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21st Annual NUPIC Vendor Meeting

Basis for Commercial Grade Item Dedication

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Topic Areas

- Background
- Regulatory Requirements
- Development of NRC Guidance
- Dedication Issues in 2012
- NRC Region II Construction Inspection at Watts Bar Unit 2

Background

- The overall function of a dedication program is to provide an alternate means of satisfying the requirements of 10 CFR 50 Appendix B with regard to procurement and acceptance of commercial grade items (and services) for use as basic components.
- What regulatory requirements exist??

Regulatory Requirements

Key Statutory requirements

- Appendix B of 10 CFR Part 50 issued by Atomic Energy Commission (AEC) in 1970
- Section 206 of the Energy Reorganization Act (ERA) of 1974
 - Failure to comply
 - Defect
 - Reporting

Regulatory Requirements

- 10 CFR Part 21, Promulgated in June 1977 to implement ERA
 - Introduced new definitions and concepts:
 - “Defect,” “Basic Component,” and “Substantial Safety Hazard”
 - Established that all suppliers of parts making up “basic component” were subject to reporting requirements of 10 CFR Part 21

Regulatory Requirements

- Part 21 amended in October 1978
 - Commercial grade items exempt from reporting requirements of Part 21 until “dedication” is successfully completed
 - Introduced new definitions and concepts: (Definitions were significantly revised in September 1995)
 - “dedication” and
 - “commercial grade item”

Regulatory Requirements

- 10 CFR 21.3, “Definitions”
 - 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, and in this respect, is deemed equivalent to an item designed and manufactured under an 10CFR50, Appendix B QA Program.

Regulatory Requirements

- ANSI N -18.7-1976/Regulatory Guide 1.33 commercially “off-the-shelf” items may be similarly procured but care must be taken to assure at least equivalent performance
- 10 CFR Part 50 Appendix B – Applies to all safety related structures, systems, and components SSCs (Basic Components)

Regulatory Requirements

- 10 CFR Part 50 Appendix B – Criterion III, Design Control, requires the **selection and review for suitability of application** of materials, parts, equipment and processes that are essential to the safety-related functions of SSCs

Development of NRC Guidance

- Mid 1980s - NRC initiated Licensee commercial grade dedication inspections
- Dedication Inspections in the mid-late 1980's identified common problems in CGI dedication
- June 1988 - Industry guidance EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07),"

Development of NRC Guidance

- March 1989, GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,”
 - conditionally endorsed EPRI NP-5652
 - identified characteristics of effective procurement and dedication programs
 - emphasized engineering involvement in the procurement process

Development of NRC Guidance

- October 1990 NUMARC 90-13, Nuclear Procurement Program Improvement
 - Comprehensive Procurement Initiative
 - Assessed licensee procurement programs
- Early 1990's
 - NRC assessments of program improvements
 - NRC Pilot inspections

Development of NRC Guidance

- April 1991, GL 91-05, “Licensee Commercial grade procurement and Dedication Programs,”
 - announces pause in NRC inspections and provides additional clarifications on CGI dedication
 - NRC inspections identified a common, programmatic deficiency in the licensees’ control of the procurement and the dedication process of commercial grade items for safety-related applications.

Development of NRC Guidance

- April 1993, NRC Public Commercial grade procurement and Dedication workshop
- November 1993, NRC issues IP 38703 “Commercial Grade Dedication”

Development of NRC Guidance

- Appendix A to IP 38703 addressed most difficult “Dedication Issues”
 - Basis for the Selection and Verification of Critical Characteristics
 - Traceability
 - Sampling
 - Commercial Grade Surveys
 - Acceptance of Certified Material Test reports (CMTRs) and Certificates of compliance (CoCs)

Development of NRC Guidance

- March 29-30, 1994, NRC “Commercial Grade Procurement and Dedication Training Dedication discussions:
 - IP 38703 inspection process
 - dedication issues in Appendix A
 - contents of dedication packages
 - Panel discussion - dedication issues and examples

Dedication in 2012

Nothing has Changed!!

- 10 CFR Part 21.3 – Definitions
- IP 38703 is used for Licensee led CGI dedication inspections
- IP 43004, “Inspection of Commercial-Grade Dedication Programs” for vendors

Dedication in 2012

- Dedication guidance contained in
 - EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)
 - NRC IP 38703 with Appendix A "Dedication Issues"
 - NRC IP 43004, "Inspection of Commercial Grade dedication programs"
 - NQA-1 Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services" provides enhanced guidance on commercial-grade dedication (2009 Addenda)

Dedication in 2012

- Dedication of CGIs is currently being used for more than the replacement items that it was designed for in the 80's
- Awareness of good dedication practices has been lacking as evidenced by NRC and NUPIC inspection findings
- Vendor Inspections have identified findings in implementation of the CGI dedication process

Dedication in 2012

- Computer Software and design and analysis computer programs that have been commercially procured
- Commercial calibration services – calibration laboratories with ILAC certification
- Implementation of appropriate dedication processes and activities

Dedication in 2012

- We continue to identify findings at vendors related to dedication of CGIs for SR applications
 - Inadequate technical evaluations
 - Critical characteristic identification
 - Acceptance of critical characteristic's
- Samantha Crane will discuss recent NRC inspection results related to CGI dedication at the NRC workshop break-out session on Thursday

TVA Watts Bar 2 Inspection

- December 2011 NRC Region II Inspection of Watts Barr Unit
2 Construction Activities
 - *Severity Level IV Notice of Violation - Commercial grade dedication activities failed to adequately establish commercial grade items as basic components*
 - Failure to incorporate requirements for commercial grade dedication into procedures
 - Failure to establish measures for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of systems, structures, and components (SSCs)

TVA Watts Bar 2 Inspection

- Programmatic Results of Region II inspection of construction activities
 - Procedures were not updated to reflect the requirements of the current revision of 10CFR21
 - Procedure allowed for “conditional” dedication (post-installation testing) but did not provide guidance for how to accomplish conditional dedication
 - Critical characteristics specified appear to be targeted at ensuring the “item received is the item specified” instead of providing reasonable assurance the item can perform its intended safety function

TVA Watts Bar 2 Inspection

- Commercial Grade Dedication Program Unresolved Item (URI)
 - Insufficient Documentation to demonstrate selected critical characteristics provide reasonable assurance items would perform safety function
 - Some evaluations did not identify safety functions, postulated failure modes, and critical characteristics that provide reasonable assurance items would perform its intended safety function
 - Inadequate maintenance of the TVA Commercial Grade Dedication program including procedures and processes

TVA Watts Bar 2 Inspection

- Commercial Grade Dedication Program Unresolved Item (URI)
 - Definition of “Critical Characteristic”
 - TVA Procedures included old definition from EPRI NP-5652 (June, 1988)
 - Derived from original issue of 10 CFR Part 21
 - EPRI definitions were subsequently revised in EPRI NP-6406 (December 1989) “Technical Evaluation of Replacement Items” and TR-102260 (May 1994) (Supplemental Guidance to NP-5652)
 - 10 CFR Part 21 definition was added in 1995

Questions/Comments



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