ISO 9001:2015 – Approaching Your Transition With Confidence!

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- Please type your questions in the “Question” section of the dashboard – we will answer all questions at the conclusion of this presentation.
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Overview of topics

- Why were the changes so dramatic?
- How will the transition process be handled?
- What are the key changes?
- What impact are the new requirements going to have on our audits?
- FAQs from past presentations
- Concluding remarks
- Questions

Why were the changes so dramatic?

- The ISO recognizes that the needs of the industries that utilize ISO 9001have evolved (and will continue to evolve) based on changing needs from those industries.
- There is a desire to promote continued adoption of the ISO 9001 standard into more and more sectors and industries (particularly those in Service sectors.)
- There has been a targeted effort to simplify language used to aid in understanding and promote consistency.
- It was recognized that there was a desire to improve the cross-compatibility between standards for companies that wished to achieve more than one certification (ISO 9001, ISO 14001, etc.)

A new resource!

- ISO/TS 9002:2016 was published on November 1, 2016 (hereafter this document will be referred to as ISO 9002.)
- ISO 9002's full title is "Quality Management Systems – Guidelines for the application of ISO 9001:2015."
- It is an officially sanctioned guidance document that provides clause-by-clause ideas on fulfilling the requirements.
- It is similar in style and content to the older (2000) version of ISO 9004.
- We will be providing references to key pieces of ISO 9002 content throughout today's presentation.

The clock is ticking on ISO 9001:2008

- By virtue of the ISO 9001:2015 reflecting a publication date of September 15, 2015, the official cut-off for ISO 9001:2008 has been established as **September 14, 2018**

- Working backwards from this date, PJR established a two part policy on the cut-off for ISO 9001:2008 auditing.

  - New certification (Stage 2, Recertification) audits to ISO 9001:2008 ceased to be available on March 14, 2017. The date represented the halfway point in the transition timeline and ensured that all new certifications would have at least a year of operation prior to an attempted transition;

  - Surveillance audits to ISO 9001:2008 will no longer be available after May 14, 2018. This date was selected to ensure that all last minute transitions will be processed with no lapse in certification.

- Both of these dates are PJR internal requirements only, and exceptions will be considered on a case by case basis.

How will our transition audit be handled?

- PJR offers three 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 our transition audit 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 amount of additional audit time that is needed?

PJR has prepared a special grid to help calculate the additional audit time needed for a transition audit (when the transition is performed as part of a surveillance 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.

What are the key changes?

Annex SL – A key input to the changes in ISO 9001:2015

- ISO 9001:2015 is among the first ISO standards to make use of the standardized structure represented by "Annex SL."

- A 10 section "blueprint" for authoring all of the ISO family of standards. Annex SL promotes (among other things) utilization of common terms and core definitions.

  - Sections 1-3 – Non-Auditable (Scope, Definition, etc.)
  - Sections 4-7 – Foundation Requirements (Competency, Policy, Processes, Exemptions, etc.)
  - Section 8 – Day to Day Activities (Sales, Design, Purchasing, etc.)
  - Section 9 – Evaluation Methods (Inspection, Internal Audit, Management review)
  - Section 10 – Improvement Methods (Corrective Action, etc.)

- Taken together, the auditable portion of the standard follows a Plan-Do-Check-Act cycle.

Risk (the scary new requirement)

- The term “risk” is used 16 times in the auditable portion of the ISO 9001:2015;
- Identification and management of risk is being viewed as a new system wide strategy in much the same light that Continual Improvement was when ISO 9001:2000 was published.
- A formal/documented Risk Management Process is NOT specifically required.
- Expands the idea of Risk aversion to one that affects all of the various areas of the Quality Management System.
- ISO 9002 discusses key risks including *“the failure of processes, products, and services to meet their requirements, or the organization not achieving customer satisfaction.”*

Risk

- Clause 6.1.1 of the ISO 9001:2015 standard states:
  - *When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:*

    a) give assurance that the quality management system can achieve its intended result(s);

    b) enhance desirable effects;

    c) prevent, or reduce, undesired effects;

    d) achieve improvement.

Risk

- Clause 6.1.2 of the ISO 9001:2015 standard states:
  - *The organization shall plan:*

    a) actions to address these risks and opportunities;

    b) how to:
    - *1) integrate and implement the actions into its quality management system processes (see 4.4);*
    - *2) evaluate the effectiveness of these actions.*

  - *Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.*

NOTE 1
- *Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*

NOTE 2
- *Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.*

What do they mean by “actions to address risks and opportunities”?

- ISO 9002 provides further guidance in this area, and identifies the following possibilities:
  - Risk avoidance – by no longer performing the process in question;
  - Risk limitation – such as establishment of procedures or work instructions to assist personnel and thereby reduce the risk; and
  - Risk sharing – such as working with customers to agree to advance/bulk purchasing of raw materials.

What ISO 9001:2008 requirements most directly correlate to Risk Based Thinking/Risk Management?

- There are a number of activities that are required under ISO 9001:2008 standard that are likely going to help you demonstrate compliance to Risk Management. These include:
  - 5.6 Management Review (an assessment of your overall quality system leading to targeted improvement efforts),
  - 7.2.2 Review of Requirements related to the Product (an assessment of customer expectations against your current capabilities with steps taken to resolve discrepancies),
  - 6.2.2 Training (an assessment of competency needs with steps taken to ensure that personnel are fully qualified and competent),
  - 8.5.3 Preventive Action (an assessment of potential problems with actions taken to avoid those issues in the first place.)

How is risk going to be audited?

- Auditors have been directed to ask about Risk Management and are 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.
- Most importantly, we expect our clients to understand the concept and be prepared to explain what their approach has been.

Key changes in terminology

- “Procedures”, “Records”, and “Documents” have all been eliminated in favor of “Documented Information.”
- Annex A-6 provides an important clarification by pointing out the use of the terms “Maintain” and “Retain.”
  - “Maintained Documented Information” is generally understood to be a replacement for past references to “document”, “procedure”, or “quality manual” – examples of required maintained documented information include clause 4.3, which requires that the scope of the quality management system be documented;
  - “Retained Documented Information” is generally understood to be a replacement for past references to “record.” – examples of required retained documented information include clause 9.3.3, which requires records of management review be retained.

Key changes in terminology

- All references to “Product” now read “Products and Services.”
  - This has long been the case already, as clause 3 of ISO 9001:2008 stated “Wherever the term “Product” appears it can also mean Service.”
  - The standard is further pushing the idea of ISO 9001 as being applicable to multiple types of businesses (those with and those without a tangible product.)

Key changes in terminology

- "Management Responsibility" has become "Leadership"
  - Pushes further the concept that Management must lead by example and involvement, rather than simply directing that activities are performed.

- "Continual Improvement" has evolved into a larger section called "Improvement"
  - Promotes the concept that Continual Improvement is not the only aspect of improvement strived for in a quality system (improvement can also be characterized by breakthroughs, reactive changes, and reorganizations.)

Key changes in terminology

- Suppliers are now referred to as “External Providers”
  - This is intended to better accommodate service organizations.
  - The explanation provided in ISO 9001:2015:Annex A, clause A.8 indicates that “External Providers” includes the following:
    - Outside suppliers;
    - Associate companies; and
    - Outsourcing.
  - ISO 9002 mentions these and also lists “Corporate Headquarters” as a further example of an External Provider.

Elimination of required content

- ISO 9001:2015 does not specifically require any of the following:
  - Quality Manual
  - Procedures Manual
  - Work Instructions

- Organizations could theoretically achieve certification without any of these documents, however auditors will still be required to verify consistency with the applicable requirement, consequently the organization will need to be prepared to show a **consistent, effective process** for whatever activity is being reviewed.

- Additionally, it is important to remember that anything an organization has is admissible as audit criteria. This means that auditors cannot demand a procedure for any particular activity, but if an organization chooses to have a procedure, the content of that procedure is still considered relevant audit criteria.

Elimination of the Management Representative

- The title of “Management Representative” does not appear within the ISO 9001:2015 standard.
- The implication is not that this responsibility has been eliminated, but rather that many of this party’s key functions should now fall to top management itself.
- An organization can certainly appoint a “key” person (arrangements for audits, key contact for corrective actions, etc.,) but the management of the quality management system should NOT be solely that person’s responsibility.
- This reflects the current “in practice” arrangement for many of the companies already certified.

Elimination of Permissible Exclusions

- ISO 9001:2015 has removed all verbiage related to “Permissible Exclusions.”
- Organizations can now claim any item from ISO 9001:2015 under a “Non-Applicable” designation.
- This means that the validity of such designations will be verified at each audit.
- In practice – not terribly different from current approach, except that the scope of what can be claimed for exemption now encompasses the entire standard. Your current method for documenting these very likely will not change.

The introduction of "Interested Parties"

- ISO 9001:2015 includes a new term that is intended to be applied to all Annex SL based standard – "Interested Parties."
- The definition of this term is as follows:
  - *"Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity."* Examples given include customers, owners, people within the organization, suppliers, bankers, unions, partners, and even competitors.
- Clause 4.2 requires that organization determine who their interested parties are, but emphasizes "relevant to the quality management system."
- The intention is that as an organization, you will ensure that your quality management system considers all relevant input requirements. The term "Interested Party" is intended to broaden the scope of who such requirements might come from.
- In practice, this will not require a great deal of additional implementation activity on the part of the organization. Ensuring that you are cognizant of all applicable requirements is simply good business.

“Interested Parties” – Year One Lesson Learned

- As PJR began the process of assessing our auditor’s performance in the area of Interested Parties in Year One, it became apparent that a few points of clarity were needed.

- Let’s review the guidance that was shared with the PJR auditing team.

Auditing Interested Parties

(guidance originally provided to PJR auditors)

- When inquiring about Interested Parties, it is important to ask some leading questions:
  - Who are your interested parties?
  - Which ones are relevant to your QMS and how?
  - What part of your QMS are they relevant to?

Not just customers

(guidance originally provided to PJR auditors)

- One point should be emphasized. It is most likely inappropriate for an organization to conclude that their only Interested Party group is their customer base.

- Let's go back to the ISO 9000:2015 definition for "Interested Party":
  - *"Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity."*

Who else do they mean?

(guidance originally provided to PJR auditors)

- The new guidance publication ISO/TS 9002:2016 includes an extensive list of potential interested parties:
  - customers;
  - end users or beneficiaries;
  - joint venture partners;
  - franchisors;
  - owners of intellectual property;
  - parent and subsidiary organizations;
  - owners, shareholders;
  - bankers;
  - unions;
  - external providers;
  - employees and others working on behalf of the organization;
  - statutory and regulatory authorities (local, regional, national or international);
  - trade and professional associations;
  - local community groups;
  - non-governmental organizations;
  - neighboring organizations; and
  - competitors.

How do we figure out what the interested parties want?

(guidance originally provided to PJR auditors)

- Further guidance is provided in ISO 9002 on what the client should be doing to ascertain the needs of their Interested Parties, including the following:
  - reviewing orders received;
  - reviewing statutory and regulatory requirements with compliance or legal departments;
  - lobbying and networking;
  - participating in relevant associations;
  - benchmarking;
  - market surveillance;
  - reviewing supply chain relationships;
  - conducting customer or user surveys; and
  - monitoring customer needs, expectations and satisfaction.

If the auditee says "customers only"

(guidance originally provided to PJR auditors)

- We need to ask leading questions to determine how they concluded that their customers are the only relevant interested party.

- If the organization cannot provide evidence of a structured analysis having been performed, it is likely that the process by which interested parties were selected was flawed, and a nonconformance should be issued.

When does this become a nonconformance during an audit?

(guidance originally provided to PJR auditors)

- There are two circumstances where a nonconformance is likely appropriate:
  - If you have no evidence (or limited evidence) of an implemented process for monitoring and reviewing information – this would represent a violation of ISO 9001:2015 clause 4.2;
  - If you have no evidence that interested party feedback (not just customer feedback) is being discussed within Management Review – this would represent a violation of ISO 9001:2015 clause 9.3.2c1

What impact are the new requirements going to have on our audits?

Let's take a deeper look at the changes, and provide some context on how each one will impact the audit process

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.

Guidance from ISO 9002

- ISO 9002 provides extensive guidance on the new idea of internal and external issues, including suggested lists for organizations to consider. These include:

- Internal Issues:
  - Overall performance;
  - Resource needs;
  - Competency needs; and
  - Operational performance (new or existing equipment, etc.)

- External Issues:
  - Economic issues (foreign trade, exchange rates, etc.);
  - Social issues (local unemployment, safety requirements, etc.); and
  - Market issues (competition, market trends, etc.)

New requirements

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

Probable audit method:

  - We have incorporated existing methods used when assessing other external inputs (contractual, design, etc.) Interviews with these parties (as well as top management) are a recommended 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 is accountable for the effectiveness of the quality management system? (Clause 5.1.1a)*

Probable audit method:

  - This item led to dramatic changes in PJR's workbook, let's discuss what those changes were.

How has PJR approached the concept of Leadership?

- 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, under the heading “Leadership Interview.”
- The audit report also directs auditors to ensure that Leadership is directly involved in the management of the quality system.

“The Leadership Interview” – Year One Lesson Learned

- As PJR began the process of assessing our auditor’s performance in the area of Leadership Interviews in Year One, it became apparent that a few points of clarity were needed.

- Let’s review the guidance that was shared with the PJR auditing team.

Leadership means multiple persons in most cases

(guidance originally provided to PJR auditors)

- In some cases, when we receive the completed audit report, we are noting only a single individual was included in the Leadership interview.

- While this is conceivable in a small (3-5 person) operation, it becomes less plausible in any situation with a higher employee count.

Guidance from ISO 9002

- ISO 9002 provides clarification on the role of Top Management. It states that *"although certain authorities and responsibilities can be delegated, the accountability remains with top management."*

- In other words, you can certainly still appoint a Management Representative, but you can no longer expect to have limited to no involvement in the quality management system.

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.

Guidance from ISO 9002

- ISO 9002 provides another critical point in conjunction with this portion of section 5.1, stating the following:

- *"(Top Management shall ensure that) the organization's quality management system processes are integrated and managed within its overall business processes, and not treated as "add-on" or conflicting activities."*

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. ISO 9002 provides guidance indicating that access to the quality policy can also be established as “available upon request.”

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.

Guidance from ISO 9002

- ISO 9002 provides the following ideas on meeting the organizational knowledge requirement:

  - Succession planning;
  - Benchmarking for future planning;
  - Awareness sessions; and
  - Company newsletters.

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 the following topics:*
  - *Internal and external issue changes, including the effect therein on the strategic direction of the company? (Clause 9.3.2b);*
  - *External Provider (supplier) performance? (Clause 9.3.2c7);and*
  - *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.

Annex A – A Key Section

- One of the most important sections in ISO 9001:2015, Annex A provides plainspoken interpretations of several key requirements intended to help companies make sense of what the expectations are. Let's review this guidance step by step:
  - A.1 – Structure and terminology – reinforces the doctrine that an organization does not have to align their documentation to match ISO 9001:2015, nor does it have to use the specific terms found in the standard;
  - A.2 – Products and services – a fuller explanation of intent in changing all references of "product" to read "products and services";
  - A.3 – Understanding the needs and expectations of interested parties – a more full explanation of intent in the identification of interested parties;
  - A.4 – Risk based thinking– an extensive section intended to assist in the more full understanding of this concept, emphasizing that a formal structure/process for Risk Management is not required;

Annex A – A Key Section

- Annex A continued
  - A.5 – Applicability – Further discussion on the logic for removing "exclusions" from the ISO 9001 standard and the new concept of "non-applicables"
  - A.6 – Documented Information – Further discussion on the new term that has replaced "Procedure", "Record", and "Document";
  - A.7 – Organizational Knowledge – An explanation of requirements pertaining to competency and ongoing competency through various challenges an organization might face, including the loss of long-time employees;
  - A.8 – Control of externally provided products and services – Provides an expansive explanation of this phrase and who it applies to.

FAQs from past presentations

- The next several slides include key FAQs that have come up in past offerings of this training and the answers to those questions.

Will our staff have to complete transition training?

- It will depend on the extent of revisions that you make to your quality management system, but generally – yes you will be expected to provide some form of transition training to your staff.
- At a minimum, PJR would expect that awareness training of the new standard would be provided, as well as an assessment of the new standard's impact on the various processes and personnel.
- It is entirely conceivable that the majority of your staff will feel no effect from your company's transition to ISO 9001:2015.

What about our internal auditors, will they have to complete transitional training?

- Internal auditing is viewed in the same light as any other required competency within a quality management system. Namely, the organization is responsible for determining what competencies are required for its internal auditors, as well as the methods to be used to achieve those competencies.
- To put it more plainly, each organization will have to decide on its own the extent to which transition training will be needed.
- It is conceivable that a seasoned team of internal auditors could complete a period of self-study and successfully transition to auditing ISO 9001:2015.
- As has always been the case, the competency of your internal auditors will be judged by the overall effectiveness of your internal audit process.

What is the recommended order of steps?

- The International Accreditation Forum (IAF) has published an Informative Document (ID 9) which recommends the following steps be taken in a transition to ISO 9001:2015.
  - 1) A full review of the ISO 9001:2015 standard should be performed by Top Management to identify the gaps that need to be addressed.
  - 2) A plan of implementation should be developed with assigned responsibilities.
  - 3) All quality management system documents (including the quality and procedures manual (if applicable)) should be updated to reflect any new or revised processes.
  - 4) All necessary awareness and transition training should be completed.
  - 5) A full system internal audit followed by a Management Review should be complete.
  - 6) Corrective Actions for all internal audit findings should be in process or complete.
  - 7) Coordination with PJR for planning of transition arrangements.

Looking ahead

- This is an exciting time for quality system certification. ISO 9001:2015 is a beneficial update to a standard with a long track record of contribution to the world.
- 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.
- PJR stands ready to ensure that your organization experiences a smooth transition to ISO 9001:2015.

Please visit our website!

PJR's website (www.pjr.com) has a wealth of resources available on ISO 9001;2015 and a variety of other topics. PJR has prepared two reports that we feel will be very beneficial to our clients, these are:

- An side by side comparison between ISO 9001:2008 and ISO 9001:2015; and
- An FAQ report highlighting key questions and answers.

- Do you want to be kept informed of the latest news automatically? At the bottom of the page, enter your email address in the provided space and click "Subscribe."

Thank you!

- Questions?