NRC Staff Responses to Public Comments on DG-1292:
"DEDICATION OF COMMERCIAL-GRADE ITEMS FOR USE IN NUCLEAR POWER PLANTS"
Federal Register 81 FR 44671 (July 8, 2016)

I. INTRODUCTION

This document presents the NRC's responses to written public comments received on Draft Guide (DG)-1292, "Dedication of Commercial-Grade Items For Use In Nuclear Power Plants" (ADAMS Accession No. ML15313A425), in response to a separate *Federal Register* entry (81 FR 44671, July 8, 2016).

II. OVERVIEW OF COMMENTERS AND COMMENTS

The staff received 9 comment submissions and a total of 29 individual comments. Table 1 presents information on the commenters who submitted comments on DG-1292.

Table 1.

Name	Affiliation	ADAMS Accession No.	Identifier
Patricia Lougheed	-	ML16221A164	VPL
Mark Burzynski	NewClear Day, Inc.	ML16223A740	NCD
Christopher Wiegand	Electric Power Research Institute	ML16237A051	EPRI
Christopher E. Earls	Nuclear Energy Institute	ML16245A011	NEI
Larry Nicholson	NextEra Energy	ML16250A012	LNEE
Justin T. Wheat	Southern Nuclear Operating Company, Inc.	ML16250A011	JSN
Dennis Weaver	-	ML16256A103	DWW
J. W. Shea	Tennessee Valley Authority	ML16256A110	TVA
David P. Helker	Exelon Generation Company, LLC	ML16306A044	ECC

The comments submitted by NextEra Energy, Southern Nuclear Operating Company Inc., Tennessee Valley Authority, and Exelon Generation Company LLC., were a general endorsement of the comments provided by the Nuclear Energy Institute. The NRC response to NEI's comments should be taken as responding to comments from LNEE, JSN, TVA, and ECC for ease of reading. Also, the comment submitted by the Tennessee Valley Authority are a general endorsement of the comment provided by Electric Power Research Institute. The NRC response to EPRI's comments should be taken as responding to TVA's comment for ease of reading. Similar comments were grouped as appropriate to facilitate providing NRC responses.

Comments were grouped into the following categories for convenience:

a. Comments on the Scope of EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications
b. Comments related to Qualification of Commercial Digital Equipment
c. Editorial Comments

d. Other Comments

a. Comments on the Scope of EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications

Comment: A question arose in a recent discussion on Eng-Tips.com asking about dedication of items produced through 3D printing (additive manufacture technology). Is dedication of items produced by 3D printing addressed (I don't have access to the underlying EPRI documents)? If not, would consideration of it be appropriate as 3D printing is a rapidly growing and evolving industry? [VPL]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The guidance provided in EPRI 3002002982 is not technology specific, it covers the essential steps needed to create and implement a commercial-grade dedication program. Once the commercial-grade dedication program have being established then as applicable it can be used to dedicate commercial-grade items and services.

b. Comments related to Qualification of Commercial Digital Equipment

Comment: The discussion in DG-1292, Section B (bottom of page 4 and top of page 5) makes a strong distinction between qualification and dedication. Section C.2 reinforces the acceptability of EPRI TR-106439 and EPRI TR-107330 for the dedication of digital I&C equipment. The two EPRI documents and the associated NRC safety evaluation reports use dedication and qualification interchangeably with respect to commercial digital I&C equipment. In particular, qualification testing for seismic, environmental, EMI/RFI and electrical isolation capabilities are discussed in the context of critical characteristics for dedication.

I would also note that Regulatory Guide 1.152, Revision 3, also uses the qualification and dedication terminology interchangeably. For example, it notes that EPRI TR-106439 can be used to satisfy IEEE Std 7-4.3 .2-2003 requirement 5 .4.2 for qualification of existing commercial computers.

It would be useful to clarify whether qualification testing done in accordance with EPRI TR-107330 is a dedication task (e.g., Method 1 verification of critical performance characteristics as outlined in EPRI TR-106439) or a separate qualification task performed independently of the dedication effort. [NCD]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The qualification guidance provided by EPRI TR-107330 is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. Once an item is qualified and the design parameters have being established any subsequent commercial item procured under the same controls and possibly from the same supplier can be dedicated (e.g. using the guidance provided by EPRI TR-106439). This can be achieved using the parameters established during the qualification phase (e.g. EPRI TR-107330) which will provide engineering with the information necessary to select those quantifiable/verifiable critical characteristics that will provide reasonable assurance that the item will perform its intended safety function. As described in EPRI 3002002982, commercial-grade dedication is an acceptance process that

once completed will provide reasonable assurance that the component supplied can perform the same safety function as the design that was qualified.

Comment: EPRI takes exception to the following statement in the DG: "The NRC does not find these two EPRI documents to be acceptable for use, and in general does not find the use of generic testing data bases acceptable as a means for maintaining or providing seismic qualification of seismically sensitive replacement components". To EPRI's knowledge, these documents have not been formally reviewed by the NRC nor have any comments been submitted to EPRI. [EPRI, TVA]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, Item 1, Page 7

1. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, in Section I.3 of Appendix I, "Qualification Versus Dedication," refers to two EPRI guidance documents, NP-7484 "Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)" (Ref. 14) and TR 105849 "Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants," Revision 1 (Ref. 15). NP-7484 and TR 105849 have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement. NRC guidance on qualification is found in RG 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," (Ref 16). Refer to Section 6.6, Appendix B, "Technical Evaluation Process Overview," and Appendix I for guidance on documenting an adequate technical justification.

Comment: The following statement pertains to seismic qualification and is inappropriate for the scope of the DG as it does not benefit the discussion on commercial-grade dedication: "The NRC ... in general does not find the use of generic testing data bases acceptable as a means for maintaining or providing seismic qualification of seismically sensitive replacement components". Regulatory Guide 1.100 addresses the NRC's position on seismic qualification. Including guidance on seismic qualification in a separate location (DG) could result in misunderstanding and misinterpretation. [EPRI, TVA]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, Item 1, Page 7

1. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, in Section I.3 of Appendix I, "Qualification Versus Dedication," refers to two EPRI guidance documents, NP-7484 "Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)" (Ref. 14) and TR 105849 "Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants," Revision 1 (Ref. 15). NP-7484 and TR 105849 have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement. NRC guidance on qualification is found in RG 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," (Ref 16).

Refer to Section 6.6, Appendix B, “Technical Evaluation Process Overview,” and Appendix I for guidance on documenting an adequate technical justification.

Comment: The following statement conflicts with IEEE-344 and RG 1.100 and is not technically correct: "The NRC …in general does not find the use of generic testing data bases acceptable as a means for maintaining or providing seismic qualification of seismically sensitive replacement components”. Qualification involving the use of generic testing data (similarity) is an accepted method of qualification addressed in IEEE Std 344 and NRC RG 1.100. Page 3 of NRC RG 1.100, Revision 3, clearly addresses the use of "actual earthquake experience data from nonnuclear plants located worldwide (e.g., fossil-fueled power plants, substations, petrochemical plants) and existing test experience data from domestic NPPs to evaluate the performance of electrical and mechanical equipment in those facilities to infer the susceptibility of similar NPP equipment to seismic loads”. And states that" The SQUG concluded, and the NRC agreed, that the use of experience data was feasible for the purpose of verifying the seismic adequacy of equipment in the older, USI A-46 plants”.

In addition, use of earthquake experience data for seismic qualification of new and replacement equipment is included in the plant specific SERs closing out the USI A-46 reviews. Furthermore, clauses 9 and 10 of IEEE Std 344-2004, accepted for use in NRC RG 1.100, discuss the use of similarity to demonstrate seismic qualification of equipment that is similar to equipment for which performance in testing and in earthquakes has been demonstrated. [EPRI, TVA]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, Item 1, Page 7

1. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, in Section I.3 of Appendix I, “Qualification Versus Dedication,” refers to two EPRI guidance documents, NP-7484 “Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)” (Ref. 14) and TR 105849 “Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants,” Revision 1 (Ref. 15). NP-7484 and TR 105849 have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement. NRC guidance on qualification is found in RG 1.100, “Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants,” (Ref 16). Refer to Section 6.6, Appendix B, “Technical Evaluation Process Overview,” and Appendix I for guidance on documenting an adequate technical justification.

Comment: EPRI takes exception to following statement regarding four (4) EPRI guidance documents related to digital devices: "The remaining four guidance documents, EPRI 1025283, "Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities" (Ref. 18); EPRI TR-107339, "Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439" (Ref. 19); EPRI 1011710, "Handbook for Evaluating Critical Digital Equipment and Systems" (Ref. 20); and EPRI TR-103291 "Handbook for Verification and Validation of Digital Systems" (Ref 21), have not been approved by the NRC as an acceptable approach for meeting an NRC requirement".

DG-1292 includes a statement affirming that EPRI TR-106439 and TR-107330 have been reviewed and endorsed by the NRC. The context in which these two statement are presented conveys a message that the NRC has formally reviewed all six (6) documents, and found two (2) acceptable. To EPRI's knowledge, these documents have not been formally reviewed by the NRC nor have any comments been submitted to EPRI. [EPRI, TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, Item 2, Page 7

2. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, Section 14.1, "Digital Equipment and Computer Programs Integral to Plant SSCs," lists six EPRI guidance documents for accepting digital devices. Only TR-106439 "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications" and TR-107330 "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," have been reviewed and endorsed by the NRC in letters dated July 17, 1997 (Ref. 17) and July 30, 1998 (Ref. 18), respectively, as an acceptable approach for meeting an NRC requirement. The following four guidance documents reference in EPRI 3002002982: EPRI 1025283, "Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities" (Ref.19); EPRI TR-107339, "Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439" (Ref. 20); EPRI 1011710, "Handbook for Evaluating Critical Digital Equipment and Systems" (Ref. 21); and EPRI TR-103291 "Handbook for Verification and Validation of Digital Systems" (Ref 22), have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement.

Comment: The discussion in Section B, page 4 last paragraph continuing to top of page 5 makes a strong distinction between qualification and dedication. Section C.2 reinforces the acceptability of EPRI TR-106439 and EPRI TR-107330 for the dedication of digital I & C equipment. The two EPRI documents and the associated NRC safety evaluation reports use dedication and qualification interchangeably with respect to commercial digital I & C equipment. In particular, qualification testing for seismic, environmental, EMI/RFI and electrical isolation capabilities are discussed in the context of critical characteristics for dedication. RG 1.152, Revision 3, also uses the terminology interchangeably. It notes that EPRI TR-106439 can be used to satisfy IEEE Std 7-4.3.2-2003 requirement 5.4.2 for qualification of existing commercial computers. [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this particular comment. The qualification guidance provided by EPRI TR-107330 is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. Once an item is qualified and the design parameters have being established any subsequent commercial item procured under the same controls and possibly from the same supplier can be dedicated (e.g. using the guidance provided by EPRI TR-106439). This can be achieved using the parameters established during the qualification phase (e.g. EPRI TR-107330) which will provide engineering with the information necessary to select those quantifiable critical characteristics that will

provide reasonable assurance that the item will perform its intended safety function. As described in EPRI 3002002982, commercial-grade dedication is an acceptance process that once completed will provide reasonable assurance that the component supplied can perform the same safety function as the design that was qualified.

As a result of other comments related to Section C, Item 2, Page 5 - that are of similar inquiry, request for clarification, the NRC revised Item 2 to provide clarification and maintain consistency.

Change in the Guidance: Section C, Item 2, Page 7

2. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, Section 14.1, "Digital Equipment and Computer Programs Integral to Plant SSCs," lists six EPRI guidance documents for accepting digital devices. Only TR-106439 "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications" and TR-107330 "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," have been reviewed and endorsed by the NRC in letters dated July 17, 1997 (Ref. 17) and July 30, 1998 (Ref. 18), respectively, as an acceptable approach for meeting an NRC requirement. The following four guidance documents reference in EPRI 3002002982: EPRI 1025283, "Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities" (Ref.19); EPRI TR-107339, "Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439" (Ref. 20); EPRI 1011710, "Handbook for Evaluating Critical Digital Equipment and Systems" (Ref. 21); and EPRI TR-103291 "Handbook for Verification and Validation of Digital Systems" (Ref 22), have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement.

c. Editorial Comments

Comment: Multiple locations in the draft guide do not include the current reference number for the EPRI guidance. The correct reference number is 3002002982. Use of the correct reference number will facilitate access to the document and will help avoid inadvertent use of the older version (NP-5652). [EPRI, TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to the guidance as a result of this comment.

Comment: The following sentence in Section B, page 5 does not accurately represent the intent of EPRI 3002002982.

"The EPRI report specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, the item should be procured as a basic component."

In its correct, complete context, this sentence is part of a paragraph in Section 5.2.2, Page 5-23 of the report that reads: "If absolute assurance of compliance with all applicable requirements of a code or standard is required, the item should be procured as a basic component. If not, and it is possible to dedicate the item based on intended end-use applications, proceed to Step

5.2.3." Section 5.2.2, Page 5-23 is guidance on how to proceed with the dedication process after deciding the item will be dedicated (instead of being otherwise controlled in accordance with an Appendix B QA program without dedication), and after the dedication process has been started for the item. In this context, the sentence is the first part of a condition that offers the option of dedicating the item for its specific end use application(s).

Without including the follow on-sentence, the DG can be misinterpreted as meaning it is not permissible to dedicate an item that must comply with any code or standard - which will restrict the ability to dedicate items for specific end-use applications/safety functions (without certifying to all the requirements of the specification) and restrict the ability to accept items for use using Appendix B quality controls without any dedication.

Section 5.2, Page 5-7 (basic description of screening for eligibility sub-process) of the EPRI report includes the following statement that correctly represents the intent of the EPRI report and is appropriate for use in the context of the draft guide: "If the item is not eligible for dedication, it must be procured as a basic component or otherwise controlled in accordance with a 10CFR50, appendix B compliant QA program." [EPRI, TVA]

NRC Response: NRC evaluated this comment and Section B of the guidance was clarified to be in alignment with Section 5.2.2 of EPRI 3002002982.

Change in the Guidance: Section B, Last paragraph of Page 4, continuing to Page 5

> EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260 in Appendix I, “Qualification versus Dedication,” describes the difference between the process for qualification of a component and the commercial-grade dedication process. Appendix I states that attempting to use one process to accomplish the objectives of both qualification and commercial-grade dedication is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements. As noted by EPRI, equipment qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. The purpose of commercial-grade dedication acceptance is to provide reasonable assurance that the commercial item intended to be used as a basic component will perform its intended safety-. Therefore, equipment qualification requirements become an important input to the commercial-grade acceptance process when the selection of critical characteristics is performed. In addition, Step 5.2.2, “Is the Item Required to Comply with Codes and/or Standards?” of EPRI 3002002982, indicates that dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function, and is not intended for use as a basis for providing certification to a Code or standard. EPRI 3002002982 specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, and the item is not eligible for dedication, then the item should be procured as a basic component or otherwise controlled in accordance with a 10 CFR Part 50, Appendix B compliant QA program.

Comment: There is a typographical error in the EPRI document number referenced in the following statement in the DG: "Revision 1 of EPRI NP-5652 and 1R-102260, in Section I.3 refers to two EPRI guidance documents, NP-7874 "Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)" (Ref. 14), and 1R 105849 "Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power

Plants," Revision 1 (Ref. 15). The correct document number is NP-7484. [EPRI, TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and the reference number was corrected in the guidance.

Comment: DG-1292 does not include clarification that the term "item" also includes services. EPRI 3002002982 provides the following definition of items: "An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (See ASME NQA-1-2008, NQA-1a-2009 Addenda [1].) For the purposes of this report, item includes services." (Emphasis added) [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to the guidance to be in alignment with the language contained in 10 CFR Part 21.

Comment: The wording used in Section B, page 4, Reason for Issuance, 1st paragraph is slightly confusing. Change "commercial-grade dedication for items used" to "commercial-grade items to be used" [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to the guidance as a result of this comment.

Change in the Guidance: Section B, 1st paragraph, Page 4. Also, the changes were made across the entire guidance to maintain consistency.

> This new RG approves for use, in part, the Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items In Nuclear Safety-Related Applications” (Ref. 6), with respect to acceptance of commercial-grade dedication of items and services to be used as basic components for nuclear power plants.

Comment: The wording used in Section B, page 4, Background, 1st paragraph, 1st sentence is slightly confusing. Change "acceptance processes vary for these programs" to "acceptance processes for these items vary." [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section B of the guidance as a result of this comment.

Change in the Guidance: Section B, 1st paragraph, Page 4.

> Use of commercial-grade dedication for items and services used in nuclear power plants is common in the nuclear industry, but the acceptance processes for those items or services vary. Industry guidance for acceptance of commercial-grade products was developed in the late 1980s. In the early 1990s, the NRC performed a series of procurement inspections at licensees’ facilities that identified weaknesses in licensees’ procurement and dedication programs. In the late 1980s, the industry issued supplemental guidance in the initial version [Revision 0] of EPRI NP-5652 (Ref. 7), to do the following: 1) provide clarifications in certain areas, 2) share lessons learned, and 3) address industry and regulatory developments after the issuance of the original industry guidance.

Comment: Section C, page 7, Staff Position, 1st indented paragraph change "commercial-grade dedication of parts" to "commercial-grade dedication of items". [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, 2nd paragraph, Page 7.

> EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," addresses the acceptance of commercial-grade dedication of items and services for use in nuclear power plants. EPRI 3002002982 is acceptable to the NRC staff in providing an adequate basis for dedication as defined in 10 CFR Part 21, and fulfills the QA requirement in Appendix B to 10 CFR Part 50, subject to the following exceptions or clarifications:

Comments: Part B, Discussion - Background - 1st paragraph The NRC performed a series of procurement inspections at licensees' in the mid-1980's, not the mid-1990's, which resulted in revision 0 of EPRI 5652 being issued in June, 1988. The Discussion in Generic Letter 91-05 contains the correct dates. [DWW]

NRC Response: The NRC evaluated this comment and changes were made to Section B of the guidance as a result of this comment.

Change in the Guidance: Section B, 2nd paragraph, Page 4.

> Use of commercial-grade dedication for items and services used in nuclear power plants is common in the nuclear industry, but the acceptance processes for those items or services vary. Industry guidance for acceptance of commercial-grade products was developed in the late 1980s. In the early 1990s, the NRC performed a series of procurement inspections at licensees' facilities that identified weaknesses in licensees' procurement and dedication programs. In the late 1980s, the industry issued supplemental guidance in the initial version [Revision 0] of EPRI NP-5652 (Ref. 7), to do the following: 1) provide clarifications in certain areas, 2) share lessons learned, and 3) address industry and regulatory developments after the issuance of the original industry guidance.

d. <u>Other Comments</u>

Comment: The 1st sentences in this paragraph does not seem to be related to the 2nd and 3rd. The first one describes a commission action in 2011 (issuing a paper), and the other sentences describes things that apparently happened in 2014, Revision 1 to NP-5652 and TR-102260, and a determination by the NRC. Also, the determination by the NRC does not have a reference (e.g. a generic letter number, etc.), revise paragraph to provide clarification. [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section B of the guidance as a result of this comment.

Change in the Guidance: Section B, 6th paragraph, Page 4.

Commission paper SECY-11-0135, “Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the *Code of Federal Regulations* Part 21, Reporting of Defects and Noncompliance” (Ref. 10), was issued in September 2011. In SECY-11-0135, the staff indicated to the Commission that development of regulatory guides for dedication activities will be an important milestone. In September 2014, EPRI issued EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260. The NRC determined that this latest EPRI (3002002982) dedication guidance is consistent with the existing 10 CFR Part 21, which is subject to this regulatory guide.

Comment: Section B, background, page 5, paragraph from page 4, 1st sentence: The stated purpose of commercial-grade dedication confuses the objective of dedication (acceptance process) with the design process. As defined in 10 CFR Part 21 and confirmed in NRC DCS-000654 letter from NRC to Shaw AREVA MOX Services dated December 17, 2012, U.S. Nuclear Regulatory 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. [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to the guidance to be in alignment with the language contained in 10 CFR part 21.

Change in the Guidance: Section B, last paragraph Page, 1st paragraph Page 5.

EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260 in Appendix I, “Qualification versus Dedication,” describes the difference between the process for qualification of a component and the commercial-grade dedication process. Appendix I states that attempting to use one process to accomplish the objectives of both qualification and commercial-grade dedication is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements. As noted by EPRI, equipment qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. The purpose of commercial-grade dedication acceptance is to provide reasonable assurance that the commercial item intended to be used as a basic component will perform its intended safety. Therefore, equipment qualification requirements become an important input to the commercial-grade acceptance process when the selection of critical characteristics is performed. In addition, Step 5.2.2, “Is the Item Required to Comply with Codes and/or Standards?” of EPRI 3002002982, indicates that dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function, and is not intended for use as a basis for providing certification to a Code or standard. EPRI 3002002982 specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, and the item is not eligible for dedication, then the item should be procured as a basic component or otherwise controlled in accordance with a 10 CFR Part 50, Appendix B compliant QA program.

Comment: The following sentence does not accurately represent the intent of EPRI 3002002982. "The EPRI report specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, the item should be procured as a basic component.” In its correct context this sentence is part of a paragraph in EPRI 3002002982 Section 5.2.2, Page 5-23 that reads: "If absolute assurance of compliance with all applicable requirements of a code or standard is required, the item should be procured as a

basic component. If not, and it is possible to dedicate the item based on intended end-use applications, proceed to Steg 5.2.3". (Emphasis added)

Section 5.2.2, Page 5-23 is guidance on how to proceed with the dedication process after deciding the item will be dedicated (instead of being otherwise controlled in accordance with an Appendix B QA program without dedication), and after the dedication process has been started for the item. In this context, the sentence is the first part of a condition that offers the option of dedicating the item for its specific end use application(s). Without including the follow on-sentence, the NRC document could be misinterpreted to mean that it is not permissible to dedicate an item that must comply with any code or standard - which will restrict the ability to dedicate items for specific end-use applications / safety functions (without certifying to all the requirements of the specification) and restrict the ability to accept items for use using Appendix B quality controls without any dedication. Section 5.2, Page 5-7 (basic description of screening for eligibility sub-process) of the EPRI report includes the following statement that correctly represents the intent of the EPRI report and is appropriate for use in the context of the regulatory guide: "If the item is not eligible for dedication, it must be procured as a basic component or otherwise controlled in accordance with a 10CFR50, appendix B-compliant QA program". [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section B of the guidance as a result of this comment.

Change in the Guidance: Section B, last paragraph Page, 1st paragraph Page 5.

> EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260 in Appendix I, "Qualification versus Dedication," describes the difference between the process for qualification of a component and the commercial-grade dedication process. Appendix I states that attempting to use one process to accomplish the objectives of both qualification and commercial-grade dedication is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements. As noted by EPRI, equipment qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. The purpose of commercial-grade dedication acceptance is to provide reasonable assurance that the commercial item intended to be used as a basic component will perform its intended safety-. Therefore, equipment qualification requirements become an important input to the commercial-grade acceptance process when the selection of critical characteristics is performed. In addition, Step 5.2.2, "Is the Item Required to Comply with Codes and/or Standards?" of EPRI 3002002982, indicates that dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function, and is not intended for use as a basis for providing certification to a Code or standard. EPRI 3002002982 specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, and the item is not eligible for dedication, then the item should be procured as a basic component or otherwise controlled in accordance with a 10 CFR Part 50, Appendix B compliant QA program.

Comment: Section C, page 7, Staff Position, item 1, next to last sentence the use of "No changes" is inconsistent with accepted practices and is an unrealistic acceptance criterion for an equivalency evaluation to "confirm that an alternative item not identical to the original item will satisfactorily perform the design function(s) of the original item". The previous comment

recommends that the sentence be deleted. Any discussion of equivalency evaluation in the regulatory guide for commercial-grade dedication should be limited to the inter-relationship and guided by the discussion from EPRI 3002002982 Section B.3.3.2 page B-5: "The equivalency evaluation in itself is not a means to accept a commercial-grade item for safety-related use as defined herein. Rather, it is a sound engineering method to ensure that an alternative item specified is an acceptable substitute for the originally designed item. For a commercial-grade item requiring dedication, verification of the identified critical characteristics by an appropriate dedication method(s) would still be required to verify the acceptability of the replacement item". [TVA, NEI, LNEE, JSN, ECC]

NRC Response: The NRC evaluated this comment and changes were made to Section C of the guidance as a result of this comment.

Change in the Guidance: Section C, Item 1, Page 7

1. EPRI 3002002982, Revision 1 of EPRI NP-5652 and TR-102260, in Section I.3 of Appendix I, "Qualification Versus Dedication," refers to two EPRI guidance documents, NP-7484 "Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)" (Ref. 14) and TR 105849 "Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants," Revision 1 (Ref. 15). NP-7484 and TR 105849 have not been reviewed or approved by the NRC as an acceptable approach for meeting an NRC requirement. NRC guidance on qualification is found in RG 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," (Ref 16). Refer to Section 6.6, Appendix B, "Technical Evaluation Process Overview," and Appendix I for guidance on documenting an adequate technical justification.

Comment: Part B, Discussion - Background - 6th paragraph - This paragraph contains a good discussion of qualification vs dedication. The value of this discussion would be significantly improved by including the following after the statement on the purpose of dedication: "Nearly all parts of qualified components begin as discrete items or as subassemblies produced by a commercial company that are assembled into a qualified component by a nuclear manufacturer responsible for maintaining the qualified configuration. A significant aspect of dedication of these items by the nuclear manufacturer is selecting critical characteristics of those parts which will assure maintenance of qualification." [DWW]

NRC Response: The NRC evaluated this comment and does not agree with this comment. The purpose of this RG is not to provide guidance on how to maintain qualification. The proposed comment cover one of many possible examples that could be encountered by industry and could create confusion if it is added to this guidance. The RG does not go down to that level of detail.

Comment: Part B, Discussion: Background - 6th paragraph - The last sentence of the 6th paragraph quotes the EPRI guidance as saying that procuring an item as a basic component provides absolute assurance of compliance. This is far from accurate. 10CFR50 Appendix B provides a graded approach commensurate with safety significance. Judgement is used throughout nuclear QA program implementation for sampling, selection of certain hold points, limited oversight, etc. Dedication planning follows the same logic. Procurement of items as basic components does not assure compliance as evidenced by many NRC inspections that have discovered otherwise. [DWW]

NRC Response: The NRC evaluated this comment along with similar comments submitted and changes were made to Section B of the guidance as a result of these comments.

Change in the Guidance: Section B, last paragraph Page, 1st paragraph Page 5.

> EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260 in Appendix I, "Qualification versus Dedication," describes the difference between the process for qualification of a component and the commercial-grade dedication process. Appendix I states that attempting to use one process to accomplish the objectives of both qualification and commercial-grade dedication is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements. As noted by EPRI, equipment qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. The purpose of commercial-grade dedication acceptance is to provide reasonable assurance that the commercial item intended to be used as a basic component will perform its intended safety. Therefore, equipment qualification requirements become an important input to the commercial-grade acceptance process when the selection of critical characteristics is performed. In addition, Step 5.2.2, "Is the Item Required to Comply with Codes and/or Standards?" of EPRI 3002002982, indicates that dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function, and is not intended for use as a basis for providing certification to a Code or standard. EPRI 3002002982 specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, and the item is not eligible for dedication, then the item should be procured as a basic component or otherwise controlled in accordance with a 10 CFR Part 50, Appendix B compliant QA program.

Comment: Part B, Discussion - Background - 7th paragraph -This paragraph refers to a statement in step 5.2.2 of EPRI TR-102260. Section 5.2.2 addresses methods to determine whether an item is required to meet a material code or standard. This is not relevant to the Regulatory Guide discussion stated here regarding use of reverse engineering to determine significant design and performance attributes for replacement components. EPRI already has a guide on performance of reverse engineering which should be referenced here. [DWW]

NRC Response: The NRC partially agrees and disagree with this comment. Clarification was provided that the scope of EPRI 3002002982 does not cover reverse engineering. The NRC would not reference an EPRI document that has not been reviewed or endorse as an acceptable guidance to meet an NRC requirement.

Change in the Guidance: Section B, 2nd paragraph, Page 5.

> EPRI 3002002982, Section 5.14, "Screen for Eligibility Process: Steps 5.2.1-5.2.6," states that one option to obtain information that will help determine if an item can be dedicated is "reverse engineering" of the component. Operating experience has revealed challenges associated with the use of reverse engineering in determining significant design and performance attributes for replacement components in nuclear power plants. Reverse engineering is not within the scope of EPRI 3002002982. EPRI is preparing a separate guidance document for the use of reverse engineering to provide reasonable assurance of the capability of replacement components to perform their intended functions consistent with the design and performance of the original component.

Comment: Part B, Discussion - Harmonization with International Standards - It is not clear how the section "Harmonization With International Standards" is relevant to the organizations stated in Part A, Introduction -Applicability, or valuable as regulatory guidance. [DWW]

NRC Response: The NRC disagree with this comment and no changes were made to the guidance as a result of this comment. The intent of this paragraph is to document if the international community has guidance related to the purpose and guidance within the regulatory guide being developed or revised. If such international guidance exists, the documentation will reflect that the NRC guidance is in harmony with the international guidance or provide a basis why a different position would be taken. This paragraph indicates that both the International Atomic Energy Agency and the Nuclear Energy Agency's Committee on Nuclear Regulatory Activities have developed guidance that is similar to the guidance provided in this regulatory guide and the this guide is in harmony with that guidance. The relevance is to all stakeholders, including international stakeholders, and not just the organizations stated in Part A and it reflects that this guidance is generally consistent with the basic safety principles provided in the referenced international standards.

Comment: Part C, Staff Regulatory Guidance - Add the following: The first paragraph, and Table 3-1, imply that prior to 1978 items used in nuclear facilities were produced completely, from origin through delivery, to a QA program that meets 10 CFR 50 Appendix B. In fact, nearly all items always were and are now originally produced at a commercial facility and at some point are purchased by a nuclear supplier and then subject to further manufacturing or assembly to produce a nuclear product. That point of transition from the commercial supply chain to nuclear supply chain is when 10 CFR 50 Appendix B Criteria 7 controls are applied to evaluate whether the commercially produced item can perform its intended safety function. Those controls may take the form of a process commonly referred to as dedication, or those same activities which meet 10 CFR 50 Appendix B without being specifically labelled a "dedication" process. These are expected to be applied equally to items and subcontracted services.

A series of NRC communications, such as Information Notices, and Inspection Reports, in the 1980's identified that suppliers were not consistently applying nuclear acceptance activities to commercial items and services. When NRC Generic Letter 89-02 was issued summarizing these communications, the NRC clearly stated to the industry that licensees were expected to monitor suppliers for implementation of acceptance activities/dedication programs. As licensees began challenging suppliers in this regard, it became evident that suppliers had traditionally not implemented these practices effectively. It is a common misconception that suppliers opting to leave the nuclear marketplace drove the need to have effective dedication programs. The reality is that suppliers traditionally had not been performing nuclear acceptance activities that met NRC expectations.

Generic Letter 89-02 provided guidance on conduct of effective supplier audits to evaluate supplier programs. NRC experience with observation of cooperative industry audits has been mixed. There have been repeated situations where the industry has approved suppliers which when later inspected by the NRC were determined to be less that fully compliant. The overall trend is negative as evidenced by recent NRC inspection activities. In addition, 10 CFR 21 reports filed with the NRC are increasingly more common and the majority are related to commercial grade dedication.

This evidence indicates that there is a need for suppliers to improve their evaluation and acceptance activities for commercial items and services." [DWW]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The RG does not go down to that level of detail.

Comment: Part C, Staff Regulatory Guidance - Add the following: EPRI TR-102260 section 3.4.1: This section states that it is not a regulatory requirement to use dedication when an item is designed and manufactured under a QA program that meets 10 CFR 50 Appendix B. The NRC concurs with this statement but recognizes that very few items are wholly designed and manufactured under a nuclear QA program. Nearly all nuclear suppliers routinely purchase commercial items, and commercial services, which in various stages of fabrication are under commercial controls. Therefore, an effective program for acceptance of commercial items and services is an integral part of a nuclear supplier's program. EPRI TR-102260 describes processes which, when effectively implemented, could accomplish this activity, whether or not they are labelled as a commercial grade dedication process.

The NRC cautions the industry when using the guidance in section 3.4.1 to consider:

- When using "design information" in lieu of performance of a technical evaluation based on safety function, confirm that the design information contains a technical evaluation for the item or service being evaluated which is consistent with that described in the guideline and addresses the characteristics of the item related to seismic and, if required, environmental qualification. System level and component level design analysis may provide supporting information to develop a part level technical evaluation, but are not by themselves adequate.
- In many cases it has been several decades since the original design occurred for most nuclear components, therefore information may not be readily available or stated in a context appropriate for use in lieu of a technical evaluation.
- Due to corporate acquisitions and restructuring, accurate original design information may not be available.
- Design information may be based on outdated configurations of items. Note that for an item to be the same for the purposes of dedication, it must be constructed of the same materials, the same dimensions, the same processes and assembled and tested in the same manner.

Table 3-1 implies that prior to 1979 suppliers could not purchase commercial items and services, and that every item had to be manufactured from origin to a nuclear QA program. The NRC position is that the content of 10 CFR 50 Appendix B, Criteria 7 applies to purchase of any item or service, whether it was purchased to a nuclear QA program or the met by the content of a commercial program. 10 CFR 21 only added defect reporting requirements. In the 1970's suppliers routinely purchased commercial items for use in nuclear components". [DWW]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The RG does not go down to that level of detail.

Comment: Part C, Staff Regulatory Guidance - Add the following: EPRI TR-102260 step 5.2.2: 1. The NRC does not concur that compliance with 10 CFR 50 Appendix B provides absolute assurance of compliance. 2. Use of dedication is not restricted to verifying less than the complete set of requirements in a code or standard. The NRC recognizes that there are not nuclear mills, forges and manufacturers for all items governed by material standards and that it is common practice for nuclear suppliers to effectively dedicate items produced by those commercial suppliers by complementing their commercial controls with those necessary to meet NRC regulations". [DWW]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The RG does not go down to that level of detail.

Comment: Part C, Staff Regulatory Guidance - Add the following: EPRI TR-102260 section 4.3: Accurate identification of safety function is critical to performance of a technical evaluation, and safety function of parts is based on the safety function of host system and components. It is important that purchase orders at each level of procurement state the safety function when the supplier is expected to perform evaluations using the safety function. If the safety functions are not stated in the purchase order, the purchaser is responsible for the accuracy of the relationship of the technical evaluation to the safety function". [DWW]

NRC Response: The NRC evaluated this comment and no changes were made to the guidance as a result of this comment. The RG does not go down to that level of detail.