

NRC RESPONSE REGARDING AUDITOR INDEPENDENCE

David Soward – Xcel Energy
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- NUPIC issued letter to NRC February 2018 requesting interpretation of 10CFR50 Appendix B Criterion XVIII specifically the requirement that audits be performed by appropriately trained personnel not having direct responsibilities in the areas being audited.
- The request for interpretation of this requirement is based on NUPIC audits continuing to identify instances where suppliers are performing a single internal audit annually to verify compliance with all aspects of the quality assurance program utilizing the same person to perform the supplier's internal audit in consecutive years.
- The same internal auditor utilizes the previous internal audit as objective evidence to determine if the supplier is complying with Criterion XVIII of 10CFR50 Appendix B.



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- By utilizing the previous internal audit as objective evidence to assess compliance with the internal audit controls of the supplier's QA program and 10CFR50 Appendix B, it is the position of NUPIC that the auditor is evaluating their own work.
- This position appeared to be consistent with NRC Inspection Procedure 43002 (1/27/17) Section 03.18.c which states in part..."Verify that selected auditors are not auditing their own work."
- Supplier challenged a NUPIC audit finding stating that although the same auditor utilized a previous internal audit they performed in order to evaluate the supplier's internal audit controls, the auditor was not "responsible" for the supplier's internal audit program and therefore met the requirements of 10CFR50 Appendix B Criterion XVIII for not having direct responsibility in the area audited.



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- NUPIC requested an interpretation from the NRC for the following question:
- With regard to appropriately trained personnel not having direct responsibilities in the areas being audited, would this requirement be met if an individual responsible for evaluating the internal audit controls during an annual internal audit utilized the internal audit from the previous year performed by the same individual as objective evidence that the supplier's internal audit controls were in compliance with the supplier's QA program and 10CFR50 Appendix B Criterion XVIII?



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- NRC provided the following response August 2018:
 - If a person performed an audit of the previous audit (for which the person was directly responsible) with the twin goals of verifying compliance with Criterion XVIII “Audits” aspect of the quality assurance program and determining the effectiveness of the previous Criterion XVIII audit, then the audit of the Criterion XVIII aspect of the previous audit likely would not meet the “not having direct responsibilities” clause of Criterion XVIII.



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- NRC provided the following response August 2018:
 - However, if a person simply noted the existence of the previous audit (for which the person was directly responsible), but made no assertions concerning compliance or effectiveness of the previous audit, then the practice likely would not run afoul of Criterion XVIII. Noting the existence of the previous audit is not the same as carrying out an audit of the previous audit. In this scenario, another individual would be required to do the audit to verify the effectiveness of the previous internal audit consistent with the requirements of Criterion XVIII.



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- So what does this mean?
- For those suppliers that perform only one internal audit each year evaluating all elements of their QA program for effective implementation and compliance with 10CFR50 Appendix B, the following condition would not be considered acceptable:
 - The same internal auditor who performed the previous internal audit of the supplier's QA program (including internal audit process) utilizes the previous internal audit as objective evidence to determine compliance/effective implementation of Criterion XVIII (Audits) of 10CFR50 Appendix B.

Examples of Findings/Deficiencies associated with Auditor Independence

- Internal Audits were performed by the individual that performed the previous audits were used as objective evidence for performance determination. This is a violation of QAM Section 18.2, which prohibits auditors from auditing work in which they had direct responsibility.
- The Audit checklist does not identify who performed what checklist sections.
- An Auditor reviewed the quality system including assessment of the effectiveness of Internal Audits. The review of the 2017 Audits effectiveness was conducted by the same auditor in 2018 and was not independent.
- The QA Manager performed the Internal Audit and reviewed activities including test activity for which he was involved as review and approver. In addition the QA Manager also audited special processes and included objective evidence which included tests he had performed.

Examples of Findings/Deficiencies associated with Auditor Independence

- The 2016 and 2017 Internal Audits were performed by the same contract Lead Auditor. In the 2017 Internal Audit Report, the Lead Auditor used the 2016 audit to evaluate the effectiveness of the internal audit process for which he was the Auditor.
- The Lead Auditor (the Quality Manager) had direct responsibilities in the area being audited in four 2018 Internal Audits (audited Sections #4.2, Quality Systems; #4.1, Management Responsibility; #4.8, Identification and Traceability; and #4.17, Quality Audits). Although the Quality Manager was a new hire, he was responsible for the areas he reviewed.
- The 2018 audit was performed solely by the QA Manager, even though several of the checklist questions involved work for which he had direct responsibilities, such as internal audits, review of purchasing documents that affect the quality of calibrations, maintenance of the CQAPM, review and approval of corrective actions, etc.
- The 2016, 2017 and 2018 internal audits covered all aspects of the QA Program and were all performed by one individual. This results in an issue with auditor independence as the auditor assessed his own work for performance of internal audits



Corrective Actions Taken

- Alternation of Contractors from year to year to obtain independence.
- Additional staff qualified as Lead Auditors to support QA Manager to maintain independence.
- Lead Auditors from separate divisions within the company performing the Audit to ensure independence.



In Summary

- When planning Internal Audits assess the Team and ensure no one is auditing their own work.
- Alternate the use of contractors every year to ensure independence. At a minimum add team members to avoid auditing their own work.
- Assessing “effectiveness” of the program is key. The individual auditing has the responsibility of assessing effective implementation, consequently they cannot evaluate their previous work in making that determination.

INDEPENDENCE FROM THE WORK BEING AUDITED!



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QUESTIONS ????