

NUPIC

Nuclear Procurement Issues Corporation

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February 22, 2018

Ms. Kerri Kavanagh
Branch Chief, Quality Assurance Vendor Inspection Branch 2
Office of New Reactors
U. S. Nuclear Regulatory Commission
Mail Stop T-6C20M
Washington, DC 20555

SUBJECT: 10CFR50 Appendix B Criterion XVIII Interpretation

Dear Ms. Kavanagh,

10CFR50 Appendix B Criterion XVIII "Audits" states in part that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited.

NUPIC audits are identifying 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. This person may be a direct employee of the supplier or an individual contracted by the supplier to perform the internal audit in accordance with the supplier's QA program controls. The internal auditor utilizes the previous internal audit as objective evidence to determine if the supplier is complying with Criterion XVIII of 10CFR50 Appendix B. 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 situation has resulted in audit findings being issued by the NUPIC auditors based on the individual having direct responsibility in the area audited since the auditor was responsible for determining compliance with the supplier's QA program controls and 10CFR50 Appendix B Criterion XVIII for internal audits by evaluating work that he/she was responsible for performing in accordance with those same controls. The basis for NUPIC auditors issuing a finding for this condition also appears 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."

Recently, a 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

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responsibility in the area audited. As a result, NUPIC requests a response to the following question regarding the requirement specified in 10CFR50 Appendix B Criterion XVIII, which specifies the use of appropriately trained personnel not having direct responsibilities in the areas being audited for evaluating compliance with all aspects of the QA program.

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?

Please provide a basis for the conclusion.

Sincerely,

A handwritten signature in black ink that reads "MARK COREN". The signature is stylized with a large, looped "M" and "C".

Mark Coren
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cc: NUPIC Representatives
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