Introduction to 3002002982, Updated Commercial Grade Item Dedication Guidance

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Why was the guidance updated?

What has changed

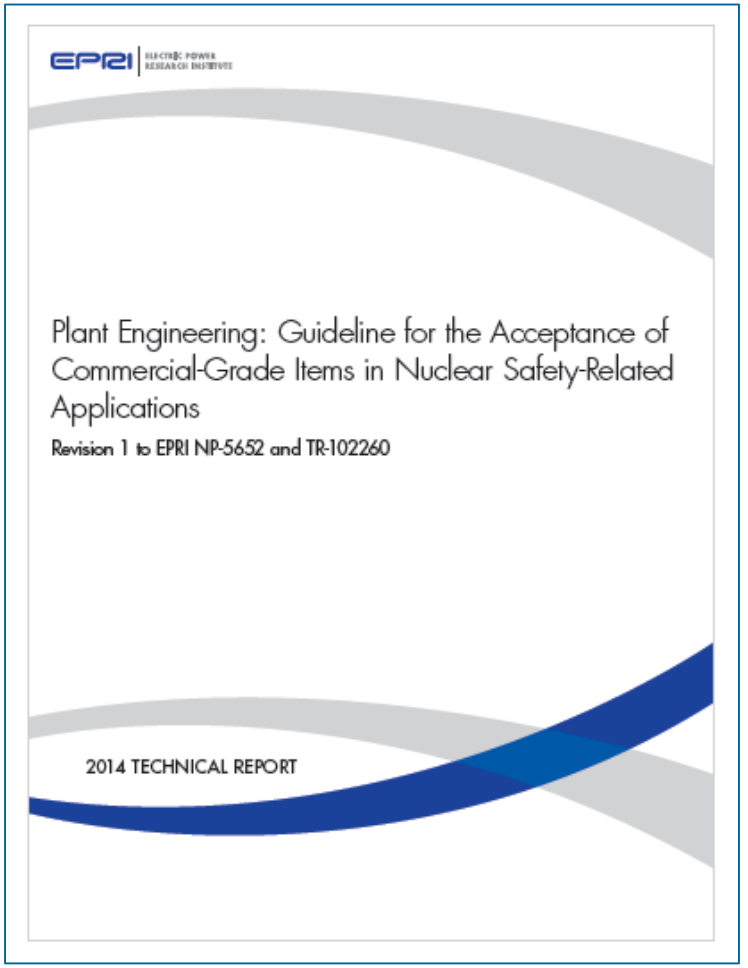
- Dedication is no longer used only as a last-resort
- Suppliers started to use dedication
- Devices being dedicated are more complex
- Additional EPRI guidance has been written over the years on related topics
- Other organizations have published guidance and requirements
- NRC published inspection procedures

What has ***not*** changed?

- Intent 10CFR, Part 21 (subsequent to a revision in 1995)
- Requirements
- Expectations
- Intent of EPRI dedication process
  - *Provide reasonable assurance the item being dedicated is capable of performing its safety-related function(s)*

Revision to EPRI Dedication Guidance

- 3002002982
  - Supersedes NP-5652 and TR-102260
- References other associated documents
  - Computer Program Dedication
    - 3002002289 (12/2013)
  - Use of sampling in dedication
    - TR-017218-R1 (01/1999)
  - Acceptance of digital devices
    - TR-106439 (11/1996)
    - TR-107339 (12/1997)
    - 1009659 (3/2005)
    - 1001452 (9/2001)
  - Accepting Calibration and Laboratory Services
    - NEI 14-05A

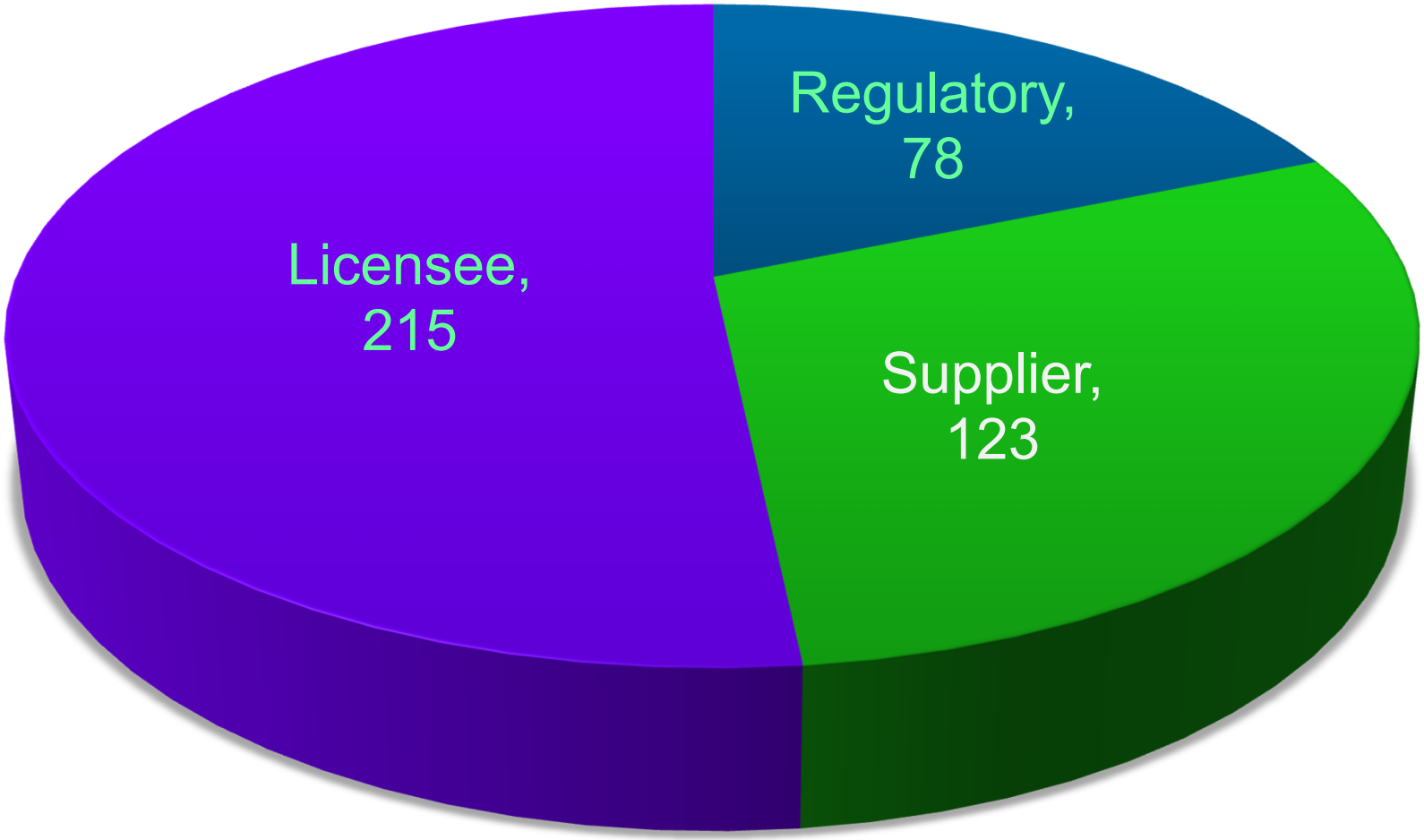


Diverse Technical Team Developed the Guidance

Development Team

Preview Team

416 years of dedication experience on the guidance revision team



Updates linked to the 1995 revision to 10CFR21

Legacy	Update
Critical Characteristics for Acceptance	Critical Characteristics
Critical Characteristics for Design	Design Characteristics
Identifiable and measurable characteristics	Characteristics necessary to perform safety function
No use of failure mode and effects analysis in the dedication process	failure modes and effects analysis (FMEA) is an effective tool to determine critical characteristics when complete design information is not available

Discussion related to the Supplier's Perspective

- Discussion related to the two paths a supplier can use to provide a basic component
  - Control in accordance with a 10CFR50, Appendix B-compliant QA program *without* dedication
  - Control in accordance with a 10CFR50, Appendix B-compliant QA program *with* dedication
- Difference between establishing specification compliance and dedication
- Options for dedication when the dedicating entity has design information and knowledge
- Focus on documenting engineering decisions

Discussion related to the Supplier's Perspective

- Unqualified source material upgraded via ASME NCA-3855.5
  - Does *NOT* require dedication
  - Satisfies 10CFR50, appendix B through meeting ASME & Material Specification Requirements

- Clarification that product identification attributes are not necessarily "critical characteristics" as defined in 10CFR, Part 21
  - However, product identification attributes such as part and model number, nameplate data, and so forth are important and should always be verified as part of the receipt inspection process.

Discussion related to identified problem areas

- Concept of dedication “at the level of supply”

- Clarification that a completed and accepted design (including seismic and environmental qualification) is required prior to beginning the commercial grade dedication process

- “Dedication” is not the same as “qualification”
  - The difference between *qualification* and *dedication*
  - *Qualification* must be maintained during the dedication process

Discussion related to identified problem areas

- Services – Calibration example
  - Use of ILAC accreditation in lieu of commercial grade survey
  - *NOT* in lieu of commercial grade dedication

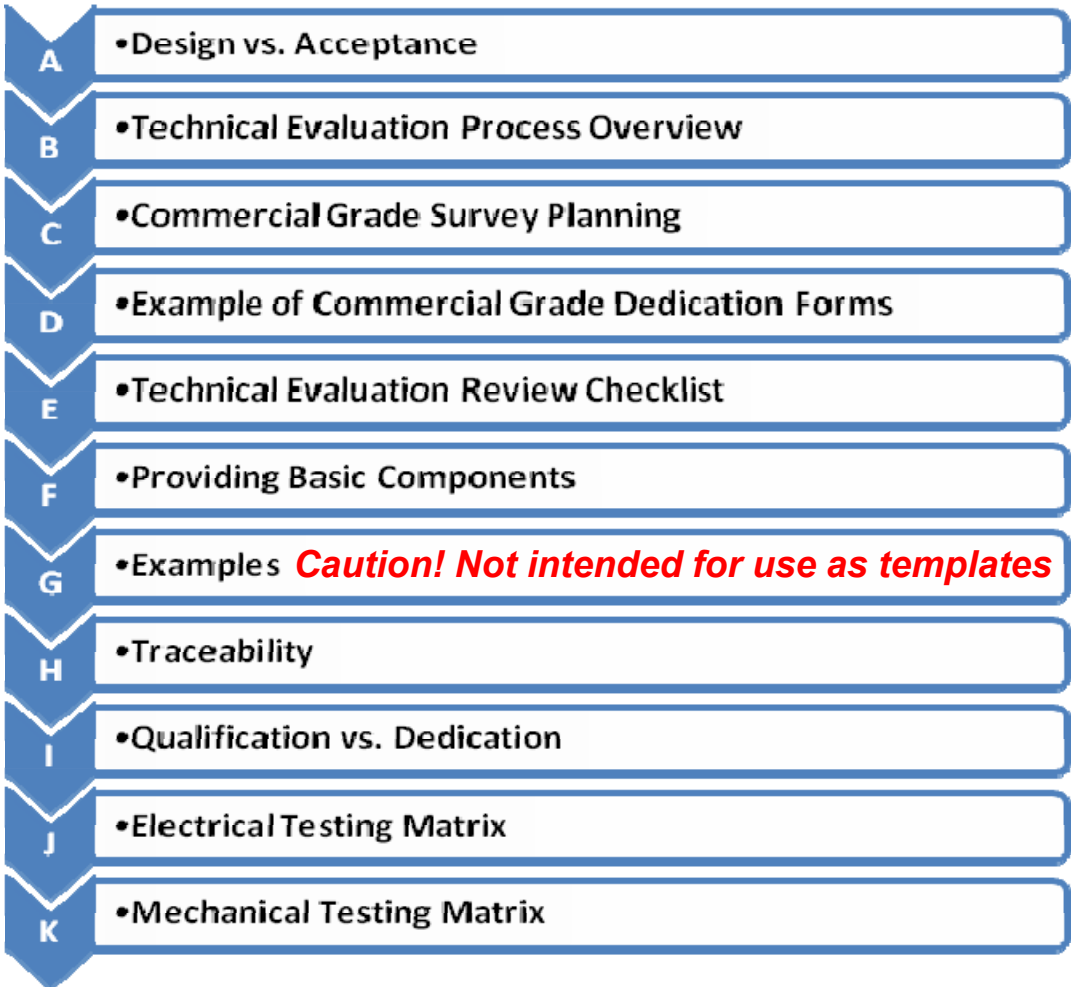
- Commercial-grade survey versus audit – Survey involves:
  - Use of Critical Characteristics (CCs)
  - Link between CC's and supplier's controls
  - Appropriate technical, quality, and certification requirements in the purchase order
    - Includes specifying the supplier's controls accepted via the survey and requesting certification that the controls were applied

- References to applicable content in ASME NQA-1 (in addition to ANSI N42.2-1978)

Contents:

1 •Background and Introduction
2 •Baseline Terminology
3 •Overview of Commercial Grade Dedication
4 •Generic Technical Evaluation & Acceptance Process
5 •Commercial Grade Dedication Process
6 •Critical Characteristics
7 •Method 1 - Special Tests and Inspections
8 •Method 2 – Commercial Grade Survey
9 •Method 3 – Source Verification
10 •Method 4 – Item/Supplier History
11 •Commercial Grade Services
12 •Use of Dedication to Accept Accredited Calibration Services
13 •Reasonable Assurance
14 •Digital Equipment and Computer Programs
15 •References and Bibliography

Appendices



Example Technical Evaluation Forms

Commercial Grade Item Dedication
Technical Evaluation

EPRI Joint Utility Task Group
Revision 0

Evaluation Number _____ Revision _____

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	
Identification Number	Visual	

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)

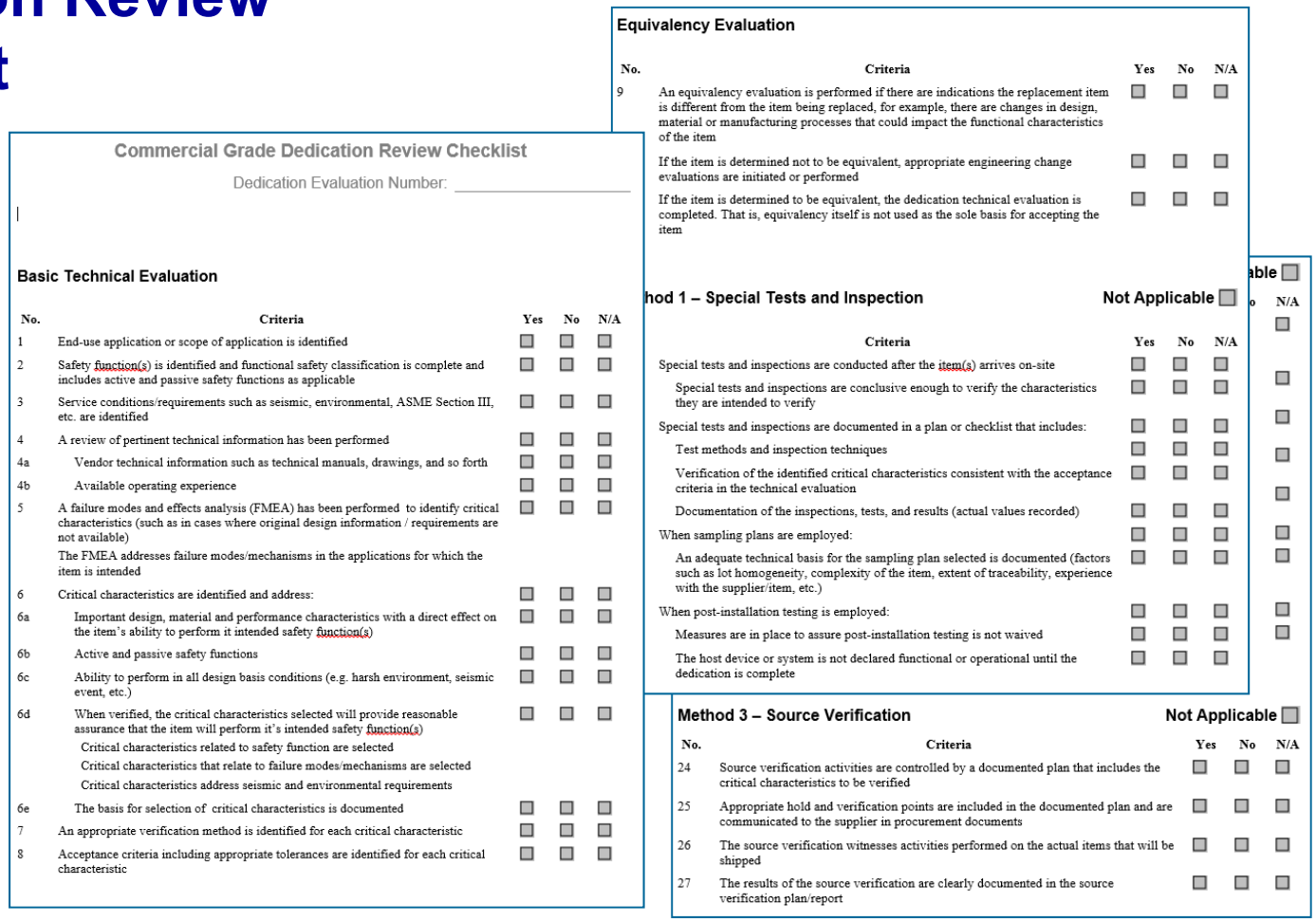
DESCRIPTION OF SAMPLING PLANS (if "see below" is selected in the sampling plan column above)

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

Basis for selection of Critical Characteristics

Report Appendix D

Dedication Technical Evaluation Review Checklist



Commercial Grade Dedication Review Checklist

Dedication Evaluation Number: _____

Basic Technical Evaluation

No.	Criteria	Yes	No	N/A
1	End-use application or scope of application is identified	☐	☐	☐
2	Safety function(s) is identified and functional safety classification is complete and includes active and passive safety functions as applicable	☐	☐	☐
3	Service conditions/requirements such as seismic, environmental, ASME Section III, etc. are identified	☐	☐	☐
4	A review of pertinent technical information has been performed	☐	☐	☐
4a	Vendor technical information such as technical manuals, drawings, and so forth	☐	☐	☐
4b	Available operating experience	☐	☐	☐
5	A failure modes and effects analysis (FMEA) has been performed to identify critical characteristics (such as in cases where original design information / requirements are not available) The FMEA addresses failure modes/mechanisms in the applications for which the item is intended	☐	☐	☐
6	Critical characteristics are identified and address:	☐	☐	☐
6a	Important design, material and performance characteristics with a direct effect on the item's ability to perform it intended safety function(s)	☐	☐	☐
6b	Active and passive safety functions	☐	☐	☐
6c	Ability to perform in all design basis conditions (e.g. harsh environment, seismic event, etc.)	☐	☐	☐
6d	When verified, the critical characteristics selected will provide reasonable assurance that the item will perform it's intended safety function(s) Critical characteristics related to safety function are selected Critical characteristics that relate to failure modes/mechanisms are selected Critical characteristics address seismic and environmental requirements	☐	☐	☐
6e	The basis for selection of critical characteristics is documented	☐	☐	☐
7	An appropriate verification method is identified for each critical characteristic	☐	☐	☐
8	Acceptance criteria including appropriate tolerances are identified for each critical characteristic	☐	☐	☐

Equivalency Evaluation

No.	Criteria	Yes	No	N/A
9	An equivalency evaluation is performed if there are indications the replacement item is different from the item being replaced, for example, there are changes in design, material or manufacturing processes that could impact the functional characteristics of the item	☐	☐	☐
	If the item is determined not to be equivalent, appropriate engineering change evaluations are initiated or performed	☐	☐	☐
	If the item is determined to be equivalent, the dedication technical evaluation is completed. That is, equivalency itself is not used as the sole basis for accepting the item	☐	☐	☐

hod 1 – Special Tests and Inspection Not Applicable ☐

Criteria	Yes	No	N/A
Special tests and inspections are conducted after the item(s) arrives on-site	☐	☐	☐
Special tests and inspections are conclusive enough to verify the characteristics they are intended to verify	☐	☐	☐
Special tests and inspections are documented in a plan or checklist that includes:	☐	☐	☐
Test methods and inspection techniques	☐	☐	☐
Verification of the identified critical characteristics consistent with the acceptance criteria in the technical evaluation	☐	☐	☐
Documentation of the inspections, tests, and results (actual values recorded)	☐	☐	☐
When sampling plans are employed:	☐	☐	☐
An adequate technical basis for the sampling plan selected is documented (factors such as lot homogeneity, complexity of the item, extent of traceability, experience with the supplier/item, etc.)	☐	☐	☐
When post-installation testing is employed:	☐	☐	☐
Measures are in place to assure post-installation testing is not waived	☐	☐	☐
The host device or system is not declared functional or operational until the dedication is complete	☐	☐	☐

Method 3 – Source Verification Not Applicable ☐

No.	Criteria	Yes	No	N/A
24	Source verification activities are controlled by a documented plan that includes the critical characteristics to be verified	☐	☐	☐
25	Appropriate hold and verification points are included in the documented plan and are communicated to the supplier in procurement documents	☐	☐	☐
26	The source verification witnesses activities performed on the actual items that will be shipped	☐	☐	☐
27	The results of the source verification are clearly documented in the source verification plan/report	☐	☐	☐

Report Appendix E

Electrical & Mechanical Test Method Matrices

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

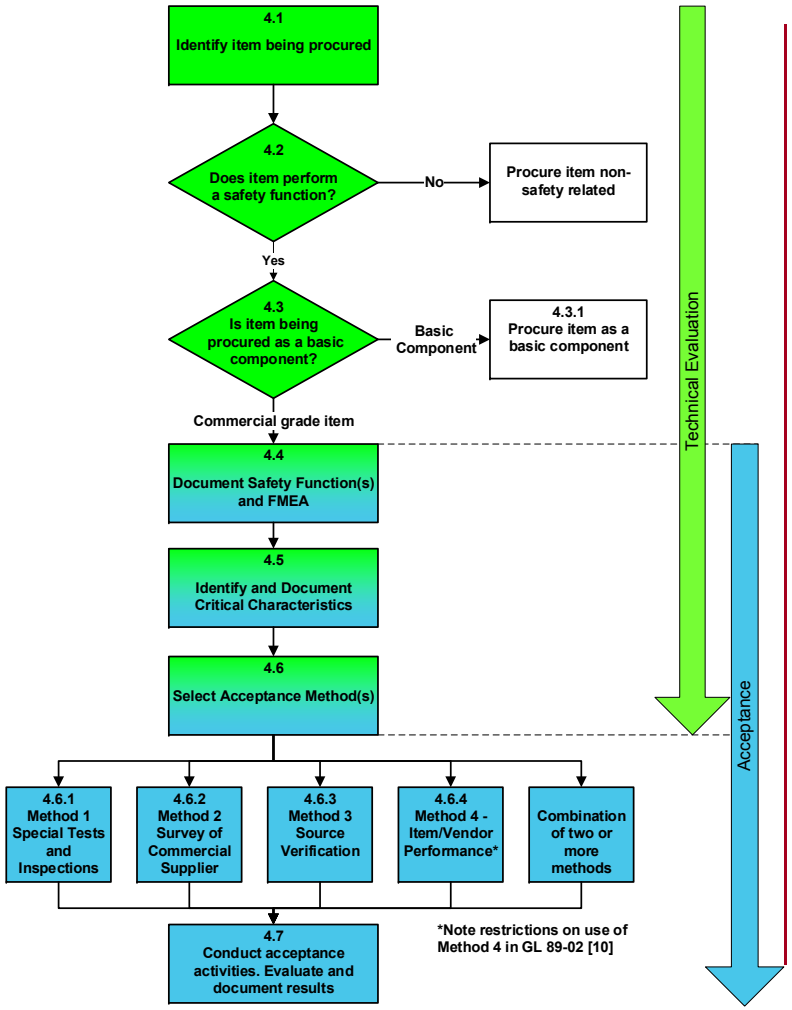
Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Chemical spot tests	Sorting of some alloys. Provides some indica of the material type, must be used in conjunction with othe or inspections to mak determination.	Can identify alloy groups but does not provide	Yes, because the surface is chemically attacked.	Use of a prepared kit with battery and dilute acids is
Positive material verification: X-ray fluorescence	Sorting of some alloy Semiquantitative che analysis of some ele and a search of its available internal allo library will produce a identification.			

Table J-1
Electrical test methods

Type of Item	Test Equipment Used	Typical Indication of Characteristics	Destructive to the Sample?	Notes
Fuse	Digital low-resistance ohmmeter Circuit breaker or relay test set (or any capable current source) Timing device	Fuse resistance (document lot homogeneity) Hold in Clearing per specifications	Yes, but only fuses selected for clearing	Circuit breaker or relay test set if available allows streamlined testing.
Capacitor	LCR meter Digital multimeter AC or dc power source Timing device	Capacitance and leakage current at rated working voltage per specifications.	No	Sometimes date codes are overlooked. Ensure that shelf life has not expired. May elect to reform based on age.
Resistor	Digital multimeter Power supply capable of supplying required voltage and current Digital low-resistance ohmmeter	Resistance value, power capacity	No	Post power capacity test is typically resistance verification and visual for heat damage.
Semiconductors	Curve tracer or Calibrated data acquisition equipment	Transistor: breakdown voltage, saturation voltage, cutoff current, current gain Diode: forward voltage at rated current, reverse leakage current, reverse breakdown voltage	No	Look for counterfeit items, especially if surplus suppliers are used for purchases. See the EPRI report *Counterfeit, Fraudulent, and Substandard Items* [28].

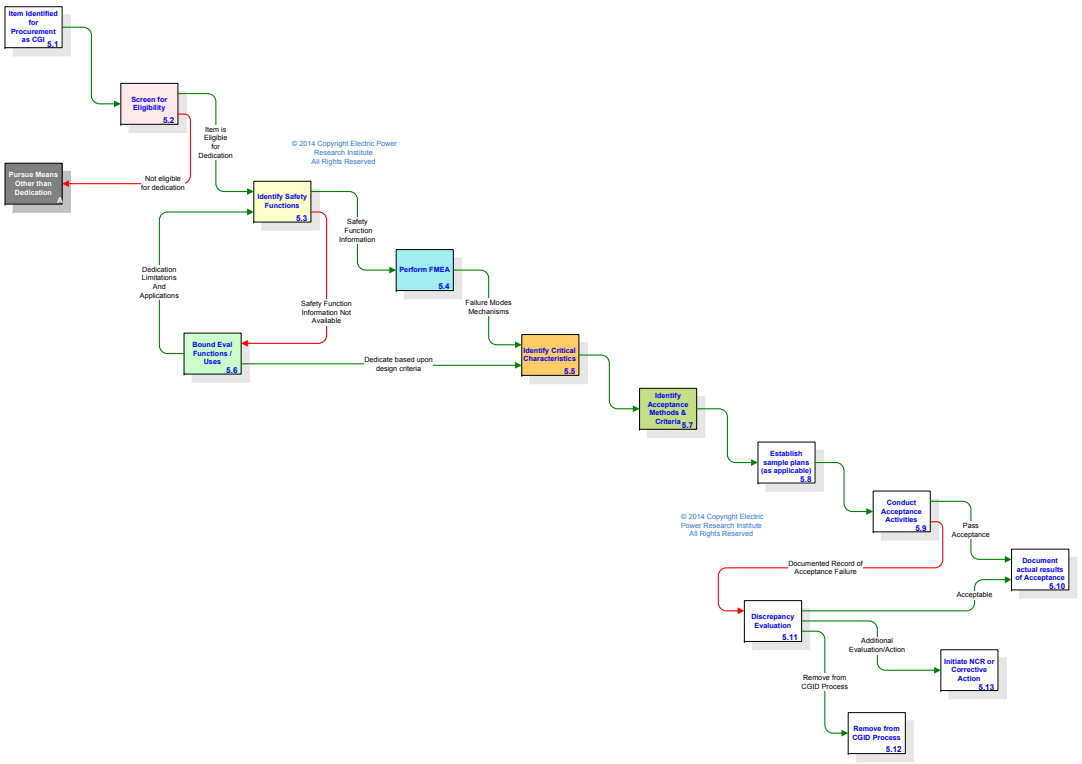
Report Pages J1-J2, K1-K20

Legacy Dedication Process



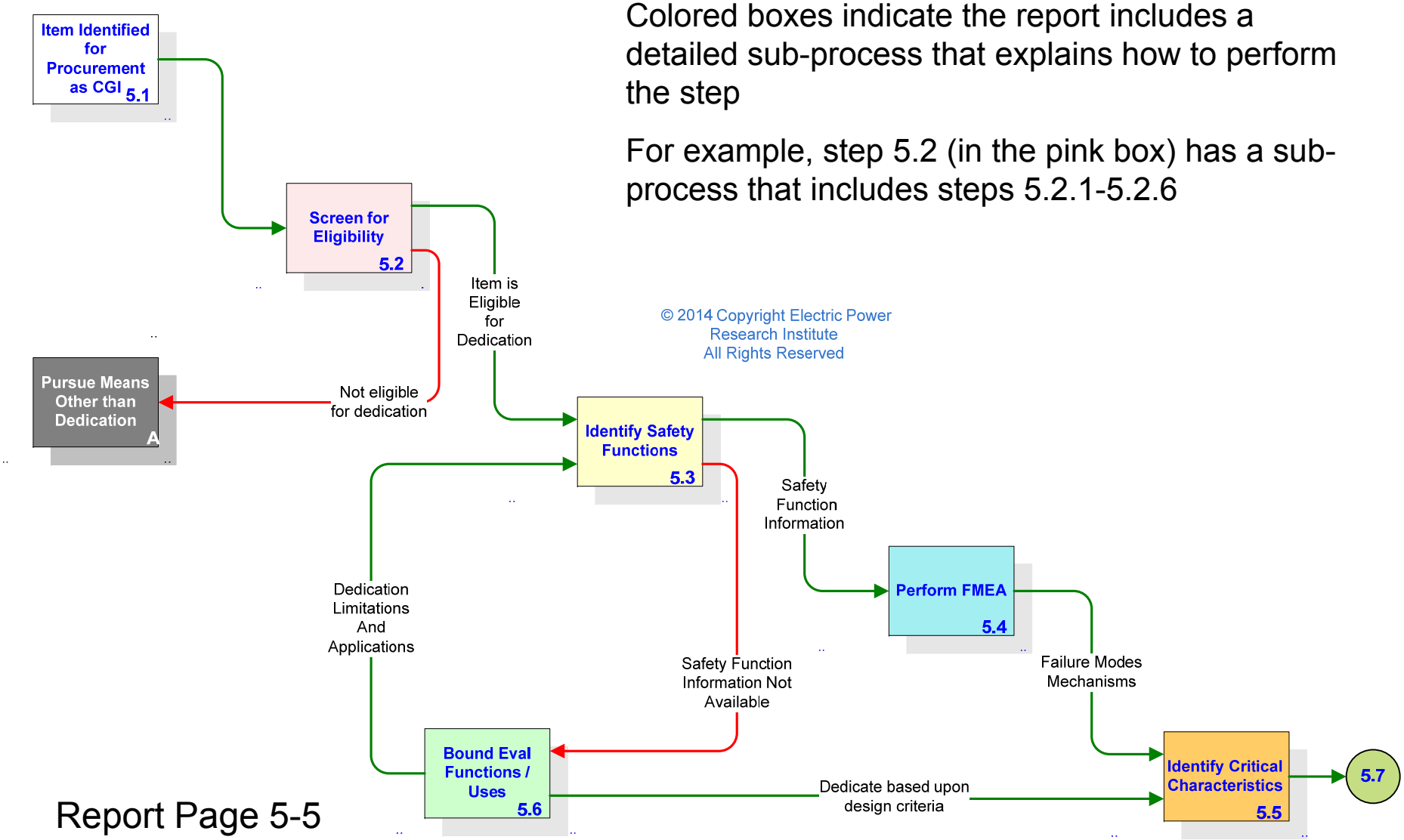
Report Page 4-2

Updated Dedication Process



Report Pages 5-5, 5-6

Detailed Basic Process – Steps 5.1-5.6

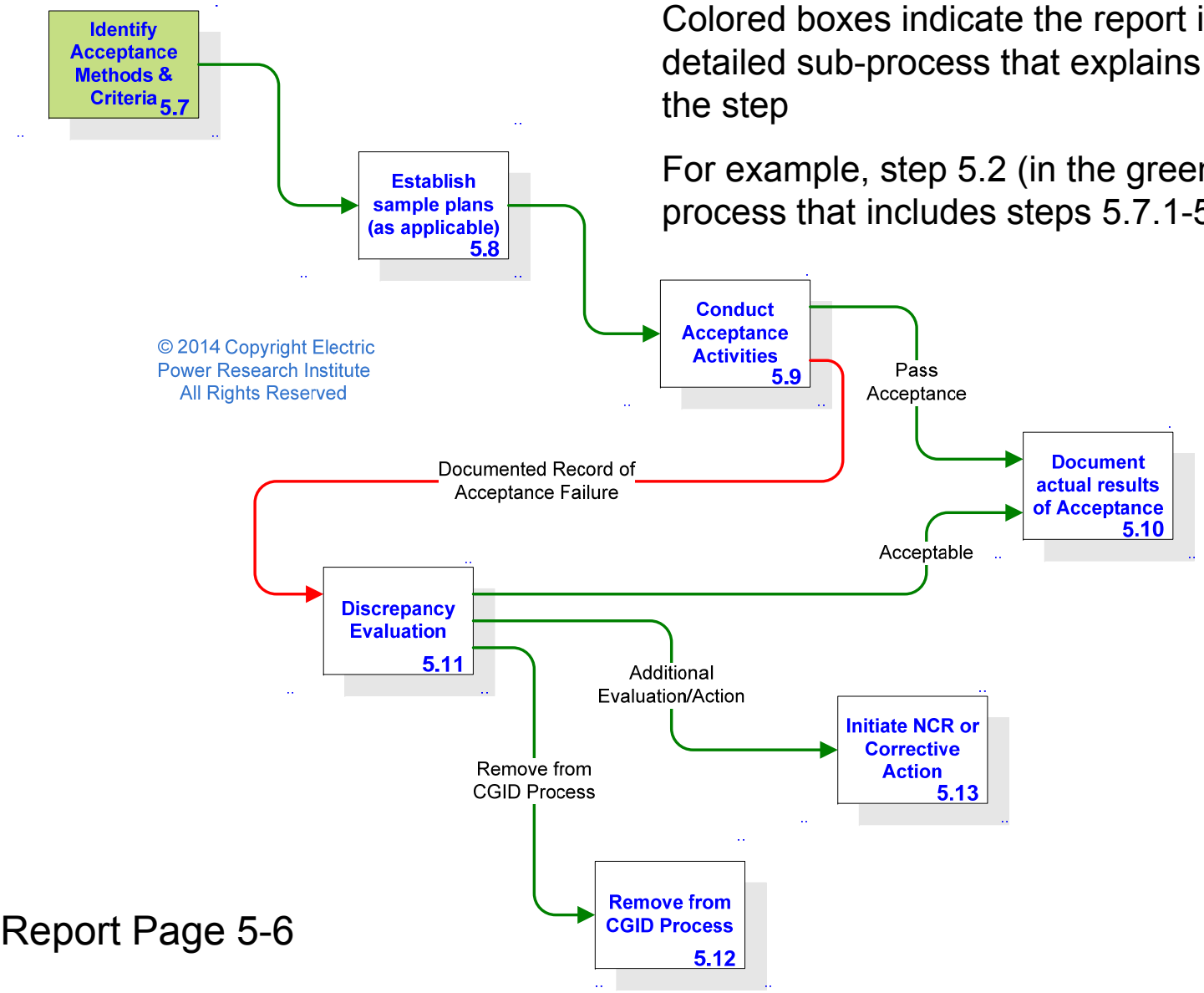


Colored boxes indicate the report includes a detailed sub-process that explains how to perform the step

For example, step 5.2 (in the pink box) has a sub-process that includes steps 5.2.1-5.2.6

Report Page 5-5

Detailed Basic Process – Steps 5.7-5.13



Colored boxes indicate the report includes a detailed sub-process that explains how to perform the step

For example, step 5.2 (in the green box) has a sub-process that includes steps 5.7.1-5.7.22

Report Page 5-6

Information included in Section 5 for each step:

Description

Methodology

Precautions and Lessons Learned

Step 5.6.1: Gather Original Requirements and Design Information

Description

In cases where the dedicating entity is not aware of the specific safety function(s) and end-use application(s) for the item or service being dedicated, the first step in developing a commercial-grade dedication plan is to gather the original requirements and/or design information.

Methodology

This step involves assembling original specifications, design information, and design requirements pertaining to the item or service being dedicated. Useful information includes the following:

- Original purchase orders and purchase specifications
- Operating plant/system design information relative to end-use applications
- Drawings and bills of materials provided with the original equipment
- Original manufacturing information and tolerances
- Original equipment design information
- For replacement items, other applicable information obtained from entities involved in the original procurement, such as the OEM, OES, NSSS, or licensee

Precautions/Lessons Learned

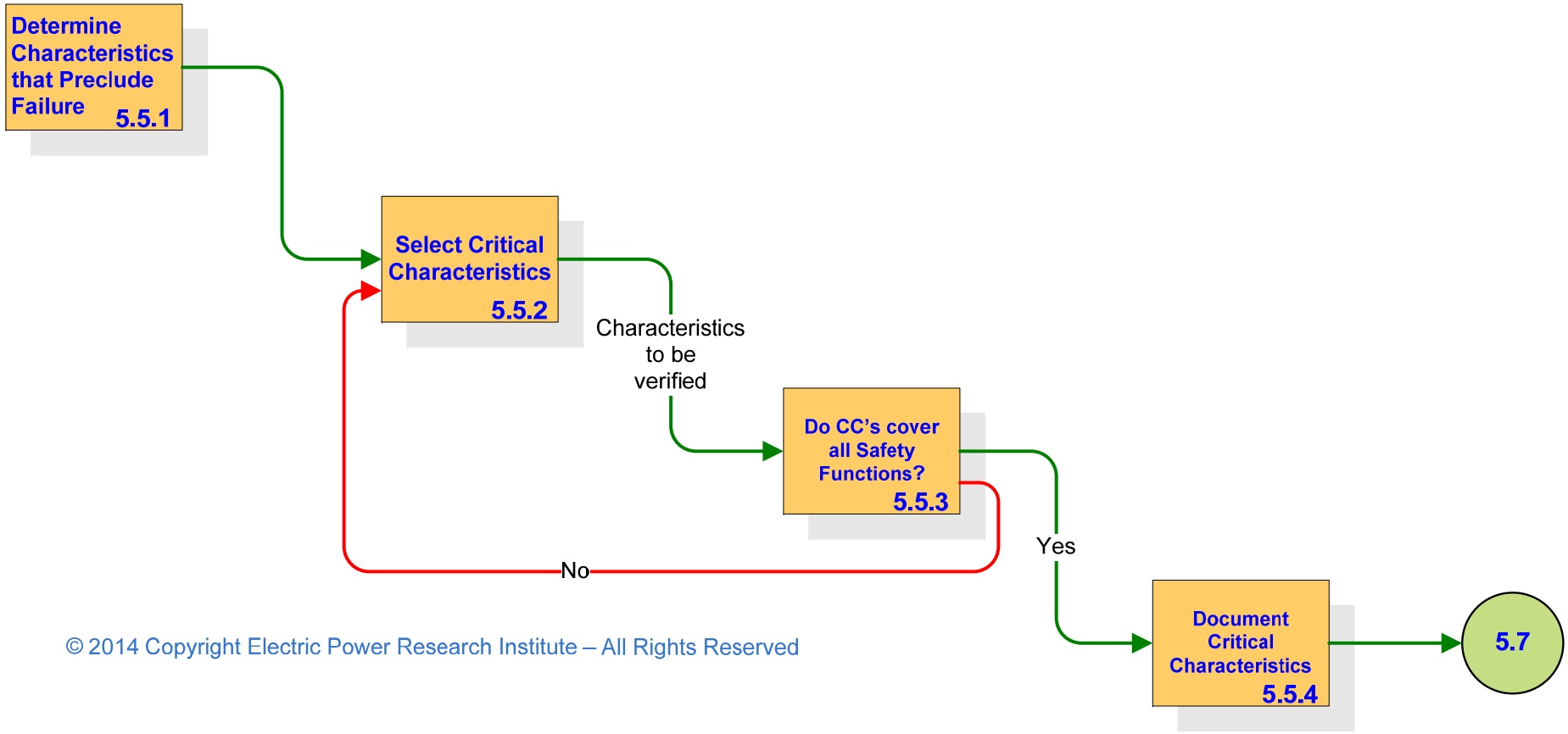
The best practice for organizations that are responsible for the original design of the item or service being procured is to accept the items based on verification of all applicable design requirements using QA activities conducted under a QA program meeting the requirements of 10CFR50, Appendix B [7]. However, it is possible to use original design information to develop critical characteristics for accepting a commercial-grade item using the dedication process.

Primary Process Step 5.5

Identify Critical Characteristics

5.5

Sub Process 5.5, Steps 5.5.1 – 5.5.4



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Detailed Process & Expanded Sub-processes

Figure	Content	Major Step	Expanded Steps
5-2	Overview of commercial grade Item dedication process	5.1-5.6	
5-3	Overview of commercial grade Item dedication process	5.7-5.13	
5-4	Screen for Eligibility	5.2	5.2.1 – 5.2.6
5-5	Identification of safety function	5.3	5.3.1 – 5.3.3
5-7	Failure Modes and Effects Analysis	5.4	5.4.1 – 5.4.2
5-8	Identification of critical characteristics	5.5	5.5.1 – 5.5.4
5-9	Establishing dedication boundaries when safety function is unknown	5.6	5.6.1 – 5.6.5
5-10	Identification of acceptance methods – Method 1, special tests and Inspections	5.7	5.7.1 – 5.7.7
5-11	Method 2 – Commercial grade survey	5.7	5.7.8 – 5.7.14
5-12	Method 3 – Source verification	5.7	5.7.15 – 5.7.19
5-13	Method 4 – Item / supplier performance	5.7	5.7.20 –5.7.22

Report Page 5-2

How can a copy of the updated guidance be obtained

- Available to the public at www.epri.com

- 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
  - https://membercenter.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=000000003002002982

- 3002006066 - Typical Format for Documenting Commercial-Grade Item Dedication Technical Evaluations
  - http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=000000003002006066

For more discussion

- EPRI Joint Utility Task Group meetings are available to the public

  - August 2-4, 2016 SandPearl Hotel, Clearwater Beach, Florida

  - Discussion topics:
    - Commercial Grade Dedication
    - Reverse Engineering
    - Equivalency Evaluation
    - Critical Spare Parts programs
    - Maintaining qualification during dedication
    - Undeclared digital content
    - Quality of procured items

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