

# **Control of Items Under 10CFR50, Appendix B**

*With, and without, commercial  
grade item dedication*

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## In the beginning . . .

- World War II identified the need for systematic control of manufactured items such as munitions



*Joseph Juran*

- First to apply statistics to quality (age 21)
- Industrial Engineer at Western Electric
- Re-engineered military logistics in WWII
- Founded Total Quality Management
- Involved in rebuilding Japan



*W. Edwards Deming*

- Physicist (PhD Yale 1928)
- USDA Mathematical physicist
- Introduced sampling at Bureau of the Census
- Consultant to Secretary of War – WW II (1942)
- Involved in rebuilding Japan (1946)

- These guys invented quality assurance
- Both were awarded the Order of the Sacred Treasure Metal by Emperor Hirohito of Japan
- *Neither of them ever heard of commercial grade dedication*

## In the beginning . . .

- Quality practices from World War II were applied to industrial and military products including nuclear weapons
- QA became an engineering practice



- In 1962, Vice Admiral Rickover called for better understanding and enforcement of specifications (on both sides) and more effective use of QA programs



- In 1966, AEC Commissioner James Ramey defined quality assurance as comprising *“all actions necessary to provide adequate confidence that a product or facility will operate satisfactorily in service.”*

## In the beginning . . .

- In 1968, Mr. Ramey's concerns and a number of other issues prompted AEC to create 10CFR50, Appendix B – which was issued in 1970 for use by licensees
- Licensees imposed it on suppliers for convenience - Suppliers obliged (in 1966, 52 units were on order)
- In 1971 ANSI N45.2 was issued
- In 1974 NRC was established
- *Appendix B's requirements find basis in actually knowing what the organization's activities are, and knowing criteria for what constitutes satisfactory quality*

## In the beginning . . .

- Manufacturers adjusted well-established commercial QA programs so that they were compliant with 10CFR50, Appendix B
- Manufacturers started with well-established, high performing commercial equipment, and started to control “design and manufacture” under their newly minted 10CFR50, Appendix B-compliant QA programs
- Licensees audited the suppliers’ QA programs and relied on them to assure quality of purchased equipment and services

## In the beginning . . .

- Manufacturers' engineers' determined what important attributes (design requirements) should be verified during and after the manufacturing process:
  - Raw material attributes
  - In-process statistical quality control checks
  - In-process and post completion functional tests
- Manufacturers' QA/QC made sure the attributes were verified (products met applicable design requirements)

## In the middle . . .

- The Three Mile Island accident occurred in 1979
- New construction projects were cancelled
- Orders for new plants decreased . . .
- Suppliers abandoned their Appendix B QA programs
- Existing plants needed to purchase and accept equipment from the suppliers
- Plants asked the suppliers for the acceptance criteria
- The suppliers said . . . **“Sorry, that information is proprietary”**
- So licensees had to find some way to *develop appropriate acceptance criteria*

# The primary difference . . . is origin of acceptance criteria

Without CGID	Quality Control Factor	With CGID
	Entity accepting item as a basic component	
	Source of product function and design knowledge	
	Source of acceptance criteria	
	Acceptance criteria is based upon	



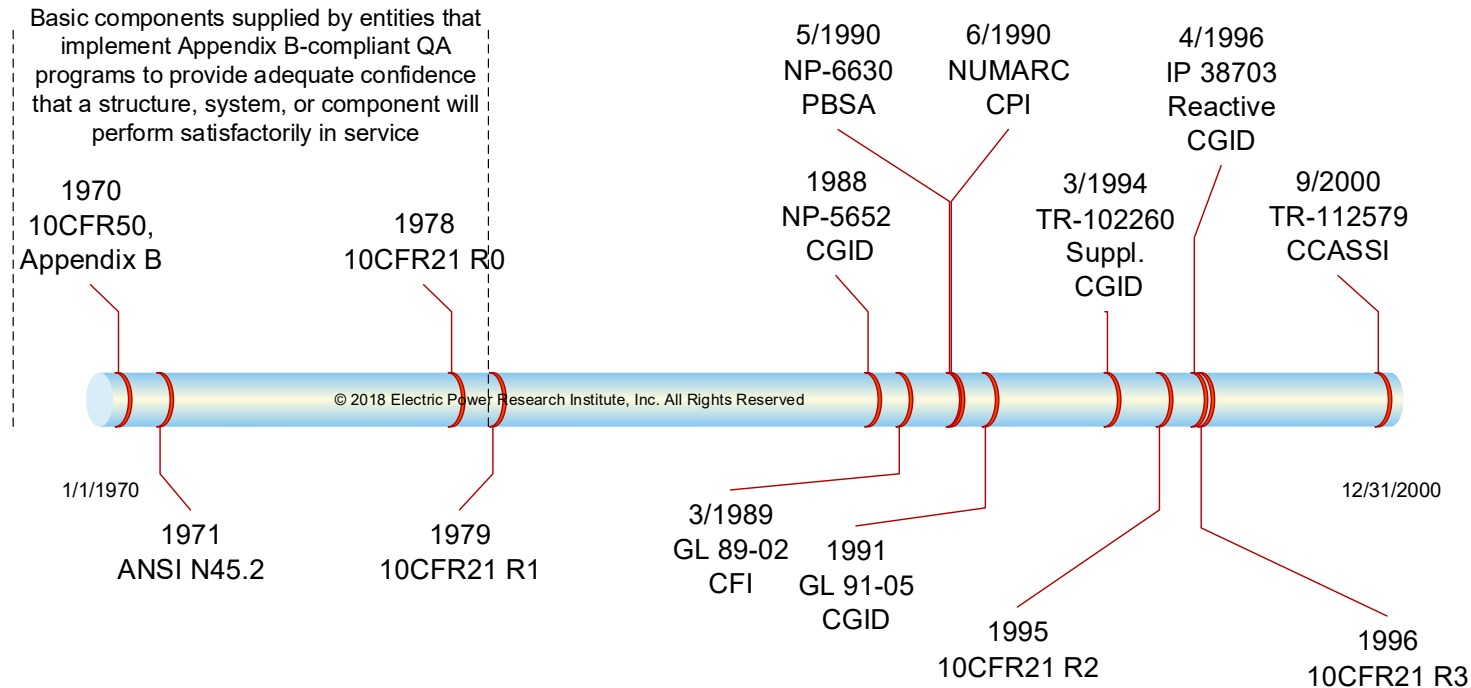
## **Nuclear Quality Assurance is possible without dedication**

- 10CFR50, Appendix B does not mention dedication
- ANSI N45.2 and daughter standards do not mention dedication
- No quality standard on earth other than NQA-1 mentions dedication
- Dedication is not a central tenet of quality assurance – it is an alternative acceptance method that is performed under the auspices of an Appendix B-compliant QA program

## Dedication is NOT a shortcut

- If it seems like dedication is a shortcut or easier option, it is not being done correctly

# Dedication has evolved, Appendix B is the same



# Conbolt Appendix B Controls without Dedication

Design Requirements			
Appendix B Criterion	Materials of Construction	Dimensions	Performance
(during receiving) Criterion III Criterion IV Criterion V Criterion VII (accept raw material)	Test raw materials upon receipt* to ensure they comply with design requirements: Barstock (for bolts) Nuts Expansion wing material	Verify dimensions of nuts meet specified standard upon receipt	
(during manufacture) Criterion V Criterion VIII Criterion X Criterion XI Criterion XII		Verify dimensions comply with design requirements via statistical process control: Completed bolt Completed wings	
(after manufacture) Criterion V Criterion VIII Criterion X Criterion XI Criterion XII			Perform pull-test for X samples from each manufactured lot/batch

# Conbolt Dedication Plan

Critical Characteristics			
	Materials of Construction	Dimensions	Performance
Method 1 (accept raw material)	Test raw materials upon receipt to ensure they comply with design requirements: Barstock (for bolts) Nuts Expansion wing material	Verify dimensions of nuts meet specified standard upon receipt	
Method 1 (during manufacture)		Verify dimensions comply with design requirements via statistical process control: Completed bolt Completed wings	
Method 1 (after manufacture)			Perform pull-test for X samples from each manufactured lot/batch

## Example of Control under Appendix B without Dedication

- A supplier with an Appendix B-compliant QA program establishing that unqualified source material meets applicable material specification requirements in accordance with ASME NCA-3855.5
  - No dedication is required
  - NCA-3855.5 and the material specification provide design and acceptance requirement
  - Control (under Appendix B) is accomplished through quality activities that verify ASME and material specification requirements are met

# Who can tell me what dedication is in 2 words?

- Hint – remember the 4<sup>th</sup> and 5<sup>th</sup> words of the definition of dedication in 10CFR21

# Dedication is an Acceptance Process that finds basis in Criterion VII

10CFR50, Appendix B Criterion VII, Control of Purchased Material, Equipment, and Services	EPRI 3002002982
Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, <i>conform to the procurement documents</i> . These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. . . .	Method 2 – Commercial Grade Survey Method 4 – Item/Supplier performance  Method 3 – Source Surveillance Method 1 – Special Tests and Inspection



- If a dedicating entity needs to implement all 18 criteria, and the activities in Criterion VII are essentially the same as the 4 dedication methods – why do we have two approaches?

Because some suppliers dropped their Appendix B-compliant QA programs and we didn't have the detailed design information required to duplicate their acceptance processes

Because NRC wanted to establish when reporting of defects and noncompliance became the licensees'/suppliers' responsibility (part of defense in depth)

- Do you think it is safe to say that the NRC intended for licensees to start with good, high quality proven products and apply the “good old” quality controls/activities necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service?
- Does anyone remember where the underlined words come from?
  - 10CFR50, Appendix B / AEC Commissioner James Ramey (1966)

# Appendix B

## Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

. . . . This appendix establishes quality assurance requirements for the design, manufacture, construction and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, “quality assurance” comprises all those planned and systematic actions necessary to **provide adequate confidence that a structure, system, or component will perform satisfactorily in service**. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

# 10CFR21

## PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

### § 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 a 10 CFR Part 50, appendix B, quality assurance program.

“equivalent” to an item *designed and manufactured*  
under a 10CFR50, appendix B QA program

# Clarifications in the new dedication guidance

## ■ **Existing Regulation**

- *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 . . . (i.e., one or more critical characteristics of the item cannot be verified).
- (1)(ii) Basic components are **items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter**, or commercial grade items which have successfully completed the dedication process.

## ■ **The guidance defines “designed and manufactured”**

- When applied to basic components the **term “designed and manufactured” means “controlled” under a quality assurance program complying with appendix B to 10 CFR Part 50.**

Page 2-7 of the Document

# 1995 Revision to 10CFR21

From definition of basic component in 10CFR21:

“(1)(ii) Basic components are items **designed and manufactured** under a QA program complying with Appendix B to 10 CFR Part 50, or commercial-grade items which have successfully completed the dedication process.”

Guidance Clarification:

- The second paragraph (1)(ii) of the definition clarifies that there are two methods by which a basic component is created —by controlling the item under a 10 CFR Part 50, Appendix B [7]-compliant QA program or by successfully completing the dedication process for the item (note that the dedication process is itself controlled under a 10 CFR Part 50, Appendix B [7] QA program). Since these are two distinct processes for creating a basic component, **an item does not need to be subject to both processes to become a basic component.**
- In that light, paragraph (1)(ii) [*basic component*] is appropriately considered to include items ‘controlled’ under a quality assurance program complying with 10 CFR Part 50, Appendix B.

Page F-2 of the document

# Conventions in the new dedication guidance

Dedication	Control under 10CFR50, Appendix B-compliant QA Program
Provides reasonable assurance the commercially-manufactured item conforms to its design, and will perform its intended safety function (adopted from 10CFR21)	Provides adequate confidence that a structure, system, or component will perform satisfactorily in service (adopted from the introduction to 10CFR50 Appendix B)

# How do I know which method to use / is being used?

- There is no simple answer . . . but considerations might include:

Control under Appendix B-compliant QA Program	Commercial Grade Dedication
Original equipment manufacturer / NSSS	Third party / Licensee
Access to original design requirements	Does not have access to original design requirements
Knows what design requirements are important to ensure design functions can be performed	A failure modes and effects or other analysis is needed to postulate critical characteristics
Is verifying important design requirements using Appendix B QA program controls	Might need to use reverse engineering techniques to determine acceptance criteria/tolerances
Uses Appendix B controls to ensure materials and parts used meet the original design requirements (drawings, specifications, etc.)	Does not use Appendix B controls to ensure materials and parts used meet the original design requirements (drawings, specifications, etc.)



## Evolution of Acceptance Methodologies

1970	1980	1990	2000	2010	2015
Traditional Application of Appendix B		Commercial Grade Dedication		Integrated Approach	
<p>When the accepting entity has access to and sufficient knowledge of the design requirements, they can accept the item by ensuring (through the use of quality activities included in 10CFR50, Appendix B – with no dedication at all) that the item they are accepting for use/designating as a basic component meets the design requirements.</p> <p>This is the way all basic components were provided to our plants prior to 1979. (The way suppliers did things before dedication existed)</p>		<p>When the accepting entity does not have access to and sufficient knowledge of the design requirements, the accepting entity does not have adequate information necessary to establish that the item meets design requirements using <i>traditional</i> quality activities included in 10CFR50, Appendix B. Therefore, they must use dedication as an alternative means of acceptance. Lacking design information, the accepting entity postulates critical characteristics and acceptance criteria based upon safety functions. (this is the way licensees accepted items provided by suppliers that no longer maintained their 10CFR50, Appendix B QA programs)</p>		<p>The accepting entity has access to and sufficient knowledge of the design requirements. However, instead of accepting the item by ensuring the item meets design requirements through the use of <i>traditional</i> quality activities included in 10CFR50 Appendix B, dedication methodology is used to accept the item.</p>	

## Options for Providing a Basic Component

Access to and Sufficient Knowledge of Design Information		Limited or No Access to Design Information
Traditional Application of Appendix B	Integrated Approach	Commercial Grade Dedication
<p>When the accepting entity has access to and sufficient knowledge of the design requirements, they can accept the item by ensuring (through the use of <i>traditional</i> quality activities included in 10CFR50, Appendix B – with no dedication at all) that the item they are accepting for use/designating as a basic component meets the design requirements. This is the way all basic components were provided to our plants prior to 1979 (the way suppliers and licensees accepted items before “dedication” existed).</p>	<p>The accepting entity has access to and sufficient knowledge of the design requirements. However, instead of accepting the item by ensuring the item meets design requirements through the use of <i>traditional</i> quality activities included in 10CFR50 Appendix B, dedication methodology is used to accept the item.</p> <ol style="list-style-type: none"> <li>1) The dedicating entity uses commercial grade dedication to ensure that the item meets design requirements by documenting the design requirements as the critical characteristics in a technical evaluation which does not require identification of safety function(s).</li> <li>2) In lieu of using design requirements as critical characteristics, the dedicating entity identifies critical characteristics based upon identifying safety function(s) and performing a failure modes and effects analysis (FMEA).</li> </ol>	<p>When the accepting entity does not have access to and sufficient knowledge of the design requirements, the accepting entity does not have adequate information necessary to establish that the item meets design requirements using <i>traditional</i> quality activities included in a 10CFR50, Appendix B QA program. Therefore, they must use dedication as an alternative means of acceptance. Lacking design information, the accepting entity postulates critical characteristics and acceptance criteria based upon safety functions. (this is the way licensees accepted items provided by suppliers that no longer maintained their 10CFR50, Appendix B QA programs)</p>

## Precautions / Considerations

Access to and Sufficient Knowledge of Design Information		Limited or No Access to Design Information
Traditional Application of Appendix B	Integrated Approach	Commercial Grade Dedication
	<p>1) The dedicating entity uses commercial grade dedication to ensure that the item meets design requirements by documenting the design requirements as critical characteristics in a technical evaluation that does not require identification of safety function(s).</p> <p><i>Precautions:</i></p> <ul style="list-style-type: none"> <li>a. Confusion may occur because dedication is typically based on safety function as it was originally intended for use when design information is not available. As a result, assessors may ask the dedicating entity to identify safety function even though this information is not required because the dedicating entity is using dedication to ensure the item meets the design requirements – not to ensure it will perform a specific safety function.</li> </ul> <p>2) In lieu of using the design requirements as critical characteristics, the dedicating entity identifies critical characteristics based upon identifying safety function(s) and performing a failure modes and effects analysis (FMEA).</p> <p><i>Precautions:</i></p> <ul style="list-style-type: none"> <li>a. Supplier reduces their focus on the item's ability to meet the original design requirements approved by the licensee for use during construction.</li> <li>b. Supplier may need to ask their customer to provide plant safety function information in order to dedicate the item - even though the supplier may not have the knowledge necessary to understand plant safety functions.</li> <li>c. Reduced focus on design can result in unintentional incremental design changes.</li> <li>d. Suppliers may perceive this option as an opportunity to forgo verification of certain design requirements.</li> </ul>	<p>The accepting entity postulates critical characteristics and acceptance criteria based upon the item's safety functions and accepts the item for use upon successful completion of acceptance activities.</p> <p><i>Precautions:</i></p> <ul style="list-style-type: none"> <li>a. It is important to remember that entities lacking design experience with the type of item in question may need to perform research in order to develop appropriate critical characteristics and acceptance criteria to address failure modes that may not be readily apparent. Documentation in the technical evaluation should explain the relationship between the critical characteristics selected and the associated safety functions and failure modes.</li> </ul>

# Important take-away thoughts

- Key elements for implementing 10CFR50 Appendix B controls to accept commercial items for use as a basic component
  - Possess the design requirements for the commercial item? (e.g., drawings, BOM, qualification reports, functional/operability requirements, material specification requirements, etc.)
  - Documented controls in place to verify the applicable design requirements? (e.g., inspection/test procedures specific to the commercial item requiring verification of the applicable design requirements.)
  - Objective evidence demonstrating applicable design requirements have been adequately verified?
  
- Examples:
  - Commercial Round Bar for generic use – Procedure requiring verification of size and applicable material specification requirements – physical **and** chemical properties required by the specification
  - Spring used in valve actuator. Actuator manufacturer's drawing specifies "steel," spring constant, maximum coil OD dimension, number of coils and associated tolerances.
    - What should be verified?

## Important take-away thoughts

- Both approaches are legitimate
  - Control (design and manufacture) under Appendix B
  - Commercial grade dedication
- Suppliers can provide commercially procured items as basic components in accordance with the requirements of 10CFR50, Appendix B without performing any commercial grade dedication
- 10CFR50, Appendix B controls are effective. In fact, Criterion VII is the basis for the 4 commercial grade dedication methods

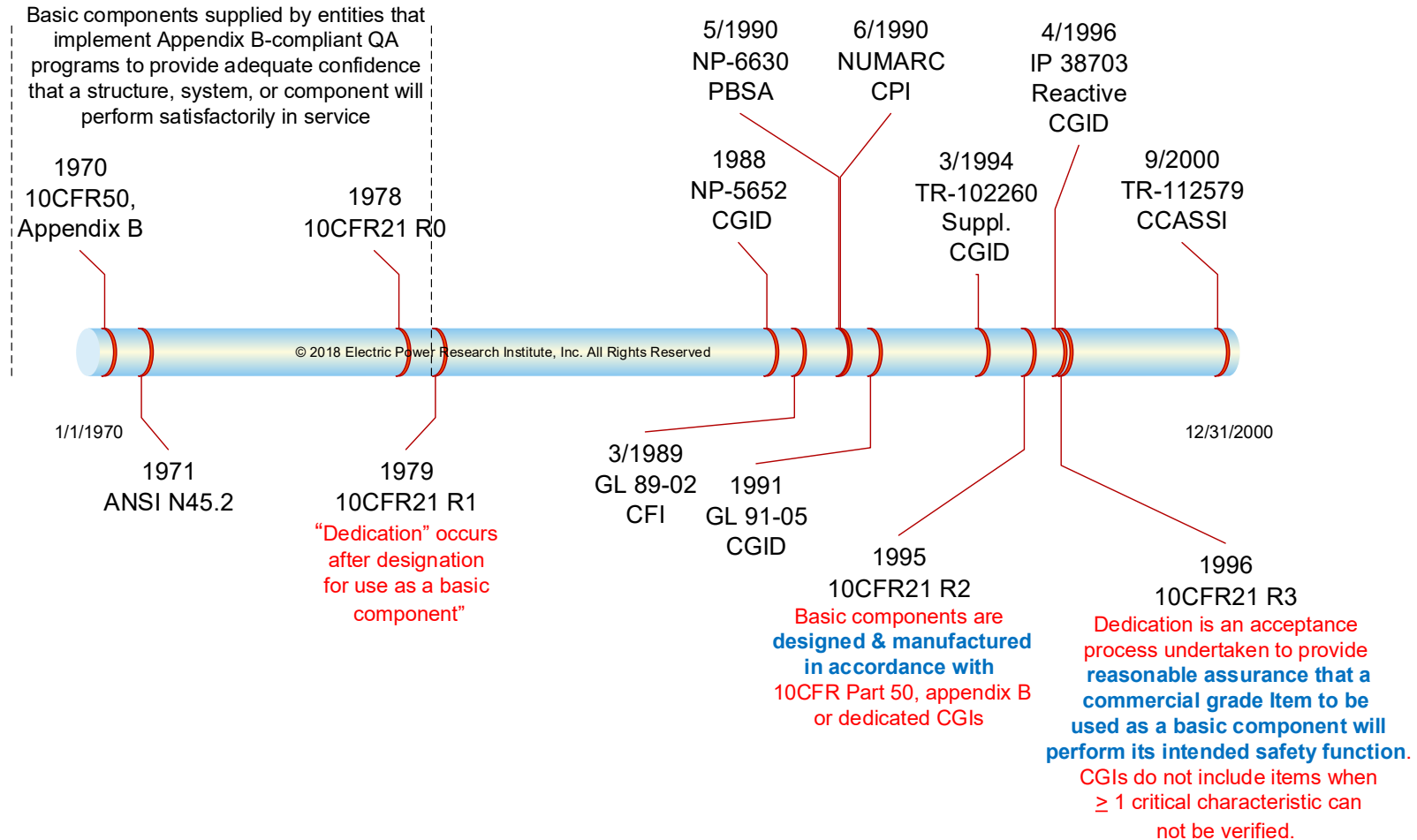
## Important take-away thoughts

- If done correctly, the acceptance activities should be similar
- Focus should be on assuring the right controls are implemented to provide adequate confidence that a structure, system, or component will perform satisfactorily in service or provide reasonable assurance the commercially-manufactured item conforms to its design, and will perform as designed once installed in the customer's safety-related application




# Together...Shaping the Future of Electricity

# Dedication has evolved, Appendix B is the same



# The primary difference . . . is origin of acceptance criteria

Without CGID	Quality Control Factor	With CGID
Original equipment manufacturer or supplier	Entity accepting item as a basic component	Licensee that uses the equipment in their plant or other entity
Design & manufacturing drawings Manufacturing methods Product history and evolution Product user base experience Engineers that designed products Design validation & qualification	Source of product function and design knowledge	Plant equipment specifications Supplier-provided outline drawings Bills of material on drawings Technical manuals Industry operating experience Equipment qualification reports
The actual acceptance criteria included in the product design used to fabricate the product 	Source of acceptance criteria	Design information and standards (if available) Determination of characteristics necessary to support safety function, and to prevent failure Reverse engineering techniques
Product design, performance history, deep product knowledge	Acceptance criteria is based upon	Plant function, FMEA, available information on product