

EPEI ELECTRIC POWER RESEARCH INSTITUTE

# Commercial Grade Item Dedication Guidance Revision

Marc Tannenbaum Principle Technical Leader, EPRI NRC Workshop on Vendor Oversight June 12, 2014

## **Revision to EPRI Dedication Guidance**

- 3002002982 will supersede NP-5652 and TR-102260
- Will reference other associated documents
  - Computer Program Dedication
    - 3002002289 (12/2013)
  - Sampling
    - TR-017218-R1
  - Acceptance of digital devices
    - TR-106439 (11/1996)
    - TR-107339 (12/1997)
    - 1009659 (3/2005)
    - 1001452 (9/2001)

	Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications: Revision 1
	3002002982
	Draft00, April 2014
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# **Revision to EPRI Dedication Guidance**

- Will reference other associated documents:
  - Use of Laboratory Accreditation in lieu of Commercial Grade Survey
    - NEI 14-05, Rev. 0

NEI 14-05, Revision 0
GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION AND TEST
CALIBRATION AND TEST SERVICES

April 2014



### **Diverse Technical Team**

• Licensee, supplier, regulator and construction perspectives





### **Key Points**

- The document summarizes and discusses important updates to dedication methodology that reflect key additions as well as differences between the original guidelines and this update to the guidance.
  - Supplier as well as utility perspectives
  - Discussion related to the two paths a supplier can use to provide a basic component.
  - Clarification that a completed and accepted design is required prior to beginning the commercial grade dedication process
  - A shift in focus from "identifiable and measurable characteristics" to characteristics necessary to perform safety function.
  - Clarification that a failure modes and effects analysis (FMEA) is an effective tool to determine critical characteristics when complete design information is not available.



# **Key Points**

- Continued
  - 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.
  - Use of the term "critical characteristics" in place of "critical characteristics for acceptance" and "design characteristics" in place of "critical characteristics for design"
  - References to applicable content in ASME NQA-1 (in addition to ANSI N42.2-1978)



# **Contents:**

Background and Introduction

Baseline Terminology

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- Overview of Commercial Grade Dedication
- Generic Technical Evaluation & Acceptance Process
- •Commercial Grade Dedication Process

Critical Characteristics

- Method 1 Special Tests and Inspections
- Method 2 Commercial Grade Survey
- Method 3 Source Verification
- Method 4 Item/Supplier History
- •Commercial Grade Services
- •Use of Dedication to Accept Accredited Calibration Services
- Reasonable Assurance
- •Digital Equipment and Computer Programs
- •References and Bibliography







### **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
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# How the diagrams work



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### **Detailed Basic Process – Steps 5.1-5.6**



### **Detailed Basic Process – Steps 5.7-5.13**



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# Detailed Sub-process for Step 5.6 (includes steps 5.6.1 – 5.6.5





### Step Dialog – Description, Methodology, Precautions & Lessons Learned

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:

- 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 who were involved in the original procurement such as the OEM, OES, NSSS and 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 upon verification of all applicable design requirements using quality assurance 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.

# **Step Dialog – Precautions / Lessons Learned**

### Precautions / Lessons Learned

- When postulating functions, be careful to consider requirements associated with the item's ability to function in both normal and accident conditions.
- IN 2011-01 suggests that "the purchaser or licensee should review and approve the commercial grade dedication package before the dedication of the item." [31] Review may be requested by either the purchaser or the dedicating entity.
- Review by the licensee or purchaser is particularly important in cases where:
  - The dedicating entity may not be familiar with the end-use applications and safety functions of the items being dedicated.
  - Problems have been identified with the dedicating entity's commercial grade dedication program.
- Review by the licensee or purchaser may not be appropriate in the situations involving:
  - Dedications performed by entities with access to design information (with 10CFR50, Appendix B [7] QA programs) on materials and part-level items that may have been purchased to support manufacturing prior to identification of a purchaser
  - Dedications performed by suppliers that are familiar with end-use applications and safety functions of the items being dedicated
  - When developing lists of applications and functions, the intent is not to develop a comprehensive list of all the unique identification numbers or locations associated with the item. Rather, the intent is to establish the ways in which the item will be used. For example, if the item being dedicated is a pipe elbow, it is not necessary to identify all the piping systems or specifications that use the elbow. Instead, the application can be described in generic terms as "maintains pressure boundary integrity."



# **Commercial Grade Survey Planning Tool**

### Figure C-1

### **Commercial Grade Survey Planning Worksheet**

Supplier Name	Description of Item(s)/Service(s) in scope of survey	
Item / Service Safety Function(s)	1	
Operating Experience		

Critical Characteristic	Process(es) that influence / impart Critical Characteristic	Supplier Controls to be Evaluated during the Commercial Grade Survey (Reference Table 8-1 for supplier controls that are typically surveyed)



**Commercial Grade Item Dedication Evaluation** 

EPRI Joint Utility Task Group Form CGI1, Rev. 0

**Evaluation Number** 

Revision

SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO: NOUN IDENTIFIER: MANUFACTURER NAME: MANUFACTURER MODEL / PART / CATALOG NUMBER(S)

### SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

Not Applicable (Section C Competed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

PARENT COMPONENT/HOST DESCRIPTION:

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:		BASIS / SOURCE:
Safety-Relat	ed	
Non-Safety I	Related (If non-safety, item is not a	
candidate for dedica	tion)	
IDENTIFICATION O	F PARENT COMPONENT/HOST EQUIPME	ENT FUNCTION(S)
FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
Active		
Passive		
Active		
Passive		
Active		
Passive		
Active		
Passive		
PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):		
EQ       ASME SECTION III         CLASS 1E       CONTAINMENT PRESSURE BOUNDARY         SEISMIC CLASS 1       SERVICE LEVEL 1 COATING         OTHER: (see below)       OTHER: (see below)		

# **Example Technical Evaluation Forms**



Commercial Grade Item Dedication Evaluation

EPRI Joint Utility Task Group Form CGI1, Rev. 0

Evaluation Number

Revision

BOUNDED SCOPE OF USE Only complete Section C when specific end-use of the item being dedicated unknown.

Not Applicable (Section B Competed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?

LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION

EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):

CONSIDERATION

QUALIFICATION BASIS / LIMITATIONS OF USE:

- ENVIRONMENTAL QUALIFICATION
   SEISMIC QUALIFICATION
- SEISMIC QUALIFICA OTHER: (see below)

### SECTION D ITEM INFORMATION

ITEM DESCRIPTION:					
FUNCTIONAL SAFE	ETY CLASS OF ITEM:	BASIS / SOURCE:			
Safety-Relat Non-Safety I candidate for d	ed Related (If non-safety, item is not a edication)				
IDENTIFICATION O	F ITEM FUNCTION(S)				
FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)			
Active					
Passive					
Active					
Passive					
Active					
Passive					

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# **Example Technical Evaluation Forms**

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Commercial	Grade	ltem	Dedication	Evaluation
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EPRI Joint Utility Task Group Form CGI1. Rev. 0

**Evaluation Number** 

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#### ITEM IS (CHECK ALL THAT APPLY):

- $\square$ EQ CLASS 1E
  CLASS 1E
  SEISMIC CLASS 1
  OTHER: (see below)
- ASME SECTION III CONTAINMENT PRESSURE BOUNDARY
- Click here to enter text.

- SERVICE LEVEL 1 COATING

#### SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21?

Yes No

If the answer is no, this item cannot be dedicated.

#### SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION	
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)		

#### **OPERATING EXPERIENCE / HISTORICAL PERFORMANCE** SECTION G INFORMATION

SOURCES REVIEWED AND RESULTS

# **Example Technical Evaluation Forms**

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### **Example Technical Evaluation Forms**

commercial Grade Item Ded echnical Evaluation	ication		EPF	RI Joint Utility Task Group Revision 0
valuation Number		Revision		
CTION H IDENTIFICAT	ON CHARAC	TERISTICS		
IDENTIFICATION CHARACTERIS	TICS D	ESCRIPTION OF INSPECTION	ACCEPTA	NCE CRITERIA
lanufacturer	Visual			
lentification Number	Visual			
CTION I CRITICAL CH	ARACTERIST	ics		
RITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACT	IVITY SAMPLE Plan	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
SCRIPTION OF SAMPLING PLA	N (if "see below" i	s selected in the sample plan column abov	re)	
			-1	· ·
AFETY FUNCTION(S) SUPPORTE	D / BASIS FOR SE	LECTION OF CRITICAL CHARACTERISTIC	S / ACCEPTANCE CRITE	RIA INCLUDING MAINTAINING
				•
				Page 4 of 5

### **Example Technical Evaluation Forms**

### Commercial Grade Item Dedication Technical Evaluation

EPRI Joint Utility Task Group Revision 0

Evaluation Number Revision

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

### SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS

### SECTION K REVIEW AND APPROVAL

Prepared by:	 Date:	
Reviewed by:	Date:	

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### **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.			
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 if necessary 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:			
ба	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			
7	An appropriate verification method is identified for each critical characteristic			
8	Acceptance criteria including appropriate tolerances are identified for each critical characteristic			





### **Commercial Grade Dedication Review Checklist**

Dedication Evaluation Number:

### **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.			
10	If the item is determined not to be equivalent, appropriate engineering change evaluations are initiated.			
11	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.			
Metl	nod 1 – Special Tests and Inspection No	ot App	licab	le 🗌
No.	Criteria	Yes	No	N/A
12	Special tests and inspections are conducted after the item(s) arrives on-site			
12a	Special tests and inspections are conclusive enough to verify the characteristics they are intended to verify			
13	Special tests and inspections are documented in a plan or checklist that includes:			
13a	Test methods and inspection techniques			
13b	Verification of the identified critical characteristics consistent with the acceptance criteria in the technical evaluation			
13c	Documentation of the inspection and tests and results (actual values recorded)			
14	When sampling plans are employed:			
14a	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.)			
15	When post-installation testing is employed:			
15a	Measures are in place to assure post-installation testing is not waived			
15b	The host device or system is not declared functional or operational until the dedication is complete			



### **Commercial Grade Dedication Review Checklist**

Dedication Evaluation Number:

Meth	nod 2 – Commercial Grade Survey No	ot App	licab	le 🗌
No.	Criteria	Yes	No	$\mathbf{N}/2$
16	A commercial grade survey was conducted to verify the supplier implements adequate programmatic controls over the specific critical characteristics and items identified in the survey plan			
17	The results of the commercial grade survey are clearly documented in the survey plan/report.			
18	The vendor's controls are documented in the instructions and procedures identified in the completed survey report.			
19	Applicable vendor controls are invoked in the procurement documents for each order (for example, by vendor instruction number and revision)			
20	Certification to the vendor controls invoked is also a requirement in the procurement document			
20a	Documentation including certification is verified during the acceptance process			
21	Critical characteristics that were determined not to be adequately controlled during the survey are verified by other means in the dedication technical evaluation and acceptance plan			
22	Measures are in place to ensure dedication is based upon a valid, current survey.			
23	If items are provided by a distributor, the distributor was surveyed or a requirement to drop-ship from the location surveyed is included in the procurement document			
Meth	nod 3 – Source Verification No	ot App	olicab	le [
No.	Criteria	Yes	No	<b>N</b> /.
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.



#### Commercial Grade Dedication Review Checklist Dedication Evaluation Number: Method 4 - Acceptable Supplier/Item Performance Record Not Applicable No. Criteria Yes No N/A 28 Is Method 4 being used as the acceptance method for all critical characteristics? (If the answer is Yes, the dedication violates the restrictions for the use of Method 4 discussed in NRC GL 89-02 and the dedication requires use of additional Methods.) 29 Is the basis for use of Method 4 explained with adequate references to documented records of the item/supplier's performance history? Are the documented historical records directly related to verification of the critical 30 characteristic(s) identified in the dedication technical evaluation?

# More detail and discussion at JUTG

Content will be focused on the commercial grade dedication guidance revision



# August 19-21, 2014

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# Questions?

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