



Sampling as Part of Commercial-Grade Dedication

NRC Workshop on Vendor Oversight

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QUALITY ASSURANCE VENDOR INSPECTION BRANCH-2

OFFICE OF NEW REACTORS

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SAMPLING

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. Other means of demonstrating adequate lot/batch control may include satisfactory performance history and the results of receipt inspections/testing. When such methods are used as a basis for developing product sampling strategy, they should be supported by documented objective evidence.

IP 43004



SAMPLING

- ❖ Requirement 10 - “Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval”
- ❖ Part II, Subpart 2.2 - “Where specific inspection requirements can be achieved, statistical sampling methods may be used for groups of similar items”
- ❖ Part II, Subpart 2.14 – “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”



NQA-1



Regulatory Guidance

- ❖ Dedication - Acceptance process that provides reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function..... 10 CFR 21.3
- ❖ The only guidance provided to the staff with regards of the use of Sampling in commercial grade dedication resides in Appendix A, “Dedication Issues Basis for The Selection and Verification of Critical Characteristics,” of IP 43004
- ❖ RG 1.164 - endorses the industry guidance of Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items In Nuclear Safety-Related Applications”



Regulatory Guidance

- ❖ Neither the regulation or the EPRI 3002002982 guidance address the use of sampling in detail
- ❖ EPRI 3002002982 makes reference to TR-017218-R1, “Guidance for Sampling in the Commercial-Grade Item Acceptance Process”
- ❖ As of today the staff has not received a request to evaluate the guidance provided by EPRI TR-017218-R1 for endorsement





NRC Inspections (IP 43004) - App. A

Provides the basis used by the inspectors for the verification of the sampling process. The guidance provides the following:

1. Established Heat Traceability (Materials)
2. Established Lot/Batch Control (Items)
3. Material and Items with No Lot/Batch Control





NRC Inspections (IP 43004)

Documented basis for the sample plan selected is important as emphasized by App. A. The inspectors will look for objective evidence supporting the sampling plan selected.

- ❖ Engineering must document the technical justifications for selecting Sampling Plan
- ❖ Documentation should address the factors that were considered prior to selecting a sampling plan (e.g. lot traceability/homogeneity, complexity of item, supplier controls)

These should be part of the technical evaluation.





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