Implementation of the Electric Power Research Institute's (EPRI) Guidance on Hybrid & Remote Assessments

A viable alternative during exigent conditions

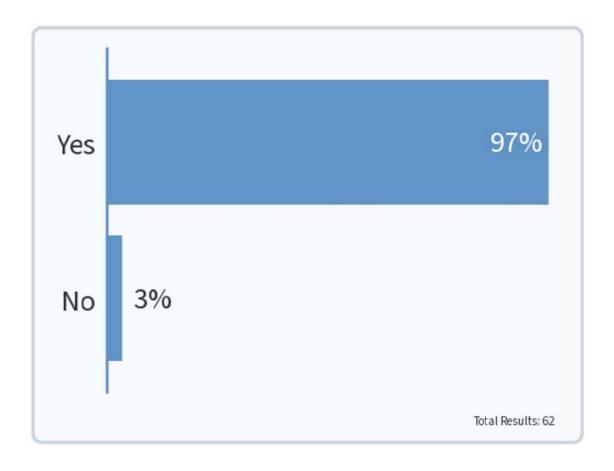
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US Nuclear Regulatory Commission June 2, 2022





Has the pandemic impacted your ability to perform assessments such as audits and commercial-grade surveys?





Exigent conditions can make travel a go/no-go proposition







Remote Supplier Source Verification and Assessment is possible during a pandemic

Remote <u>Source Verification</u> during a Pandemic or Similar State of Emergency, Screening Criteria and Process Guidance

EPRI 3002019436-A

Published April 4, 2020
"-A" version published October 2020
(includes NRC safety evaluation report)

- Screening criteria to determine eligibility for remote source verification
- Process for establishing objectives, primary plan, and contingency plans
- Discussion on use of information and communication technology

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

EPRI 3002020796

Published April 15, 2021 Rollout June 1, 2021

NRC issued a <u>Safety Evaluation</u> June 22 that accepts use of the EPRI guidance during a pandemic (NRC Adams ML21161A201)

- 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)





Typical Assessment Activities

Review of Documentation

Access to Production Facilities

Access to Supplier Personnel

Access to Processes for Observation

Assessment Team Collaboration

Assessment and Assessment Resource Planning

Can these be accomplished remotely?



Section 3 – Assessment Activities

Section 4 – Remote Techniques

Section 3
Access to Processes for Observation
Assessment Activities

Indications of effective traceability and material controls

Special processes implementation

Processes affecting product fit, form, and ability to perform safety-related functions

Process flow of items and materials

In-process and final inspection and testing

Supplier controls for the prevention and detection of counterfeit and fraudulent items (CFI)

Section 4

Access to Processes for Observation Remote Assessment Techniques

Advance identification of the processes and work activities anticipated to be observed and notifying the supplier so that appropriate equipment and internet access can be in place in advance of the assessment

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

Training personnel in use of the equipment

Before the assessment begins, trial run of the equipment performed in the most challenging (such as the noisiest or dimmest) areas

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



Tables in Sections 3 and 4 also provide examples / practical experience

Table 3-4 Assessment activities associated with direct access to processes

Activity	Examples/Practical Experience
Indications of effective traceability and material controls	Control of limited-life items (shelf life) Controls to mitigate use of suspected CFI Control of nonconforming items Identification of stored and in-process materials and items
Special processes implementation	Witness activities such as NDE, welding, and heat treatment to assess compliance with applicable procedures and controls
Processes affecting product fit, form, and ability to perform safety- related functions	Technical specialist observation and evaluation of important processes
Process flow of items and materials	Compare observed sequence to documented instructions Review of hold-point processing Determine if any processes underway are undocumented Determine if processes are based on skill of the craft or in accordance with controlled documents Control of rework
In-process and final inspection and testing	Review of commercial-grade dedication acceptance methods Control of rework
Supplier controls for the prevention and detection of CFI	Personnel awareness of the threat caused by CFI, preventive measures during specification and procurement Measures to detect CFI during receiving, fabrication, inspection Process for controlling suspected CFI

Table 4-4 (continued)
Remote assessment techniques for successful observation of processes and individuals performing them

Technique	Examples/Practical Experience
Acquisition, setup, and testing of appropriate cameras, live-streaming, and audio communication applications	Communicate with supplier to determine the type and amount of ICT equipment required as well as personnel to operate the equipment.
	Mobile phones (iPhone, Samsung, and so on)
	Cameras (GoPro, RealWear, and so on)
	Laptops
	Tablets (such as an iPad)
	Microphones
	Recording options
	Evaluate the ability of the primary assessor to observe, or individual performing the activity for limitations in controlling audio and video. Are different angles or fields of view required? In addition, their ability to enact contingency plans may be limited.
	Consider arranging for another individual to manage the ICT equipment to avoid distracting the individual performing the activity and allow a more efficient process for the assessor to obtain necessary information.
Training personnel in use of the equipment	Ensure that supplier personnel and assessment team members have adequate experience with ICT monitoring equipment and software.
Before the assessment begins, trial run of the equipment performed in the most challenging (such as the noisiest or dimmest) areas	If practical, create a mockup to test the equipment prior to the actual test or observation. This may expose unknown interference, low bandwidth, and other previously unrecognized conditions that can be corrected in advance.

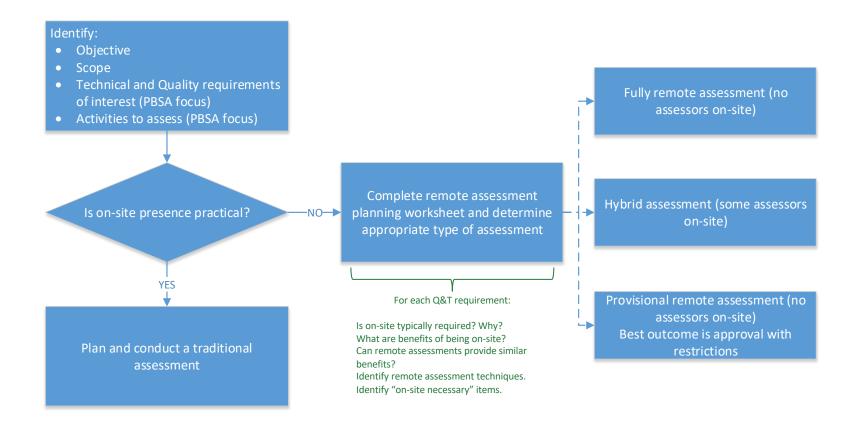


Section 5 - Review of the performance-based approach

Review item/supplier operating Audit objective Identify items to be considered A performance-based assessment is enabled by engineering quality requirements of interest Contact Engineering input, advance preparation and planning that involves: Understanding the scope of items provided by the supplier YES Identification of the safety function(s) performed by Identify supplier's processes Identify technical and quality related to technical and quality items provided by the supplier requirements of interest requirements of interest Identification of the attributes necessary for the items the supplier provides to perform their safety functions Identify acceptance criteria & remote assessment techniques for Identification of the supplier's activities that impart those supplier processes the necessary attributes Identification of a means for evaluating those supplier activities Focus is on the *technical* and quality requirements of interest



Evaluating use of Remote Assessment Techniques





Three types of remote assessments

A *fully remote* assessment is an assessment conducted with all team members participating remotely. Fully remote assessments evaluate all applicable technical and quality requirements of interest.

A *hybrid* assessment is an assessment conducted with one or more team members participating in-person at the facility being assessed while other team members are participating remotely. Hybrid assessments evaluate all applicable technical and quality requirements of interest.

A *provisional remote* assessment is an assessment conducted with all team members participating remotely that does not assess all technical and quality requirements of interest. The objective of a provisional remote assessment is to approve a supplier for use with appropriate restrictions during exigent conditions until an assessment that evaluates all technical and quality requirements of interest can be performed.

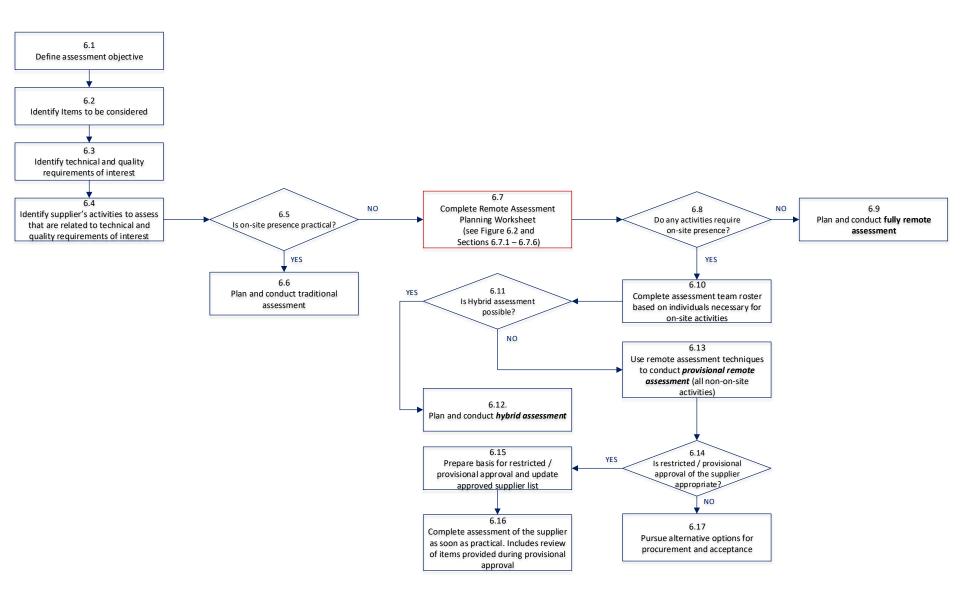


Eligibility Requirements

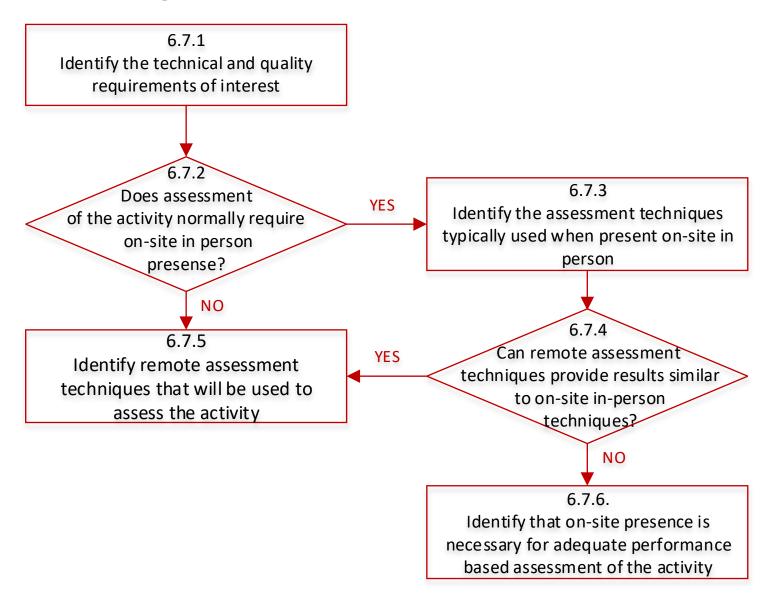
Provisional Remote Assessment (6.13.1)	Fully Remote Assessment (6.9.1)
In-person on-site presence of assessors is not possible due to exigent conditions	In-person on-site presence of assessors is not possible due to exigent conditions
The supplier has been previously qualified by a traditional assessment (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.	A review of the 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



Selection Process



Expanded Step 6.7



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
		Тур	e of Assessment to Pursu	e (8)	1
⊠	Hybrid Assessment		Remote assessment techniques alone cannot provide the necessary insight for performance-based assessment technical and quality requirements of interest or critical characteristics		ent of
		At least one team member	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 technical and quality requirements of interest or critical characteristics		ent of
		It is not possible for any t	It is not possible for any team members to be in-person on-site		
	Fully Remote Assessment		Remote assessment techniques alone can 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/Ration	al for Type of Assessmen	t 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.



Appendices

Current applications and experience

Remote Assessment Planning Worksheet

Performance Based Assessment Worksheet

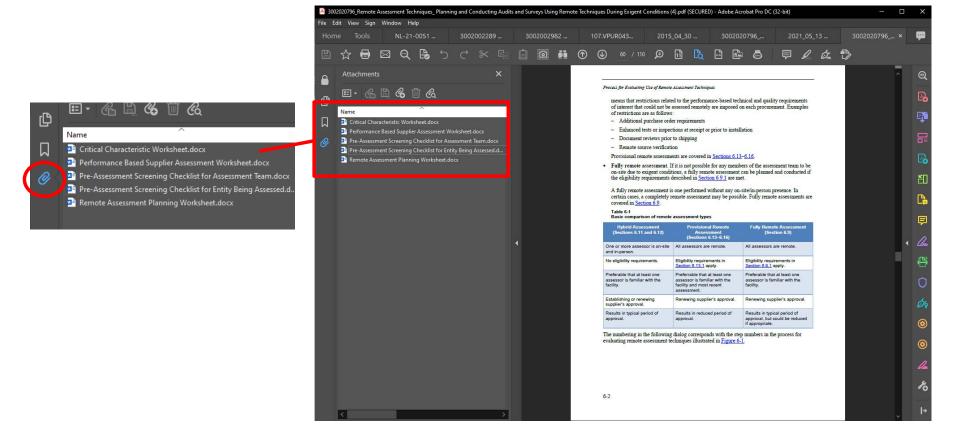
Critical Characteristics Worksheet

Pre- Assessment Checklists for assessor and entity being assessed

Frequently asked questions



Word format forms are attached to 3002020796





Advance planning is essential

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.		

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.	



Lessons learned

Planning

Identify technical and quality requirements of interest and related supplier processes

Identify Acceptance Criteria, documents, and methods for assessing supplier processes related to technical and quality requirements of interest

Determine supplier's ability to support remote assessment (willingness, non-disclosures, ICT capabilities, use of cameras, medical screening, personal protective equipment and protocols)



onduct of Assessment

Establish protocol for remote communication

Daily team and supplier briefings

Protocol for emerging concerns

Pre-job briefs - Primary and contingency plans, safety hazards, spotters

Trial run of all technology before use

Effectiveness and efficiency improves with practice

Follow-Jocumentatio Develop and impose restrictions that should be applied to each procurement (Provisional Remote Assessments)

Update Approved
Supplier List/Action
Tracking programs with
any future actions







Lessons learned



Time will pass quickly - coordinate virtual meetings and interviews to ensure that all aspects of the assessment are completed during the assessment period



Assessment team leader must ensure that on-site assessors maintain focus required to complete witnessing and assessment of all applicable on-site activities



Predetermine how to document assessment activities in a format that provides the verifying entity with objective evidence of the witnessing/verification



Technology will be required to remotely witness/assess important aspects of the activity in real time – have contingency plans in-place to address the potential for technology failures



Have a plan to address emergent health concerns during the assessment



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