Delivering the nuclear promise:

COMMON FINDING/DEFICIENCY DEFINITIONS for VENDOR AUDITS

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Establish Common Finding/Deficiency Definitions Used During Vendor Audits

Color Code: Red

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Implement a uniform approach for identification, follow-up and closure of performance issues found during audits of supplier facilities.

Desired end-state and value

- Desired end-state – NUPIC processes provide specific guidance that allows identification of a broad range of issues but requires formal, resource intensive follow-up activities for only a subset of risk significant issues. Supplier performance issues are consistently and properly classified based upon their significance.

- Value proposition (vision of excellence) – Significantly reduced audit team leader and supplier resources are spent conducting and supporting rigorous follow-up and closure documentation for low risk significant issues.

Why is it important?

- NUPIC Audit or Survey issues currently classified as Finding or Significant Finding.
- Out of 10 NUPIC audits sampled, 70% of NUPIC audit issues identified related to failing to follow approved supplier processes.
- Many member utilities would classify these as a deficiency requiring less rigorous or no follow-up.

Utility and supplier resources are expended unnecessarily to follow-up on lower significant issues.

Finding

- **Definition: Any defect, characteristic, noncompliance or activity that detracts from the quality of products and/or services and is a condition that could have credible impact to the intended function of the products and/or services provided. It also includes undesirable or abnormal pattern of events, failures, problems and programmatic issues.**
- **Findings are:**
  - **Documented on condition reports.**
  - **Follow-up is performed in accordance with the utility's implementing procedures and NUPIC guidelines.**
  - **Immediate notification(s) IAW NUPIC guidelines shall be provided when the Findings' net result places the product's ability to function properly in its intended application in question, such as:**
    1. **falsification of documentation,**
    2. **inadequate commercial grade dedication,**
    3. **nullified product qualification, or**
    4. **potential 10 CFR 21 issue**

Deficiency

- **Definition: A deviation in the implementation of a Quality Assurance Program requirement or a deviation in the implementation of a Quality Assurance procedure, including inadequate/conflicting procedures.**
- **Deficiencies would be documented in the vendor's corrective action program and the corrective action document number referenced in the applicable Audit Report.**
- **Deficiencies will not require a response or follow-up verification of corrective action completion prior to closure of the NUPIC audit.**
- **Deficiency review will be performed during the next scheduled NUPIC audit as part of the Corrective Action Program evaluation.**

Types of Findings/Deficiencies

NRC Inspection Manual Chapter 0617 (Vendor and Quality Assurance Implementation Inspection Reports) Appendix E used as guide:

1. **The vendor's 10CFR21 procedure does not address all of the requirements of 10CFR21.21(a) for evaluating deviations and failures to comply.**

   Deficiency if: A review of a sample of recent Nonconformance Reports and Corrective Action Reports failed to identify any specific issues that would have warranted further evaluation under the vendor's Part 21 program.

   Finding if: The same review did identify specific issues that would have warranted further review under the vendor's Part 21 program, or the vendor does not have a procedure for evaluating deviations and failures to comply in accordance with 10CFR21 and a deviation is identified that required evaluation.

Types of Findings/Deficiencies

2. **The vendor failed to ensure personnel performing inspection and test activities for safety-related components had completed required training. This same vendor also failed to maintain accurate training records in accordance with the vendor's testing procedures.**

   Deficiency if: The testing and inspection personnel had not performed inspection on safety-related components, or the personnel's lack of qualification was solely an administrative issue. The ability or competence of the inspector was not in question.

   Finding if: Testing was performed on safety-related components with personnel who were not qualified for the inspection/testing procedures and whose competence was suspect.

Types of Findings/Deficiencies

3. **A vendor procedure had undergone a major revision and contained reference to another procedure that was cancelled prior to the date of the revision.**

   Deficiency if: The issue was insignificant, in that the cancelled procedure was not required to provide information that was material to the successful completion of the specific work activity (i.e., the issue was administrative.)

   Finding if: The issue was significant, in that the revised procedure relied on a cancelled procedure to provide information that was important to the successful completion of a work activity that affected a SSC (e.g., acceptance criteria for an inspection, guidance for technical evaluation of data, qualification criteria, etc.), and the procedure was used in a safety-related activity.

Types if findings/Deficiencies

4. **Measuring and testing devices used in activities affecting quality were not properly calibrated for the full range of intended use.**

   Deficiency if: The M&TE has been retested and the results are clearly within the prescribed acceptance standards.

   Finding if: The M&TE has not been or cannot be retested and the issue calls into question the results of previous measurements or tests.

Previous audit examples

- The supplier's program allowed for acceptance of a Commercial Grade domestic calibration supplier based on accreditation to ISO-ILEC 17025.
- The audit team found that the supplier's procurement of Commercial Grade calibration services was deficient based on:
  - No Commercial Grade Dedication plan developed that identified the safety function, critical characteristics (CCs), acceptance method and verification methods for CCs.
  - The supplier waived the triennial survey for one calibration services supplier based on one sub-supplier's having a Z540 accreditation certificate.
  - The certification of one calibration services could only be verified to a ISO 9001 certification.

Finding, or Deficiency?

Previous audit examples

- 10 CFR 50, App. B, Criterion 18, states in part that, "The audits shall be performed in accordance with the written procedures or checklists.
- The audit team found that the supplier's internal audit program was deficient based on the following:
  - The internal audits used an ISO 9001 format, which did not cover all of the 10 CFR 50, App. B, criteria.
  - Limited detail in the audit reports provided insufficient objective evidence.

Finding, or Deficiency?

Previous audit examples

- The supplier's Nondestructive Examination (NDE) program required that measure be established to ensure that NDE is performed in a controlled deliberate manner in accordance with sufficiently detailed procedures and documented to a level of detail that demonstrates quality affecting activities have been satisfactorily performed.
- The audit team that found by direct observation that the supplier's NDE practices were deficient based on:
  - Penetrant materials being used were beyond their "Best if used by" date stamped on the bottom of the can; the procedure did not address shelf life of consumable materials. The temperature of the part was not verified as required by the procedure.
  - The water pressure was not regulated as required by procedure.
  - The maximum intensity of the amber light was not measured during fluorescent MT examination.
- The supplier resolved these issues upon notification.

Finding, or Deficiency?

Previous audit examples

- The supplier's quality assurance program required that each nonconforming item be documented, identified, and resolved.
- The audit team found that the supplier's Nonconformance program was deficient in that two nonconforming items that had been dispositioned as "Scrapped" were found in the fabrication, not tagged or segregated, and the associated Nonconformance Reports were closed.

Finding, or Deficiency?

Key Takeaways

- Final determination of conditions adverse to quality identified by the audit team to be classified as either a Finding or Deficiency will be made by the ATL.
- Deficiencies must be documented in the supplier's corrective action program.
- The next NUPIC audit will verify adequate corrective action was taken to address the Deficiencies and continues to be effectively implemented.

Questions?