Remote Assessment

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Remote Assessment Techniques

Intended Benefits



Enables maintaining approved suppliers when it is not possible to do a traditional on-site, in-person assessment (audit/commercial grade survey)

Assessment Options

- Fully Remote (all team members are remote evaluation per guidance concludes on-site presence is not required)
- Provisional Remote (all team members are remote – evaluation per guidance concludes on-site presence is required)
- Hybrid (> 1 team member on-site)

EPRI 3003030796 Published April 15, 2021

EPRI 3002020796, Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions

https://www.epri.com/research/products/0000000 3002020796

- EPRI member utility has submitted a request for NRC to review the methodology in the report as acceptable for qualifying suppliers during exigent conditions – NRC is expediting review.
- Rollout session was held June 1, 2021



Existing Options for Nuclear Licensees

Alternative Procurement

- Hybrid Assessments
- Shared Inventory/transfers
- Commercial Grade Dedication
- Third-party Suppliers

Extension on audit expiry

- 90-day "grace period" discussed in 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
- 25%/9-month grace period as discussed in Ameren UE Callaway Plant QA Program Change (ML20216A681)

Corrective Action Program to track items procured from "unapproved" sources

 Provisional Procurement Authorization in conjunction with corrective action program as described in Summary of Public Meeting to Discuss Licensees' plans for supplier oversight beyond frequency extension limits allowed during the current exigent condition (ML20324A216)



Scope and Limitations

Developed for conduct of supplier assessments *during exigent conditions*

Performance-based approach for evaluating use of remote assessment techniques

- Hybrid Assessment
- Provisional Remote Assessment
- Fully Remote Assessment

Report does not assert regulatory boundaries

- Regulations vary based on jurisdiction
- Use of remote assessment techniques might require prior authorization by regulatory agencies



Focus on Assessment Activities

- 1. Review of Documentation
- 2. Access to Production facilities
- 3. Access to, and interaction with supplier personnel
- 4. Access to and Observation of Processes
- 5. Management of Assessment Team
- 6. Assessment and Assessment Resource Planning
- 7. Knowledge Transfer and Retention



Access to Production Facilities

Section 3

Assessment Activities

Foreign material exclusion controls

Product flow throughout manufacturing process and inspection activities

Condition of manufacturing equipment and tools used to conduct activities affecting quality

Processes or machinery that involve software controls

Supplier capabilities that are not included in the current assessment scope (new or existing) Nuclear safety culture

Section 4

Remote Assessment Techniques

Advance discussion of required safety and security protocols, such as health screening, testing, social distancing, and personal protective equipment

Assessor should identify in advance associated considerations and areas of interest during the observation, such as cleanliness, safety culture, and industrial safety practices

Acquisition, setup, and testing of appropriate cameras, live-streaming, and audio communication applications

Training personnel in use of the equipment

Development and communication of contingency plans to address loss or deterioration of audio or video signals

Trial run of primary and contingency equipment and internet access before the assessment starts



Section 3 – Assessment Activities **Section 4 – Remote Assessment Techniques**

Table 3-3

Assessment activities associated with direct access to personnel

Assessment activities associated with direct access to personnel		
Activity	Examples / Practical Experience	
Quality functions' independence and sufficient authority	Gain an understanding of the chain of command and other "go-to" personnel and practices when resolving questions or uncertainty	
	Knowledge of regulatory requirements such as reporting of defects and noncompliance.	
	Witness interactions between supplier's quality departments and other departments	
Knowledge base of supplier personnel including those that are not in the quality assurance organization	Ability to interview personnel being observed about the activity, applicable controls and procedures directly instead of relying on the designated supplier representatives to respond	
	Evaluate awareness of	
	CFI and measures to prevent their use	
	 Presence of safety and quality cultures, questioning attitude, and freedom to raise concerns 	
	Assessing supplier personnel reactions to questions including	
	Body language and other non-verbal cues	
	Amount of time required to respond	
Rapport between supplier's quality departments and other supplier departments	Ability to quickly locate the correct people, documents and activities necessary to answer questions	
	Gain insights into safety culture and cooperation	
Rapport building between supplier personnel and assessors	Develop a level of trust and enhanced communication and understanding of requirements	
	Ability to use instincts and experience	
	Allows ad-hoc questions and emerging concerns to be addressed with minimal impact on schedule	
	Ability to quickly locate the correct people, documents and activities necessary to answer questions.	
	Flexibility in scheduling interviews, follow-up questions, etc.	
	Quick access to individuals and ability to quickly adjust schedule to accommodate unexpected changes in availability	

Table 4-3

Remote assessment techniques for successful observation and interviews of personnel

Technique	Examples / Practical Experience
Advance identification of interview schedules, and locations, and interviewee expectations	Determine the setting the interviewee will be in during the interview Get agreement from interviewee to maintain video and audio communication during interviews (for example, keeping cameras on) Plan ahead to minimize distractions in the local environments during interviews Be familiar with ICT platform functions such as adding attendees to virtual meetings, sharing documents, images, and other information Request the interviewee be able to share their screen as needed
Acquisition, set-up, and testing of remote and local computers, including cameras and microphones as necessary	Ensure remote and local computers being used have high-enough resolution and are positioned to ensure adequate lighting and visual field necessary to discern facial expressions and enable clear audio transmission. In some cases, external cameras and microphones may be required to achieve adequate clarity Ensure internet bandwidth can accommodate the video/audio platform including document sharing and multiple locations.
Development and communication of contingency plans to address loss or deterioration of audio or video signals	Trial run of primary and contingency equipment before the assessment starts



Process Overview

Identify:

- Objective
- Scope
- Technical and Quality requirements of interest (PBSA focus)
- Activities to assess (PBSA focus)

Is on-site presence practical?

YES

Plan and conduct a traditional assessment

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-NO--> Complete remote assessment planning worksheet and determine appropriate type of assessment

For each Q&T requirement:

Is on-site typically required? Why? What are benefits from being on-site? Can remote assessments provide similar benefits?

Identify remote assessment techniques. Identify "on-site necessary" items. Fully remote assessment (no assessors on-site)

Hybrid assessment (some assessors on-site)

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Provisional remote assessment (no assessors on-site) Best outcome is approval with restrictions

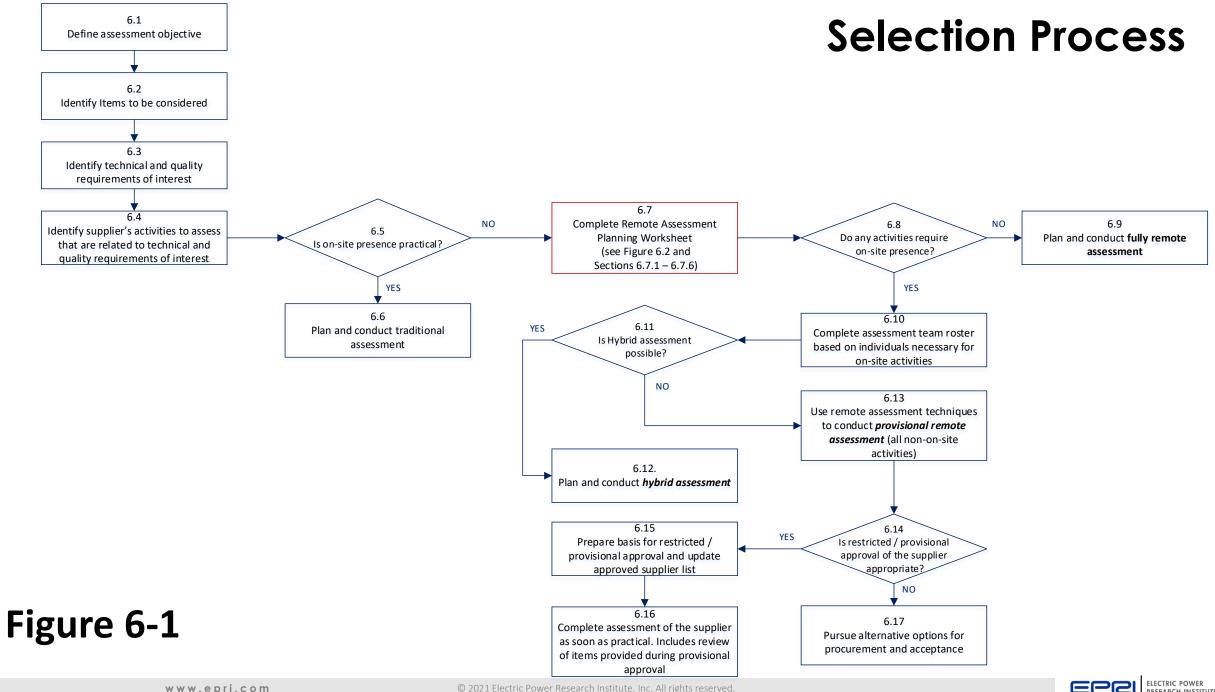


Eligibility Requirements

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Provisional Remote Assessment (6.13.1)	Fully Remote Assessment (6.9.1)
In-person on-site presence of assessors is not possible due to exigent conditions	In-person on-site presence of assessors is not possible due to exigent conditions
The supplier has been previously qualified by a traditional assessment (a provisional remote assessment cannot be used to qualify a new supplier)	The supplier has been previously qualified by a traditional assessment (a fully remote assessment cannot be used to qualify a new supplier)
A commitment can be made to complete assessment of the supplier as soon as practical when the exigent conditions no longer exist.	Review of procurement history since last triennial or other regularly scheduled audit/survey, including receipt inspection results does not identify potential issues that could not be addressed without on-site in person presence during the assessment
	Evaluation (through completion of a Remote Assessment Planning Worksheet such as the one depicted in Figure 6-3 and Appendix B) leads to the determination (in Step 6.8) that on-site presence is not required to observe any of the technical and quality requirements of interest because remote techniques alone can be used to successfully complete activities associated with assessing the technical and quality requirements of interest.





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Expanded Step 6.7

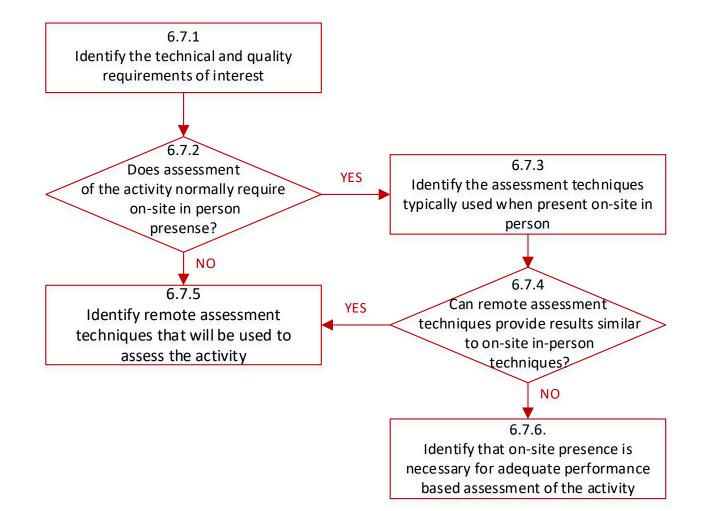


Figure 6-2



Remote Assessment Planning Worksheet					
No.	Technical/Quality Requirement of Interest or Critical Characteristic	Activity Used to Assess (more than one can be entered)	Can Remote Assessment Techniques provide insight? (YES/NO)	Remote Assessment Technique to Apply	On-site Necessary? (YES/NO)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Final Testing	Direct observation	YES	Camera (smart phone and gimbal) video-capable communications (2-way)	NO
2.	Welding	Witness welding, confirm operator qualifications, procedure, etc.	NO		YES
Type of Assessment to Pursue (8)					
⊠	Hybrid Assessment	ssessment Remote assessment techniques alone <i>cannot</i> provide the necessary insight for performance-based assessment of technical and quality requirements of interest or critical characteristics		ent of	
		At least one team member can be present in-person on-site			
	Provisional Remote Assessment	technical and quality requ	Remote assessment techniques alone <i>cannot</i> provide the necessary insight for performance-based assessment of technical and quality requirements of interest or critical characteristics		ent of
	It is not possible for any team members to be in-person on-site				
	Fully Remote Assessment	ssment Remote assessment techniques alone <i>can</i> provide all necessary insight for performance-based assessment of technical and quality requirements of interest or critical characteristics (no on-site necessary items indicated in column 6)			
Basis/Rational for Type of Assessment Selected (9)					
It is not possible to use technology to witness welding using remote assessment techniques as the supplier will not permit cameras in the welding area. For this reason, on-site in person presences is required and a hybrid assessment was selected since travel to the facility is possible for some team members, but team size must be kept to a minimum in the interest of assessment team and supplier health and safety.					

Pre-Assessment Planning Checklist for Assessment Team

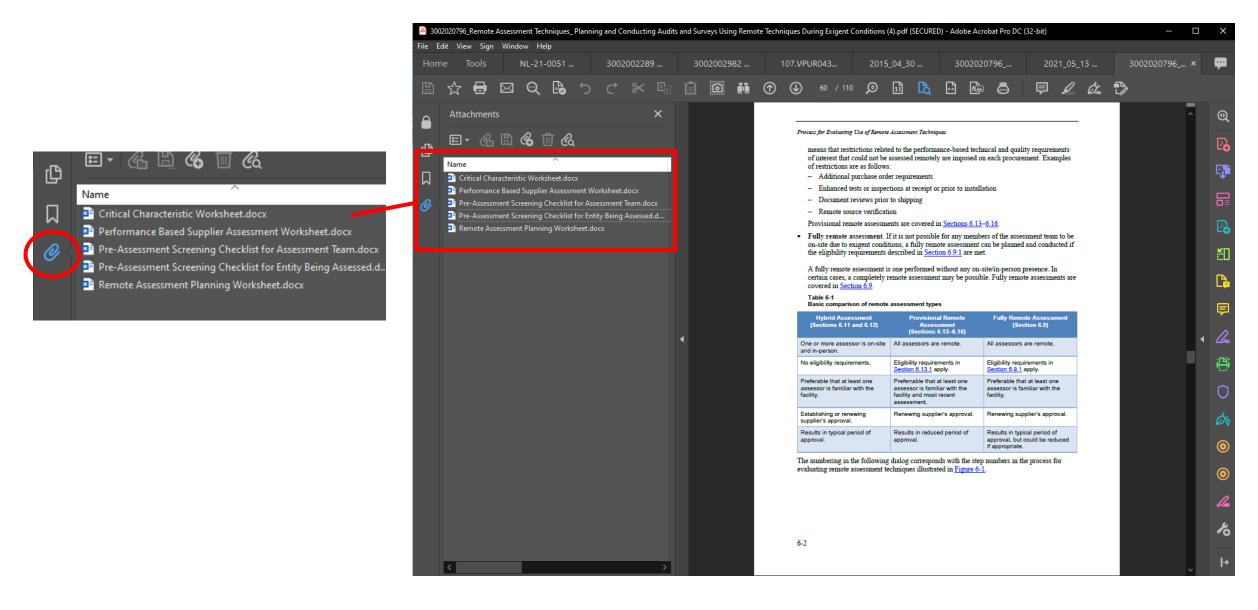
No.	Criteria	
	Access Requirements	
1.	Access requirements imposed by the entity being assessed such as daily health screening measures, evidence of vaccination or testing, etc. have been identified and agreed to by team members.	
	Assessment Team Composition	
2.	If practical, at least one member of the team, is familiar with the facility (for example, has previously been to the facility). Ideally, the assessment team leader and technical specialist will have visited the facility being assessed in the past and be familiar with the products and processes of the entity being assessed. As an alternative, the assessment team leader could consult with the assessment team leader(s) and technical specialist(s) from previous assessments.	
3.	It is preferable that one or more members of the assessment team have previous experience performing a remote or hybrid assessment.	
4.	Team members or subject matter experts that have experience with the entity being assessed or the types of products and services provided have been identified.	
5.	Assessment team members have reviewed the most recent previous assessment, including PBSA and CC worksheets (as applicable) and technical specialist summary.	
	Information and Communications Technology (ICT)	
6.	ICT including remote and local computers, cameras and microphones as necessary for real-time, two-way communication between remote and on-site assessors and remote and on-site representatives from the entity being assessed have been arranged, acquired, set-up, and tested.	
7.	Contingency plans to address loss or deterioration of audio or video signals or failure of primary information and communication technology (ICT) have been developed and communicated to assessment team members and the entity being assessed.	
8.	Determine how two-way communication will be enabled between team members and representatives of the entity being assessed during observation of production activities. Consider if facility structures (for example, a metal roof) nearby processes (for example, welding that generates electromagnetic interference) impacts selection and use of ICT. Headphones or equivalent might be needed.	
9.	Trial run of primary and contingency equipment is completed before the assessment starts.	
	Assessment Team Preparation	
10.	A method for timely notification to the Assessment Team Leader of issues identified during assessment or has been established and communicated to team members.	
11.	Differences in time zones have been discussed with assessment team members and remote assessors have confirmed calendar invites are at the correct local time.	
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Pre-Assessment Screening Checklist for Entity Being Assessed

No.	Criteria	
	Access Requirements - Facility	
1.	Access requirements such as daily health screening measures, evidence of vaccination or testing, etc. have been discussed with the entity being assessed.	
2.	Entity being assessed is willing to allow observation of any activities on shop floor as selected by the assessor	
3.	Entity being assessed is willing to allow remote interviews and interactions with personnel including shop personnel as necessary.	
4.	The entity being assessed understands the types of assessment activities that will be remote and is willing to provide the necessary time and support to allow for a thorough and efficient assessment.	
5.	When different regions or languages are involved, language proficiency of the camera operator to hear and understand requests and instructions should be considered.	
6.	Time zone difference considerations are addressed	
7.	For international engagements, differences in languages and arrangements tor translation have been made (as necessary). Translators are trained in use of ICT.	
8.	Entity being assessed has video and audio capabilities to allow observation on the shop floor or they can be arranged by organization being assessed or assessment team.	
	Access Requirements - Documentation	
9.	Entity being assessed is willing to share necessary documents with remote assessors through a content sharing application.	
10.	Requirements (as applicable) for nondisclosure agreements have been discussed with the entity being assessed and agreements are executed prior to start of assessment.	
11.	The entity being assessed agrees to promptly provide Assessment Team with documentation requested during the assessment to provide objective evidence of quality assurance program implementation.	
12.	The Assessment Team will have access to the quality assurance manual, second level procedures and other necessary documents to enable timely review and reference as required during the assessment.	
	Entity Being Assessed Personnel	
13.	Personnel from the entity being assessed are willing to appear on camera for interviews and observations.	
	Information and Communications Technology (ICT)	
14.	The entity being assessed is able and willing to support remote, real-time observation of the performance of activities that are required to be observed as to provide objective evidence of the quality assurance program implementation.	



Word format forms are attached to 3002020796





Successful application of remote techniques involves:

Maintaining a performance- based approach	Clearly defined scope and objectives	Identification of activities that should be witnessed as part of the assessment
When possible, identification of techniques for witnessing/assessing	Identification of those activities that can be witnessed/assessed only in-person	Coordination of virtual meetings and interviews to ensure that all aspects of the assessment are completed during the assessment period
Careful planning to ensure that on-site assessors maintain focus required to complete witnessing and assessment of all applicable on-site activities	 Technology required to remotely witness/assess important aspects of the activity in real time Contingency plans to address the potential for technology failures 	Means for documenting any assessment activities in a format that provides the verifying entity with objective evidence of the witnessing/verification



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