Virtual Audits In A Post Pandemic World

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Please note:

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.

Please note that copies of today's presentation will be available for download shortly.

This webinar (and all other past PJR webinars) will also be available for re-viewing on our website under "Previously Recorded Webinars."

Please also note that significant parts of this presentation do NOT apply to other scopes (R2, IATF 16949 or AS91XX) – those programs also have separate requirements that will not be reviewed today.

Overview of Topics

- Where does virtual audit policy come from?
- How does an audit get approved to be virtual?
- New controls/oversight introduced in 2024
- Hybrid Audits
- Audit Report and Nonconformance Expectations
- Conclusion/Questions

Official policy comes from the IAF

- There are two primary documents that PJR must abide by in providing remote audit services to our clients. PJR is held accountable to these requirements (and many others) during our accreditation assessment by parties like ANAB and UKAS.

  - 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 (www.iaf.nu.)

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 has established form "F-108ict" in order to enable us to gather information from the client and make the specified risk-based assessment.

Format of the F-108ict

- The F108ict includes the following sections:

  - Part A – Completed by PJR Scheduler if applicable

  - Part B – Completed by Client if appliable

  - Part C – Completed by Client in all cases

F108ict Part A – PJR Scheduler Portion

- In Part A of the F-108ict we've provided a space for our team to capture some of the remote audit justifications that originate from PJR's end. Such items include:

  - An auditor that is immune-compromised and cannot travel;
  - An audit that will only include review of administrative areas (for example a revisit audit for a major nonconformance written against management review);
  - A Hybrid Audit arrangement whereby some of the audit will be done onsite and some of it will be remote (more on this coming later); or
  - A travel warning impacting the client's city, state, or country – note that PJR will be performing it's own verification in these instances.

When to complete F-108ict Part B

- If you receive the F-108ict from your scheduler and Part A has been left blank – this should be taken as an indication that you need to complete Part B.

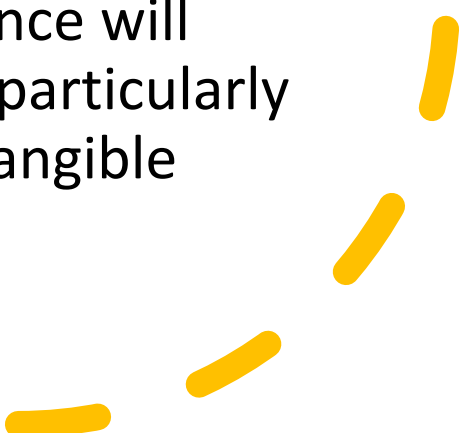# F108ict Part B – Client Portion (Justification)

- Part B of our F-108ict provides a list of approved justifications for a remote audit, these include:

  - A positive COVID19 test for one of your onsite team members. Requests of this nature will only be permitted if:
    - You provide evidence of the positive test (redacted); and
    - Only if the audit is set to take place within the next 14 days.

  - Companies with remote and/or administrative business models (data processing, staffing services, etc.);

F108ict Part B – Client Portion (Justification)

- (list of justifications continued):

  - A company with a current "No Visitors" policy. Requests of this nature will only be approved if we are provided evidence that the policy is current and also that it has been applied to all other potential visitors (customers, suppliers, etc.)
    - Please note that our auditors have been trained to verify enforcement of said policy during the audit.

  - Applicable governmental travel restrictions (proof required);

  - A request for a hybrid audit (more details later in this presentation);

  - Other justifications will be considered.

Justification options that <u>will not</u> 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 **onsite audit**, particularly for organizations that manufacture a tangible product.

F108ict Part C – Eligibility (Part 1)

- These are the actual questions that appear in Part C:

1. *Is GoToMeeting or Microsoft Teams acceptable for use to conduct the virtual audit?* (clients are prompted to specify if they answer "No")

2. *Are 100% of your records maintained in an electronic fashion?*

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 C – 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 **are not** 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?*

F108ict Part C – Eligibility (Part 3)

9. *Do you consent to PJR recording all or some of the audit activity for later review to ensure the audit process was carried out in accordance with our policies and procedures?*

10. *Do you consent to PJR management staff potentially joining the virtual audit to validate its integrity?*

11. *Do you agree to a technology test session in advance of the 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 move past the COVID driven "emergency use" arrangement.
    - It should be noted that the CDC declared the COVID19 pandemic over in May 2023.

  - We have many clients with business models that are a natural fit for remote auditing. The key is capturing a **satisfactory** rationale in a traceable manner.

- Clients have a responsibility to ensure the remote audit is successful.
  - Remote auditing is a privilege and not a right for either the client or the auditor.
  - Onsite audits are the default position being taken by PJR in making audit arrangements and thus we have stepped 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 – <u>the following three conditions must be met</u>.
  - Live chat over a person-to-person interface (with live sharing of the auditee's screen) is mandatory;
  - Records must be 100% or nearly 100% electronic (exceptions potentially permitted); and
  - **<u>Production assessments must take place in person (audit must be hybrid) unless there is a documented current risk to auditor and/or client health.</u>**

PJR oversight of the remote audit process

- Two new layers that have been added to our remote audit process in 2024 are random witness assessments and recording of audits.

- Let's unpack these two new controls a bit more thoroughly.

Random Witness Assessments

- In order to demonstrate appropriate control over the remote audit process and ensure auditor rigor we have instituted a system of unannounced witness assessments.

- If your audit is selected you will not be told when the witness assessor will be joining the audit – only that it is possible they will join the audit.

- Witness assessors will have cameras off and microphones muted during the assessment and will not interfere in any way with the audit process.

- Refusal on your part to consent to a witness assessor will likely lead to your request for a remote audit being rejected.
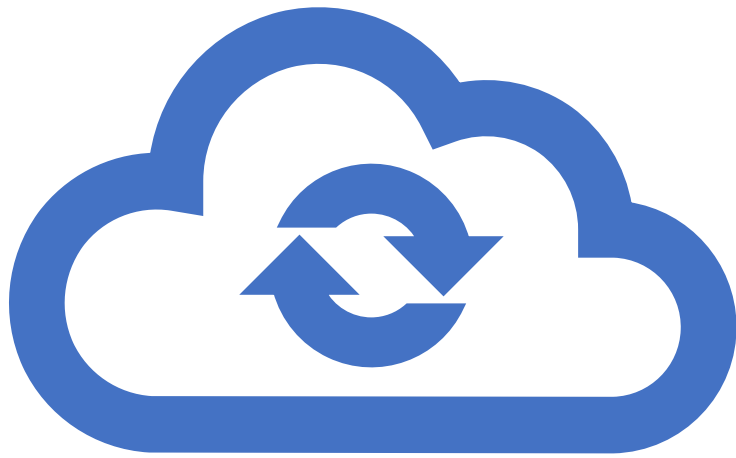
Recording of audit events

- In rare instances PJR may request that a recording of the remote audit be saved and shared with our internal team.

- Such requests will always be shared in advance.

- Refusal on your part to consent to a recording or partial recording of your audit will likely lead to your request for a remote audit being rejected.

Technology Test Sessions (TTS)

- One of the other newer controls introduced in 2024 was the Technology Test Session.

- This activity is actually mandated by IAF MD4 clause 4.2.2 which reads as follows:
  - "*When ICT is proposed for the audit/assessment activities, the application review shall include a check that the client and the audit/assessment body have the necessary infrastructure to support the use of the ICT proposed.*"

Technology Test Sessions (TTS)

- The TTS must be completed in advance of the actual audit and must utilize the same systems that will be used on audit day.

- A TTS that results in a negative recommendation will mean that your audit must be conducted onsite.

- PJR technical management will participate in/witness TTS activity at it's discretion.

Hybrid Audits

- As prior indicated PJR 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.

- If your organization's scope includes any form of manufacturing, product storage, etc. and you're requesting a remote audit for anything other than an actual health emergency, our preference will be for a hybrid audit (if your audit will include assessment of your manufacturing area.)
  - It is possible in certain surveillance audit situations for us to plan on NOT seeing manufacturing thus making a remote audit more likely.

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

   i. 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

3. 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.

    i. 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.
  - These include companies whose records are hard copy in all or most cases.

- Based on guidance provided in IAF ID3 and depending on your circumstances, PJR can make one of three decisions (depending on your circumstances):

  - Delay your first surveillance assessment following initial certification by up to six months;
  - Delay your surveillance assessment to take place later in the same calendar year; or
  - Extend your current certification by up to six months.

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

- When our team 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

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 selects must their own audit samples as if they were onsite.

- **<u>As previously stated – offsite auditing and virtual auditing are not the same thing!</u>**

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 wants to be reasonable in offering as many options to our clients as possible to ensure a value added audit experience.

- We also must be cognizant of industry requirements and ensure that we're not performing a remote audit with insufficient justification.

- We hope you find benefit in our remote audit options.

Please tune in for one of our other webinars

- *"Understanding PJR's PRO-3 and related bylaws governing proper promotion of your management system certification"*

  - This webinar unpacks the various requirements that impact promotion of your certification and the related usage of the many available logos.

- *"Your ongoing relationship with PJR"*

  - This webinar explores our expectations for those times when things change at your organization, and also provides a detailed explanation of our disputes process.

- 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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