or no longer manufactured and therefore no longer included in published product literature.**
- (2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, commercial grade item means an item that is:
 - (I) Not subject to design or specification requirements that are unique to those facilities or activities;
 - (II) Used in applications other than those facilities or activities; and
 - (III) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).
 - Significance: **Eligibility requirements for commercial grade dedication are different for different types of facilities.**

1996, 10CFR, Part 21 is revised

- **Critical characteristics.** When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those Important design, material, and performance characteristics of a commercial grade Item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.
 - Significance: Established a requirement that a relationship be established between critical characteristics and safety functions. Increased expectations for documenting the relationship or basis for selecting critical characteristics.

1996, 10CFR, Part 21 is revised

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, 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 holdpoints 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.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Significance: (1) Reinforced changed meaning of "dedication" from a point in time when the item is designated for use as a basic component to an acceptance process undertaken to accept an item for use as a basic component. (2) The new definition of dedication establishes that the dedication process is equivalent to an item controlled (designed and manufactured) under a 10CFR50, appendix B QA program, thereby pointing out that control under a 10CFR50, appendix B QA program with or without commercial grade dedication are acceptable means of establishing an item as a basic component.

2015 - Final Regulatory Basis to revise 10CFR21

- Revision of 10CFR21 cancelled due to budgetary cutbacks associated with “Project Aim,”
- The “Final Regulatory Basis to Clarify 10 CFR Part 21, Reporting of Defects and Noncompliance,” was issued in August 2015 (ADAMS Accession Number ML15152A457). The NRC staff positions described in the Final Regulatory Basis did receive NRC Office of General Counsel (legal) and NRC management approval
- Language in the Final Regulatory Basis provides insight regarding NRC staff thinking, expectations, and interpretation of 10CFR21
- Updated definitions to remove “methodology and process information” and added section 21.71 to address methodology and process.

2015 - Final Regulatory Basis to revise 10CFR21

Basic component (1)(i) When applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52 of this chapter, a basic component means a structure, system, component, or part thereof relied upon to remain functional during and following design basis events to assure:

- (A) The integrity of the reactor coolant pressure boundary;
- (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter.

(ii) Basic components are controlled under a quality assurance program complying with Appendix B to Part 50 of this chapter.

(2) When applied to facilities and activities licensed under 10 CFR Part 70 of this chapter and subject to the requirements of Subpart H of Part 70, basic component means a structure, system, or component (SSC), or any part thereof that affects the SSC's safety function, that is designated as an item relied on for safety in accordance with § 70.61, is directly procured by the licensee, and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could cause the performance requirements of § 70.61 to be exceeded. The SSC is not a basic component if diverse SSCs (but not redundant SSCs) exist whose independent action could prevent the performance requirements of § 70.61 from being exceeded.

2015 - Final Regulatory Basis to revise 10CFR21

(3) When applied to facilities and activities licensed under 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than facilities subject to the requirements of Subpart H of Part 70), 71, 72, or 76 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) Basic components include all activities affecting the safety-related functions of those structures, systems, and components, including, design, analysis, inspection, testing, fabrication, replacement of parts, services, software, or information within the scope of a design certification or early site permit under part 52 of this chapter.

Significance: Although much of the definition repeats the definition of basic component in 10CFR50.2, the language in (ii), “Basic components are *controlled* under a quality assurance program complying with Appendix B to Part 50 of this chapter” is important as it removes the phrase “*designed and manufactured*” which resulted in confusion since many items are not designed and/or manufactured under an Appendix B QA program. For example, interpretation of the phrase “designed and manufactured” was cited as a reason that items such as structural steel and piping, that were procured as basic components from ASME certificate holders, should then be dedicated (since there is no steel mill in the world that implements a 10CFR50, Appendix B-compliant QA program).

2015 – Final Regulatory Basis to revise 10CFR21

- **Commercial grade item** means an item that is not a basic component.
 - Significance: Like the definition for “basic component,” the definition for commercial grade item **removes the phrase “designed and manufactured.”** In addition, text that explains “how-to” dedicate and describes criteria related to eligibility to dedication is removed and relocated to 21.71.
- **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.
 - Significance: **Text that explains “how-to” dedicate and describes the dedication methodology is removed and relocated to 21.71.**

2015 – Final Regulatory Basis to revise 10CFR21

§ 21.71 Commercial grade dedication requirements

(a)(1) When applied to nuclear power plants licensed under 10 CFR part 50 or nuclear fuel fabrication plants licensed under 10 CFR part 70, dedication occurs after receipt when that item is controlled under a quality assurance program complying with appendix B to part 50 and the item is acceptable for use as a basic component. To dedicate an item, a dedicating entity must:

- (i) Perform a technical evaluation that identifies the item's critical characteristics;
- (ii) Identify acceptance criteria for each critical characteristic;
- (iii) Verify that the item meets the acceptance criteria using one or more of the following acceptance methods:

- (A) Method 1: Visual inspection (e.g., visual inspection of the item's critical characteristics);
- (B) Method 2: Supplier/Item history (e.g., Historical records for acceptable performance);
- (C) Method 3: Supplier/Item history (e.g., Historical records for acceptable performance);
- (D) Method 4: Supplier/Item history (e.g., Historical records for acceptable performance). Method 4 must be based on industry-wide performance data applicable to the item's critical characteristic. Method 4 shall not be used as the sole method of acceptance for all of the item's critical characteristics.

(2) Dedication is complete when all of the item's critical characteristics have been verified and documented.

(3) Dedication must be completed in accordance with the provisions of 10 CFR part 50, appendix B.

(4) If any critical characteristic of the item cannot be verified acceptable, that item cannot be dedicated.

(b) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than plutonium processing and fuel fabrication plants), 71, or 72, or 76, dedication occurs after receipt when that item is designated for use as a basic component.

**IF YOU ARE INVOLVED IN DEDICATION -
YOU SHOULD HAVE THIS DOCUMENT
DOWNLOAD [ML15152A457](#) FROM ADAMS**

NRC IP43004, INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS

- Technical Evaluations. Technical evaluations are conducted and documented by the responsible engineering organization. Technical evaluations identify the necessary technical and quality requirements that ensure the item will meet the intended design conditions. These requirements should include:
 1. Determination of the item's safety function, performance requirements, component/part functional classification, and application requirements (e.g., service conditions).
 2. Review of the vendor's technical data as well as industry operating experience, including feedback from previous dedication activities, NRC bulletins and information notices, supplier information letters, available industry data, and customer feedback to identify relevant technical information that may affect the suitability of the item.

NRC IP43004, INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS

3. Performance of a Failure Modes and Effects Analyses (FMEA), if necessary to identify the credible failure mechanisms of the item in the specific application under consideration.
4. The identification of the item's critical characteristics based on the information developed above that will assure the suitability of all parts, materials, and services for their intended safety-related applications. Factors that should be considered include:
 - a. The important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function.
 - b. Active/passive safety-related functions, system safety/non-safety interfaces, and system compatibility under all design basis conditions.
 - c. Any changes in design, material, or manufacturing process that could impact the functional characteristics of the item.
 - d. Appropriate interface with the vendor to identify and characterize the design and functional parameters of specific parts.
 - e. The number and nature of the critical characteristics are to be based on the intended safety function, application requirements, complexity, credible failure modes and effects, and performance requirements of the item.
 - f. Those critical characteristics that cannot be effectively verified during post-receipt inspection and testing should be identified in order to apply an appropriate verification method during the manufacturing process.

June 2019

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- January 28-30, Hilton Bayfront St. Petersburg, FL
- Joint meeting with NUPIC

Summer 2020 JUTG

- August 4-6, 2020, SandPearl, Clearwater, FL



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Course	Dates
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Procurement of Reactor Coolant Pressure Boundary Replacement Items (ASME procurement)	July 18-19, 2019
NUPIC Audit Team Leader Training	August 13-15, 2019
Nuclear Utility Procurement	December 3-5, 2019

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Please contact Lori at lwarneke@epri.com for more information*

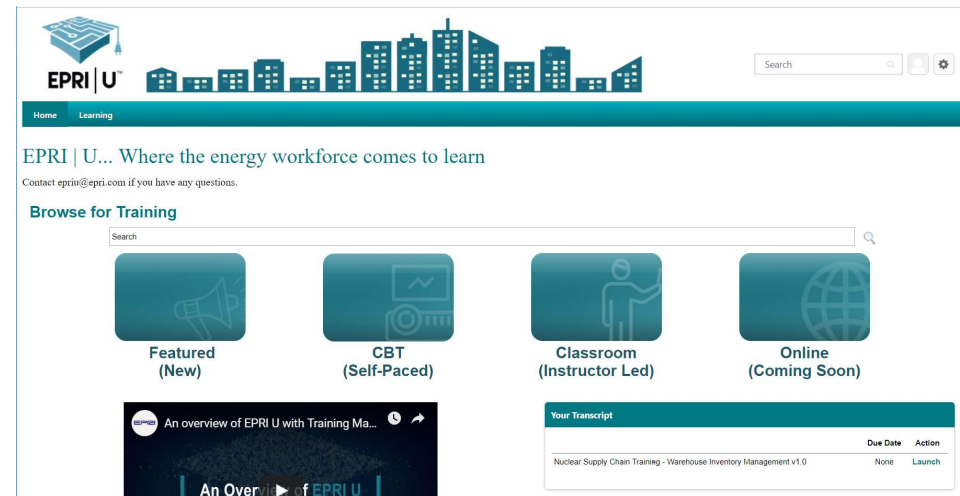


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- Some CBTs related to procurement are now available



- Other are in the queue
 - Audit Technical Specialist (3002006989)
 - Procurement Engineering Basics (3002005397)
 - Procurement Engineering Safety Classification (3002011679)
 - Undeclared Digital Content (3002009558)
- Non-Member, training-only login IDs are available



Your Transcript		
	Due Date	Action
Nuclear Supply Chain Training - Warehouse Inventory Management v1.0	None	Launch