

# Virtual Audits Explaining PJR's Approach and Expectations (with 2022 updates!)

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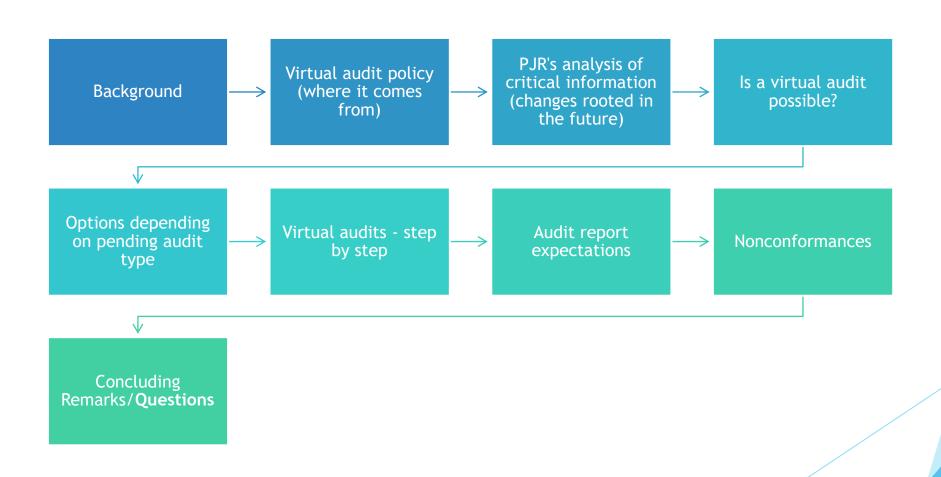
All participants have been muted.

Please type your questions in the "Question" section of the dashboard - we will answer all questions at the conclusion of this presentation.

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#### Overview of topics



#### Background - what is driving the change?

- For all of 2020 and 2021, PJR's approach to remote audits was solely rooted in a response to the COVID19 pandemic.
- As vaccination rates and COVID19 case numbers have improved in many locales it has become harder to justify a remote audit taking place "due to COVID19."
- Other (more sensitive data) has shown that remote audits are likely less effective than onsite audits (particularly in production areas.)
  - This perception has been expressed by clients, auditors, PJR, and the industry at large.

# Official policy comes from the IAF

- There are two primary documents that PJR has referred to throughout this process to ensure that we are still meeting all expectations from the industry and avoiding repercussions later when we are assessed by ANAB, UKAS, or any of the other accreditation bodies.
  - ► IAF ID3 "Management of Extraordinary Event or Circumstances Affecting ABs, CABs, and Certified Organizations."
  - ► IAF MD4 "The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes"
  - Both of these documents are public domain and can be obtained from the IAF website (<u>www.iaf.nu</u>.)

# What is PJR required to do before scheduling a virtual audit?

- ▶ Both ID3 and MD4 require that PJR contact the client and conduct a risk-based assessment of whether the virtual audit is possible.
- ▶ PJR issued the F-108ict in 2020 in order to enable us to gather information from the client and make the specified risk-based assessment.
- In early 2022 we made significant changes to the F-108ict in order to pivot towards virtual auditing that takes place for more reasons than just the pandemic.

### Format of the F-108ict

- ► The F108ict is a two page document consisting of two parts:
  - Part 1 Rationale
  - Part 2 Eligibility

#### F108ict Part 1 - Rationale

In Part 1 we've given our clients a checklist of rationale options that they can select from. Two notes have also been provided and read as follows:

#### Note 1:

If your reasoning is primarily rooted in the COVID19 pandemic your approval will be for the current audit only. If your rationale is rooted in other factors it may be possible for PJR to approve you for remote audits on an ongoing basis.

#### Note 2:

If prior audits have resulted in auditor feedback that you were not a satisfactory candidate for remote audits (connectivity issues, hard copy records, etc.) your request will not be approved.

#### F108ict Part 1 - Rationale - Options

We will review the various rationale options over the next few slides - please note the content from F-108ict has been provided in italicized text with commentary in plain text.

#### F108ict Part 1 - Rationale - Options (1)

- We've had one or more of our team members test positive for COVID19.
- We've instituted a temporary "No Visitor Policy"
- ► There are current applicable governmental travel restrictions pertaining to COVID19
  - □ Note that these options are only accepted if there is less than 30 days between the request and the start date of the audit.

#### F108ict Part 1 - Rationale - Options (2)

- Our auditor and/or PJR specifically requested a virtual audit.
  - □PJR is working to limit the instances where this is the case but we do recognize that some members of our team are unwilling or unable to travel at this time.

□This option may only be selected if you are prompted by your scheduler and/or your auditor.

#### F108ict Part 1 - Rationale - Options (3)

Due to the nature of our business, most of our team is working remotely

Our scope of activity is largely administrative (i.e. no or very limited manufacturing).

□PJR will verify the validity of these claims by reviewing your scope statement and past audit records.

#### F108ict Part 1 - Rationale - Options (4)

► We only need a portion of the audit to be performed virtually (please specify below) - this may include requests like "Only our corporate headquarters needs to be seen virtually" or "Only 2 of the 5 audits days need to be virtual", etc.

□This is a "Hybrid" audit option - we will discuss this option in a few more slides.

#### F108ict Part 1 - Rationale - Options (5)

There is a final option available if you happen to manufacture a tangible product - it reads as follows:

- ► We've had past successful virtual audits with PJR and we have a mature quality management system as evidenced by the results of our recent PJR audits.
  - □PJR will verify the validity of this claim by reviewing your scope statement and past audit records.

### Rationale options that will not be accepted

- "We wish to save money on auditor travel"
- "Last year's audit was virtual and we want that again this year"
- "It's more convenient for our team if the audit is virtual"
- "Our salesperson promised us our audit could be virtual"
- "Our scheduler promised us our audit could be virtual"
- Understand that PJR's ongoing preference will always be to perform an <u>onsite</u> <u>audit</u>, particularly for organizations that manufacture a tangible product.

#### F108ict Part 2 - Eligibility (Part 1)

- The first four questions pertaining to eligibility are largely unchanged from the prior revision of the F108ict.
- 1. Is GoToMeeting or Microsoft Teams acceptable for use to conduct the virtual audit? (clients are prompted to specify if they answer "No")
- Does your management system support a virtual audit? (are records primarily electronic?)
- 3. Will your company be running normal operations based on your scope of certification at the time of the audit?
- 4. Does your organization have sufficient hardware and WiFi coverage or cell phone signal to audit all activities including production if required?

  Additionally, is it okay for the cell phone or tablet camera to live stream video to our auditor in all areas of the facility that will be assessed virtually?

#### F108ict Part 2 - Eligibility (Part 2)

- 5. Will our auditor(s) be permitted to perform live video interviews with all staff necessary including management, process owners, etc. Please note that telephone interviews <u>are not</u> considered an acceptable substitute for video interviews.
- 6. Does your organization have the necessary technical capability to support a remote audit? Note that this may include troubleshooting on connectivity problems as needed.
- 7. Have you been audited virtually in the past? If "Yes" was it a positive/value-added experience?
- 8. Have there been any changes in your organization affecting your management system since your last audit?
- 9. For R2V3 Transition audits, will you commit to uploading required documents in sufficient time for the auditor to confirm their presence at least 7 days before the first day of your audit?

#### Key takeaways from the F108ict

- There is more than one reason to have a virtual audit.
  - ▶ PJR's long term plan for our virtual audit program was always to expand it beyond emergency use. We have many clients with business models that are a natural fit for remote auditing. The key is capturing a <u>satisfactory</u> rationale in a traceable manner.
- Clients have a responsibility to ensure the remote audit is successful.
  - Particularly now that onsite audits are an option in so many circumstances, PJR has had to step up our rhetoric in terms of the client "selling us" on their ability to not only participate in a remote audit, but for that remote audit to be as effective as an onsite audit.

#### Key takeaways from the F108ict

- To make our position perfectly clear the following three conditions must be met.
  - Live chat over a person-to-person interface (with live sharing of the auditee's screen) is mandatory;
  - Records must be primarily electronic (exceptions permitted); and
  - If Production is to be assessed, it must include livestreaming in the production areas with real time interactions between the auditor and production staff.

#### Permanent approval is now a possibility!

- If the preparation of the F-108ict indicates that you're requesting a virtual audit for something other than COVID19 (and you indicate strong capabilities/experience in hosting remote meetings) it is possible that PJR will:
  - Approve full virtual audits permanently.
    - In this scenario the client would have to have a business model that does not have any manufacturing or other "shop floor" type activities.
  - Approve partial virtual audits permanently.
    - In this scenario the client would have at least some onsite audit time to account for their manufacturing/shop floor processes.
- The various feedback we've received (both anecdotal and data driven) have shown that remote auditing of production/shop floor areas are not as effective as onsite auditing. Accordingly our strategy for the future of remote auditing includes an aspect that will require onsite auditing for an organization's production area.

# Emergency approval (i.e - due to the pandemic) is still an option, but justification needs to be more robust

- Clients will no longer be permitted to simply state "COVID19" as their logic in requesting a remote audit.
- Such clients will also be required to prepare a new F108ict in preparation for their next audit (if they wish it to be done virtually.)

# Hybrid Audits are now a possibility!

- PJR also offers a hybrid audit option (some virtual, some onsite.)
- This can offer many benefits including auditor quality of life, client cost savings, and scheduling flexibility in terms of assigning an auditor.

#### Possible Hybrid Audit scenarios

- 1. Client has a 5 day audit to be performed
  - i. Days 1 and 2 are done remotely and include all administrative areas (management review, internal audit, sales, etc.)
  - ii. Days 3-5 are done onsite and include production and other key technical areas (design, etc.)
- 2. Client has a 4 day audit to be performed
  - Auditor A performs the administrative aspects of the audit on Days 1 and 2 (virtually)
  - ii. Auditor B performs the onsite (production) aspects of the audit on Days 1 and 2

#### Possible Hybrid Audit scenarios

- Client has an onsite audit that results in multiple majors and requiring a revisit.
  - i. The revisit is done 100% virtually as all majors are rooted in administrative areas.
- 4. Client has an audit and the auditor learns that there has been a headcount increase that leads to an additional 0.5 day of required audit time.
  - The additional audit time is performed concurrently by another auditor (remotely)

#### What a virtual audit is not:

- It is important to distinguish that virtual auditing is not accomplished by the auditee simply emailing a cache of information to an auditor for offsite review.
  - Among other things this would likely represent a violation of IAF MD4's contention that "adequate controls (be) place to avoid abuses that could compromise the integrity of the audit/assessment process."
  - If the client is selecting all audit samples themselves, this principle is not met.
  - ▶ This includes situations where the client gives their auditor "everything" via Dropbox or Google Drive.
- For an audit to be truly virtual (and thus meet the requirements espoused by the IAF and ISO) the auditing technique must permit the auditor to assess the system with the same rigor and technique as if they were sitting in the client's facility.
- Random sampling and all other auditing techniques mandated by the IAF, ISO 17021-1, ISO 19011:2018 and all other applicable standards are still in effect in a virtual assessment.
- ▶ To be very clear an offsite audit is NOT the same as a truly virtual audit.

What if the information leads PJR to conclude that a virtual audit is not possible (and the audit cannot be done onsite?)

- While we have had great success running virtual audits with many different types of clients, there are definitely situations where PJR has concluded that a virtual audit is simply not possible.
- If this decision is reached in your case, we again turn to the IAF ID3 for official guidance on how to proceed. We will explore this guidance based on pending audit type.

If your upcoming audit is the first surveillance following initial certification (and it has been decided by PJR that a virtual audit is not possible)

- For the first surveillance audit following initial certification note that ISO 17021-1:2015 clause 9.1.3.3 mandates that the first surveillance audit be performed "not more than 12 months from the certification decision date."
- IAF ID3 states that "providing that sufficient evidence has been collected to provide confidence that the certified management system is effective consideration may be given to postpone the first surveillance for a period not normally exceeding 6 months (18 months from date of initial certification.)"
- We will explore what is meant by "sufficient evidence to provide confidence" in a few slides.

If your upcoming audit is a subsequent surveillance assessment (and it has been decided by PJR that a virtual audit is not possible)

- ISO 17021-1:2015 clause 9.1.3.3 states that "surveillance audits shall be conducted at least once a calendar year, except in recertification years."
- This provision gives PJR a tremendous amount of flexibility in performing your surveillance audit.
  - For example, an organization who had their First Annual Surveillance Audit performed in January 2021 could conceivably have their Second Annual Surveillance Audit performed in July 2022.
- In situations where the audit cannot be performed in the calendar year the IAF ID3 permits PJR reasonable flexibility in performing the audit when it could not be performed due to extraordinary circumstances.

If your upcoming audit is a recertification assessment (and it has been decided by PJR that a virtual audit is not possible)

- ISO 17021-1:2015 clause 9.6.3 mandates that "recertification activities" must be completed prior to the expiry of the client's certificate. In extreme circumstances this is understood to mean that the audit itself must be completed prior to certificate expiry, with the understanding that the subsequent certificate will reflect a lapse in the certification.
- IAF ID3 indicates that provided "sufficient evidence has been collected to provide confidence that the certified management system is effective consideration may be given to extend the certification for a period not normally exceeding 6 month beyond the original expiry date."

"Sufficient evidence to provide confidence"

- Let's examine this statement a bit more closely now as it is paramount to PJR's ability to make an informed decision in two key cases (first surveillance, recertification.)
- IAF ID3 states the following:
  - "If the risk of continuing certification is low, and based on the collected information the CAB (PJR) may need to consider alternative short-term methods of assessment to verify continuing system effectiveness for the organization."
  - This may include requesting relevant documentation to be reviewed off site by the CAB to determine continuing suitability of the certification (on a short-term basis only.)"
    - management review meeting minutes,
    - corrective action records,
    - results of internal audits,
    - ▶ test/inspection reports, etc.

# What does that mean in plain English?

- Essentially if neither an onsite nor a virtual audit is not possible - we can review certain critical information provided via email/file-share/etc. and make one of two decisions (depending on your circumstances):
  - Delay your first surveillance assessment by up to six months;
  - Extend your current certification by up to six months.

#### How does the virtual audit process work?

- We will now review PJR's protocol for assessment of possibility and completion of a virtual audit.
  - This protocol should be considered available for the following schemes: ISO 9001, ISO 14001, OHSAS 18001, ISO 45001, ISO 13485, TL 9000, RIOS, BA 9000, ISO 27001, e-Stewards, and ISO 37001.
  - As of October 2020, IATF 16949 audits can also be conducted virtually, but the process by which they are approved is different from what we will be reviewing today. Please refer to the separate webinar presentation on this topic.
  - Applicable authorities for R2, FSSC22000 and AS91XX have indicated that some aspects of their audit processes can be performed virtually.
- In all cases, clients will need to speak with their schedulers to ascertain their options.

- You will be sent the aforementioned PJR Form F-108ict
- This form will be sent to you by your assigned scheduler.
  - Alternatively your scheduler may conduct a short phone conference with you to complete the form.
  - It is also possible that your auditor may contact you to request completion of this form.

- The F-108ict is forwarded by the Scheduler to the appropriate Virtual Audit Assessment Team (VAAT) (QMS, EHS, AS91XX) for review and determination of client eligibility for a virtual audit.
- This decision will take one of several forms:
  - ▶ The client's audit can be conducted 100% virtually;
  - ▶ A portion of the client's audit can be conducted virtually (1-99% virtually) this is the aforementioned "hybrid audit";
  - None of the client's audit can be conducted virtually.
- This will include review of prior virtual audits for assessment of auditor commentary on how well (or how poorly) the virtual audit went. Note that if the prior auditor indicated things did not go well your request for a virtual audit will likely be denied.

- The VAAT will advise the scheduler of the decision and request that (if a virtual audit component is to be used) that a date be set for the virtual portion of the audit.
  - Note that this will very likely include some or all of the dates that were previously held for an onsite assessment.
  - If an onsite portion to complete the audit is also required, this may be scheduled at the same time. It is also possible that the onsite portion will be rescheduled at a later date.

- Once the virtual audit arrangements are set a virtual meeting using either Go-To-Meeting or Microsoft Teams will be created by a representative of PJR.
  - Please note that multiple day audits will have a separate meeting assigned for each day of the audit.
  - ▶ If for whatever reason Go-To-Meeting or Microsoft Teams is not to be used, it is dependent on the client to make the virtual communication arrangements. Please ensure that you are discussing these steps with your auditor in advance of the audit. PJR accepts all major virtual meeting software programs (WebEx, Zoom, Skype For Business.) The only program we do not accept is the free version of Skype.
  - Please be advised that both Go-To-Meeting and Microsoft Teams have fantastic smartphone apps that will likely make things much easier for shop floor assessments.
- ▶ PJR has created multiple virtual auditor accounts within GTM for this express purpose. This arrangement means that numerous virtual audits can be performed at the same time on the same day. Most of these accounts have been assigned to individual auditors who perform numerous audits for PJR.



A PJR representative will send an email to the client with instructions for accessing the virtual meeting on the date of the audit.



If GTM is being used, the instructions will include a link that reads similarly to the below:

New to GoToMeeting? Get the app now and be ready when your first meeting starts:

https://global.gotomeeting.com/install/xxxxxxx



You are encouraged to follow this link to ensure that your computer is all set to run the virtual meeting on the date of the audit. This will need to include ensuring that you have both a working microphone and working speakers.

### Step 5 (if PJR is managing virtual interface)

#### Step 6

- You should expect to receive an audit plan from your auditor highlighting the portions of the audit that are to be performed virtually.
- ▶ We have taken great pains to emphasize the importance of a detailed audit plan to our auditor team. We recognize that many of our clients are working to coordinate teams of people who themselves are working virtually. You should expect the audit plan to paint a very clear picture on what will be reviewed and when it will be reviewed.
- As with all audit plans we encourage a careful review of content and sharing of the plan to ensure your team is ready on audit day.

# What can ideally be reviewed during a virtual audit? - Audit Plan content

- When the VAAT receives the F-108ict from the Scheduler, one of the critical steps being taken (for surveillance audits) is modification of the client's audit program.
  - ► These actions include moving all production related areas off of the forthcoming audit if possible.
- What this typically leaves for audit assessment are the typical administrative areas of an organization, including:

Management Review	Internal Audit	Corrective Action	Customer Satisfaction	KPIs/Quality Objectives
Order Entry	Product Design	Production Scheduling	Training	Calibration
Complaint Resolution	Returns Processing	Confirmation of Scope/Exemptions	Website Review	Closure of PNCRs

# Helping your auditor prepare for the virtual audit

- Assessments of production areas can be greatly assisted by the client providing a shop floor plan/map.
- Providing the auditor with a list of your procedures in advance may also be a good way for your auditor to prepare a list of follow-up items to ensure a proper depth of auditing.

#### Step 7 - Audit Day

When the date of the audit arrives we ask that you access the remote interface at least 10-15 minutes before your scheduled start time to ensure that you're logged in and ready to go when the auditor initiates the audit on their end.

Most remote interfaces permits several (usually at least 100) persons to be joined in at the same time.

#### **Technical Reminders**

- Once the audit has started you'll need to make sure that your audio and visual settings are working properly.
- Generally any computer with a built-in microphone will work sufficiently, but you may find it optimal to use a computer headset.
- If no good audio option is available, you may choose to call the auditor on a cell phone or land line to facilitate audio communication.
  - Note that this implies simultaneous usage not substitute usage.

### Random Sampling is still required

- It is vital to the integrity of the audit process that the principle of random sampling be utilized in performing these assessments.
- The screen sharing capabilities offered by virtual meeting software are intended to make it feasible for your auditor to review your screen and select the items they wish to review during the audit.
- Wherever possible the auditor select must their own audit samples as if they were onsite.
- As previously stated offsite auditing and virtual auditing are not the same thing!

#### Audit report expectations

- If the entire audit was done virtually and no onsite portion will be needed the "full" audit package will be turned over to you in accordance with PJR's established policy on audit package preparation. In these circumstances you should expect to receive the following:
  - Audit Report;
  - Nonconformances (if any);
  - Audit Plan; and
  - ▶ The Auditee Acceptance of Findings form signed by both auditor and auditee.
- If the audit includes an onsite portion to be done at a later date, your audit package will be provided upon completion of the onsite portion.
  - ▶ PJR can provide documented verification that the virtual portion was completed for any client who needs it.

#### NCRs - business as usual

- Any Virtual Audit issued nonconformances will follow PJR's established protocol for resolution. You will still be expected to provide the full response (correction, extent analysis, root cause analysis, corrective action) as found on PJR's standard nonconformity report.
  - Please note that if a nonconformance is issued in a hybrid audit you cannot simply "fix it" in the time between the virtual portion and onsite portion. The full documented response is still required.
- All timing requirements pertaining to nonconformances are also in effect (60 days, etc.) from the <u>full</u> completion of the audit.
  - Sector specific rules also remain in effect.

### Conclusion



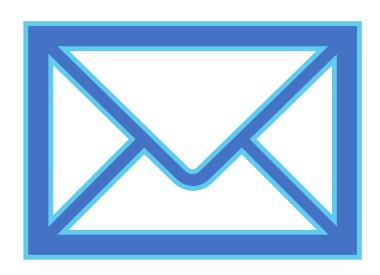
PJR is committed to ensuring a continuance of certification for our valued clients.



We thank you all for your part in ensuring that auditing can continue in this difficult time.

### Please tune in for one of our other webinars

- "IATF Common Audit Report Application (CARA) and Remote Auditing"
  - This webinar includes an examination of virtual auditing specific to the automotive industry.
- "The Interaction of Processes and its importance to a successful audit."
  - This webinar explores the crucial topic of processes and how to correctly understand them.
- We offer a variety of webinars on other topics including Corrective Action, Stage 1 Audits, AS9100, ISO 13485:2016, IATF 16949, and ISO 14001:2015.



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