

Controlling a Commercial Item Under a Quality Assurance Program Complying with 10CFR50, Appendix B

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Why was the dedication option developed?

- Suppliers were discontinuing 10CFR50, Appendix B QA programs
- Counterfeit and fraudulent items were being identified
- Suppliers would not provide licensees with “proprietary” design and acceptance criteria
- Licensees needed method to develop acceptance criteria to accept items (purchased from commercial suppliers) as basic components

Dedication was developed as an *alternative* acceptance method

Commercial Grade Dedication is

- NOT meant to replace 10CFR50, Appendix B controls for acceptance of items to be used as, or to fabricate, basic components
- NOT meant to be a shortcut
- NOT meant to be the only way to accept items

Has increased industry dependence on the alternative commercial-grade dedication method resulted in loss of proficiency in implementing the basic quality assurance criteria included in 10CFR50, Appendix B?

Why is dedication an acceptable approach?

- The definition of “basic component” in 10CFR21 says:
 - i(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.
- 10CFR50 Appendix B came before 10CFR21
 - 10CFR50 Appendix B provides the quality program elements necessary to design and manufacture (control) a basic component

What does “design and manufacture” mean?

What does “designed and manufactured” under an Appendix B-compliant Quality Assurance (QA) program mean?

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

Getting to “basic component” without dedication is the original option, and is the topic of today’s discussion

How is an item controlled using an Appendix B-compliant QA program? (the traditional approach)

- Acceptance of the item is based on QA activities conducted to support the 18 criteria in 10CFR50, Appendix B
 - The supplier implements QA activities to control the approved design and to ensure that the item being manufactured meets the design requirements.
 - Documented controls (such as procedures and work instructions) detail the verifications, inspections, personnel qualifications, and other activities necessary throughout the production to ensure that the item is manufactured to meet the design requirements.
 - Implementation of these controls provides the supplier with objective evidence that the item meets all of the design requirements.
 - Sufficient objective evidence must exist to establish that the basic component conforms to the design
 - The objective evidence is not necessarily documented in the form of a commercial-grade item dedication technical evaluation and acceptance plan.

Two Primary Frames of Reference for a Quality Program

LICENSEE

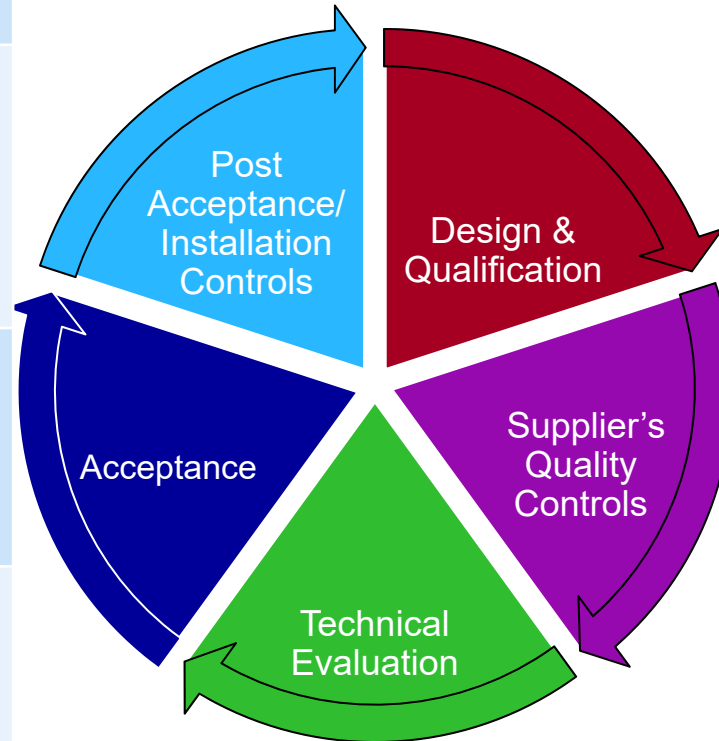
- Assure quality of the plant
- Build meets the design
- Design is controlled
 - Design, establish suitability of design, and control design of the plant
 - Operate the plant
 - Maintain the plant
 - Control modification of the plant
 - Purchase spare and replacement items needed to support operation and maintenance

SUPPLIER

- Assure quality of the products
- Products meet design specification
- Design is controlled
 - Design, establish suitability of design, and control design of products
 - Manufacture products
 - Control changes to products
 - Purchase raw materials and parts needed to manufacture products

Providing adequate confidence of item performance

Licensee
<ul style="list-style-type: none"> • Select <i>suitable structures, systems and components</i> • Verify adequacy of design
<ul style="list-style-type: none"> • Include applicable requirements in procurement documents • Establish measures to ensure purchased items conform to procurement documents
<ul style="list-style-type: none"> • Translate regulatory and design basis for SSCs into documents • Include or reference applicable requirements & design bases in procurement documents
<ul style="list-style-type: none"> • Establish measures to assure that purchased material, equipment, and conform to the procurement documents
<ul style="list-style-type: none"> • Identification and control Handling, storage, shipping • Inspection, Test, and Operating Status • Corrective Action



Supplier
<ul style="list-style-type: none"> • Select <i>suitable components materials & parts</i> • Verify adequacy of design
<ul style="list-style-type: none"> • Include applicable requirements in procurement documents • Establish measures to ensure purchased items conform to procurement documents
<ul style="list-style-type: none"> • Translate regulatory and design basis for <i>components</i> into documents • Include or reference applicable requirements & design bases in procurement documents
<ul style="list-style-type: none"> • Establish measures to assure that purchased material, equipment, and conform to the procurement documents
<ul style="list-style-type: none"> • Identification and control Handling, storage, shipping • Inspection, Test, and Operating Status • Corrective Action

Traditional procurement quality activities

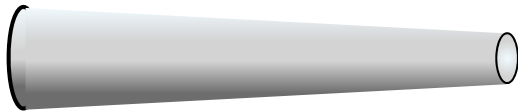
Licensee	10CFR50, Appendix B	NQA-1-2019
<ul style="list-style-type: none"> • Select materials, parts and equipment that meet the design • Translate regulatory and design basis requirements for SSCs into specifications, drawings, procedures, and instructions 	Criterion III	Requirement 3
<ul style="list-style-type: none"> • Include or reference applicable requirements & design bases in procurement documents 	Criterion IV	Requirement 4
<ul style="list-style-type: none"> • Evaluate supplier's capability to provide items that meet the procurement specifications/requirements • Establish measures to assure that purchased material, equipment, and conform to the procurement documents 	Criterion VII	Requirement 7
<ul style="list-style-type: none"> • Identify and control materials, parts and components • Establish measures to control handling, storage, shipping • Establish measures to identify items which have satisfactorily passed required inspections and tests • Assure that conditions adverse to quality are promptly identified and corrected 	Criterion VIII Criterion XIII Criterion XIV Criterion XVI	Requirements 8 Requirement 13 Requirement 14 Requirement 16

Programmatic Support for quality activities

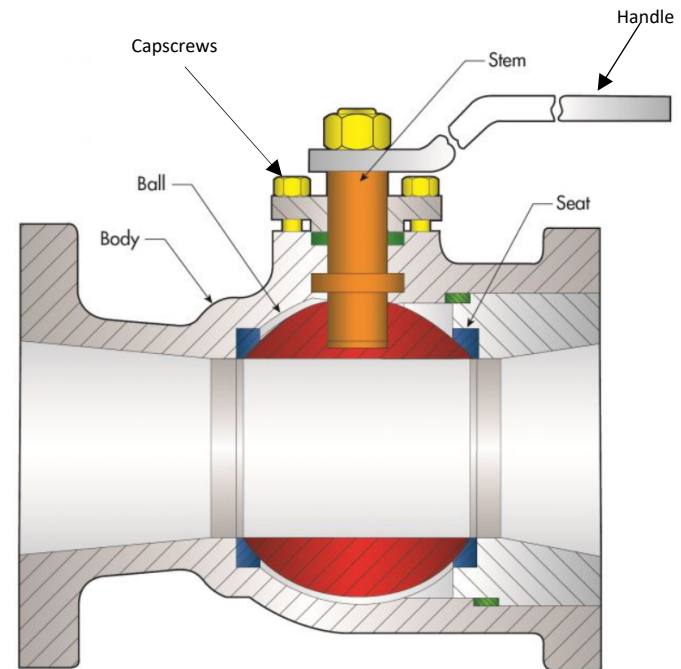
Quality Infrastructure	10CFR50, Appendix B	NQA-1-2019
Organization	Criterion I	Requirement 1
QA Program	Criterion II	Requirement 2
Instructions, Procedures and Drawings	Criterion V	Requirement 5
Document Control	Criterion VI	Requirement 6
Control of Special Processes	Criterion IX	Requirement 9
Inspection	Criterion X	Requirement 10
Test Control	Criterion XI	Requirement 11
Control of Measuring and Test Equipment	Criterion XII	Requirement 12
Control of Nonconforming Items	Criterion XV	Requirement 15
Quality Assurance Records	Criterion XVII	Requirement 17
Audits	Criterion XVIII	Requirement 18

Using Appendix B quality activities to accept a commercial item as a basic component without dedication

- Let's look at a few examples



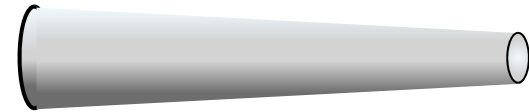
Taper Pin



Ball Valve

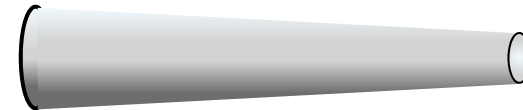
Control a purchased taper pin essential for specified function

- Review **existing design** to determine the requirements
 - Material specification or material properties?
 - Dimensions and tolerances?
 - Are there any other requirements (class, protective finish?)



Control a purchased taper pin essential for specified function

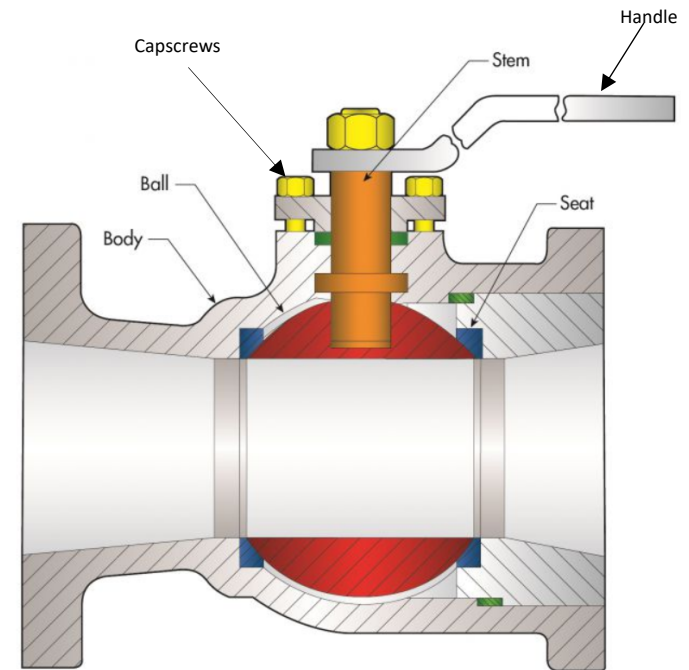
- Develop acceptance measures that demonstrate **design requirements** are met



Design Attribute	Design Requirement	Acceptance Criteria	Acceptance Measure	10CFR50, Appendix B Controls that might be used	NQA-1 Requirement
Material	AISI 1212	Material meets AISI 1212	Verification of chemical and physical properties included in AISI 1212. Destructive testing and sampling may be required	Calibrated M&TE Testing procedure Personnel Qualifications Procurement document control Supplier qualification	12 7, 11 2, 11 4 7
Dimensions	Length, Major Diameter, End Crown	Dimensions for ANSI B18.8.2 No. 3 taper pin	Micrometer	Calibrated M&TE Inspection procedure Personnel Qualifications	12 7, 10 2, 10
Protective Finish	Zinc Plated	Plating material is Zinc	Verification of plating material	Procurement document control Supplier qualification (outside lab)	4 7

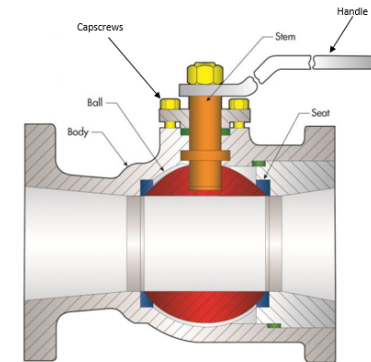
Control items procured for a Ball Valve

- Barstock (for body, ball, stem)
- A-193, B7 capscrews
- Handle (prefabricated metal with rubber grip)
- Seat (prefabricated elastomer)



Control bar stock to machine valve body – essential to function

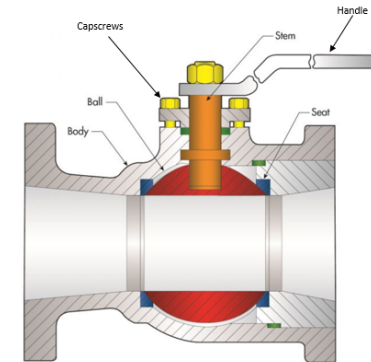
- Develop acceptance measures based on design that demonstrate the design requirements are met



Design Attribute	Design Requirement	Acceptance Criteria	Acceptance Measure	10CFR50, Appendix B Controls that might be used	NQA-1 Requirement
Material	ASTM A 479	Material meets ASTM A 479	Verification of chemical and physical properties included ASTM A 479 Destructive testing and sampling may be required	Calibrated M&TE Testing procedure Personnel Qualifications Procurement document control Supplier qualification	12 7, 11 2, 11 4 7
Dimensions	Thickness	Dimensions meet procurement description	Calipers	Calibrated M&TE Inspection procedure Personnel Qualifications	12 7, 10 2, 10

Control ball valve seat – essential to function

- Develop acceptance measures based on design that demonstrate the design requirements are met



Design Attribute	Design Requirement	Acceptance Criteria	Acceptance Measure	10CFR50, Appendix B Controls that might be used	NQA-1 Requirement
Material	EPDM	Material is EPDM	Verification of material composition using Fourier transfer infra-red photo spectroscopy	Calibrated M&TE Testing procedure Personnel Qualifications Procurement document control Supplier qualification	12 7, 11 2, 11 4 7
Dimensions	Thickness Diameters Other custom dimensions (radial cut)	Dimensions meet procurement description/seat design drawing	Calipers	Calibrated M&TE Inspection procedure Personnel Qualifications	12 7, 10 2, 10

Key Take-Aways

- 10CFR50, Appendix B can be used to control a commercially procured item and establish it as a basic component *that meets design requirements* without dedication
- Prerequisites:
 - Must have original design information (OEM or access to design information)
 - All applicable design requirements (e.g., dimensions, material properties, etc.) must be verified for the commercial item
 - A documented engineering evaluation may be performed to provide the basis for verification of only certain design requirements
 - Procedures for verification activities
 - Inspection/test activities verify design requirements are met
 - Qualified personnel
 - Documentation of quality activities performed



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