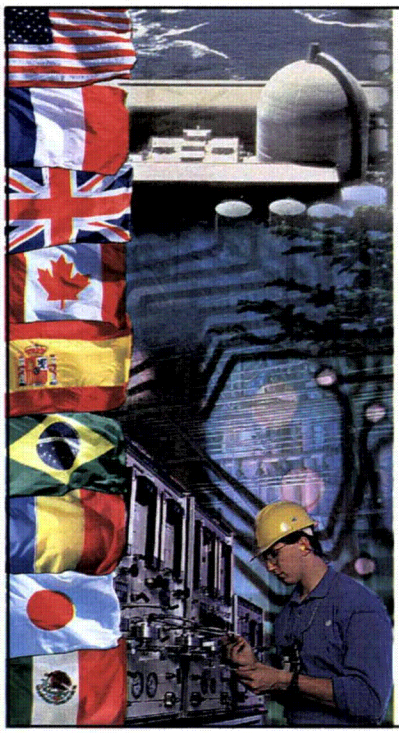

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NRC Category 2 Meeting to discuss Draft Inspection Manual for Commercial Grade Item Dedication

July 18, 2007

Background

- The NRC announced plans to issue a new Inspection Manual to consolidate guidance applicable to Commercial Grade Item Dedication in a single document
- Some context and language in the Draft IM are different from that contained in existing regulatory documents
- These proposed changes will significantly impact all licensees
- Licensees want to ensure the Draft IM terminology is consistent with existing regulatory documents

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Existing Regulatory Requirements & Guidance

10CFR, Part 21 - *Reporting of Defects and Noncompliance*

10CFR50, Appendix B - *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*

NRC Bulletin no. 88-10, & 88-10, Supplement 1: *Nonconforming Molded-case Circuit Breakers*

Generic Letter 89-02 - *Actions to improve the detection of counterfeit and fraudulently marketed products*

Generic Letter 91-05 - *Licensee Commercial-grade Procurement and Dedication Programs*

NRC Inspection Procedure 38703 - *Commercial Grade Dedication*

Existing Industry Guidance

EPRI NP-5652 - *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (June, 1988)

EPRI NP-6406 - *Technical Evaluation of Replacement Items Guideline* (December,1989)

EPRI NP-7218 - *Guideline for the Utilization of Sampling Plans for Commercial-Grade Item Acceptance (NCIG-19) (June, 1992)*

EPRI TR-102260 - *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (May, 1994)

EPRI TR-017218-R1 - *Guideline for Sampling in the Commercial-Grade Item Acceptance Process* (February,1999)

EPRI TR-112579 - *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* (August, 2000)

EPRI 1008256 – *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (Revision 1)(July, 2006)*

Key Areas of Concern

1. Requirements for a replacement Commercial Grade Item (CGI) to be traceable to the same manufactured batch or time of manufacture as the original item to be considered "like-for-like" (3.02 A 1)
2. Equivalency Evaluation Guidance and the relationship of EE's to Commercial Grade Item Dedication (CGID)(3.02 A 2)
3. Addition of the word "All" pertaining to verification of Critical characteristics (3.01 A 4f)
4. Absence of the term "reasonable assurance" in the body of Inspection Manual (IM) text (01.02)
5. Traceability of a CGI to its Original Equipment Manufacturer (OEM) (XX-02 7a)
6. CG Survey required to utilize sampling plan for tests and inspections (3.03 A M1 6)

Key Areas of Concern

7. Applicability of Design Control Measures to the Commercial Grade Item Dedication (CGID) acceptance process (XX-02 2 a)
8. Procurement Document Control "traceability" requirements (XX-02 3 b)
9. Long Term Reliability / Durability (3.01 A 4b)
10. Including special tests and inspections performed during manufacture in Method 1 instead of Methods 2 & 3 (3.03 A M1 1)
11. Equivalency Evaluation Guidance (3.02 A 6)

1. Traceability to Same Manufactured Batch/Time (3.02 A 1)

HIGH IMPACT

"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 replacement may be considered identical if: . . . The item has the same manufacturing time frame as determined by, for example, date purchased or date shipped from factory, date code, same batch or lot number"

*"A like-for-like replacement is defined as the replacement of an item with an item that is identical. For example, the replacement item would be identical if it was purchased at the same time from the same vendor as the item it is replacing, **or** if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced."* (GL 91-05, Encl. 1, Response to NUMARC CPI)

In utility guidance documents, the term "Like-for-Like" is associated with the Technical Evaluation of Replacement Items (TERI) process, not the acceptance process. This will result in **an Equivalency Evaluation being required any time a replacement item (material, part or component) is procured** – this is applicable to all procurement (not specific to CGID or licensees)

2. Equivalency Evaluation Guidance (3.02 A 2)

HIGH IMPACT

"An equivalency evaluation should demonstrate that an alternate replacement is **identical** in form, fit, function process and material to the item it is replacing, and that it will function under all design conditions (including design basis event conditions)." (Draft IM)

"If differences from the original item are identified in the replacement item, then the item is not identical, but similar to the item being replaced, and an evaluation is necessary to determine if any changes in design, material, or the manufacturing process could impact the functional characteristics and ultimately the component's ability to perform its required safety function" (Draft IM 3.02 A 5, GL 91-05, Response to NUMARC CPI)

Equivalency Evaluations are associated with the Technical Evaluation of Replacement Items (TERI) process and are not employed as a basis to accept CGI's. The term "identical" in this context should be replaced with the term "equivalent (equal to or better than)"

3. All Critical characteristics (3.01 A 4f)

HIGH IMPACT

"**All** critical characteristics (i.e., those that are important for the item to perform its safety function, as determined in the technical evaluation) are to be verified. Not all design requirements need to be considered critical characteristics; however, licensees must assure the suitability of all parts, materials, and services for their intended safety-related applications." (Draft IM)

"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."*

(IP 38703 App. A, GL 91-05 p. 4)

4. Absence of "reasonable assurance" in the body of Inspection Manual (IM) text (01.02)

HIGH IMPACT

"To determine whether the commercial-grade dedication program includes provisions to demonstrate that a dedicated item or service is suitable for safety-related applications." [Draft IM – "reasonable assurance" is contained in 03.06 (definitions) for Critical Characteristics and Dedication]

"Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those 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" (10CFR, Part 21, Proposed IM, IP 88114, IP 38703)

5. Guidance pertaining to Traceability of a CGI to its Original Equipment Manufacturer (OEM) (XX-02 7a) HIGH IMPACT

"Measures are established to control the identification or traceability of a CGI to its original manufacturer and to the results of dedication inspections and tests. Unique identifiers are to be maintained either on the item or on records traceable to the item." (Draft IM)

"Traceability is not aimed at introducing additional or unnecessary paperwork into the procurement process but rather to validate documentation supplied from the original equipment manufacturer (OEM). Generic Letter 89-02 states in Section B that in addition to receipt/source inspections and tests, effective licensee programs normally verify traceability to the OEMs of procured materials, equipment, and components in those cases ***where OEM certifications are elements of the licensee's commercial-grade dedication program****."* (Response to CPI, GL-89-02, IP 38703)

6. CG Survey Required to utilize Sampling Plan (3.03 A M1 6) HIGH IMPACT

"Sampling plans for testing should be used in accordance with nationally recognized industry standards, and should have an adequate documented technical basis. This technical basis includes homogeneity, complexity of the item, lot/batch control for items, heat traceability for materials, and **adequacy of the vendor's controls as confirmed by a survey**. The CGI sampling process should be documented to develop the necessary objective evidence of the vendor's ability to consistently provide acceptable items." (Draft IM)

"Licensees may implement alternative measures to audit or survey which would be acceptable to the staff for demonstrating lot homogeneity." (Response to NUMARC CPI)

"*Verify that sampling plans are controlled and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of supplier controls.*" (IP 38703 3.01 a. 2 M2, IP 88114)

7. Applicability of Design Control Measures to Dedication (XX-02 2 a)

HIGH IMPACT

"Design control measures are applied to the delineation of critical characteristics and the acceptance criteria for inspections and tests." (Draft IM, 10CFR50, App. B, III)

"Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, 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 and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program."
(10CFR21)(10CFR50, App. B, VII) (Draft IM, XX-02 6 c)

8. Procurement Document Control "traceability" requirements (XX-02 3 b)

"Criterion IV - Procurement Document Control (b.) Procurement documents invoke the commercial-grade vendor's commercial quality program documents by revision and/or date, and also establish requirements for documented traceability." (Draft IM)

What is the regulatory basis for including "*documented traceability*"?

Documented traceability is applicable only when relying on the vendor's certification to verify critical characteristics (i.e. when using Method 2 - Commercial Grade Survey)

Ref. GL 91-05, Inspection Findings 1b

9. Long Term Reliability / Durability (3.01 A 4b)

"The identification of the item's critical characteristics based on the information developed above that will assure the suitability of all parts, materials, and services for their intended safety-related applications. Factors that should be considered include: . . . b. Active/passive safety-related functions, long-term reliability/durability, system safety/non-safety interfaces, and system compatibility under all design basis conditions." (Draft IM)

What is the regulatory basis for relating reliability and durability to critical characteristics and acceptance criteria?

Long-term durability and system compatibility are an inherent part of the design function when originally specifying the item.

"When engineering personnel specify design requirements for inclusion on the purchase documents for replacement components, they need not reconstruct and reverify design adequacy for procurement" (GL 91-05)

10. Including Method 2 or 3 Inspections done prior to delivery as Method 1 Special Tests and Inspections (3.03 A M1 1)

"Method 1: Special Test and Inspections, 1. Special test and inspections should be used after the CGI is received **or during manufacture** to assure that the purchased material, equipment, or services, whether purchased directly or through contractors and subcontractors, meet the technical and quality requirements." (Draft IM)

Method 1 does not include tests and inspections performed during manufacture, but is intended for those performed during and after receipt.

Tests and inspections performed during manufacture are covered by Methods 2 or 3.

11. Equivalency Evaluation Guidance (3.02 A 6)

"Equivalency evaluations should not be used as the sole basis to accept a CGI for safety-related use. All critical characteristics should still be verified as part of the acceptance process." (Draft IM)

Equivalency Evaluations (EE) are not used as a basis for accepting CGI's for use.

When applicable, an EE is performed as part of the technical evaluation (TERI) process to demonstrate acceptability of the proposed replacement item for its intended application.

In addition, a CGID evaluation is prepared to provide a basis for accepting the CGI for use in its approved safety-related application(s).

The term "**All**" appears again (refer to discussion for Item 3).

We recommend that this statement be removed from the Draft IM.

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