Sampling in the Commercial-Grade Dedication Process & Issues Identified with the Use of the ILAC Alternative

2nd Town Hall Meeting On Vendor Oversight

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Agenda

- Commercial-Grade Dedication (CGD)
- Regulatory & Industry Guidance
- Sampling as Part of CGD
- Use of the ILAC Alternative
- Questions and Contact Information

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Commercial-Grade Dedication

- What is commercial-grade dedication supposed to achieve?
  - Acceptance process that provides ***reasonable assurance*** that a commercial-grade item to be used as a basic component will perform its intended safety function.

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Sampling as Part of CGD

- Sampling as part of CGD is a way to verify the critical characteristics on a representative number of commercial-grade items ***vs.*** doing 100% verification testing.
- Sample plans for testing should be used in accordance with nationally recognized industry standards and ***have an adequate documented technical basis.***

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Sampling as Part of CGD

- NQA-1, Part II, Subpart 2.14 states:
  - "Sampling plans utilized to select items for special test(s), inspection(s), and/or analyses ***shall be based*** upon standard statistical methods ***with supporting engineering justification*** and shall consider lot/batch traceability, homogeneity, and the complexity of the item."

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Regulatory & Industry Guidance

- Appendix A, “Dedication Issues Basis For The Selection and Verification of Critical Characteristics,” of Inspection Procedure (IP) 43004, “Inspection of Commercial-Grade Dedication Programs,” dated February 10, 2023.
- Regulatory Guide 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, dated June 2017.

Regulatory & Industry Guidance

- Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI 5652 and TR 102260, “Plant Engineering: Guidelines for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications,” dated September 2014.
- EPRI 30020022082 refers to EPRI TR-017218-R1, “Guideline for Sampling in the Commercial-Grade Item Acceptance Process,” dated January 1999.

Regulatory & Industry Guidance

- Section D.2.9 of EPRI 3002002082 states: "Basis for selection of sampling plans. ***When sampling is used, document the sampling plan selected for each critical characteristic and the basis/factors considered when selecting the sampling plan***."
- Section 1.4.5 of EPRI TR-017218-R1 states: "The commercial grade item acceptance sampling process ***and the bases for sampling plan selection and application should be adequately documented.*** Documentation should address such factors as lot formation, complexity of the item, adequacy of supplier control as appropriate, safety function, test methodology, product performance, acceptance history of a supplier, item performance history, and other qualitative factors."
- The NRC has not endorsed EPRI TR-017218-R1.

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Sampling as Part of CGD

- Documented technical basis/engineering justification:
  - Part of the technical evaluation
  - Engineering involvement
  - Homogeneity, heat traceability
  - Complexity of the item
  - Lot/batch control
  - Supplier controls

Sampling as Part of CGD

- What is traceability?
  - "The ability to verify history, location, or application of an item by means of recorded identification." (IP 43004)
- What is lot/batch control?
  - "Units of product of a single type, grade, class, size, and composition, manufactured essentially under the same conditions and at the same time." (IP 43004)

Sampling as Part of CGD

- How does the NRC inspect sampling as part of CGD?
  - Use guidance in IP 43004:
    - Established heat traceability (materials)
    - Established lot/batch control (items)
    - Material and Items with no lot/batch control

Sampling as Part of CGD

- What do we look for when inspecting sampling as part of CGD?
  - Documented technical basis and/or engineering justification for the sample plan selected.
  - Engineering involvement in the selection of the sampling plan.

Sampling as Part of CGD

- What do we look for when inspecting sampling as part of CGD? (cont.)
  - Documentation should address the factors considered in the selection of the sampling plan (e.g., lot traceability/homogeneity, complexity of the item, performance history, supplier controls, etc.)

Use of the ILAC Alternative

- Issues identified with the implementation of Revision 1 of NEI 14-05A.
- Issues are considered minor but are documented in the inspection report:
  - Some conditions not adequately implemented (e.g., onsite accreditation required within the last 48 months)

Use of the ILAC Alternative

- Issues (cont.):
  - Referencing the 2005 edition of ISO 17025 in the procurement documents.
  - Incorrectly listing the conditions from NEI 14-05A Revision 1 as the critical characteristics.

Use of the ILAC Alternative

- Issues (cont.):
  - Receipt inspection not adequately performed:
    - Calibration certificates stating service was performed in accordance with the 2005 edition of ISO 17025.
    - No statement included in laboratory documentation stating that the procurement document requirements were met.
    - Not performing/documenting receipt inspection.

Questions and Contact Information

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