Attachment
EPRI Comments on Comments on NRC IP 71111 Attachment 21N.03, Commercial Grade Dedication

No.	Affected Section and Page Number	Comment/Basis	Recommendation
1.	References, page 14	IP 71111 21N.03 does not recognize documents that were published as the result of significant efforts to clarify commercial grade dedication requirements and methodology. Included are the Final Regulatory Basis to Clarify 10 CFR part 21, "Reporting of Defects and Noncompliance" (2015)(ML 15152A457), and EPRI 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" accepted for use in Regulatory Guide 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, (ML17041A206) It is not clear if omission of these references and revisions is intended to communicate that they are no longer considered valid by NRC staff. • EPRI NP-5652 was revised in 2014. The new product number is EPRI 3002002982 • EPRI TR-102260 is superseded by EPRI 3002002982 • EPRI NP-6406 was revised in 2006 and is superseded by product number 1008256 • EPRI NP-7218 was revised in 1999 and is superseded by product number is TR-017218-R1 (included in reference list) • EPRI TR-1019163 was revised in 2014 and is superseded by product number 3002002276 mentioned in SECY 15-0003.	If omission of the following references is not intentional, revise references as indicated below: Section 04 – References: Add: Final Regulatory Basis to Clarify 10 CFR PART 21, "Reporting of Defects and Noncompliance" (ML15152A457) Update: ~~EPRI NP-5652, "Guideline for the Utilization of Commercial - Grade Items in Nuclear Safety-Related Applications (NCIG-07)."~~ ~~EPRI TR-102260, "Supplemental Guidance for the Application of EPRI Report 5652 on the Utilization of Commercial-Grade Items."~~ EPRI 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" ~~EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)."~~ EPRI 1008256, "Guidelines for the Technical evaluation of Replacement Items in Nuclear Power Plants" ~~EPRI NP-7218, "Guideline for the Utilization of Sampling Plans for Commercial - Grade Item Acceptance (NCIG-19)."~~ EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process" ~~EPRI TR-1019163, "Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items – Mitigating the Increasing Risk."~~ EPRI 3002002276, "Plant Support Engineering: Counterfeit and Fraudulent Items—Mitigating the Increasing Risk, Revision 1 of 1019163"

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2.	1.02, page 1 Section 3.01 **f.,** pages 11-13 02.01, page 2	Contrary to its title, the contents of the IP indicate that the scope extends beyond commercial-grade dedication (CGD) acceptance process to include all procurement activities and design activities. Contrary to 10CFR50, Appendix B, which does not mention commercial-grade dedication, content relating to non-CGD activities is captured in Section 3.01 (3.01 **f**.) titled "Commercial-Grade Dedication." This is likely to result in misunderstanding that procuring basic components from suppliers with 10CFR50, Appendix B QA programs is CGD activity. Including 10CFR50.69 procurement is likely to result in misunderstanding that all 50.69 procurements are subject to the requirements of 10CFR50, Appendix B and 10CFR21. This is contrary to 10CFR50.69 that allows for alternative treatments in lieu of 10CFR50, Appendix B and 10CFR21 for certain categories of safety-related items. Language in 02.01 indicates the IP includes reviewing dedications performed by suppliers. Suppliers may not always be willing to provide dedication plans to licensees without nondisclosure agreements, etc. "The samples may be CGIs dedicated by the licensee, a CGI dedicated by vendor (or other licensee) and procured by the licensee, or a CGI that failed after completing the dedication process, or reviewing the procurement of a safety-related component."	If the IP is intended to cover commercial-grade dedication, procurement of basic components from suppliers with 10CFR50, Appendix B QA programs, and procurement of items pursuant to 10CFR50.69, change the title to reflect the intended scope goes beyond commercial-grade dedication. Address each topic in separate sections (e.g., commercial-grade dedication in Section 3, procuring basic components from suppliers with 10CFR50, Appendix B QA programs in Section 4, and procurement of items pursuant to 10CFR50.69 in Section 5. If the scope of the IP extends beyond CGD, revise 2.01 to indicate that: Samples may include types of procurements other than commercial-grade dedication, such as basic components procured from suppliers with 10CFR50, Appendix B-compliant QA programs and 10CFR50.69 alternative procurement treatments.
3.	7111.21N.03-02, page 1	Contrary to 10CFR21, which defines CGD as an acceptance process, content in the IP suggests it is a "designation". This may cause confusion as it seems more consistent with language in older revisions of 10CFR, Part 21 that described "dedication" as the point in time after and item has been designated for use as a basic component. 71111.21N.03-02 states "Commercial-grade dedication is a process by which a (CGI) is *designated* for use as a basic component . . . "	Revise the sentence as follows: Commercial-grade dedication is ~~a process by which a (CGI) is designated for use as a basic component. This~~ an acceptance process ~~is~~ undertaken to provide reasonable assurance that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under an Appendix B quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses by the purchaser or third-party dedicating entity.

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4.	1.01, page 1	10CFR50, Appendix B does not mention or include requirements for commercial-grade dedication. Requirements for commercial-grade dedication are included in 10CFR, Part 21.	Revise section 1.01 as follows: To review the implementation of the licensee's process for dedicating commercial-grade items (CGIs), as required in ~~applicable portions of Appendix B to~~ Title 10 of the Code of Federal Regulations (10 CFR) Part ~~50~~ 21 ~~(Appendix B)~~ to ensure reasonable assurance is provided that CGIs will perform their intended safety function.
5.	2.01 page 2	Section 2.01 states that *"the purpose of this inspection activity is to evaluate the CGI sample to determine if the licensee's activities provide reasonable assurance the CGI will perform its safety function . . ."* Contrary to this, the statement at the end, *"or reviewing the procurement of a safety-related component"* indicates that procurement of basic components from a supplier with a 10CFR50, Appendix B-compliant QA program is a CGD activity.	In accordance with Comment 2, address each topic in separate sections (e.g., commercial-grade dedication in Section 3, procuring basic components from suppliers with 10CFR50, Appendix B QA programs in Section 4, and procurement of items pursuant to 10CFR50.69 in Section 5.
6.	03.01 a., page 3	CGD is an acceptance activity as defined in 10CFR, Part 21. As defined in 10CFR21, CGD acceptance activities do not include establishing suitability of design but are intended to provide reasonable assurance that an item (for which design has already been established) can perform its safety function(s). Criterion III of 10CFR, Part 50, Appendix B addresses design activities that take place before design is finalized (such as establishing suitability of design) and after design is finalized (such as control of design). These are not CGD activities discussed in 10CFR, Part 21. CGD is an acceptance activity. Acceptance activities are discussed in Criterion VII of 10CFR, Part 50, Appendix B.	Recommend revising 3.01a to include language from 10CFR, Part 21 "Verify the established controls for performing technical evaluations of items or services to be dedicated. ~~Verify materials, parts, equipment, and processes for suitability of application regarding each CGI as established in Criterion III of Appendix B.~~ Verify that the dedication for material, equipment, and services, purchased as commercial grade items provides reasonable assurance the commercial grade items to be used as basic components will perform their intended safety function and, in this respect, are deemed equivalent to an item controlled under a 10 CFR, Part 50, Appendix B, quality assurance program. [adapted from 10CFR21 definition of dedication]
7.	03.01 a. 1. (b), page 3	Vendor technical data may not always be available for commercial grade items	Revise to: "(b) Review of ~~the~~ available vendor~~'s~~ technical data as well as industry operating experience, . . ."

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8.	03.01 a. 1. (d) (3), page 4	There has never been a requirement to record manufacturing processes, so this information is typically not available for "original" items. In the vast majority of cases, a commercial manufacturer will not provide this type of information. Therefore, it may not always be possible to meet the intent of evaluating "(3) Any changes in design, material, or *manufacturing process* that could impact the functional characteristics of the item."	Revise to: (3) Any known changes in design, material, or manufacturing process that could impact the functional characteristics of the item.
9.	03.01 a. 1. (d) (6), page 4	The dedication process can include activities that occur before and during manufacturing. As discussed in the Final Regulatory Basis to Clarify 10 CFR PART 21, "Reporting of Defects and Noncompliance" (ML15152A457), if a characteristic cannot be verified during the dedication process, the item cannot be dedicated. The second part of the statement "Not all design requirements need to be considered critical characteristics; *however, dedicating entities must ensure the suitability of all parts, materials, and services for their intended safety-related applications.*" suggests that establishing suitability of design is integral to the dedication acceptance process. As defined in 10CFR21, dedication is an ***acceptance process*** pursuant to Criterion VII, "Control of Purchased Material, Equipment and Services", not a design process pursuant to Criterion III, Design Control. Establishing suitability of design is a design activity included in Criterion III that must occur before dedication begins using the methods described in Criterion III.	Change to: (6) Any critical characteristics that cannot be effectively verified after manufacturing ~~during the dedication process~~ should be identified in order to apply an appropriate verification method (Method 2, Commercial Grade Survey or Method 3, Source Verification) during the manufacturing process. If any critical characteristic cannot be verified acceptable, that item cannot be dedicated. The identified critical characteristics that are needed for the item to perform its safety function, as determined in the technical evaluation, should be verified~~. Not all design requirements need to be considered critical characteristics; however, dedicating entities must ensure the suitability of all parts, materials, and services for their intended safety-related applications. This may involve the performance of surveys, special tests and/or inspections, or source verification on commercial-grade vendors as part of the vendor selection process to verify the adequacy of the vendor controls (see Acceptance Methods section below).~~ Using one or more of the following acceptance methods: (A) Method 1: Special tests and inspections (B) Method 2: Survey of a commercial grade supplier (C) Method 3: Source verification (e.g., Product inspections or witness holdpoints) (D) Method 4: Supplier/Item history (e.g., Historical records for acceptable performance). [source – Final Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance" August 2015 21.21(A)(4))

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10.	03.01 a. 1. (d) (3), page 4	"(3) Seismic and environmental qualification should be treated as critical characteristics to be verified, as necessary" is understandable, but operating experience indicates it could be clarified with more detail.	Consider changing to: (3) Dedication should assure (when applicable) that s~~S~~eismic and environmental qualification is maintained by verifying critical characteristics related to seismic and environmental qualification (critical characteristics that provide reasonable assurance the dedicated item will be able to perform its safety functions during and after design basis events for which the item was qualified). ~~should be treated as critical characteristics to be verified, as necessary.~~
11.	03.01 a. 2., Page 5	As indicated in comment 8, it may not always be possible to evaluate "original" versus current manufacturing processes mentioned in (a) and (c). In addition, it is common practice for suppliers and manufacturers to change nomenclature (such as part and model number) in situations that do not impact the item, such as conversion to a new information system. Clarifying that when possible, considering (a)(b) and (c) can result in reason to believe an item has changed (and therefore requires further evaluation) may be helpful.	Revise to: A like-for-like replacement is a replacement of an item with one that is identical. Characteristics of like-for-like items are described below. A like-for-like replacement may be considered identical if there is no reason to believe design, (form, fit, function, and material) has changed. For example: (a) The item is provided by the OEM (successor companies that maintain equivalent quality controls are acceptable) and has not been subject to design (form, fit, or function), materials, manufacturing, or nomenclature changes (b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification. (c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.
12.	Multiple	The terms "supplier" and "vendor" are used throughout the IP. If there is no difference in meaning intended, using one term would eliminate questions about the difference. For example, in 3.01 a. 2., page 5	Standardize on either "vendor" or "supplier" unless different meaning is intended.

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		"(b) The item was purchased at the same time and from the same ***supplier***, as determined by the purchase date, shipping date, date code, or batch/lot identification. (c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item. A like-for-like determination should not be based solely on the selection of a commercial-grade ***vendor*** with items manufactured to meet the same industry standards of the item that was originally supplied. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination."	
13.	3.01 a. 2., page 5	As indicated in comment 8, it may not always be possible to evaluate "original" versus current manufacturing processes for commercial grade items. "An equivalency evaluation is needed if differences from the original item are identified in the replacement item to determine if any changes in design, material manufacturing process, safety, form, fit, function or interchangeability could impact the replacement item's ability to function under all design conditions (including design-basis event conditions) and ultimately the component's ability to perform its required safety function. Equivalency evaluations should not be used as the sole basis to accept a CGI for safety-related use.	Revise to: An equivalency evaluation is needed if differences from the original item are identified in the replacement item to determine if any changes, such as in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the replacement item's ability to function under all design conditions (including design-basis event conditions) and ultimately the component's ability to perform its required safety function.
14.	3.01 B. 1. (f), page 6	Administrative – "recoginized" has an extra "i"	Revise to "recognized"
15.	3.01 B. 2. (d), page 7	NUPIC currently stands for Nuclear Procurement Issues ***Corporation*** "For survey reports prepared by third parties (e.g., a Nuclear Procurement Issues ***Committee*** (NUPIC) joint or member survey), the following factors should be considered:"	Revise to: "For survey reports prepared by third parties (e.g., a Nuclear Procurement Issues Corporation ~~Committee~~ (NUPIC) joint or member survey), the following factors should be considered:"

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16.	3.01 B. 2. (f), page 8	It is not always possible for a dedicating entity to impose controls on sub-tier suppliers as requirements are typically imposed in a procurement document involving the dedicating entity and the primary supplier. "The dedicating entity is required to impose the necessary controls on subsuppliers consistent with the importance of the subcontracted item or service."	Revise to: (f) The dedicating entity is responsible for assessing ~~the~~ the supplier's control of subsuppliers of parts, materials, or services when the supplier relies upon subsupplier's controls and does not otherwise verify that parts, materials, or services provided by subsuppliers meet applicable requirements. ~~The dedicating entity is required to impose the necessary controls on subsuppliers consistent with the importance of the subcontracted item or service.~~ In such cases, c~~C~~ontrol of subsuppliers should ~~also~~ be adequately addressed by survey ~~so that the supplier~~ and requirements imposed in subsupplier procurement documents to establish ~~has~~ an adequate basis ~~to~~ for accepting test results and certifications.
17.	3.01 d. 2., page 11	CGD acceptance activities typically extend beyond standard receipt inspections. 2. Consider if *receipt inspections* performed adequately check for the acceptance of the dedicated item.	Revise to: Consider if ~~receipt inspections~~ acceptance methods and activities performed adequately check for the acceptance of the dedicated item.
18.	03.01 f., page 11	As discussed in comment 2, including criteria for non-CGD procurements in a CGD section may cause confusion. "f. Verify adequate controls for procurement of Appendix B components."	Address the procurement of Appendix B components in a separate section than CGD procurement
19.	3.01 f., page 11	Section 3.01 f. describes assessment of design activities as opposed to procurement/CGD activities. Initial design and establishing suitability of design typically occur before procurement pursuant to Criterion III. The design requirements are translated into procurement documents pursuant to Criterion IV to enable control of design during procurement. Re-establishing suitability of design is not required every time an item is procured although design must be controlled, and any changes evaluated. If the IP extends beyond CGD acceptance activities, clarity could be improved by moving design activities to a separate section. Translation of design does not involve additional design calculations or testing; calculations are part establishing original	Recommend moving licensee design control content to a new section as it is a different topic than CGD, Procurement of basic components. To address CGD activities, revise 3.01 f. to: "1. Consider assessing implementation of design controls and design configuration controls by performing the following: (a) Consider if the applicable design inputs are correctly translated into procurement documents." Pursuant to Criterion IV. ~~provisions in the design process permit the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related function of the product~~.

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		suitability of design, testing can be part of establishing original suitability of design or acceptance.	~~(b) Consider if the applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions. Consider if the design translation is supported by engineering data (i.e., calculations, performance tests), including verification that design inputs are satisfied. Consider if the final design (approved design output documents and approved changes) is relatable to the design input and identifies assemblies and/or components that are part of the item being designed.~~
20.	3.01 B F. 3. (a), page 12	This section mixes Appendix B procurement with CGD procurements. Clarifying which of the inspection criteria apply to procurement of basic components from suppliers with 10CFR50, Appendix B-compliant QA programs and moving these criteria to a separate section as discussed in comment 2 would improve clarity.	Revise to: (a) Consider if procedures have been established and implemented to select and qualify vendors with Appendix B-compliant QA programs supplying basic components and procured services. Procured services can include calibration, non-destructive examination (NDE), testing laboratories, software codes/programs, heat treatment, third-party inspections, engineering and consulting services, installation, repair, or maintenance work. (b) Consider if appropriate methods are used to accept a basic component from a supplier with an Appendix B-compliant QA program, such as certificates of conformance, source verifications, audits, surveillances, receiving inspections, or a combination thereof. (c) Consider if storage requirements are met for the components including preventive maintenance, surveillances, shelf life, environmental conditions, and environmental qualifications. (d) Consider if applicable Part 21, operating experience, and corrective action program items are used to evaluate the acceptability of basic components purchased from suppliers with Appendix B-compliant QA programs. (e) Consider if licensees conduct ~~audits and~~ surveys of commercial-grade suppliers when Method 2 is used. These activities should be based upon the suppliers' capability to supply the commodity desired in accordance with applicable codes/regulations.

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			(f) Consider if the effectiveness of the control of quality is assessed at intervals consistent with the importance, complexity, and quantity of the product or service (i.e., approved suppliers list). (g) Consider if there are provisions in the procedures to verify the validity of certificates received from suppliers with Appendix B-compliant QA programs and determine the effectiveness of the certification system when desired, such as during the performance of audits. Consider if certificates of conformance/compliance identify the material, equipment, or service supplied; identify specific procurement requirements (codes, standards, certificates, or other specifications such as cyber security requirements) that have been met as well as those that have not been met, together with an explanation and the means for resolving the nonconformance; and identify the supplier's QA individual responsible for authenticating such certificates. If any criteria have not been met, consider if a nonconformance report was initiated and follow up on its resolution. (h) Consider if licensee receiving inspections examine objective evidence of purchased items by verifying attributes specified in procurement documents. Licensee receiving inspections should verify, as a minimum, item configuration, critical dimensions, physical characteristics, and identification and traceability of material and equipment, including status of licensee inspection or tests performed, as required. (i) Consider if the licensee has a documented method for the identification and control of nonconforming material and components, to preclude inadvertent use. This includes Counterfeit, Fraudulent, or Suspect Items (CFSI) that were previously accepted for use.
21.	References Page 14	Administrative error	Revise to: Final Safety Evaluation for Technical Report NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (ADAMS Accession No. ML20322A019).

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22.	References, Page 15	ADAMS number is for an older revision. ML15075A434 is associated with NEI 14-05, Revision 0 March 2015 ML20135H229 is associated with NEI 14-05, Revision 1 May 2020 ML20259B731 is associated with NEI 14-05, Revision 1 September 2020	Revise to the most recent document: NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, (~~ML15075A434~~ ML20259B731)
23.	Appendix A, b., page AppA-1	Text references ANSI N45.2.13-1976. Consider adding an updated reference to ASME NQA-1.	Revise to: (e) the quality history and degree of standardization of the item. Additional guidance on the use of graded quality assurance can be found in the non-mandatory appendix to ANSI N45.2.13-1976 and ASME NQA-1, Subpart 3.1-2.1, Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs
24.	Appendix A, d., page AppA-1	Appendix A., d. discusses activities performed by licensees and suppliers as if they were a single entity, and discusses activities performed by both commercial suppliers and suppliers with 10CFR50, Appendix B-compliant QA programs. Clarifying which activities are performed by which entity, which are part of the dedication process, and which are part of the supplier's controls would add clarity.	Revise to: Reasonable Assurance The dedication process represents an acceptable method of achieving compliance with Appendix B to 10 CFR Part 50. In this context, reasonable assurance consists of the licensee ensuring that a commercial grade item is controlled under a quality assurance program complying with appendix B to part 50 of this chapter and is therefore acceptable for use as a basic component. *(source – draft reg basis ML15152A457)* c~~ontrolling or verifying the activities affecting the item's quality to an extent consistent with the item's importance to safety or ensuring that these activities are adequately controlled by the supplier.~~ For more complex items, additional analysis and when possible, dialogue with the original equipment manufacturer may be necessary to identify the design and functional parameters of specific piece parts. Once the dedication process is completed, the quality assurance and/or other measures applied to those aspects of the item that directly affect its safety function should result in the same level of performance as for a like item manufactured or purchased under a quality assurance program of Appendix B to 10 CFR Part 50.
25.	Appendix A, USE OF INDUSTRY	Discussion related to EPRI guidance on dedication is based on older revisions of documents that are no longer available and definitions that have been reworked pursuant to revision of EPRI NP-5652 and OIG Audits *(1)* OIG-10-A-20, "Audit of	Revise to include current references and information as indicated below:

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	GUIDANCE, page App A-4	NRC's Vendor Inspection Program," dated September 28, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML102710583), and (2) OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," dated March 23, 2011 (ADAMS Accession No. ML110820426). Discussion related to EPRI guidance on counterfeit and fraudulent items is based on a document that is no longer available and was revised by and industry team in response to NRC comments. Use of the old reference does not recognize EPRI 3002002276 Plant Support Engineering: Counterfeit and Fraudulent Items—Mitigating the Increasing Risk, Revision 1 of 1019163 mentioned in NRC SECY 15-0003. References should be updated to current documents.	The Electric Power Research Institute (EPRI) ~~NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07),~~" EPRI 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" defines critical characteristics as "The important design, material, and performance characteristics of a commercial grade item that—once verified—will provide reasonable assurance that the item will perform its intended safety function." Previously, EPRI referred to "critical characteristics" as "critical Characteristics for acceptance" ~~"identifiable and measurable attributes/variables of a CGI, which once selected to be verified, provide reasonable assurance that the item received is the item specified."~~ EPRI 3002002982 also defines design characteristics as follows "Sometimes referred to as critical characteristics for design, those properties or attributes that are essential for the item's form, fit, and functional performance. Critical characteristics for design are the identifiable and/or measurable attributes of a replacement item that provide assurance that the replacement item will perform its design function. NRC's conditional ~~endorsement~~ acceptance of EPRI ~~NP-5652 by Generic Letter 89-02~~ 3002002982 by RG 1.164 recognizes the definition of an older term, "critical characteristics for acceptance" included in 3002002982, ~~was based on interpreting that in the EPRI definition of critical characteristics the "item specified" encompassed those attributes that are essential for the performance of the item's safety function. This interpretation is consistent with the definition of "critical characteristics for acceptance" found in EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants,"~~ which notes that critical characteristics for acceptance are a subset of "critical characteristics for design." (or in using current terminology, critical characteristics are a subset of design characteristics) ~~The EPRI NP-6406 definition of "critical characteristics for design" includes those attributes that ensure the performance of the item's design function.~~ ~~EPRI TR-1019163, "Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items- Mitigating the Increasing Risk" describes best practices for~~

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			~~avoiding entrance of Counterfeit, Fraudulent or Suspect items into the commercial nuclear supply chain and can be helpful to increase awareness of the potential.~~ Published NRC guidance ~~does not differentiate between design and acceptance critical characteristics and the CGI dedication guidance provided~~ in Generic Letters 89-02 and 91-05 does not suggest that all design requirements of an item need to be verified during the dedication process. Rather, the licensee is expected to identify the item's design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function and select from these characteristics a set of critical (or acceptance) characteristics that, once verified, will provide reasonable assurance that the item will perform that function. Consistency in the definition of critical characteristics can be improved by equating the NRC's definition of critical characteristics to the EPRI definition of "critical characteristics for acceptance." ~~EPRI TR-1019163~~ EPRI 3002002276, "Plant Support Engineering: Counterfeit and Fraudulent Items—Mitigating the Increasing Risk, Revision 1 of 1019163" referenced in NRC SECY 15-0003 describes best practices for avoiding entrance of Counterfeit, Fraudulent or Suspect items into the commercial nuclear supply chain and can be helpful to increase awareness of the potential. EPRI 1021493, "Plant Support Engineering: Counterfeit and Fraudulent Items, A Self-Assessment Guideline" provides questions that can be used to identify opportunities to improve identification and prevention of counterfeit and fraudulent items.
26.	Appendix B, p. 5. page AppB-1, Appendix B r. 3., page AppB-2	Listed in Dedication Documents in Appendix B p., 5. is "Identification of the supplier's quality assurance program that meets 10 CFR Part 50, Appendix B". The entity supplying a commercial-grade item to a dedicating entity would not have a 10CFR50, App B-compliant QA program. Therefore, Appendix B p., 5. Should be revised to reflect commercial quality program or other documented controls. Appendix B r. 3. refers to source *inspection*. Current language would be source *verification* as defined in Appendix C, n. on page AppC-2	Revise to: 5. identification of the supplier's commercial quality assurance program or other documented controls ~~that meets 10 CFR Part 50, Appendix B~~ r. Documents showing objective evidence: 1. special test and inspection procedures and results 2. commercial-grade survey reports –item critical characteristics, for example design, material, and specific performance characteristics (relevant to safety function) 3. source ~~inspection~~ verification reports

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27.	Appendix C, d., page App-C-1	The definition of *commercial-grade item* included in the final regulatory basis (ML15152A457) is clearer than the definition included in Appendix C, d. and addresses the potential misconception that an item has to be *manufactured* under an Appendix B-complaint QA program to be established as a basic component without CGD. In the past, the phrase "designed and manufactured" has resulted in confusion. If the phrase is used, clarification that the phrase "Designed and Manufactured," when applied to basic components, means "controlled" under a quality assurance program complying with appendix B to 10 CFR Part 50.	d. Commercial-grade item means an item that is not a basic component. ~~: A structure, system, or component, or part thereof that affects its safety function that was not designed and manufactured as a basic component~~. (Source – draft reg basis ML15152A457) or When applied to nuclear power plants licensed pursuant to 10CFR50, commercial grade item means a structure, system, component, or part thereof that affects its safety function and that was not designed and manufactured as a basic component. Commercial-grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (that is, one or more critical characteristics of the item cannot be verified). 2. When applied to facilities and activities licensed pursuant to 10CFR 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, an item that is: (1) Not subject to design or specification requirements that are unique to those facilities or activities (2) Used in applications other than those facilities or activities; and (3) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog). Designed and Manufactured: When applied to basic components the term designed and manufactured means controlled under a quality assurance program complying with appendix B to 10 CFR Part 50. *(definition source is 10CFR21)*
28.	Appendix C, e., page AppC-1	Clarify in the definition for commercial-grade survey that commercial-grade surveys are performed by the dedicating entity. Remove "designated" as CGD is an acceptance process, not a designation process. Some commercial entities may not have a formal commercial-grade quality program but may still implement quality activities in accordance with otherwise documented procedures, processes, or instructions that can be specified in procurement documents.	Consistent with EPRI 3002002982 RG 1.164 e. Commercial-grade survey: Activities conducted by the ~~purchaser~~ dedicating entity or its agent to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the ~~designated~~ commercial-grade items to be purchased and accepted. The verification can be used as a method to accept those characteristics. The commercial-grade survey should include verification of the supplementary documentation and the effective

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			implementation of the commercial-grade quality program or otherwise documented quality activities.
29.	Appendix C, j., page AppC-2	Using the first part of the definition for dedication included in 10CFR21 or the definition included in the final regulatory basis for 10CFR21 (ML15152A457) would reduce confusion related to the "supplemented as necessary" statement included in the IP definition in Appendix C, j.	Revise to: Dedication: 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 and, in this respect, is deemed equivalent to an item designed and manufactured under an Appendix B, quality assurance program. ~~This assurance is achieved by identifying the critical characteristics of the item (not required in like-for-like replacements) and verifying its acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery (Method 1), supplemented as necessary by one or more of the following: commercial-grade surveys (Method 2), product inspections or witness at holdpoints at the manufacturer's facility (Method 3), and analysis of historical records for acceptable performance (Method 4). In all cases, the dedication process must be conducted in accordance with the applicable provisions of Appendix B.~~ *(Source: 10 CFR Part 21)* When applied to basic components the term "designed and manufactured" means controlled under a quality assurance program complying with appendix B to 10 CFR Part 50. Or, from Final reg basis ML15152A457) Dedication: 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.