



Regulatory Alternatives for Supplier Oversight During Exigent Conditions



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Agenda

2

- What caused all this?
- Why it wasn't so simple
 - ▣ Regulatory requirements
- NRC/Industry Stakeholder Meetings
- Audit Extension
- Remote Source Verification
- Remote Audit Allowance and Current Status
- Summary / Questions



What caused all of this?

3

- On January 31, 2020, the U.S. Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the Coronavirus (COVID-19).
- Domestic and international travel restrictions resulting from the COVID-19 pandemic resulted in licensees confronting significant challenges meeting their regulatory commitment associated with the frequency of performing onsite supplier audits and surveys.



Why it wasn't so simple: Regulatory requirements

4

□ Criterion VII of Appendix B:

“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.”



NRC/Industry Stakeholder Preliminary Meetings

5

- NRC staff met with industry stakeholders:
 - Nuclear Energy Institute (NEI)
 - EPRI (EPRI)
 - Licensees
 - Suppliers
 - Public



NRC/Industry Stakeholder Preliminary Meetings

6

- NRC staff met with industry stakeholders on alternatives / compensatory measures to address extension limit and exceeding audit frequency.

- 1) Procure from alternate source;
- 2) commercial-grade dedication;
- 3) hybrid audit method; and
- 4) provisional procurement authorization in conjunction with the corrective action program (CAP).

- ▣ Agencywide Document Access and Management System (ADAMS)

Accession No. ML20293A173

Presentations: ML20303A043 and ML20303A041.



Audit Extension

7

- Overall extension of 25% for the triennial supplier audit and survey frequency (i.e., nine months) during exigent or emergency conditions.

- ▣ Documented evaluation
 - 1) Verify supplier's quality assurance program;
 - 2) Receipt inspection / review of operating experience;
 - 3) Review of associated documents;
 - 4) Review of previous performance; and
 - 5) Applicable to domestic / international suppliers.



Audit Extension

8

- Associated NRC Safety Evaluation Report:
 - ▣ ADAMS Accession No. ML20216A681
- Allows other licensees to adopt a similar change to their quality assurance program description (QAPD) without prior NRC approval
- Four architect engineers / Nuclear Steam Supply System suppliers adopted a similar change to their QAPDs
 - ▣ Associated NRC Safety Evaluation Reports:
 - ADAMS Accession No.: ML20132A321, ML20154K718, ML20140A322, and ML20176A494



Remote Source Verification

9

- EPRI's Technical Report 3002019436 "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance"
- NRC Safety Evaluation Report
 - ADAMS Accession No. ML20203K876



Remote Audit Allowance: Current Status

10

- March 31, 2021, Observation Public Meeting
 - ▣ ADAMS Accession No. ML21092A008
 - ▣ Southern Nuclear license amendment request (LAR)
 - LAR submitted to the NRC on May 7, 2021, ADAMS Accession No. ML21127A184
 - Allowance to perform fully and provisional remote assessments (i.e., audits and commercial-grade surveys)
 - For times of extenuating circumstances (i.e., pandemics)

Remote Audit Allowance: Audits & Commercial-Grade Surveys

11

- Southern Nuclear submittal requested to implement guidance found in the EPRI's Technical Report (TR) 3002020796 "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," for performing fully remote and provisional remote assessments.

Remote Audit Allowance: Audits & Commercial-Grade Surveys

12

- EPRI TR 3002020796 also includes guidance for conducting vendor assessments utilizing hybrid techniques.
- It is the NRC staff position that there are no regulatory restrictions or conditions for when a hybrid assessment of vendors may be utilized
 - ▣ No prior NRC approval required for performance of hybrid assessment.

Remote Audit Allowance:

EPRI TR 3002020796

13

- Provisional Remote Assessment - team members participating remotely and ***does not assess all*** technical and quality requirements of interest.
- Fully Remote Assessment - A fully remote assessment is an assessment conducted with all team members participating remotely and ***assess all*** applicable technical and quality requirements of interest.

Remote Audit Allowance:

EPRI TR 3002020796

14

Hybrid Assessment (Sections 6.11 and 6.12)	Provisional Remote Assessment (Sections 6.13–6.16)	Fully Remote Assessment (Section 6.9)
One or more assessor is on-site and in-person.	All assessors are remote.	All assessors are remote.
No eligibility requirements.	Eligibility requirements in Section 6.13.1 apply.	Eligibility requirements in Section 6.9.1 apply.
Preferable that at least one assessor is familiar with the facility.	Preferable that at least one assessor is familiar with the facility and most recent assessment.	Preferable that at least one assessor is familiar with the facility.
Establishing or renewing supplier's approval.	Renewing supplier's approval.	Renewing supplier's approval.
Results in typical period of approval.	Results in reduced period of approval.	Results in typical period of approval, but could be reduced if appropriate.

Table 6-1, Basic comparison of remote assessment types



Summary/Questions

15

