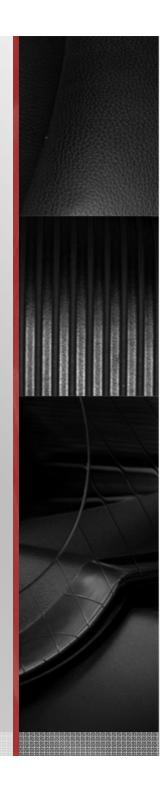
Commercial Grade Dedication

Common Weaknesses in Supplier's Program/Processes

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2017 NUPIC Vendor Conference



- NUPIC audits continue to identify issues with suppliers commercial grade dedication programs. These issues involve both inadequate program controls and implementation.
- Majority of the issues identified in the area of commercial grade dedication represent common weaknesses in program controls.

Issues identified with program controls associated with three areas for the commercial grade dedication process will be reviewed during this presentation. The areas are:

Dedication of Services

➤ Sampling

Technical Evaluations

The following examples are actual issues identified by NUPIC audits.

Dedication of Services Issues

- No CGD plan or objective evidence documenting dedication of calibration services
- Dedication of services performed without procedure guidance that describes dedication process.
- Pre-determined critical characteristics procedurally identified for various services but no safety function or failure modes identified to support selection of critical characteristics.
- Technical evaluation completed for dedication of services (may include calibration, welding, and electromagnetic qualification testing) identifying critical characteristics but does not address safety function.

Dedication of Services Issues

- Key Takeaways
 - Technical evaluation required for dedication of commercial services that can impact the safety function of the item/equipment for which the service is performed. This evaluation includes identification of safety function/failure modes, critical characteristics with acceptance criteria and acceptance methods. (EPRI 3002002982, Section 11)
 - Critical characteristics for services are generally process controls unlike physical/performance characteristics selected for dedication of items. (EPRI 3002002982, Section 11)

Sampling Issues

- Inadequate procedural guidance exists for selection of sampling plans for commercial grade dedication
- Technical justification for selection of sample plans (e.g., Tightened, Normal and Reduced) used for dedication is not documented
- For Method I, procedure states to determine the sample size but no guidance is provided on what sample plan is to be used, source of the sampling plan or guidance on providing adequate justification for selection of the sample plan/size.

Sampling Issues

- Key Takeaways
 - Procedural controls must adequately define the use of sample plans when used for verification of critical characteristics.
 - These controls should include the following:
 - Identification of the sample plan(s)
 - Source/technical basis of the plan
 - Requirement for providing a documented technical justification (sound engineering judgement) for the selection of <u>each</u> sample plan used to verify critical characteristics
 - Guidance on providing an adequate technical justification (Ex. EPRITR-017218-R1)

Sampling Issues

- Key Takeaways
 - Technical justification for selection of a sample plan to verify critical characteristics should not be a generic statement such as "Normal sample plan shall be used per EPRI 7218 unless otherwise indicated."

> Factors to consider for technical justification should include:

- Production traceability/lot homogeneity
- Supply source of the item (i.e., OEM vs. Distributor)
- <u>Documented</u> item performance history
- Item manufactured to industry standard

Sampling Issues

- Key Takeaways
 - > Factors to consider for technical justification should include:
 - Acceptance methods used to verify critical characteristics
 - Number of critical characteristics to be verified
 - Nondestructive vs destructive testing
 - The documented technical justification should include the factors considered supporting the selection of a specific sample plan used to verify critical characteristics. (EPRI 3002002982, Section 7)

Technical Evaluation Issues

- No technical evaluations or commercial grade dedication plans have been developed for dedication of certain items and services
- No technical justification to support selection of critical characteristics
- Several dedication plans provide acceptance tolerances with justification stating that the tolerance was not available from the manufacturer and tolerance provided in the dedication plan is based on the supplier's experience and provides reasonable assurance that the criteria is correct. No technical basis is documented to support why the tolerance values are acceptable for verification of the specific critical characteristic.

Technical Evaluation Issues

- Key Takeaways
 - Technical evaluations are required for all items and services which will be procured commercially and dedicated for use as basic components. (EPRI 3002002982, Section 3)
 - Technical basis for selection of critical characteristics should be documented. This is performed as part of the technical evaluation which also requires determination of the safety function/failure modes of item/service requiring dedication. The critical characteristics selected should directly correlate to the safety function and failure modes of the item/service and the documented basis for selection should support this. (EPRI 3002002982, Section 5)

Technical Evaluation Issues

Key Takeaways

Acceptance criteria including tolerances used to verify critical characteristics is determined as part of the technical evaluation and an adequate technical basis for the acceptance criteria should be documented in the technical evaluation. (EPRI 3002002982, Section 5)

QUESTIONS ???