Virtual Audits – Explaining PJR's Approach and Expectations

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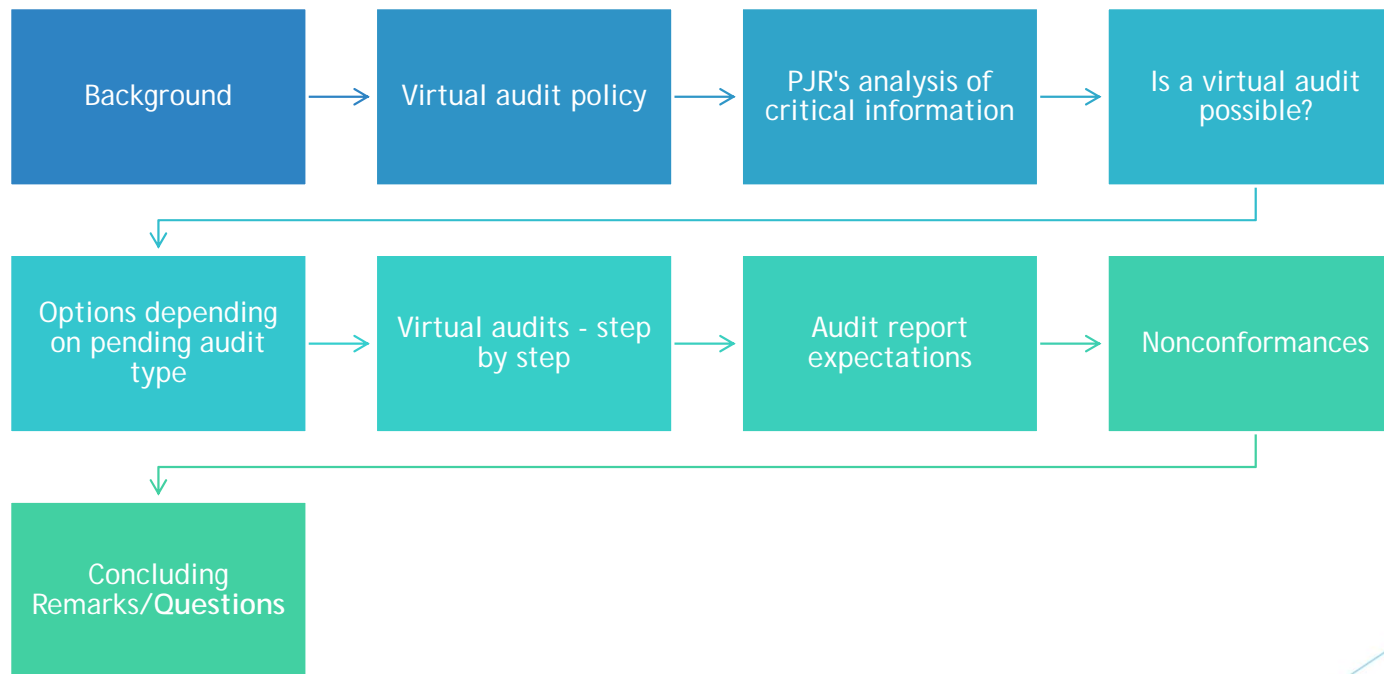
All participants have been muted.

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Overview of topics

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│  Background  │ ──> │ Virtual audit │ ──> │ PJR's analysis of │ ──> │ Is a virtual │
│              │     │    policy    │     │ critical          │     │ audit        │
│              │     │              │     │ information       │     │ possible?    │
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│ Options      │ ──> │ Virtual      │ ──> │ Audit report │ ──> │ Nonconform-  │
│ depending    │     │ audits - step│     │ expectations │     │ ances        │
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│ audit type   │     │              │     │              │     │              │
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Background → Virtual audit policy → PJR's analysis of critical information → Is a virtual audit possible?

Options depending on pending audit type → Virtual audits - step by step → Audit report expectations → Nonconformances

Concluding Remarks/Questions

Background

- The effects of the Covid-19 virus (aka Coronavirus) began to be felt in the United States in early March 2020.

- Several states still have mandates in effect pertaining to permitted gatherings of people (group size, etc.)

- Airlines have limited flight availability, and in some cases hotels remain closed.

Impact on PJR's ability to perform an onsite audit

▶ Many of our clients have contacted us indicating a variety of situations that may impact their ability to host a successful audit:

    ▶ Operations reduced or completely down;

    ▶ A "no visitor" policy;

    ▶ Restrictions on access to certain locations (Southern California, Florida) while others are still accessible for audit assessment.

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"

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

- Both ID3 and MD4 require that PJR make contact with the client and conduct a risk-based assessment of whether or not the virtual audit is possible.

- PJR has attempted to simplify the pre-audit process as much as possible for our clients. These efforts have led to our newly revised form entitled "F-108ict – Virtual Audit Questionnaire."

- Let's take a look at the content of the F-108ict on the next slide.

PJR Form F108ict – Four Questions

▶ *Is GoToMeeting acceptable for use to conduct the virtual audit?*

  ▶ *If not, please specify the software you will provide.*

▶ *Does your management system support a virtual audit?*

  ▶ *I.E. records are electronic. By checking Yes, you attest that you do not maintain mostly hard copy records, which cannot be viewed via a screen share.*

▶ *Will you be actively manufacturing product at the time of your audit?*

▶ *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?*

  ▶ **Examples of sufficient technology could be, but are not limited to, body cameras, I-PAD, Tablet or cell phone with GoToMeeting technology or similar video conferencing technology.*

Key takeaways from the revised F-108ict

Usage of Go-To-Meeting is not compulsory.

- PJR has invested a great deal of financial and manpower resources into ensuring that we have a reliable and secure platform for performing a virtual audit. However we will absolutely be flexible in this regard if the auditee has a preferred alternative (Skype for Business, Zoom, Microsoft Teams, etc.) The only platform that we will not and cannot accept at this time is the free (personal) version of Skype.

The client has to have a minimum ability to support a virtual audit on their end.

- We have strived to be as flexible as possible on this point. Particularly on surveillance audits, so long as there is "enough" for PJR to review to fulfil audit program management requirements it will be considered satisfactory.

What do we mean when we ask "Can a virtual audit be supported?"

▶ There are a number of key factors that will determine whether or not a virtual audit will be successful, including:

  ▶ Availability and speed of your internet connection;

  ▶ The propensity of electronic records (as opposed to hard copy records);

  ▶ The comfort of your staff in communicating virtually.

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 – <u>**an offsite audit is NOT the same as a truly virtual audit.**</u>

If a virtual audit can be supported

▶ ID3 specifies that the certification body (PJR) is required to establish its own policies in regards to timely completion of audits. This is also the position taken in ISO 17021-1:2015 section 9.

▶ If a virtual audit is possible, <u>PJR's policy is that a client's audit must utilize the virtual method and must take place on time in accordance with your established audit program and schedule.</u>

▶ Clients are reminded that there are a finite number of auditor resources and as we return to "normal" operations after the pandemic has passed we may not be able to guarantee timely completion of a rescheduled audit.

What if the information leads PJR to conclude that a virtual audit is not possible?

▶ 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 2019 could conceivably have their Second Annual Surveillance Audit performed in July 2020.

- 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 PJR decides that 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.

Important reminder!

- ▶ As previously mentioned, if PJR concludes that a virtual assessment is possible to ensure continuance of your established audit program – the audit must be completed virtually.

- ▶ This analysis will be done on a case by case basis using the details provided on the F-108ict as previously discussed.

What if we still want to have an onsite audit?

- If you have an audit scheduled in the immediate future and BOTH you and your auditor are able and comfortable with the audit taking place onsite as scheduled – PJR has no objection.

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.
  - Please note that IATF presently permits <u>no virtual auditing of any kind</u>;
  - 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.

Step 1

- You will be sent the aforementioned PJR Form F-108ict

- This form will be sent to you by your assigned <u>scheduler</u>.
    - 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.

Step 2

▶ 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 completely conducted virtually (100% virtually);

  ▶ A portion of the client's audit can be conducted virtually (1-99% virtually);

  ▶ None of the client's audit can be conducted virtually.

Step 3

- 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.

Step 4

▶ Once the virtual audit arrangements are set – a member of the VAAT will create the virtual meeting using Go-To-Meeting.

  ▶ 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 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.

  ▶ Please be advised that Go-To-Meeting has a fantastic smartphone app 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.

PJR will send an email to both the client and auditor with instructions for accessing the virtual meeting on the date of the audit.

The instructions will include a link that reads similar 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

Step 6

▶ You should expect to receive an audit plan (or a revised 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 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

▶ Many of the more recent virtual audits that PJR has conducted have included a virtual assessment of the client's production areas. In some cases these assessments have been 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 Go-To-Meeting 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.

   ▶ Remember that the Go-To-Meeting interface permits several (usually at least 100) persons to be joined in at the same time.

▶ We will now have a step by step review of the usage of Go-To-Meeting.

GTM Interface Part 1

When you first click the link provided in the email - you'll be directed to GTM's website for download of the installer. A screenshot of what this interface looks like has been provided here.
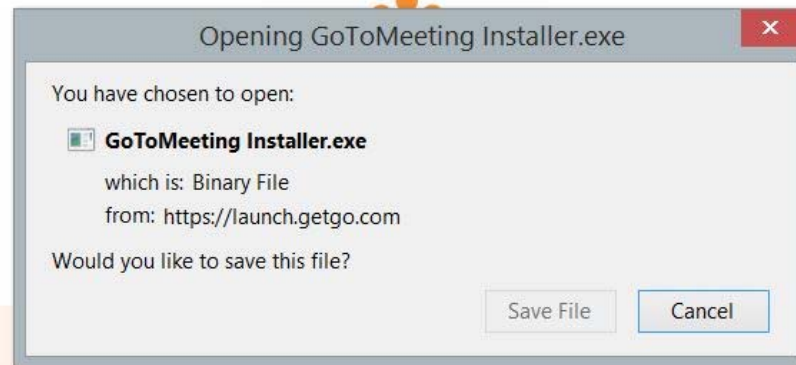
GTM Interface Part 2

Once you've installed the software – simply enter the access code provided to you in the email you received from PJR.

GTM Interface Part 3

► Once you've inputted the access code you'll be directed to input your information so that the auditor knows who you are.

GTM Interface Part 4a

▶ Once the meeting has started you'll need to make sure that your audio (and visual if desired) setting 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.
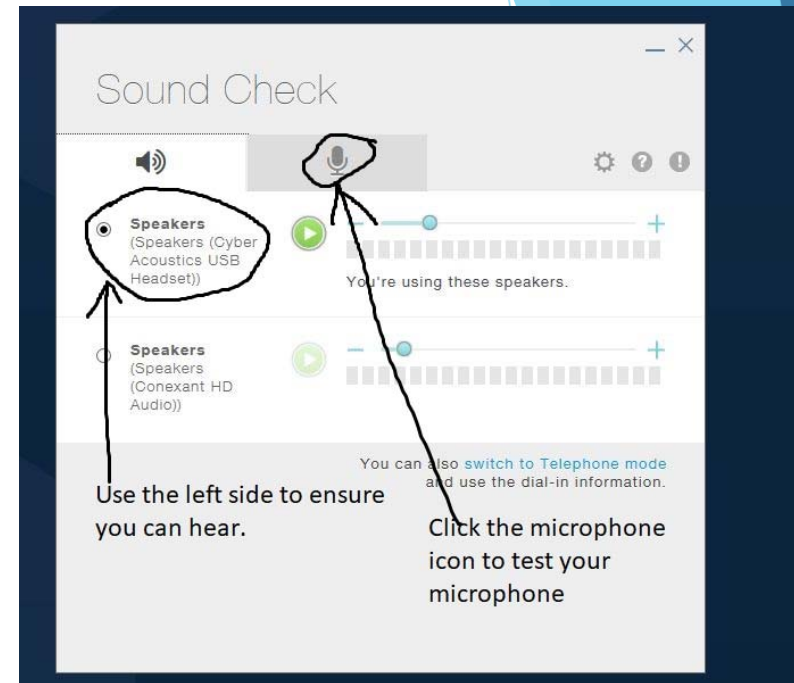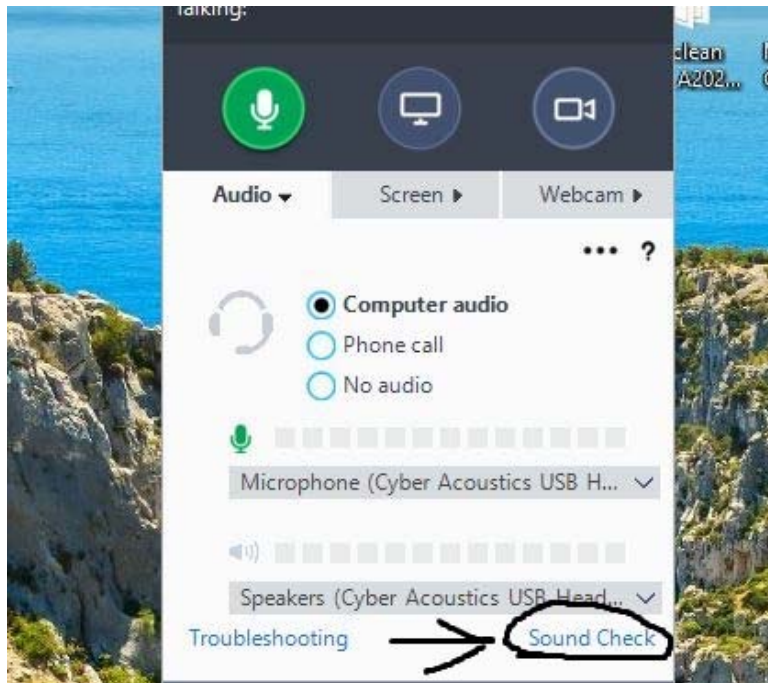
GTM Interface Part 4b

▶ It is recommended that you run a test of your microphone set-up using the "Sound Check" feature as shown above.

GTM Interface Part 5a

► Once all technical aspects have been tested the auditor will complete the standard kickoff steps (opening meeting, etc.) the auditor will determine who needs to be made "presenter."

► That is to say – who will "have the floor" and share content for auditor review.
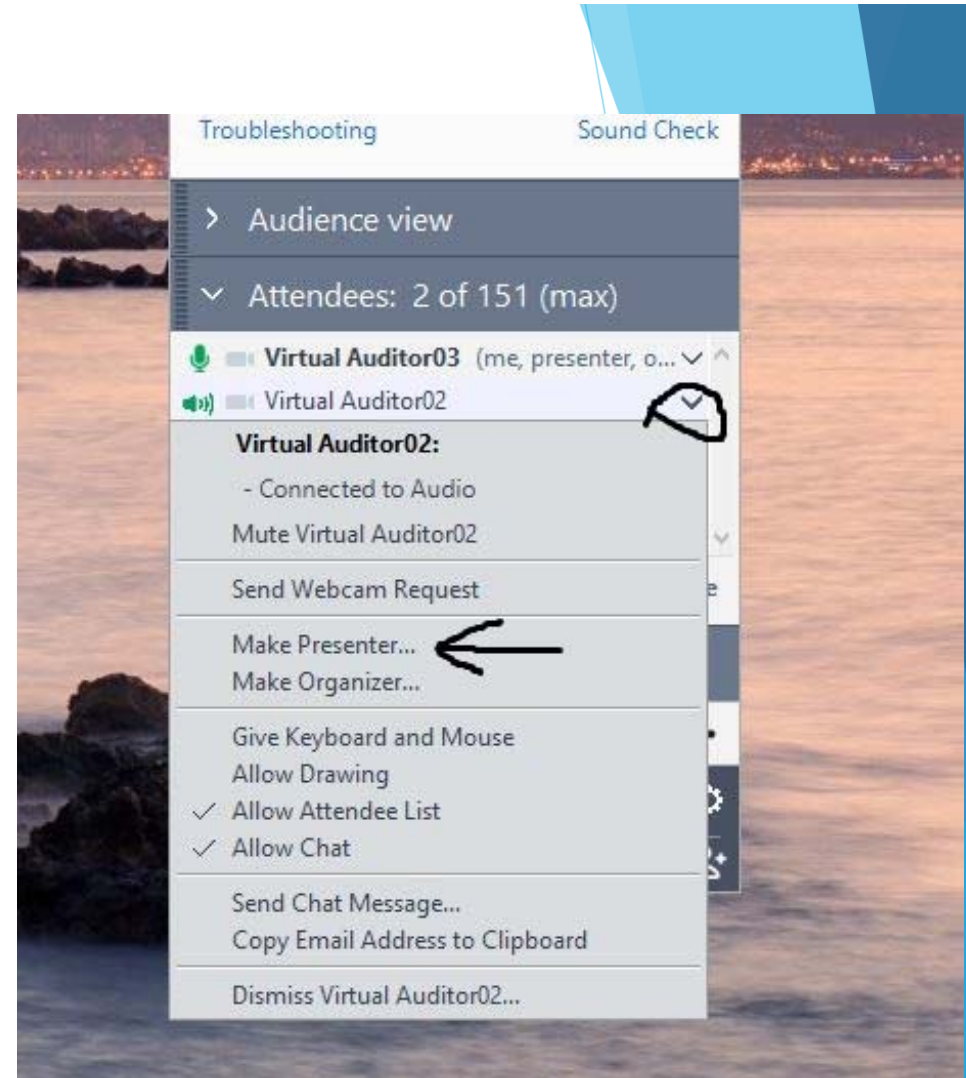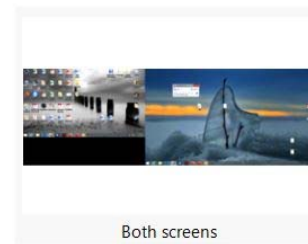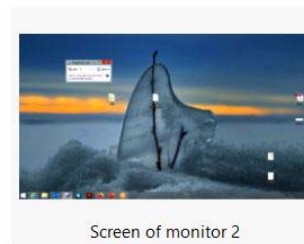
GTM Interface Part 5b

If you indicate to the auditor that you should be made presenter, the auditor will use the GTM dashboard to assign presentation control to you – which will bring up a screen that looks like that shown here. Simply select which monitor you wish to share and click "Share."
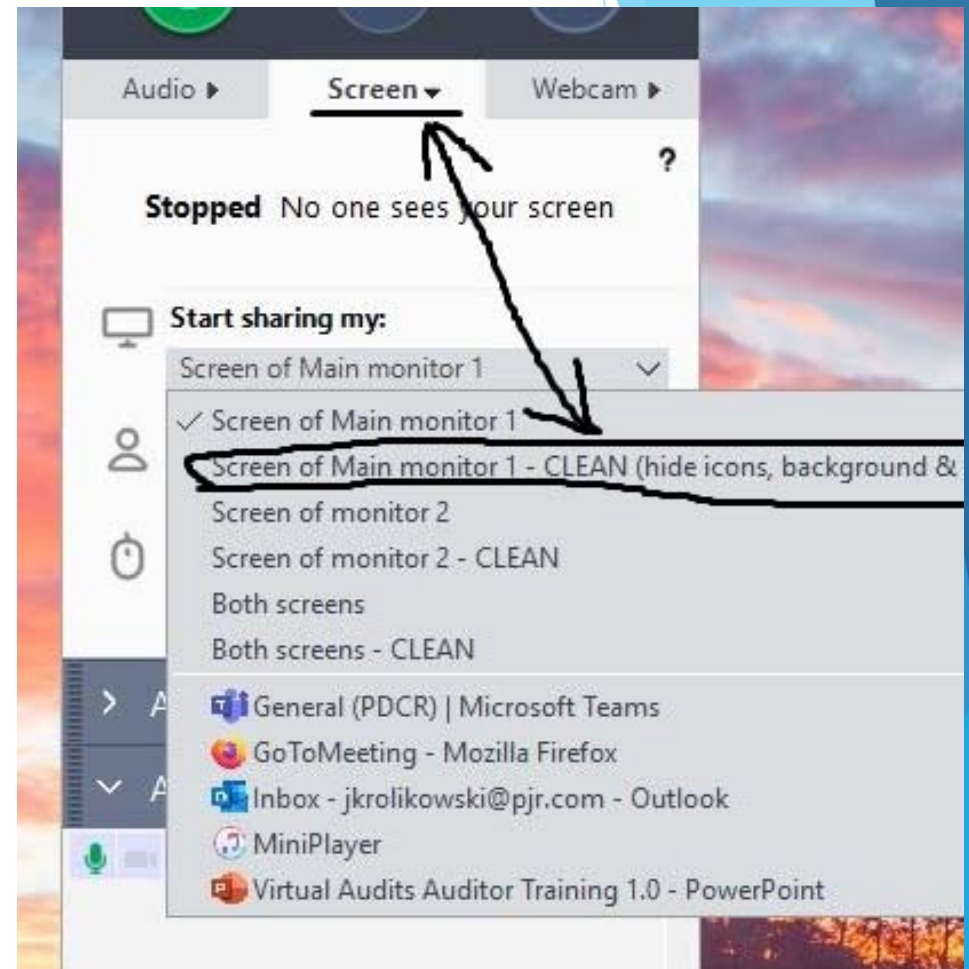
GTM Interface Part 6

▶ Once you have been assigned presentation control we recommend using the "Share My Screen CLEAN" option to avoid unwanted information leaks.

Important reminder

▶ 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 GTM 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!**
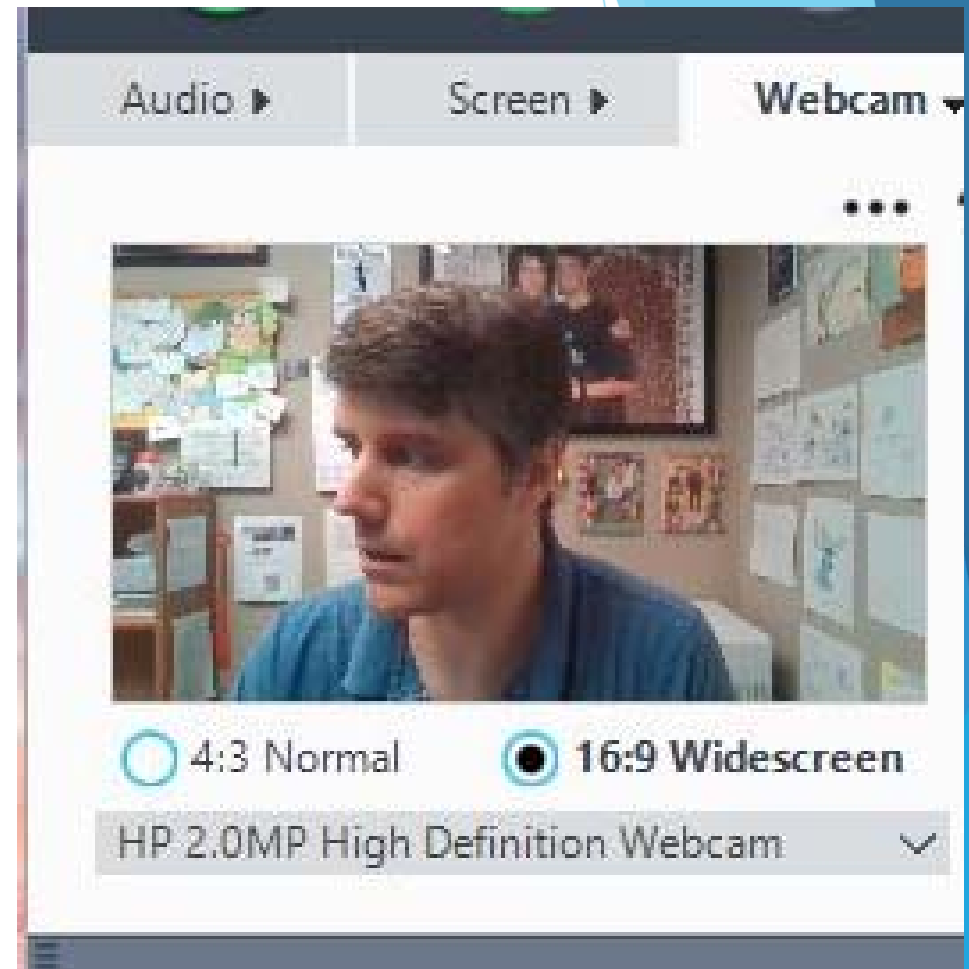
GTM Interface Part 7

When the virtual audit is complete, simply click the "X" button on the upper right corner of the GTM Interface as shown.

GTM Interface Optional Features (1 of 2)

▶ If you wish to use video share features (so the auditor can see you) you will need to have a computer with a web-cam (either built-in or added.) Simply click the "Webcam" link in the GTM interface to get it set-up.

   ▶ Please note this is purely optional and not required by PJR.

GTM Interface Optional Features (2 of 2)

▶ If you wish to minimize the GTM Interface Tool for any reason (such as to make it easier to see what the auditor is showing you) simply click the double arrow in the upper right corner of the interface as shown.
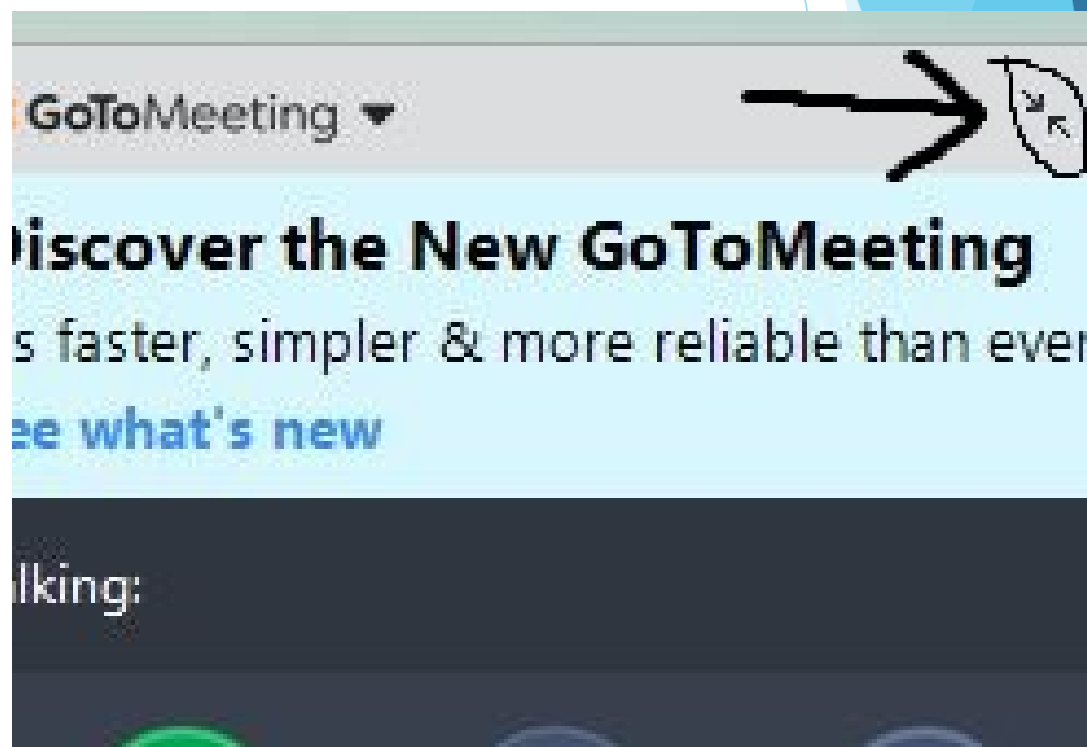
Go-To-Meeting Alternatives

As previously mentioned – PJR is willing to work with other virtual meeting platforms (Zoom, Skype for Business, Microsoft Teams, etc.) This presumes that the auditee will manage the interface.

The only platform that we cannot utilize is personal (free) Skype due to concerns over it's data security capabilities.

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 virtual 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.

Virtual Assessment of a "Shop Floor" Process

▶ As previously mentioned, in nearly all surveillance assessments we are taking steps to limit risk by directed that "shop floor" activities not be included in the audit.

▶ We do not have this luxury for any Stage 2 or Recertification Audit.

▶ Accordingly – we are asking our clients (via the F-108ict) if they have the technological means (cell phone, tablet, Wi-Fi, etc.) to support a remote assessment of their shop floor.

▶ Any client that responds positively (even with reservations) is going to be recommended for a 100% virtual recertification or Stage 2 audit.

▶ PJR is working with our clients to provide headsets to try to help facilitate this process.

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

▶ *"Non-Applicable Clauses, Permissible Exclusions, Exemptions - Developing a better understanding of what can and what cannot be excused in an audit assessment"* is presented on a quarterly basis.

  ▶ This webinar explores the critical topic of exemptions and the right approach to take in determining which apply to you.

▶ *"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.
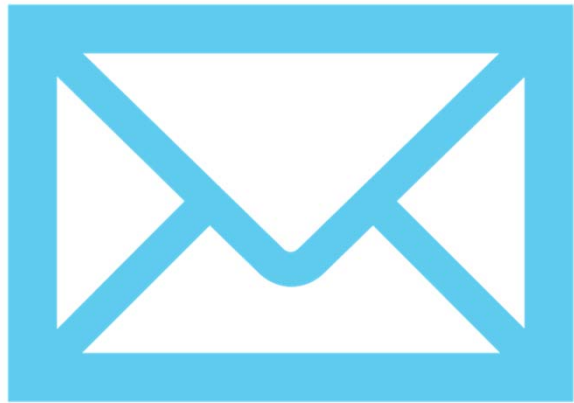
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  - ► Copies of today's presentation will be available for download shortly.

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- ► Questions?

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