



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

Mark Coren  
NUPIC Chairman  
Duke Energy  
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Charlotte, NC 28202

SUBJECT: Title 10 of the *Code of Federal Regulations* Part 50 Appendix B Criterion XVIII  
Interpretation

Dear Mr. Coren,

This letter responds to your letter dated February 22, 2018, that asks for an interpretation of Title 10 of the portion of *Code of Federal Regulations* (10 CFR) Part 50 Appendix B Criterion XVIII "Audits" stating:

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. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

Your letter states that the background for this question is that in the past NUPIC auditors have found situations where a supplier was conducting a single internal audit to verify compliance with all aspects of the Quality Assurance (QA) program year after year with the same contracted auditor. The supplier's internal auditor uses their own work from the previous year as evidence to determine that the supplier is compliant with Criterion XVIII. You go on to state that NUPIC auditors maintain that this situation is unacceptable because the vendor's internal auditor is evaluating their own work, which is a situation that the guidance in Nuclear Regulatory Commission (NRC) Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors" considers unacceptable.<sup>1</sup>

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<sup>1</sup> Step c. of Section 03.18 "Audits" of IP 43002, "Routine Inspections of Nuclear Vendors," (Jan. 27, 2017) tells inspectors to assess audit controls by doing the following: "Verify that audit teams were selected using qualified auditors. Verify that selected auditors are not auditing their own work."

Furthermore, your letter states:

Recently a supplier has challenged this, claiming that their internal auditor was not responsible for the audit program, therefore this meets the Criterion XVIII requirements. The challenge to the findings resulted in NUPIIC asking NRC for clear guidance, by posing 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 10 CFR 50 Appendix B Criterion XVIII?

You also ask that NRC explain the basis for the conclusion.

In the case presented above, it is the NRC staff's understanding that the contracted auditor performed an audit to "verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program" as required by Criterion XVIII. Your question concerns the next time the person performs the audit. Essentially, you ask: Can an auditor perform sequential audits pursuant to Criterion XVIII without violating the part of Criterion XVIII that states that the "audits shall be performed ... by ... personnel not having direct responsibilities in the areas being audited"?

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 the 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.

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.

I trust that this response provides the clarification you need to communicate with your suppliers. Please contact me, Kerri Kavanagh at 301-415-3743, if further clarification is needed.

Sincerely,



Kerri A. Kavanagh, Chief  
Quality Assurance Vendor Inspection Branch-2  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

# **NUPIC**

**Nuclear Procurement Issues Corporation**

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**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,



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cc: NUPIC Representatives  
Greg Galletti  
Richard McIntyre