



United States Nuclear Regulatory Commission

Protecting People and the Environment

Oversight of the Supply Chain Under Exigent Conditions

Supplier Audits/Surveys and Remote Source Verification

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Topics

- Problem Statement
- Proposed Solutions
- Summary



Oversight of the Supply Chain Under Exigent Conditions

Supplier Audits/Surveys

Problem Statement

- NRC licensees have historically performed supplier audits/surveys on a triennial basis as a method to meet certain requirements of Appendix B to 10 CFR Part 50 activities. Typically a 90-day grace period is allowed for unforeseen administrative issues.
 - Criterion VII includes clear language relating for source evaluation and selection, and states in part, the following:

“Measures shall include provisions, as appropriate, for **source evaluation and selection**, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.”
 - NRC Regulatory Guide 1.28, “Quality Assurance Program Requirements (Design and Construction),” Revision 4, June 2010, Section C2.b.5 and NQA-1-2015, Part 1, Requirement 18, “Audits,” discusses audit grace periods:

“A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance”



Oversight of the Supply Chain Under Exigent Conditions

Supplier Audits/Surveys

Problem Statement

- Pandemic circumstances may prevent NRC licensees and suppliers from performing scheduled supplier audits/surveys within the triennial period plus the 90-day grace period.
- Therefore, changes may be required to NRC-approved Licensee Quality Assurance Program Descriptions (QAPD) and NRC-accepted Supplier QA programs to address the current grace period limitations related to supplier audits/surveys resulting from “Exigent” conditions.
- Could an extension of the supplier audit/survey grace period be allowed to address “Exigent” conditions which might prohibit performance of supplier audits/surveys?



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Supplier Audits/Surveys

Proposed Solutions

- Early March 2020, the NRC and Industry (NEI, NUPIC, Suppliers) initiated a dialog on possible implications of the Covid-19 pandemic on supplier audit/survey schedules.
- April – Present, the NRC continues to interact with licensees and suppliers looking to update their QAPD's to address “Exigent” conditions.
- Two approaches being adopted and applied to external audits
 - Use of existing QAPD audit frequency extension approved for Southern Nuclear Company (SNC) in 2005
 - Addition of new guidance to specifically address exigent conditions based on NRC proposal



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Supplier Audits/Surveys

Proposed Solutions

- Some licensees have incorporated the SNC approach approved by NRC in SER dated June 2005 (Agencywide Documents Access and Management System [ADAMS] ML051570349) in accordance with (IAW) 10 CFR 50.54(a)(3)(ii) providing for:

“A maximum extension not to exceed 25 percent of the audit interval shall be allowed.....and when applied to supplier audits and evaluations except that a total combined time interval for any three consecutive inspection or audit intervals should not exceed 3.25 times the specified inspection or audit interval.”
- Currently 4 Vendors (WEC, GEH, S&L, & NuScale) that have NRC-accepted programs have updated their QAPDs IAW 10 CFR 50.4(b)(7)(ii) to reflect 25% extended grace periods for each audit interval with additional supplier evaluation criteria implemented.
- NRC Anticipates additional submittals from licensees/vendors to update QAPDs to address exigent conditions.



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Supplier Audits/Surveys

Proposed Solutions

- Additional Supplier Evaluation Criteria typically include the following:
 - a. prioritize completing audits or surveys of affected suppliers based on safety significance and any issues with the supplier. However, the audit or survey shall be completed within the 25 percent grace period.
 - b. There is verification that the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50. (For suppliers with delinquent surveys, the entity shall ensure that the suppliers have maintained adequate documented programmatic controls in place for the activity affecting quality.)
 - c. The alternative method of the 25 percent extension discussed above is applicable to domestic and international suppliers.
 - d. Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions.



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Supplier Audits/Surveys

Proposed Solutions

- Additional Supplier Evaluation Criteria typically include the following:
 - e. If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include, as appropriate, the following:
 - I. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
 - II. Results of previous source verifications, audits, survey and receiving inspection activities.
 - III. Operating experience of identical or similar products furnished by the same supplier.
 - IV. Results of audits and inspections from other sources (e.g., customer, ASME audits or NRC inspections).
 - f. If the contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the supplier will provide documented justification the change(s) are adequately addressed by its quality assurance program controls.



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Supplier Audits/Surveys

Summary

- Vendor Submittals and NRC SE's have been processed expeditiously to address current Covid-19 situation to allow for extended grace periods for supplier audits/surveys.
- Additional QAPD submittals are anticipated to address “exigent” conditions



Oversight of the Supply Chain Under Exigent Conditions

Remote Source Verification

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Remote Source Verification

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Oversight of the Supply Chain Under Exigent Conditions

Remote Source Verification

Problem Statement

- The regulations do not explicitly state that remote observation can be credited for source verifications or witness points of Appendix B to 10 CFR Part 50 activities.
 - Criterion VII includes clear language relating to the use of source verification to accept a basic component. Criterion VII states in part, the following:
 - Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, *inspection at the contractor or subcontractor source*, and examination of products upon delivery.



Oversight of the Supply Chain Under Exigent Conditions

Remote Source Verification

Problem Statement

- Could an alternative method be proposed to allow for remote source verification under certain conditions?
 - Typically, source verification is used to verify successful completion of certain fabrication and test activities related to equipment that is complex, expensive, or designated for use in nuclear safety-related applications.
 - Considerations: 1) health and safety of individual performing the verification; and 2) feasibility to successfully accomplish the verification without direct observation at the facility.



Oversight of the Supply Chain Under Exigent Conditions

Remote Source Verification

Proposed Solution

- Could an alternative method be proposed to allow for remote source verification under certain conditions?
 - The Electric Power Research Institute (EPRI) led an effort with industry stakeholders, including the NRC staff to develop guidance for conducting remote source verification.
 - On April 30, 2020, EPRI submitted a letter requesting a fee exemption under Section 170.11(a)(1)(ii) of Title 10 of the *Code of Federal Regulations* (10 CFR) for NRC review of Technical Report, “Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance” (EPRI 3002019436) ADAMS Accession No. ML20143A062).
 - A secondary path was sought to expedite the industry’s use of this alternative.



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Remote Source Verification

Proposed Solution

- On May 18, 2020, Columbia Generating Station (Columbia) requested approval of a proposed change to its Operational Quality Assurance Program Description (OQAPD) (ADAMS Accession No. ML20139A225).
- The NRC staff requested additional information and Columbia responded on June 1, 2020 (ADAMS Accession No. ML20153A471).
- The proposed change is considered a reduction in commitment and in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 50.54(a)(4), NRC approval is required prior to implementation.
- Columbia's submittal requested implementing guidance found in the Electric Power Research Institute's (EPRI's) Technical Report 3002019436 for performing remote source verification.



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Remote Source Verification

Alternative Overview

Screening Criteria Developed – Is the activity appropriate for conducting the activity remotely?

- 1) Is it possible to do on-site surveillance?
- 2) Is the activity an assessment?
- 3) Can the activity be surveilled remotely?
- 4) Can progress and results be captured and communicated in real time?
- 5) Can a maintainable record be created for objective evidence?
- 6) Does the initiating entity concur with the use of remote surveillance?



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Remote Source Verification

Alternative Overview

Controls to be in place prior to conducting remote source verification:

- The ability to review the actual documents and procedures online, as well as preparations, equipment, personnel, and other things going on in the vicinity of the activity.
- The ability to ask questions during the process, request adjustments, and doublecheck measurements.
- The verifier's field of vision and ability to observe and verify can be adjusted by the frame of the camera or video screen.
- The ability to verify the capabilities of the video equipment and individuals operating the video equipment prior to performance of the remote source verification.



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Remote Source Verification

Summary

- This EPRI technical report was prepared to provide licensees and vendors with guidance for using remote communication and video capabilities to perform remote source verification in extreme circumstances where it is not possible to perform on-site source verification due to conditions that threaten the health and safety of individuals performing the verification.
- § 50.54(a)(3)(ii) allows the use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility.