WHAT TO EXPECT DURING YOUR STAGE 1 AUDIT

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PLEASE NOTE:

- All participants have been muted.
- Please type your questions in the “Question” section of the dashboard – we will take 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.”

TODAY'S PRESENTATION WILL COVER:

- Why a two stage process?
- Quotation phase
- Prior to the Stage 1
- Stage 1 audit "front to back"
- Things that can prevent continuance to a Stage 2 audit
- Responding to recommendations – readiness for the Stage 2
- Conclusion/Questions

WHY A TWO STAGE PROCESS?

- PJR is held accountable to a number of requirements in our work as a certification body.
- Among the many requirements that PJR is held accountable to are those found in ISO 17021:2015.
- This standard includes a clause that reads (in part):
  - *"The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2."*
- Part of the intent behind this approach is to ensure that only those companies that are truly prepared for a certification assessment will be permitted to complete the "full" audit.

QUOTATION PHASE

- You must be a PJR contracted client before PJR can perform a Stage 1 audit at your facility.
- PJR uses a series of scope specific applications called “F-1” to help facilitate this process in an effective way.
- The F-1 series documents are complex and intended to gather a multitude of information.
  - The more information we gather about an applicant, the more competitive our quote can be the first time.
  - Your honest and detailed responses may alert us to potential logistical/readiness issues or challenges.
- The International Accreditation Forum’s Mandatory Document 5 (IAF MD 5) limits the discount that we can give on audit time to 30% of the days stipulated in that document. Available under Publications at www.iaf.nu.
- Watch for competitive quotes that exceed this discount.

PRIOR TO THE STAGE 1

- You will be assigned to an Audit Program Coordinator (your Scheduler), who will service any needs you have… Cradle to Grave Client Management.
- Schedulers are required to assign an auditor that is qualified in your standard and is competent in your technical area.
  - Ideally, they will also assign someone who is in a geographically friendly location!
- Schedulers will require you to complete an Attestation of Readiness prior to your Stage 1 audit (F-108 series of documents). Let's discuss this series of documents a bit more on the next slide.

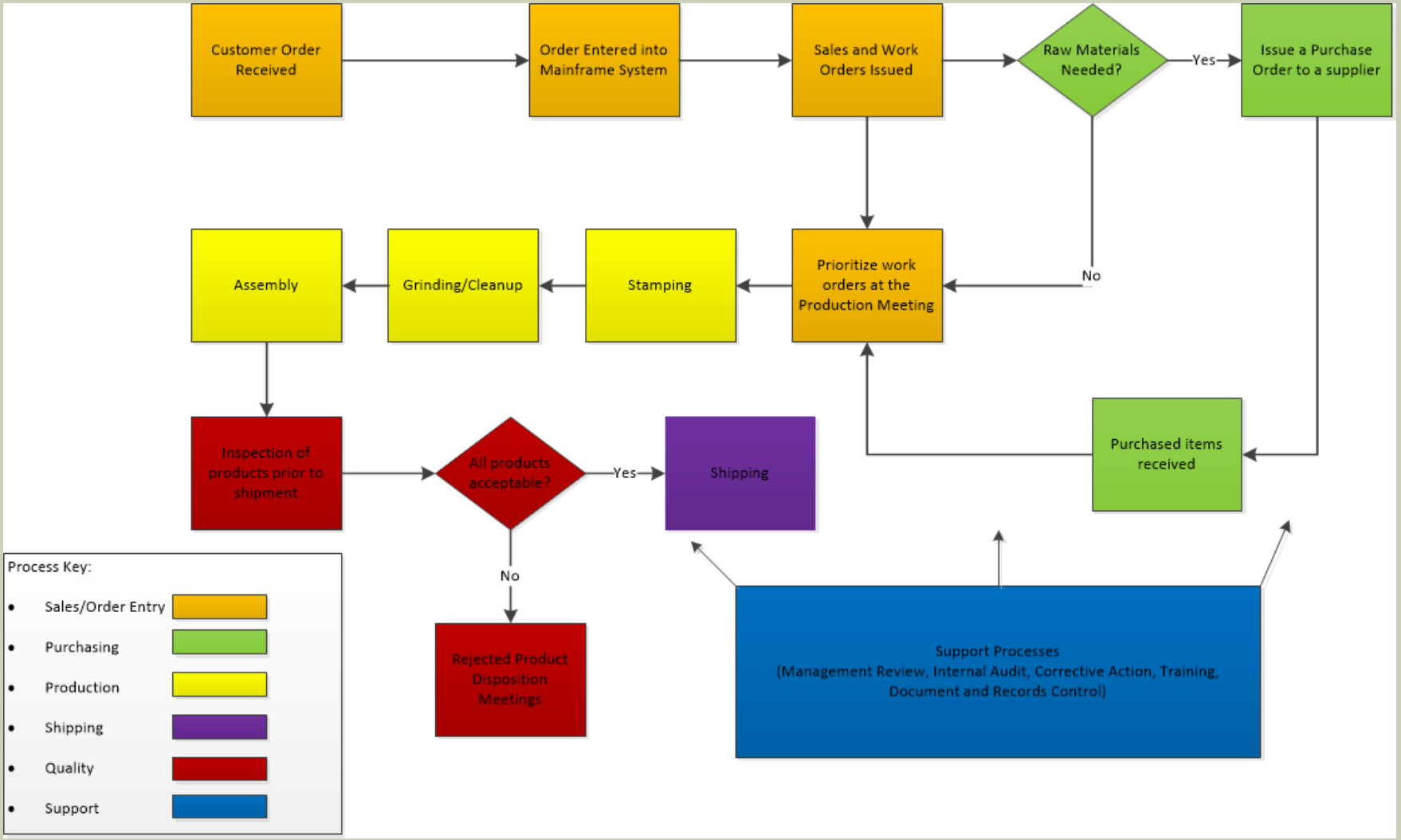
F-108 SERIES

- The F-108 series of documents requires your organization to attest to your readiness for the Stage 1 audit. You are required to complete this form and confirm you have prepared the following:
  - A scope of your quality management system, including consideration of any exclusions/exemptions.
  - A firm determination of what your processes are, and an assessment of their interaction
  - List of process measurables (KPIs) and associated performance data
  - Internal audit documentation
  - Internal auditor competency records
  - Management review records
  - Consideration (and control) of outsourced processes
  - Consideration (and control) of statutory and regulatory requirements
  - Required documentation (varies by standard)
  - PJR form F-191 (optional, but highly recommended) – more coming on the next slide

THE PJR F-191

- PJR's F-191 is a point of confusion for many of our clients.
- It is intended to help you ensure that the processes you've established for your quality management system represent a fulfillment of all the clauses of the applicable standard.
- The intent is for you to document what your processes are (taking the names used on the Interaction of Processes) and assign the clause numbers accordingly.
- An example has been provided on the following few slides.

RAW INTERACTION OF PROCESSES



OUR EXAMPLE SHOWS SIX NAMED PROCESSES

- Sales/Order Entry
- Purchasing
- Production
- Shipping
- Quality
- Support

- Let's organize these on the F-191

COMPLETED F-191

Table for verification of the completeness of the process oriented auditing versus Annex SL based standards (such as ISO 9001:2015) and applicable customer-specific requirements (use multiple copies of this document as needed)

PROCESS	4.1	4.2	4.3	4.4	5.1	5.2	5.3	6.1	6.2	6.3	7.1	7.2	7.3	7.4	7.5	8.1	8.2	8.3	8.4	8.5	8.6	8.7	9.1	9.2	9.3	10.1	10.2	10.3	Customer-specific	Customer-specific
Sales/Order Entry															X	X	X													
Purchasing															X				X											
Production											X				X	X				X	X	X	X							
Shipping															X					X	X	X	X							
Quality											X				X					X	X	X	X							
Support	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X		

STAGE 1 AUDIT – "FRONT TO BACK"

- Stage 1 audits are typically conducted on-site.
  - Off-site Stage 1 audits can be conducted for simple ISO 9001 management systems.
    - Savings in travel costs, BUT
    - More total on-site time
- Before the auditor arrives:
  - You should be contacted by your auditor at least a few days in advance of the Stage 1 (whether it is being done on-site or not.)
  - You should receive an Audit Plan. It is important for you to confirm that all information reflected on the Audit Plan is correct and advise your auditor if it isn't.

STAGE 1 AUDIT – "FRONT TO BACK"

- The audit will commence with an opening meeting
  - This is an excellent chance to confirm any last minute changes in details, and to ensure the auditor is aware of any critical information (expected visitors, key personnel availability issues, etc.)
- The Stage 1 audit will proceed from the opening meeting according to the auditor's plan.
- The auditor will use a PJR Stage 1 workbook to record the results of their assessments. Nearly everything reviewed in a Stage 1 audit is documentation based in nature.
  - The auditor is given two options for each item they review: "Conforms" or "Concern."
    - "Concern" is anything that represents a disconnect between your implemented process and the related requirement(s) from the applicable standard.

STAGE 1 AUDIT – "FRONT TO BACK"

- Once the auditor has completed their review of the required materials, they will typically need some time to prepare their audit report.
- There are no nonconformances issued in a Stage 1 audit.
- Following report completion, a Closing Meeting will be held to discuss the results.
- There are a few possible outcomes:
  - Recommend for continuance to Stage 2 with no concerns;
  - Recommend for continuance to Stage 2 with concerns;
  - Recommend a repeating of the Stage 1 audit.
- You will be asked to sign an acknowledgement of the Stage 1 results and will be given a copy of the completed audit report.
  - Due to travel circumstances, etc. it may be a few additional days before you receive the finalized audit report.

THINGS THAT CAN PREVENT CONTINUANCE TO A STAGE 2 AUDIT

- Inadequate or inappropriate interaction of processes
  - One that resembles the PDCA diagram from the standard
  - A “canned” one from a consultant
  - Your organization should document an interaction unique to your organization.
    - We highly recommend you view the PJR webinar entitled “The Interaction of Processes and it’s importance to a successful audit.”
  - The interaction of processes is the single best indicator of your understanding of the process approach prescribed in ISO 9001.

THINGS THAT CAN PREVENT CONTINUANCE TO A STAGE 2 AUDIT

- Inadequate process measurables or process performance data
  - Both versions of ISO 9001 requires your organization to "monitor, measure where applicable, and analyze these processes…"
  - Thus, every process on your interaction should be monitored or measured. There should be performance data available to prove this monitoring/measurement.
    - Some standards have minimum requirements for the amount of data that must be available.
    - For other standards, enough objective evidence must be available to demonstrate that the process works.
    - Some organizations may choose to have a few measures of effectiveness that "cover" all processes. This is generally considered acceptable.

THINGS THAT CAN PREVENT CONTINUANCE TO A STAGE 2 AUDIT

- Inadequate internal audit
  - Adequate internal audit records will include:
    - Evidence that internal audits are planned;
    - Notes/report to show that all processes and related requirements were audited. (Notes of conformity are often lacking);
    - Any nonconformities that are discovered; and
    - Corrective actions to address any identified nonconformities.
  - Make sure auditors don't audit their own work.

- Note: A recommendation to continue to Stage 2 may still be granted (does not apply to all standards) if:
  - The auditor can confirm that there is a plan to ensure that the internal audit will be completed prior to the Stage 2.
  - However, in this circumstance, you do lose the benefit of feedback on your internal audit process prior to the Stage 2.

THINGS THAT CAN PREVENT CONTINUANCE TO A STAGE 2 AUDIT

- Inadequate internal auditor competency records
  - Organizations are required to determine competency requirements for all functions within their quality system, including conducting internal audits.
  - The auditor needs to see proof that your internal auditors meet these competency requirements.
  - Certain standards and industries require additional provisions be made for internal auditor competency.

THINGS THAT CAN PREVENT CONTINUANCE TO A STAGE 2 AUDIT

- Inadequate management review
  - Make sure your records prove that all required inputs/outputs were addressed.
  - Many organizations compile PowerPoint slides. Keep in mind, we also need records of the results of the discussions of these slides.

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ALL CONCLUSIONS ARE SUBJECT TO EXECUTIVE COMMITTEE CONCURRENCE

- All Stage 1 audit reports are subject to review by a member of the PJR Executive Committee to ensure that the decisions reached are appropriate and fair.

- PJR clients are also afforded the right to issue a dispute or appeal of an auditor's decision. This process is discussed in PJR procedure PRO-10 (available anytime on our website.)

IF THE RECOMMENDATION IS TO REPEAT THE STAGE 1 AUDIT

- Work from your audit report to shore up all issues raised during the Stage 1 audit.
- You are permitted to remain in contact with your auditor and with the PJR Executive Committee to discuss your remediation actions and ensure you're on the right path to a better result during your next Stage 1 audit.

IF THE RECOMMENDATION IS TO PROCEED TO STAGE 2

- Ideally, there will be a minimum of 30 days between the Stage 1 and Stage 2.
  - 60-75 days is preferred.
  - Remember PJR's 21-day cancellation policy!
  - Back-to-back audits almost always lead to trouble.
- Use this time to address any areas of concern identified in your Stage 1 report.
  - Failure to address these will likely result in nonconformities during your Stage 2 audit.

CONCLUSION

- PJR wants our clients to feel confident and comfortable with the Stage 1 audit.
- The care taken in the pre-Stage 1 phase and the mutual support of your auditor and PJR Executive Committee are intended to help make this process as seamless as possible.
- PJR wishes you every success in your certification journey!

PLEASE TUNE IN FOR ONE OF OUR OTHER WEBINARS

- *"ISO 9001:2015 Approaching Your Transition With Confidence"* is shown on a quarterly basis.
  - This webinar provides an in depth review of the ISO 9001:2015 standard. It also provides valuable feedback from PJR's first two years of auditing ISO 9001:2015, as well as lessons learned from the new ISO 9002 guidance standard.
- *"The Interaction of Processes and its importance to a successful audit"* is shown on a quarterly basis.
  - This webinar explores the crucial topic of processes and how to correctly understand them.
- We offer a variety of webinars on other topics including ISO 13485:2016, IATF 16949, and ISO 14001:2015.

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