

# Introduction to 3002002982, Updated Commercial Grade Item Dedication Guidance

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Oversight**

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# Why was the guidance updated?

## What has changed

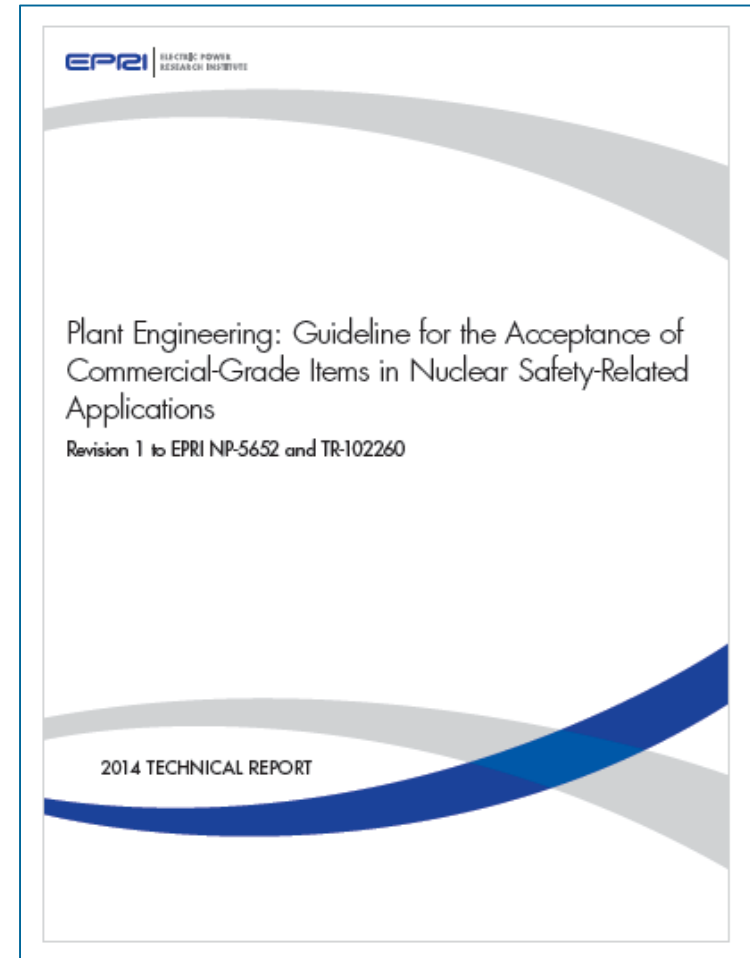
- Dedication is no longer used only as a last-resort
- Suppliers started to use dedication
- Devices being dedicated are more complex
- Additional EPRI guidance has been written over the years on related topics
- Other organizations have published guidance and requirements
- NRC published inspection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

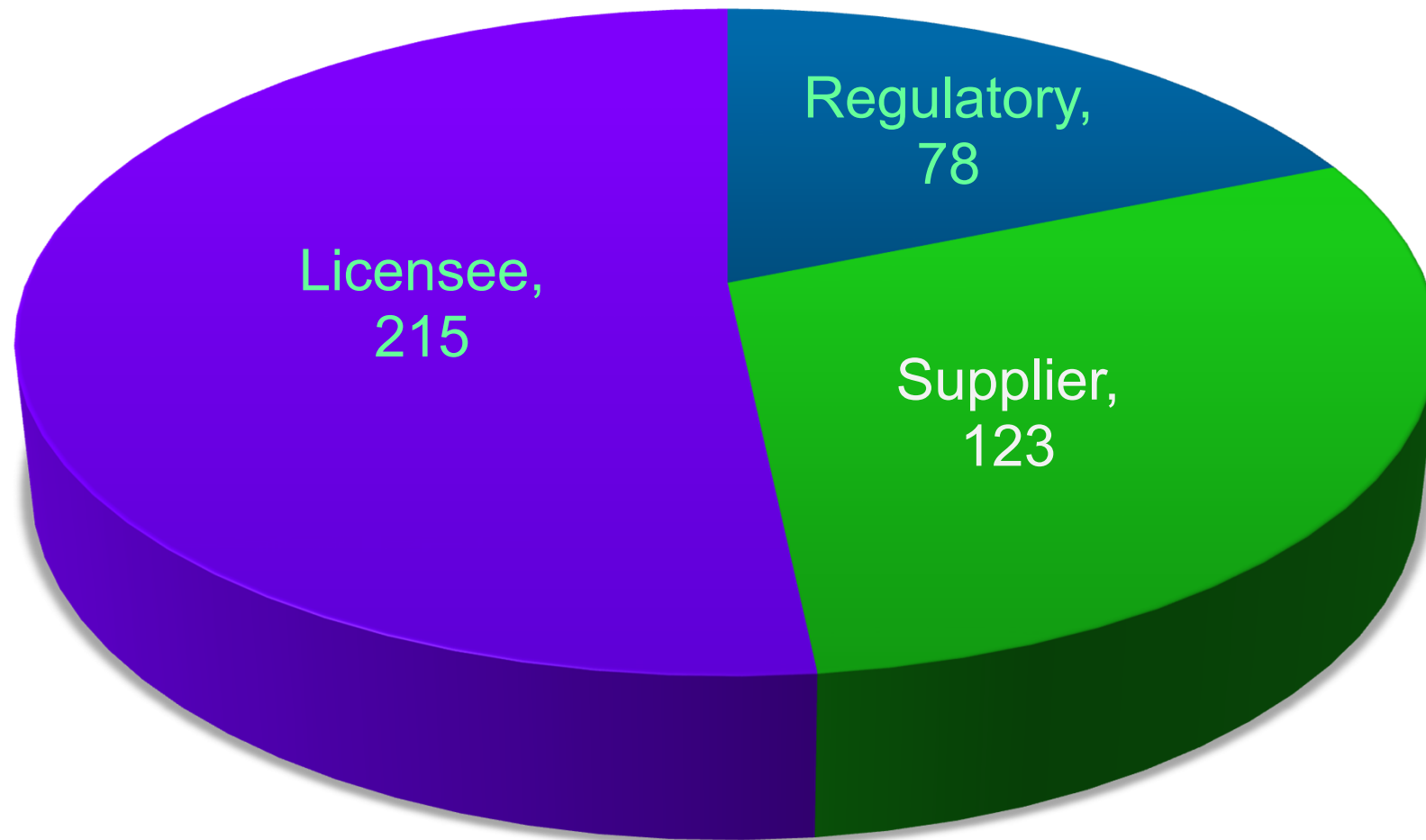
## Development Team



## 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	<b>failure modes and effects analysis (FMEA)</b> 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

A	•Design vs. Acceptance
B	•Technical Evaluation Process Overview
C	•Commercial Grade Survey Planning
D	•Example of Commercial Grade Dedication Forms
E	•Technical Evaluation Review Checklist
F	•Providing Basic Components
G	•Examples <b><i>Caution! Not intended for use as templates</i></b>
H	•Traceability
I	•Qualification vs. Dedication
J	•Electrical Testing Matrix
K	•Mechanical Testing Matrix

# Example Technical Evaluation Forms

Commercial Grade Item Dedication Technical Evaluation		EPRI Joint Utility Task Group Revision 0		
Evaluation Number _____ Revision _____				
<b>SECTION H IDENTIFICATION ATTRIBUTES</b>				
<b>IDENTIFICATION ATTRIBUTES</b>	<b>DESCRIPTION OF INSPECTION</b>	<b>ACCEPTANCE CRITERIA</b>		
Manufacturer	Visual			
Identification Number	Visual			
<b>SECTION I CRITICAL CHARACTERISTICS</b>				
<b>CRITICAL CHARACTERISTICS</b>	<b>ACCEPTANCE METHOD</b>	<b>DESCRIPTION OF ACCEPTANCE ACTIVITY</b>	<b>SAMPLING PLAN</b>	<b>ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)</b>
<b>DESCRIPTION OF SAMPLING PLANS (if "see below" is selected in the sampling plan column above)</b>				
<b>SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION</b>				
<div style="color: red; font-size: 1.2em; font-weight: bold;">Basis for selection of Critical Characteristics</div>				



Report Appendix D

# Dedication Technical Evaluation Review Checklist

Commercial Grade Dedication Review Checklist				
Dedication Evaluation Number: _____				
<b>Basic Technical Evaluation</b>				
No.	Criteria	Yes	No	N/A
1	End-use application or scope of application is identified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Safety function(s) is identified and functional safety classification is complete and includes active and passive safety functions as applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Service conditions/requirements such as seismic, environmental, ASME Section III, etc. are identified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	A review of pertinent technical information has been performed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4a	Vendor technical information such as technical manuals, drawings, and so forth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b	Available operating experience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Critical characteristics are identified and address:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6a	Important design, material and performance characteristics with a direct effect on the item's ability to perform its intended safety function(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6b	Active and passive safety functions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6c	Ability to perform in all design basis conditions (e.g. harsh environment, seismic event, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6d	When verified, the critical characteristics selected will provide reasonable assurance that the item will perform its 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6e	The basis for selection of critical characteristics is documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	An appropriate verification method is identified for each critical characteristic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Acceptance criteria including appropriate tolerances are identified for each critical characteristic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	If the item is determined not to be equivalent, appropriate engineering change evaluations are initiated or performed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Method 1 – Special Tests and Inspection</b>				
		Not Applicable <input type="checkbox"/>		
No.	Criteria	Yes	No	N/A
	Special tests and inspections are conducted after the item(s) arrives on-site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Special tests and inspections are conclusive enough to verify the characteristics they are intended to verify	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Special tests and inspections are documented in a plan or checklist that includes:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Test methods and inspection techniques	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Verification of the identified critical characteristics consistent with the acceptance criteria in the technical evaluation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Documentation of the inspections, tests, and results (actual values recorded)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	When sampling plans are employed:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	When post-installation testing is employed:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Measures are in place to assure post-installation testing is not waived	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The host device or system is not declared functional or operational until the dedication is complete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Method 3 – Source Verification</b>				
		Not Applicable <input type="checkbox"/>		
No.	Criteria	Yes	No	N/A
24	Source verification activities are controlled by a documented plan that includes the critical characteristics to be verified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25	Appropriate hold and verification points are included in the documented plan and are communicated to the supplier in procurement documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	The source verification witnesses activities performed on the actual items that will be shipped	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	The results of the source verification are clearly documented in the source verification plan/report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 indication of the material type, but must be used in conjunction with other or inspections to make 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 chemical analysis of some elements and a search of its available internal alloy library will produce an identification.			

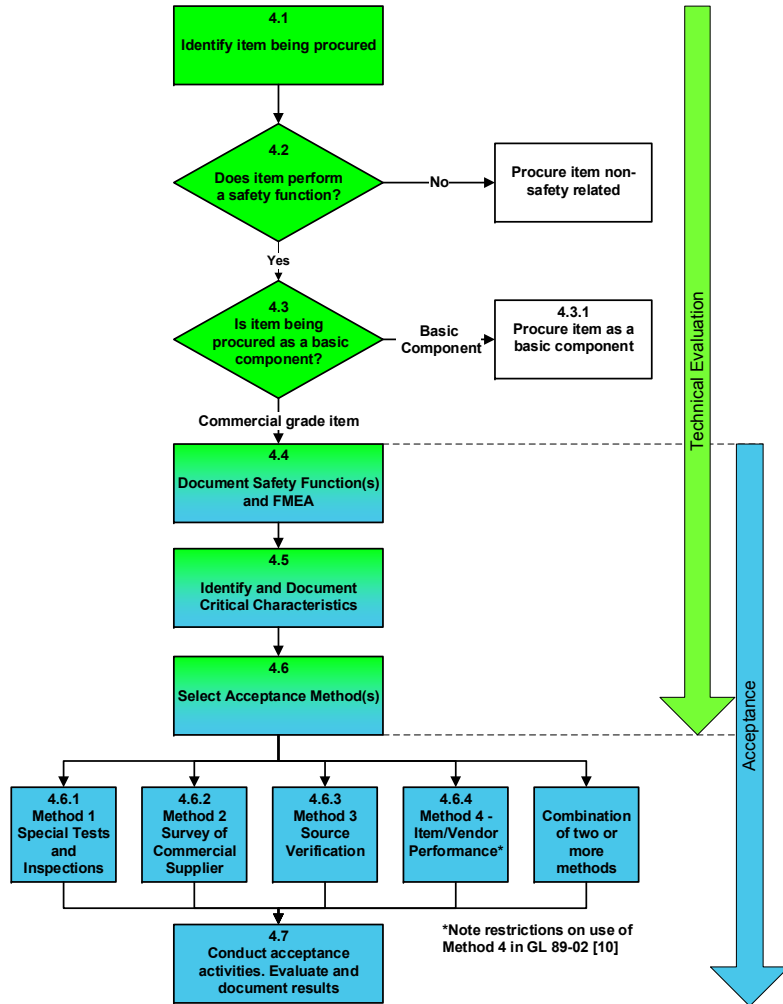
**Table J-1**  
**Electrical test methods**

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 <i>Counterfeit, Fraudulent, and Substandard Items</i> [28].

Report Pages J1-J2, K1-K20

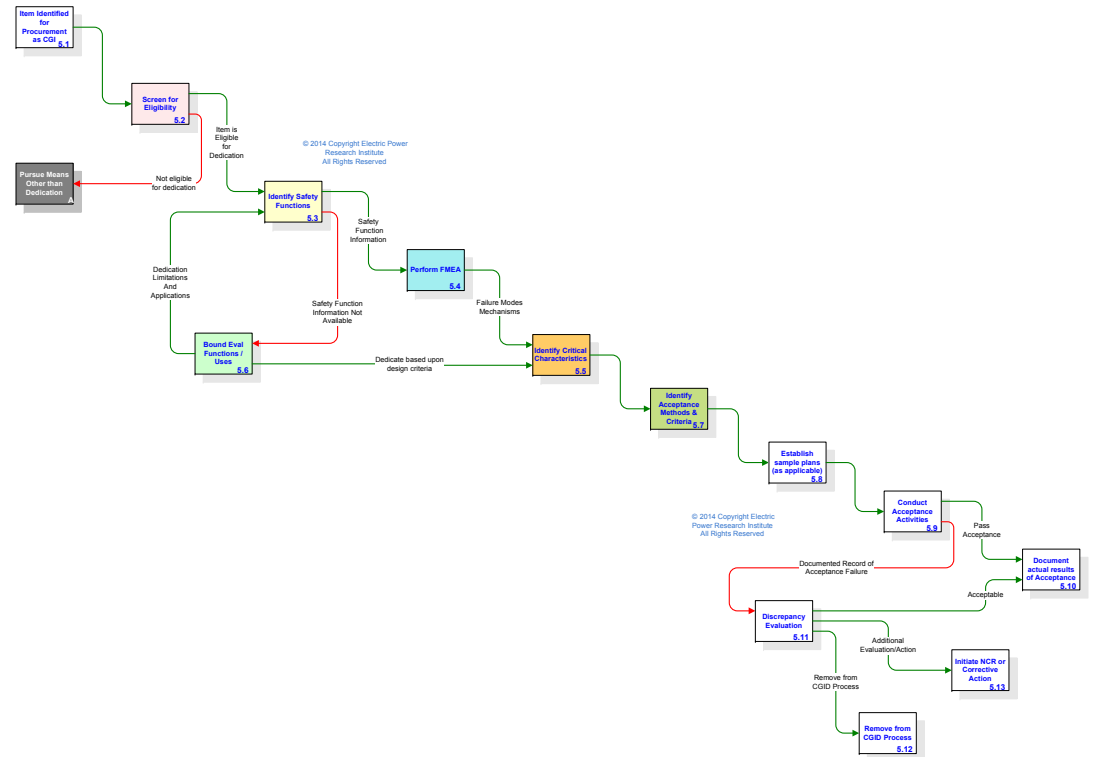


# Legacy Dedication Process



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# Updated Dedication Process

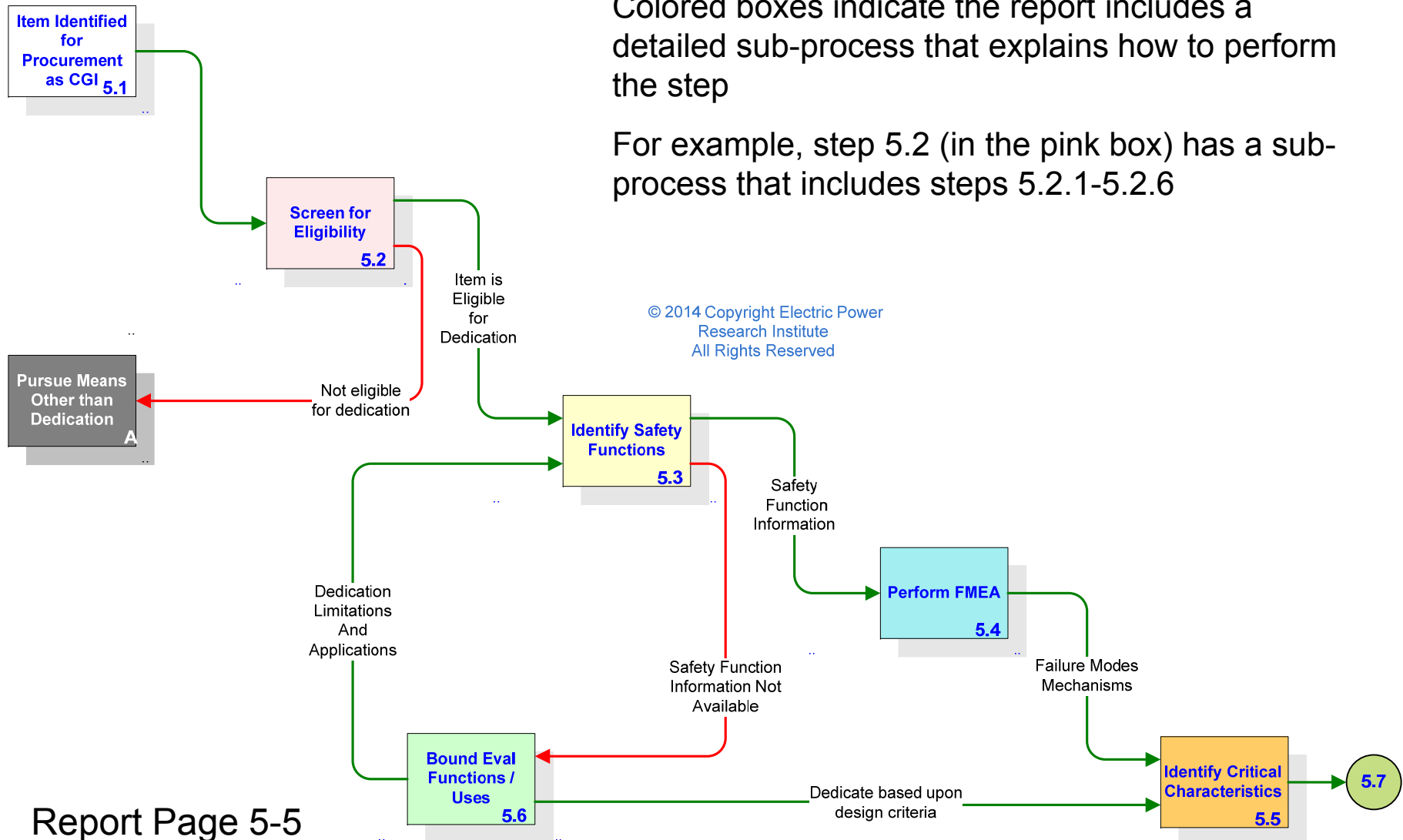


# Detailed Basic Process – Steps 5.1-5.6

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

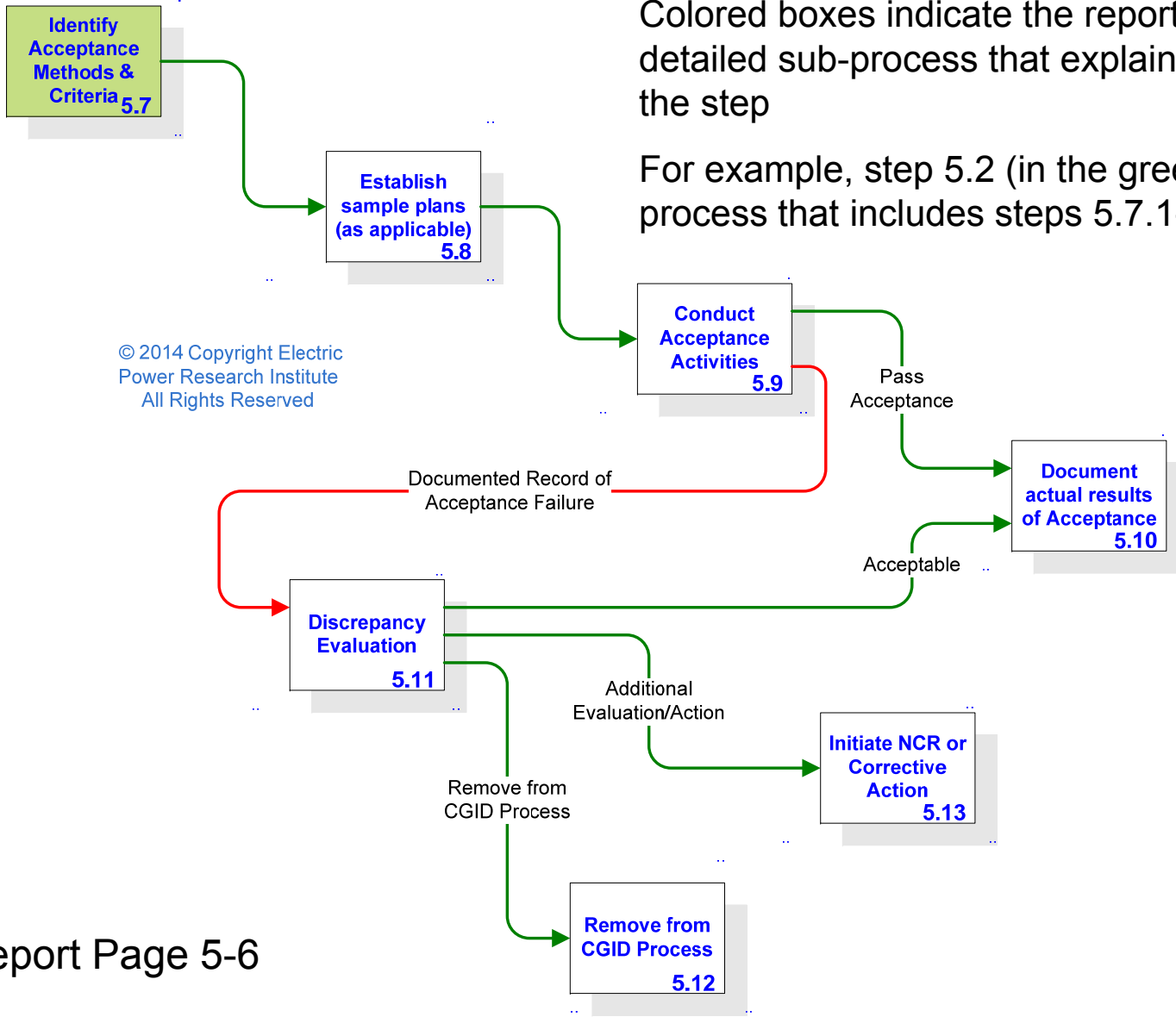
For example, step 5.2 (in the pink box) has a sub-process that includes steps 5.2.1-5.2.6

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## Detailed Basic Process – Steps 5.7-5.13

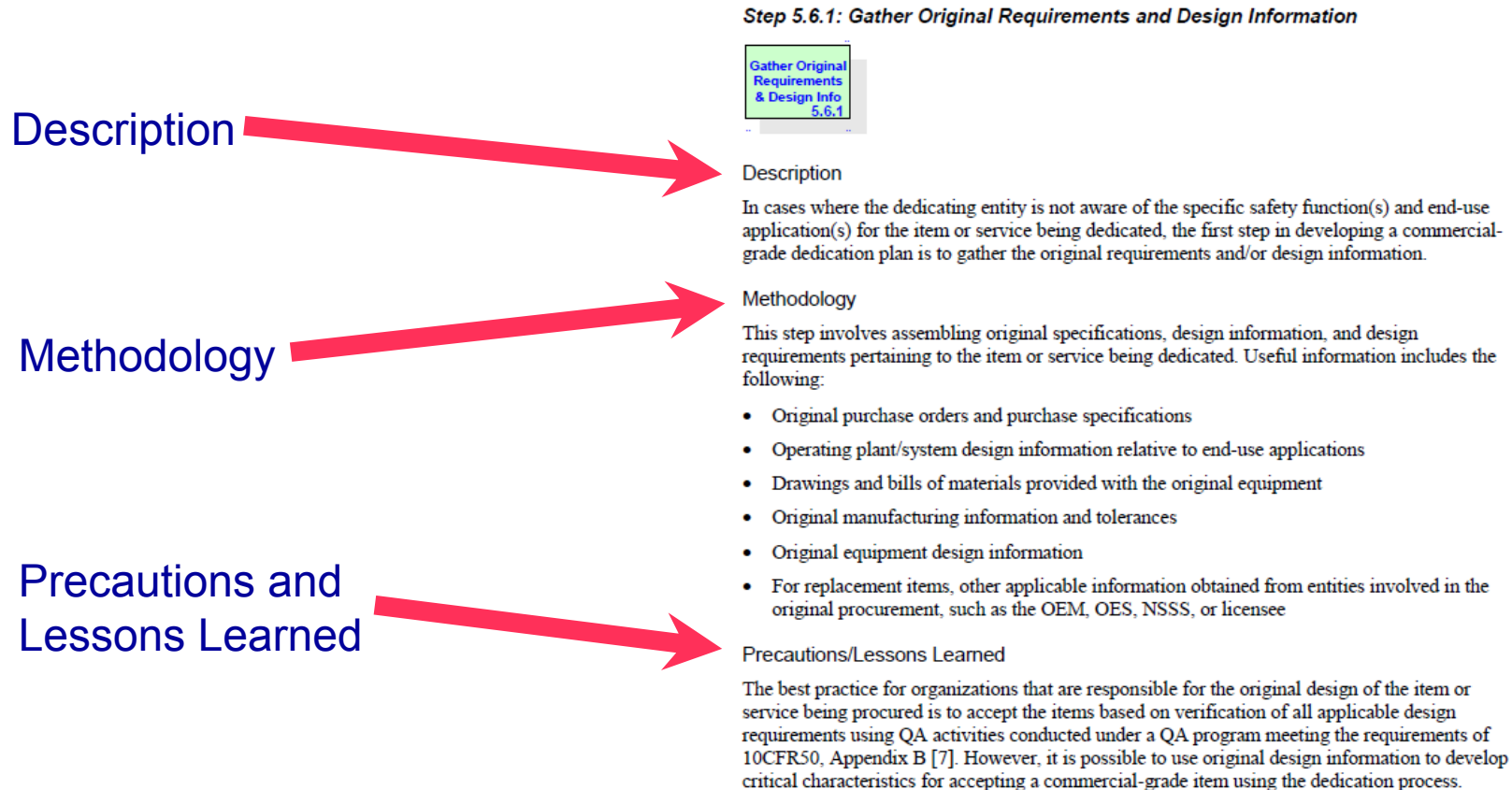


Colored boxes indicate the report includes a detailed sub-process that explains how to perform the step

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

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## Information included in Section 5 for each step:

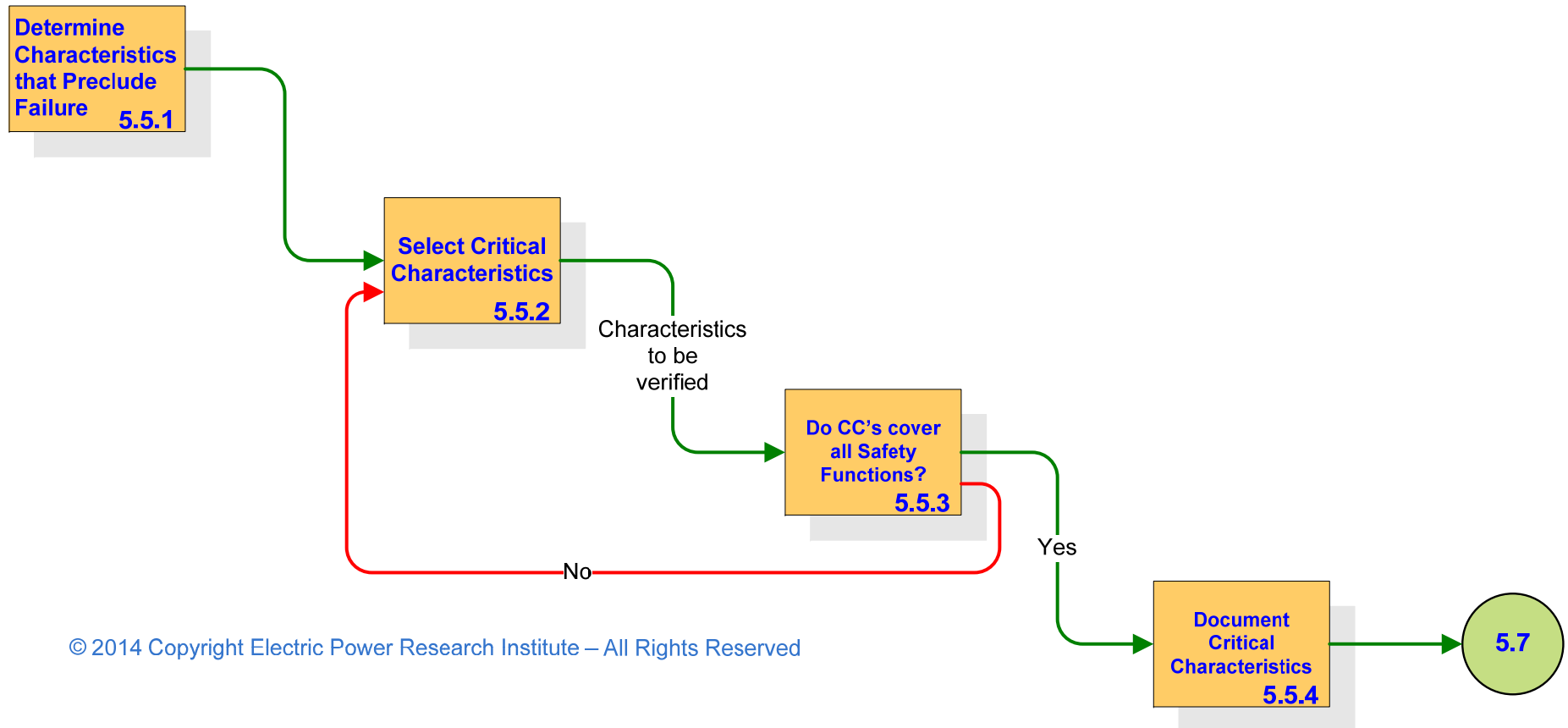


## Primary Process Step 5.5

**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

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## How can a copy of the updated guidance be obtained

- Available to the public at [www.epri.com](http://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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