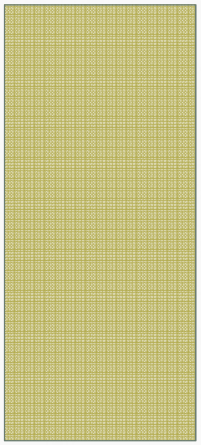
WHAT TO EXPECT ON YOUR FIRST PJR AUDIT

PRESENTED BY: SHANNON CRADDOCK,
PROGRAMS & ACCREDITATIONS MANAGER



TODAY'S PRESENTATION WILL COVER:

- Quotation Stage
- Prior to the Stage 1
- Stage 1 audit
- Stage 2 audit
- Revisit audits
- After the auditor leaves…
- Certificate Issuance
- Surveillance Mode

QUOTATION STAGE

- Our application form (F-1 series) is complex.
  - 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).

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 submit the following:
  - Quality Manual
  - List of process measurables (KPIs) and associated performance data
  - PJR form F-191 (optional, but highly recommended)
  - Internal audit documentation
  - Internal auditor competency records
  - Management review records

PRIOR TO THE STAGE 1

- Technical staff at our Headquarters will review the submitted evidence to see if there are any concerning areas which would prevent a successful Stage 1.
  - They will alert you so that you can address these concerns prior to the Stage 1.
  - We want to see you succeed!
- This is a cursory review. Not all potential nonconformities or concerns will be identified.

STAGE 1 AUDIT

- 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
- This is largely a document review to ensure readiness and to plan for the Stage 2 audit.
- There will be a formal opening and closing meeting.

COMMON STAGE 1 FAILURES

- 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. (See PJR's webinar on Process Mapping and Process Based Internal Audits).
  - The interaction of processes is the single best indicator of your understanding of the process approach prescribed in ISO 9001.

COMMON STAGE 1 FAILURES

- Inadequate process measurables or process performance data
  - Clause 4.1e 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.

COMMON STAGE 1 FAILURES

- Inadequate internal audit
  - Adequate internal audit records will include:
    - An audit schedule,
    - An audit plan,
    - Notes/report to show that all 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.
- The Stage 1 can be conducted before the internal audit is completed for some standards.
  - Auditor will still confirm that there is a plan to ensure that the audit will be completed prior to the Stage 2.
  - You do lose the benefit of feedback on your internal audit process prior to the Stage 2.

COMMON STAGE 1 FAILURES

- Internal auditor competency records
  - Fancy training certificates are not enough… and often may not even be necessary.
  - The auditor needs to see your defined competency requirements for internal auditors and proof that your internal auditors meet these competency requirements.

COMMON STAGE 1 FAILURES

- Management review
  - Make sure your records prove that all 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.

IN BETWEEN THE STAGE 1 AND 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 end horribly.
- Use this time to address any potential nonconformities or areas of concern identified in your Stage 1 report.
  - Failure to address these will result in major nonconformities on your Stage 2 audit.

STAGE 2 AUDIT

- You should receive an audit plan in advance of your audit.
- The audit starts with an Opening Meeting.
  - Your Lead Auditor notices who is present.
- Audit is then conducted in accordance with the audit plan using a process approach:
  - What is the process?
  - Who is the owner?
  - How do you know how the process is doing?
  - What do you do if the target for process performance is not met?

STAGE 2 AUDIT

- After answers to these questions are received, the auditor will then make sure that this is what is happening in practice:
  - Document/record review
  - Interviews of the people doing the work
  - Observations
- A closing meeting is held for the Lead Auditor to present audit results and the recommendation to PJR's Executive Committee, our decision-making body.
  - The auditor must leave a copy of any nonconformity reports before leaving your site.

STAGE 2 AUDIT

- PJR's expectation is that every single nonconformity is documented as such.
  - Failure to do so leads to just quick fixes, and often, the problem recurs.
  - Every auditor doing the right thing, every time, leads to consistency. Consistency is key to client satisfaction.

COMMON STAGE 2 FAILURES

- Failure to determine the necessary competence (6.2.2.a)
- Inadequate records of supplier evaluation and re-evaluation (7.4.1)
- Inadequate corrective actions (8.5.2)
- Lack of a robust preventive action process (8.5.3)
- Document control issues (4.2.3)
- Not having all required records (4.2.4)
- Calibration (7.6)

REVISIT AUDITS

- A revisit audit, typically on-site, may be done if there are a number of nonconformities or serious nonconformities (Majors) whose implementation cannot be verified remotely.
- Adequate preparation and sufficient time between the Stage 1 and Stage 2 will minimize the likelihood of a revisit.

AFTER THE AUDITOR LEAVES

- If the auditor does not leave a copy of the audit report, you should receive it within 7 days.
- The organization gets 60 days to address any nonconformities.
  - Some sectors require responses more quickly.
  - PJR requires: containment (as applicable), correction, root cause analysis and corrective action.
    - For major nonconformities, full evidence of implementation must also be submitted. (Some sectors require this for all nonconformities).
  - Please see our webinar on Root Cause Analysis and Systemic Corrective Action.
  - Take your time with this process and use a multi-disciplinary approach to ensure acceptance of your responses first-time through.

AFTER THE AUDITOR LEAVES

- After the lead auditor accepts your corrective action responses, then the entire audit package is reviewed by the Executive Committee, our decision making body.
- There must be copious evidence to convince the Executive Committee reviewer that the lead auditor's recommendation (to certify or not) is the correct one.
  - Substantial notes of conformity
  - Clear conclusions regarding process effectiveness
  - If there are any nonconformities, there should be sound responses to convince the reviewer that the issues will not recur.

CERTIFICATE ISSUANCE

- If the Executive Committee concurs with the Lead Auditor's recommendation to certify, then a certificate will be issued.
  - Certificate effective date will be the date of Executive Committee's approval of the audit package.
  - Certificate is good for three years.
  - Certificate scope statement should reflect what was audited – no more or no less.

CERTIFICATE ISSUANCE

- When you receive your certificate, you will also receive a copy of PJR's PRO-3, which is the procedure that outlines requirements for proper use of PJR's registration mark/logo and the marks/logos of our accreditation bodies.
- Be careful of advertising your certification appropriately, regarding:
  - Scope
  - Sites that are certified
  - The end user must not be misled!

SURVEILLANCE MODE

- Surveillance audits are conducted once a year or once every six months.
  - Most clients are contracted annually, as this is most cost-effective.
  - Clients may be required to amend their contract to include semi-annual surveillance if their management system is weak.
- Due date for the surveillance audits is determined by the last day of the Stage 2 (or recertification audit for subsequent audit cycles), not from the certificate effective date.
  - The very first surveillance after the Stage 2 must be conducted within 365 days of the Stage 2.

SURVEILLANCE MODE

- Surveillance audits are shorter in duration than the initial audit (one-third initial audit time). Requirements are sampled using a risk-based approach.
  - Problem areas on the Stage 2 or prior audit will be reviewed on the next audit.
  - Management review, internal audits and corrective action are covered on every audit.
- Recertification audits are conducted at the end of a certificate cycle.
  - They are two-thirds the initial audit time.
  - All requirements are audited.

QUESTIONS & ANSWERS

THANK YOU FOR YOUR TIME!