NRC Workshop on Vendor Oversight for New Reactor Construction

Critical Characteristics: Selection and Verification

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Protecting People and the Environment

Agenda

- Commercial-Grade Item (CGI) Dedication Process
- NRC's Perspective on:
  - Technical Evaluations
  - Critical Characteristics
  - Like-For-Like CGI Replacements
  - Equivalency Evaluations
  - Seismic/Environmental Qualification

CGI Dedication Process

- Two principal QA criteria that the CGI dedication process should be designed to meet:
  - Criterion III, "Design Control"
  - Criterion VII, “Control of Purchased Material, Equipment and Services”

CGI Dedication Process (cont'd)

- An acceptable dedication program consists of:
  - Technical Evaluation - identifies
    - Technical requirements
    - Quality requirements
  - Acceptance Method - verifies
    - Technical and quality requirements have been met.

Technical Evaluations

- Identify item's safety function, performance requirements, part functional classification, service conditions.
- Identify **critical characteristics**, including acceptance criteria.
- Identify dedication methods for verification of acceptance criteria.

Technical Evaluations (cont'd)

- Information sources include, but not limited to:
  - Design output documents
  - Supplier technical information
  - Industry technical/operating experience
  - Failure modes and effects analyses (FMEAs)
- Complete documentation / auditable records of rationale, justifications, engineering analyses, etc.

Critical Characteristics (CCs)

- 10 CFR 21.3, “Definitions”
  - Important design, material, and performance characteristics of a CGI (or service) that, once verified, will provide reasonable assurance that the item (or service) will perform its intended safety function.

Critical Characteristics (CCs) (cont'd)

- Basis for Selection of CCs
  - Design, material, performance characteristics
  - Active/passive safety-related functions.
  - Safety/non-safety interfaces.
  - Changes in design, material, or manufacturing process.
  - Number and nature of CCs are based on safety function, application requirements, FMEA, and performance requirements.

Like-for-Like CGI Replacements

Like-for-like CGI replacement: the replacement of an item with an item that is identical.

Source: Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," April 9, 1991.
NQA-1, Quality Assurance Requirements for Nuclear Facility Applications."

Like-for-Like CGI Replacements

(cont'd)

- Like-for-like criteria:
  - Item is provided from the original equipment manufacturer and has not been subject to design, materials, manufacturing, or nomenclature changes,

    or

  - Item was purchased at the same time and from the same supplier,

    or

  - Evaluation of item confirms that no changes in the design, materials, or manufacturing process have occurred since procurement of original item.

Like-for-Like CGI Replacements
(cont'd)

- Like-for-like determination may not always be based solely on selection of commercial-grade vendors with items manufactured to meet the same industry standards of the original item.

- If dedicating entity can demonstrate that replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. **However**, verification of the identified critical characteristics by appropriate dedication method(s) is required to verify acceptability of replacement item.

Equivalency Evaluations

Equivalency evaluation: A technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions.

Source: Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," April 9, 1991.
NQA-1, Quality Assurance Requirements for Nuclear Facility Applications."

Equivalency Evaluations (cont'd)

- Equivalency evaluations shall be documented and include the following:
  - Identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item;
  - Evaluation of the change(s);
  - Confirmation that the change(s) do not adversely affect the current design or safety function of the item.

Equivalency Evaluations (cont'd)

- Equivalency evaluations are not to be used as the sole basis to accept a commercial-grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

Seismic/Environmental Qualification

- The commercial-grade item's functional performance requirements should include design and service conditions (harsh environment, seismic conditions).
- Identify critical characteristics that will provide assurance that seismic and environmental qualification is maintained

Questions/Comments

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