

Virtual Audits - Explaining PJR's Approach and Expectations

Presented by Joe Krolikowski, QMS
Program Manager



Please note:

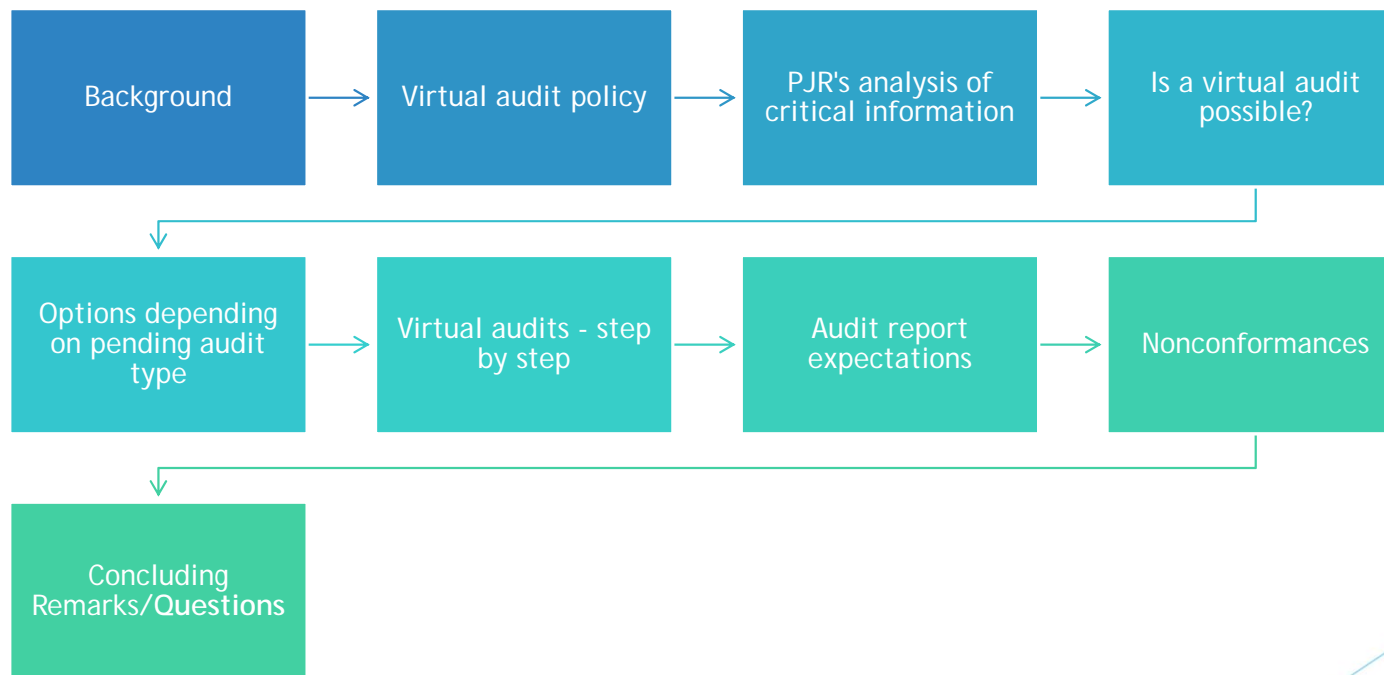
All participants have been muted.

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.”

Overview of topics



Background

- ▶ The effects of the Covid-19 virus (aka Coronavirus) began to be felt in the United States in early March 2020.
- ▶ Several states have already issued mandates pertaining to permitted gatherings of people (group size, etc.)
- ▶ Airlines have begun to cancel flights, and in some cases hotels have temporarily closed.

Impact on the 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 (Seattle, WA) while others are still accessible for audit assessment.

Virtual Auditing Policy from the “powers that be”

- ▶ PJR’s policies as a certification body are primarily driven by the requirements handed down by the International Accreditation Forum (IAF.)
- ▶ The primary document that our policy on virtual auditing in response to Covid-19 is developed from is the IAF Informative Document (ID) 3 entitled: “*Management of Extraordinary Event or Circumstances Affecting ABs, CABs, and Certified Organizations.*”
 - ▶ This document is available for free at the IAF website - www.iaf.nu.
- ▶ Most of the major international accreditation bodies have published guidance or official position papers that provide an interpretation of ID3 for their respective territories. These publications include ANAB Heads Up (HU) 448 and UKAS TPS 62.

What does IAF ID3 say?

It provides an official definition of what constitutes an “extraordinary event”, which reads as follows:

“A circumstance beyond the control of the organization, commonly referred to as “Force Majeure” or “act of God”. Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.”

What else does IAF ID3 say?

- ▶ ID3 specifies that once an extraordinary event or circumstance occurs such that an onsite audit cannot be performed the certification body shall "*gather necessary information from the certified organization before deciding on an appropriate course of action.*"
- ▶ PJR has facilitated this gathering of information via two newly developed documents:
 - ▶ F-108ict - "*Virtual Audit Questionnaire*"; and
 - ▶ F-228 - "*Novel Coronavirus (COVID-19): Survey of Current Impact(s) to Client Business Operations*".

What questions are asked on PJR's new forms? (1 of 2)

- ▶ Let's start with PJR form 228 - which essentially recreates the list of concerns from ID3 in the form of questions, which include the following:
 - ▶ Are you able to function? (if not 100%, what is your current rate of functionality?)
 - ▶ Are you able to ship products?
 - ▶ Are your products still meeting all applicable interested party requirements?
 - ▶ Has it been necessary for you to outsource any aspect of your management system?
 - ▶ Are any of your employees presently working remotely?
 - ▶ What is the overall impact on your management system?

What questions are asked on PJR's new forms? (2 of 2)

- ▶ Let's continue with PJR form F-108ict - which asks a few targeted questions intended to ensure that our primary process for virtual audits will be effective for you. These question include:
 - ▶ Is Go-To-Meeting (GTM) acceptable?
 - ▶ Do you or your colleagues have any working experience with GTM?
 - ▶ Does your management system support a virtual audit (more information coming on the next slide.)

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.
 - ▶ Note that PJR for many years has offered an “off-site Stage 1 audit” process for some of the standards we certify.
- ▶ 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.

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, 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.
- ▶ 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 early results have given us great confidence that a majority of our clients will be able to enjoy a fully or partially virtual audit, 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 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-228 and 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 no virtual auditing of any kind;
 - ▶ 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 newly created PJR forms:
 - ▶ F-108ict - "*Virtual Audit Questionnaire*"; and
 - ▶ F-228 - "*Novel Coronavirus (COVID-19): Survey of Current Impact(s) to Client Business Operations*".
- ▶ Both of these forms will be sent to you by your assigned scheduler.
 - ▶ Alternatively your scheduler may conduct a short phone conference with you to complete the forms.

Step 2

- ▶ The F-228 and F-108ict will be 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.
- ▶ 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.
- ▶ 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.

Step 7 - Audit Day

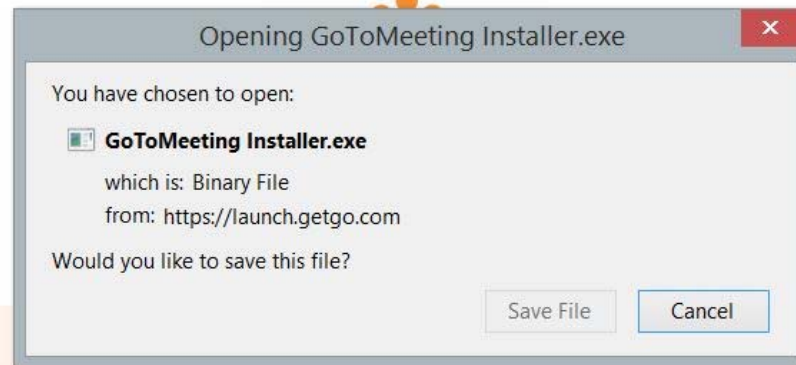
- ▶ When the date of the audit arrives we ask that you access Go-To-Meeting at least 10-15 minutes before your scheduled start time to ensure that you're logged in and ready to go when the auditor initiates the audit on their end.
 - ▶ Remember that the Go-To-Meeting interface permits several (usually 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.

Downloading GoToMeeting...

Problem downloading? [Try again](#)

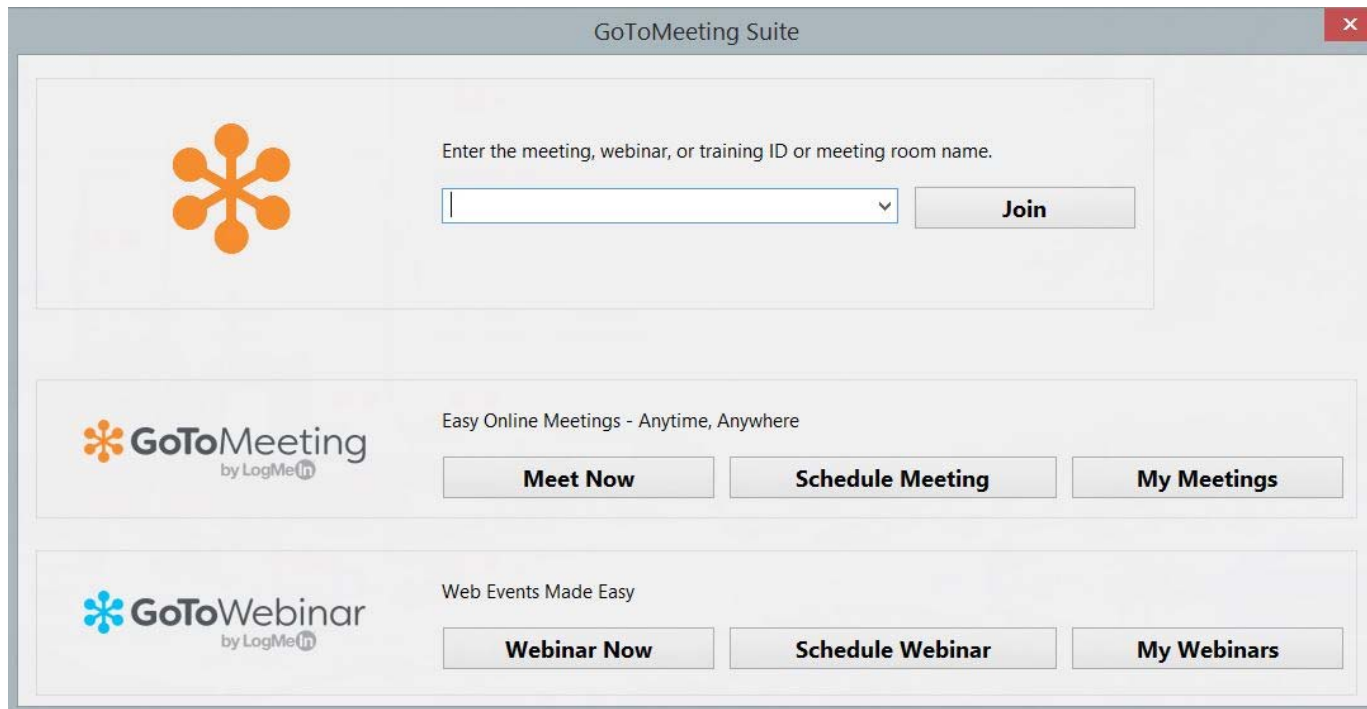


After downloading, click to run **GoToMeeting Installer.exe**.

GoToMeeting will start automatically after installation.

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.



Waiting to view **Virtual Auditor02**'s screen

Talking:



Webcams ▾



Screenshot

A2020- Client information redacted **ISO 9001**

ANS2 Virtual Audit with PJR Auditor Auditor information redacted

Organizer: Virtual Auditor

Audio: Use your microphone and speakers

United States: +1 (872) 240-3212

Access Code: 903-968-197

Audio PIN: 11

GTM Interface Part 3

Enter Your Name and Email

Enter your name and email address as you would like them to appear in the meeting organizer's attendee list.

Attendees

- John Smith
- Sue Miller (me)

Your name will appear here.

Name

Email

☐ Remember name and email

OK

GoToMeeting ▾

Talking:



Screen ▶

☒ **Computer audio**

☐ Phone call

☐ No audio

MUTED

ophone (Cyber Acoustics

kers (Cyber Acoustics US

ooting

> Attendees: 2 of 151 (m

> Chat

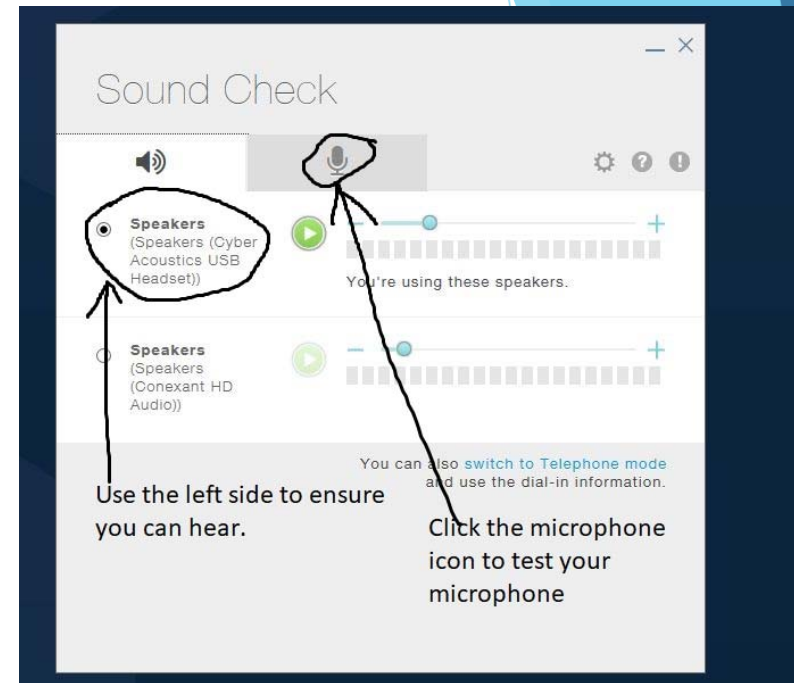
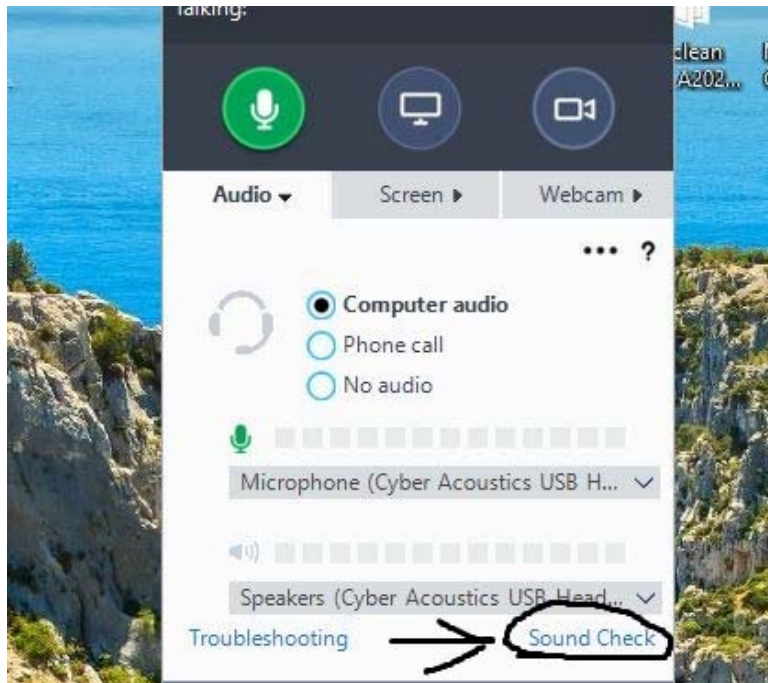
☐ Record

Meeting ID: 903-968-197

- ▶ 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.

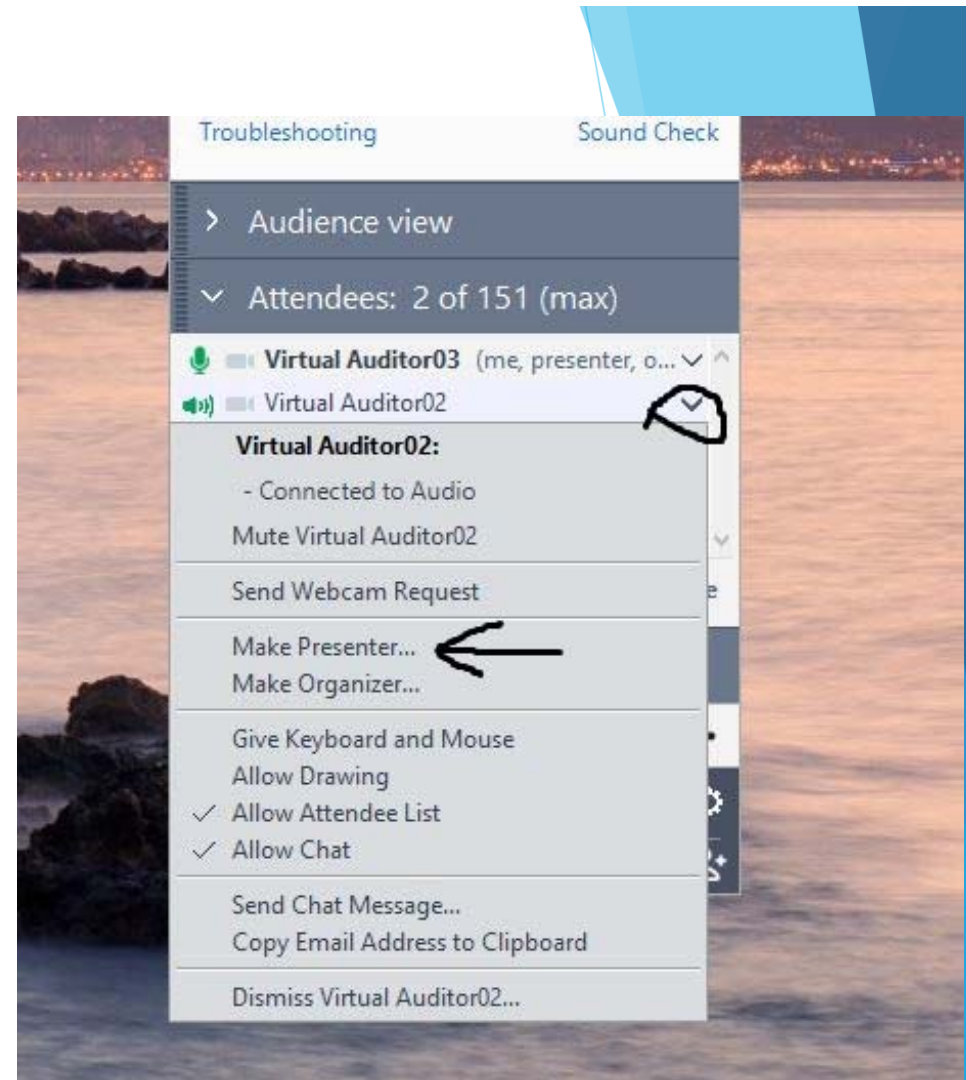


GTM Interface Part 4b

- 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

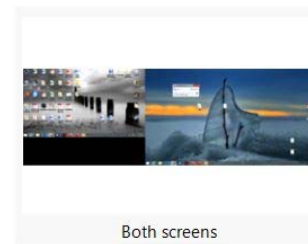
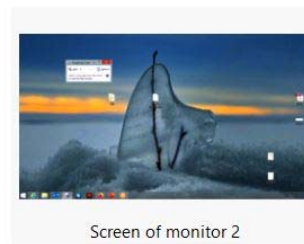
If you indicate to the auditor that you should be made presenter, the auditor will use the GTM dashboard to assign presentation control to you - which will bring up a screen that looks like that shown here. Simply select which monitor you wish to share and click "Share."

You have been made the Presenter.

Please close confidential windows.

Screen

Applications



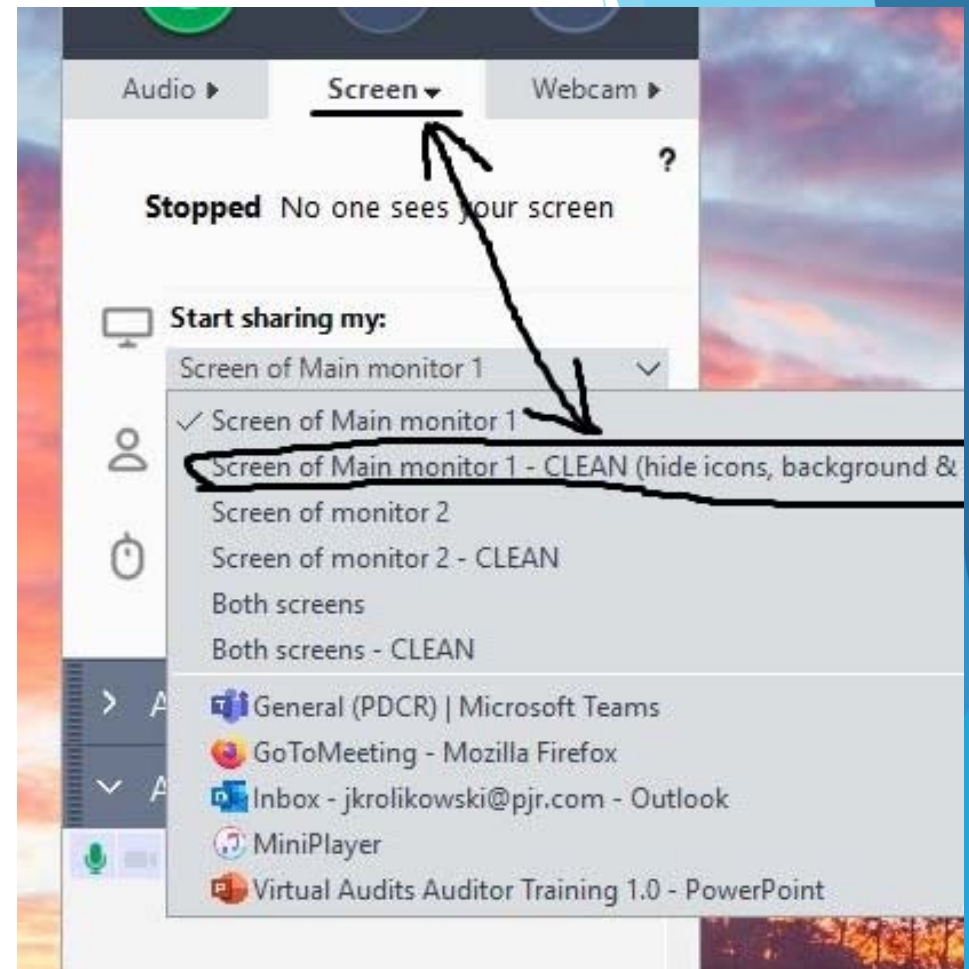
☐ Clean screen ?

Share

Cancel

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.

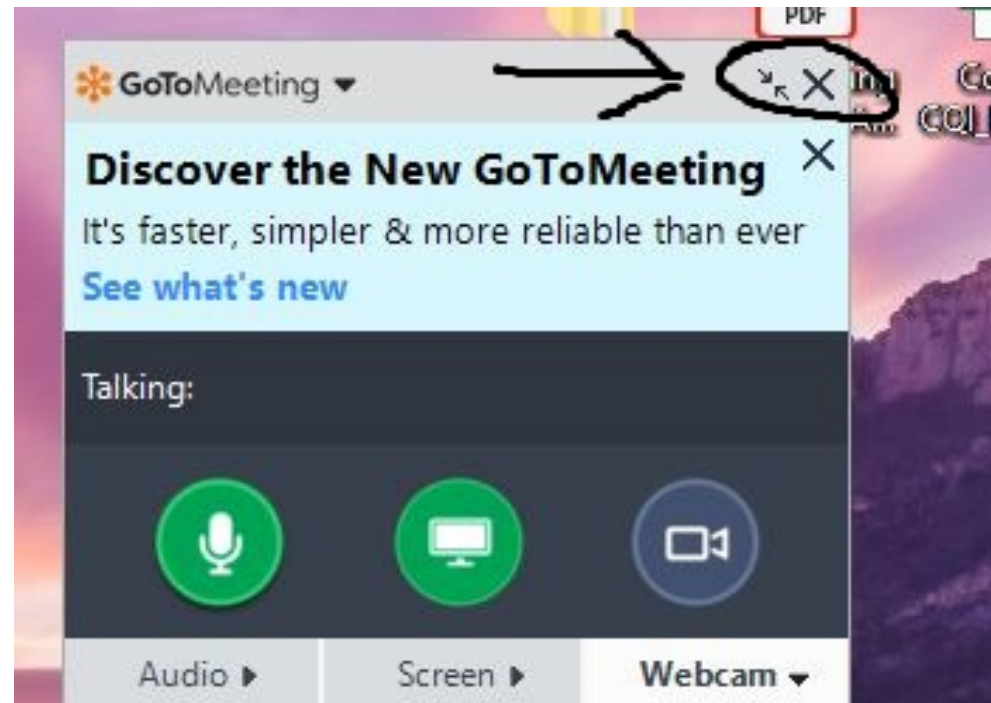


Important reminder

- ▶ 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.

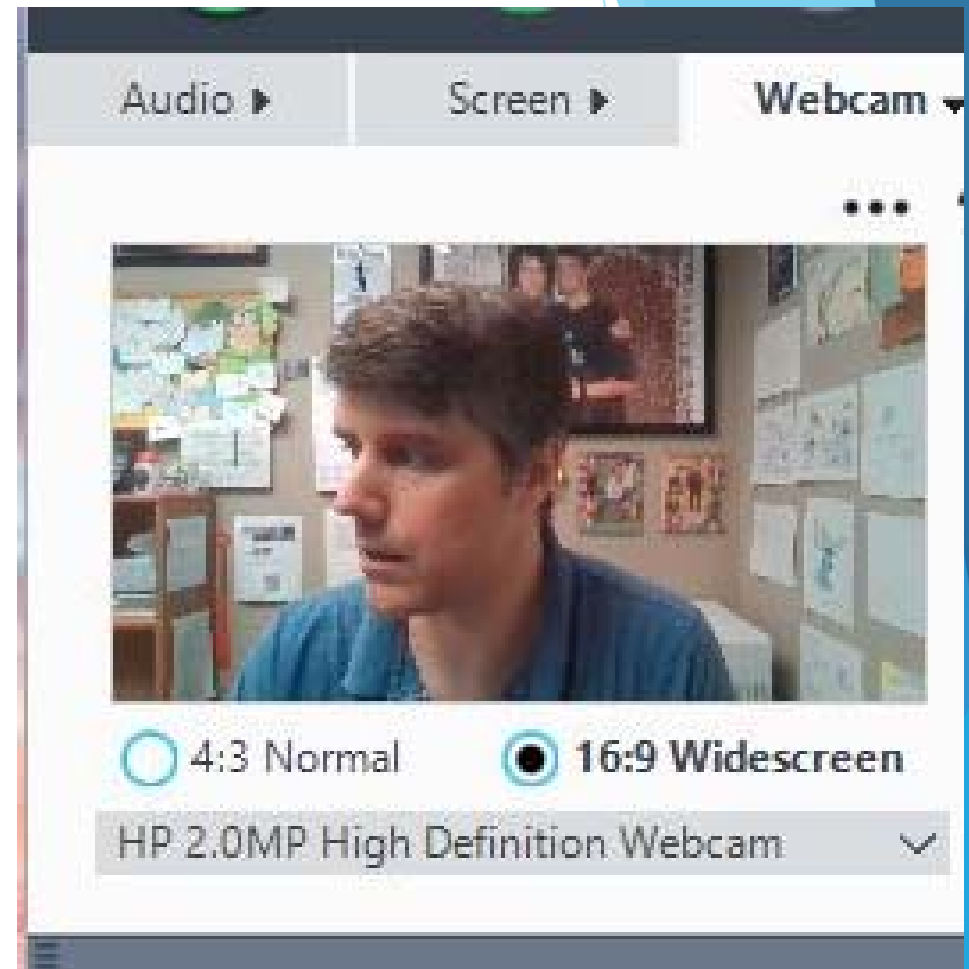
GTM Interface Part 7

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



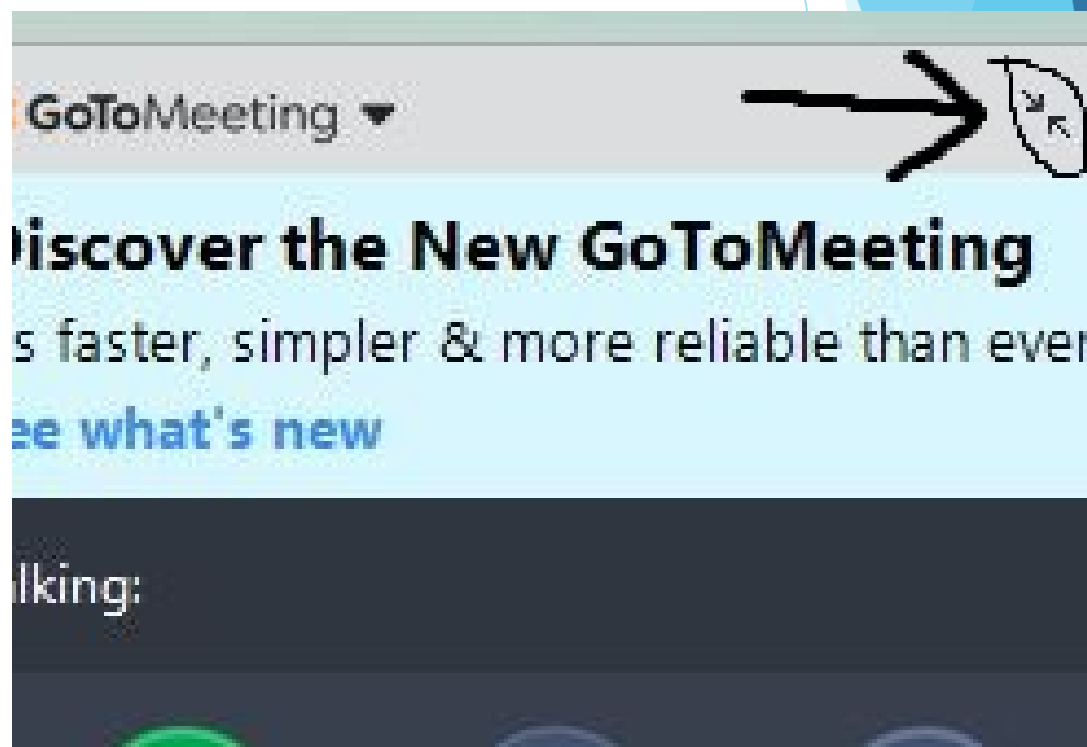
GTM Interface Optional Features (1 of 2)

- ▶ 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.



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.
- ▶ All timing requirements pertaining to nonconformances are also in effect (60 days, etc.) from the full completion of the audit.
 - ▶ Sector specific rules also remain in effect.

Conclusion



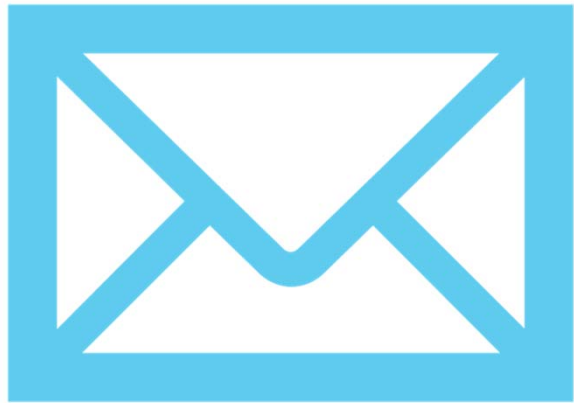
PJR is committed to ensuring a continuance of certification for our valued clients.



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

- ▶ *“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.



Want to keep in touch?

Do you want to be kept informed of the latest news automatically?

Please opt in for future updates by visiting our website at www.pjr.com

At the bottom of the page, enter your email address in the provided space and click "Subscribe."



Thank you!

▶ Reminders:

- ▶ 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."

▶ Questions?

Learn more at www.pjr.com