ISO 9001:2015 – Critical Points of Review During the Transition Audit Process

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Please note:

- All participants have been muted.

- Please type your questions in the “Question” section of the dashboard – we will make time for as many questions as possible at the conclusion of this presentation.

Overview of topics

- How will the transition be handled?
- What is the projected amount of additional audit time that will be needed?
- Anticipated new audit content
- A summary of how an audit of ISO 9001:2015 will differ from ISO 9001:2008
- Conclusion
- Questions

How will the transition be handled?

- PJR plans to offer three potential approaches that an existing client can use to complete a transition from ISO 9001:2008 to ISO 9001:2015:

1) Transitioning as part of a Recertification Audit
   This is the ideal approach, as the Recertification Audit already includes additional audit time and a new certificate.

2) Transitioning as part of an Annual Surveillance Audit
   This approach will result in a small amount of additional audit time for most clients, which will vary from case to case.

3) Transitioning as part of two consecutive Semi-Annual Surveillance Audits
   In this scenario, the additional audit time will be split between the two audits. Clients on a semi-annual frequency can also opt for all additional audit time to be performed in a single audit.

- In both scenario 2 and 3, a revised certificate will be issued, representing a revision to the existing ISO 9001:2008 certificate (further details on the next slide.)

How will the transition be handled?

- An example of how the certificate revision would work when the transition is performed during a surveillance audit:

1) ISO 9001:2008 certificate issued in January 2016 following a Recertification or Stage 2 audit.

- Certificate Number C2016-12345, Issue Date: 1/15/16, Expiration Date: 9/14/18
  - This is due to the mandatory cut-off date established by the ISO for any ISO 9001:2008 certifications.

2) Organization completes a successful transition to ISO 9001:2015 in early 2018, resulting in a revised certificate.

- Certificate Number C2016-12345-R1, Issue Date 1/15/16, Expiration Date 1/14/19
  - Now the certificate bears the full three year period.

What is the projected amount of additional audit time that will be needed?

PJR has prepared a special grid to help calculate the additional audit time needed for a transition audit. The full measure of detail therein is considered confidential, but the following details can be confirmed:

- Most average size companies will only require an additional 0.5 day (4 hours) of audit time to complete their transition audit.
- Some companies will be able to transition with no added audit time at all.
- Further information on the additional audit time is available through your PJR Scheduler or Sales Representative.

Anticipated new audit content

- Perry Johnson Registrars has identified a preliminary list of key “new” items that will require verification during the organization’s transition audit.

- We will review these items over the next several slides.

New requirements

- *Has the organization implemented a process to determine, monitor, and review external and internal issues relevant to purpose and strategic direction? (Clause 4.1)*

Probable audit method:

- This is a high level, quality system establishment activity. Various methods will be utilized to ascertain implementation, including interviews with upper management regarding strategic planning.

New requirements

- *Has the organization determined who it's interested parties are? (Clause 4.2)*

Probable audit method:

- Required audit time for this topic will be minimal, and likely be a combination of legacy documentation (quality manual) review and interviews of top management.

New requirements

- *Has the organization established a process to monitor and review information about interested parties and identify what their requirements are? (Clause 4.2)*

Probable audit method:

- We will most likely incorporate existing methods used when assessing other external inputs (contractual, design, etc.) Interviews with these parties (as well as top management) will be the likely approach.

New requirements

- *Is the scope statement appropriate/accurate and does it take into account:*
  - *All internal/external issues,*
  - *Relevant interested party requirements, and*
  - *The products and services of the organization? (Clause 4.3)*

Probable audit method:

- We have provided a question within the Audit Report that directs the auditor to assess the adequacy of the scope statement.

New requirements

- *Exemption can now be sought for any requirement of the standard, not just those from product realization. (Clause 4.3)*

Probable audit method:

- We will expect that such designations are documented and accompanied by a justification, just as they are now under the Permissible Exclusions requirement.

New requirements

- *How has management demonstrated that it has taken accountability of the effectiveness of the quality management system? (Clause 5.1.1a)*

Probable audit method:

- Management's participation in the quality management system will be assessed. This means management is a participant in key activities such as management review, corrective action, and customer complaint resolution.

New requirements

- *How has management assured that the quality policy and objectives are compatible with the strategic direction of the company? (Clause 5.1.1b)*

Probable audit method:

- "Strategic Direction" is not a term that has been officially defined within ISO 9001:2015 or ISO 9000:2015. The current general consensus is that an organization's strategic direction relates to the organization's vision of "where they want to be" in the future. Mission and Vision are two terms often used to lend clarity to this idea. The intent is that an organization's quality system (and in particular the goals associated with the processes) should contribute in a positive way to the achievement of the larger mission of the organization. Auditors will ask about this in a variety of settings, including review of management review meeting minutes, business plan minutes, and operational memorandums.

New requirements

- *How has management assured that the quality management system requirements have been integrated into the business processes? (Clause 5.1.1c)*

Probable audit method:

- In the past, Accounting and other similar activities were considered “hands off” in the audit process. Possible manifestations of this requirement could include control of documents, record retention, competency records, etc.

New requirements

- *Has the organization ensured that the quality policy is available to all relevant interested parties? (Clause 5.2.2)*

Probable audit method:

- This is essentially what was intended by the equivalent clause 5.3 under ISO 9001:2008. Auditors will look to see that you have made your quality policy generally available. This can be as simple as posting it in your front entry way or listing it on your website.

New requirements

- *Has Top Management taken on the responsibility for management of the quality management system? (Formerly the purview of the Management Representative?) (Clause 5.3)*

Probable audit method:

- Very similar to previous reviewed items. Top management interviews and evidence of participation in the quality management system will be prevalent to the assessment of this item. It has been emphasized that this revision does not imply that a "key contact" cannot be appointed.

New requirements

- *Has Top Management established a means to monitor if processes are delivering their intended outputs? (Clause 5.3b)*

Probable audit method:

- Existing audit analysis of KPIs/Objectives will most likely be brought to bear in the assessment of this requirement, as well as management's participation in the corrective action process.

New requirements

- *Has a process been developed to determine applicable risks? (Clause 6.1.1)*

Probable audit method:

- It has been stated many times, and is written into the Annex to the ISO 9001 standard itself that a formal process for Risk Management will not be required. Nevertheless, the organization will be expected to have an understanding of this requirement and be prepared to explain how it has been fulfilled within their quality system. Auditors will very likely review management review, preventive action, planning meetings, and other similar activities for proof of risk management.

New requirements

- *Has a process been developed to address identified risks (including evaluation of effectiveness?) (Clause 6.1.2)*

Probable audit method:

- Very similar to those reviewed in the previous slide. Auditors will review action plans, meeting notes, etc. for evidence that action is being taken, and that a follow-up assessment also takes place. Review of metrics will likely also factor into this process.

New requirements

- *Are quality objectives relevant to conformity of products and do they enhance customer satisfaction? (Clause 6.2.1)*

Probable audit method:

- Current assessment methods for quality objectives will likely be utilized, but the scope of information reviewed therein will be somewhat expanded. In practice this requirement is no different from past interpretation of the quality objectives requirement.

New requirements

- *Have quality objectives been sufficiently analyzed to assign resources, identify responsible parties, establish a timeline, and determine evaluation practices? (Clause 6.2.2)*

Probable audit method:

- Current assessment methods for quality objectives will likely be utilized, but the scope of information reviewed therein will be somewhat expanded.

New requirements

- *Has the organization established a process to ensure that organizational knowledge is maintained and made available? (Clause 7.1.6)*

Probable audit method:

- Organizational knowledge is generally understood to be knowledge specific to the organization that is gained through experience. The means of sharing knowledge will obviously be varied, but will likely include training methods, documentation (work instructions, production controls, etc.), and enhanced quality controls.
- Organizations are now more directly expected to "learn from past mistakes" and as a result improve their processes. This is also a form of Risk Based Thinking. Current audit assessments of corrective action, production planning, customer complaint resolution, and competency will likely be brought to bear in our review of this requirement.

New requirements

- *Has the organization established a process to assess existing competencies against changing needs and trends? (Clause 7.1.6)*

Probable audit method:

- Review of ongoing competency has been a long implied, but seldom enforced requirement. Existing audit methods used for review of competency will likely be brought to bear, along with review of meeting notes.

New requirements

- *If the organization is responsible for the design of its products, do design inputs include standards and/or codes of practice that the organization has committed to implement? (Clause 8.3.3D)*

Probable audit method:

- Current audit methods used to review design activities (completed project review, etc.) will be employed. This new requirement is very similar to the existing requirement that “statutory and regulatory” inputs be considered.

New requirements

- *If the organization is responsible for the design of its products, do design inputs include consideration of potential consequences of failure due to the nature of the products or services? (Clause 8.3.3E)*

Probable audit method:

- Current audit methods used to review design activities (completed project review, etc.) will be employed. It has been suggested that this new requirement implies consideration of safety or financial fallout (among other potential consequences.)

New requirements

- *Has the organization established a method to communicate their intentions in control and monitoring of external provider performance to external providers? (Clause 8.4.3e)*

Probable audit method:

- Existing methods for reviewing communication between organizations and their external providers will likely be utilized (purchase orders, contracts, etc.) as this represents a single new point of information to provide.

New requirements

- *Have controls been established for external provider property where ownership does not transfer to the organization? (Clause 8.5.3)*

Probable audit method:

- Assessment methods will likely include a review of agreements between organizations and their external providers (purchase order terms, contracts, etc.) It is expected that this clause will be of limited applicability in many cases.

New requirements

- *Have controls for the expanded list of applicable Post Delivery activities been established? (Clause 8.5.5)*

Probable audit method:

- This requirement will be somewhat limited in applicability. Existing assessment methods applied to review of contractual and planning processes will be likely methodologies.

New requirements

- *Has the organization determined a process for responding to unplanned changes in such a way that conformity with specified requirements is maintained? (Clause 8.5.6)*

Probable audit method:

- Existing techniques for assessment of corrective actions and customer complaint resolution will very likely be used to assess this requirement.

New requirements

- *Have the organization determined a method for retaining documented information about changes, including who authorized the change and actions arising from the change? (Clause 8.5.6)*

Probable audit method:

- Existing techniques for assessment of corrective actions and customer complaint resolution will very likely be used to assess this requirement.

New requirements

- *Has the organization structured the management review process in such a way that it includes discussion of internal and external issue changes, including the effect therein on the strategic direction of the company? (Clause 9.3.2b)*

Probable audit method:

- Existing audit methods used to review management review meeting minutes and other related records will be utilized with no anticipated change in technique.

New requirements

- *Has the organization structured the management review process in such a way that it includes discussion of External Provider (supplier) performance? (Clause 9.3.2c7)*

Probable audit method:

- Existing audit methods used to review management review meeting minutes and other related records will be utilized with no anticipated change in technique.

New requirements

- *Has the organization structured the management review to include an assessment of risk management actions? (Clause 9.3.2e)*

Probable audit method:

- Existing audit methods used to review management review meeting minutes and other related records will be utilized with no anticipated change in technique.

How will an audit of ISO 9001:2015 differ from ISO 9001:2008?

- Overall, our analysis has concluded that for most companies, the difference in an audit performed to ISO 9001:2015 will be minimal and quite manageable. The key differences are as follows:

  - The expanded role of Leadership.
  - The impact of Risk Based Thinking requirements; and
  - The elimination of previously required documentation.

How will an audit of ISO 9001:2015 differ from ISO 9001:2008?

- A more extensive discussion with the Leadership Team.
  - ISO 9001:2015 has placed numerous additional emphasis on the role of Leadership within the Quality Management System. Accordingly, PJR has had to expand the portions of the audit that deal directly with Leadership. Our audit report now includes several targeted questions that auditors will be expected to ask the management team.
  - The audit report also directs auditors to ensure that Leadership is directly involved in the management of the quality system.

How will an audit of ISO 9001:2015 differ from ISO 9001:2008?

- A targeted review of Risk Management
  - As has been stated many times over, the ISO 9001:2015 standard does not require a “formal” process for Risk Management.
  - Auditor will be directed to ask about Risk Management and will be prepared to examine the various activities presented by the auditee. It is presumed that several ISO 9001:2008 methodologies will be brought to bear including Preventive Action, Competency Planning, and Review of Requirements.

How will an audit of ISO 9001:2015 differ from ISO 9001:2008?

- No more pre-conceived expectations for documentation.
  - As has been discussed many times over, the ISO 9001:2015 standard has washed away the last of the lingering requirements for procedures, as well as the quality manual.
  - This means that auditors cannot demand a procedure for any particular activity.
  - However, if an organization chooses to have a procedure, the content of that procedure is still considered relevant audit criteria.

How will an audit of ISO 9001:2015 differ from ISO 9001:2008?

- In addition to the requirements ushered in by ISO 9001:2015, ISO 17021:2015 brings about two key new items to be verified during the audit process.
  - Auditors will now be specifically directed to review Statutory and Regulatory Requirements, and a special section of the audit report has established to record the results of these reviews.
  - Auditors will also now be specifically directed to comment on the level of overall adherence to the spirit of the IAF Expected Outcomes publication (more on the next slide.)

IAF Expected Outcomes

- Published by the IAF (International Accreditation Forum) in 2012.
- A series of key ideas pertaining to the larger picture of what a quality management system should mean for the organization that implements it.
- Available at the following URL: http://www.iaf.nu/upFiles/IAF9001expectedoutcomes0112.pdf

IAF Expected Outcomes

- Nine Key Ideas:
  - QMS suitability for processes and products;
  - Analysis and understanding of customer needs/expectations;
  - Specificity of product characteristics in order to meet applicable requirements;
  - Management of processes to achieve expected outcomes;
  - Availability of resources;
  - Monitoring and control of product characteristics;
  - Prevention of nonconformance, and appropriate actions taken when nonconformance occurs;
  - Effective processes for internal audit and management review; and
  - Monitoring, Measuring, and Continual Improvement of the QMS.

How will an audit of ISO 9001:2015 be the same?

- The key aspect of these audits remains the same as it was under ISO 9001:2008 – namely that we audit the organization's stated processes.

- Remember:
  - Element based audits became obsolete over 15 years ago.
  - PJR's transition to process based auditing was complete over 13 years ago.

How will an audit of ISO 9001:2015 be the same?

- The auditing "methods" remain the same from ISO 9001:2008 (Observation, Review of Documented Information, and Interviews.)
- All of the existing techniques of learning about a process, reviewing evidence of the process, etc. are unchanged and remain the specified method of assessment.
- The organization is still expected to demonstrate that the requirements of the ISO 9001 standard have been addressed through the processes that have been established.

Conclusion

- PJR stands ready to ensure that your organization experiences a smooth transition to ISO 9001:2015.

- We feel confident that for the vast majority of our clients, this transition will proceed with minimal difference from past assessments, and that the new standard brings with it a host of benefits.

Please tune in for one of our other webinars

- *"ISO 9001 2015 Preparing For A Successful Transition"* is delivered on a once monthly basis.
  - This webinar provides an overview of the development of the ISO 9001:2015 standard, an update on the transition timeline, a review of the format and layout of the standard, and answers some common questions that have been raised.
- *"The Interaction of Processes and its importance to a successful audit"* is also shown once monthly.
  - This webinar explores the crucial topic of processes and how to correctly understand them.
- *"What to expect during your Stage 1 Audit"* is a new webinar under development at this time and will be premiering soon!

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