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Dedication of Commercial-Grade Items for Use in Nuclear Power Plants

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Dedication of Commercial-Grade Items for Use in Nuclear Power Plants; Draft Regulatory Guide for Comment

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General Comment

Please see attached file.

Attachments

Comments on RG 1292 - 2

1. 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.

2. 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."

3. 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.

4. 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.

5. 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.

6. Part C, Staff Regulatory Guidance

   Add the following #3, #4, #5 and #6 as exceptions and clarifications to the two positions listed in the draft:

   " 3. EPRI TR-102260 section 3.4:

   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 10CFR50 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 10CFR50 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 10CFR50 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, 10CFR21 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."

"4. 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 10CFR50 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 10CFR50 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. 10CFR21 only added defect reporting requirements. In the 1970's suppliers routinely purchased commercial items for use in nuclear components."

"5. EPRI TR-102260 step 5.2.2:

1. The NRC does not concur that compliance with 10CFR50 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."

"6. 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."