ISO 9001:2015 – Preparing For A Successful Transition

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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

- Where do these standards come from?
- Why are things changing (again!)
- What is the timeline for transition?
- What are the key changes?
- Do we have to overhaul our current system?
- FAQs from past presentations
- Final points
- Questions

Where do these standards come from?

- The International Organization for Standardization (ISO) is a collective made up of numerous international members;
- Each standard is assigned a Technical Committee (TC) for authorship;
- TC 176 is the Technical Committee assigned to ISO 9001;
- TC 176 includes members from each of the major industrialized nations;
- American National Standards Institute (ANSI)

Why are things changing (again!)

- 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.
- 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.)

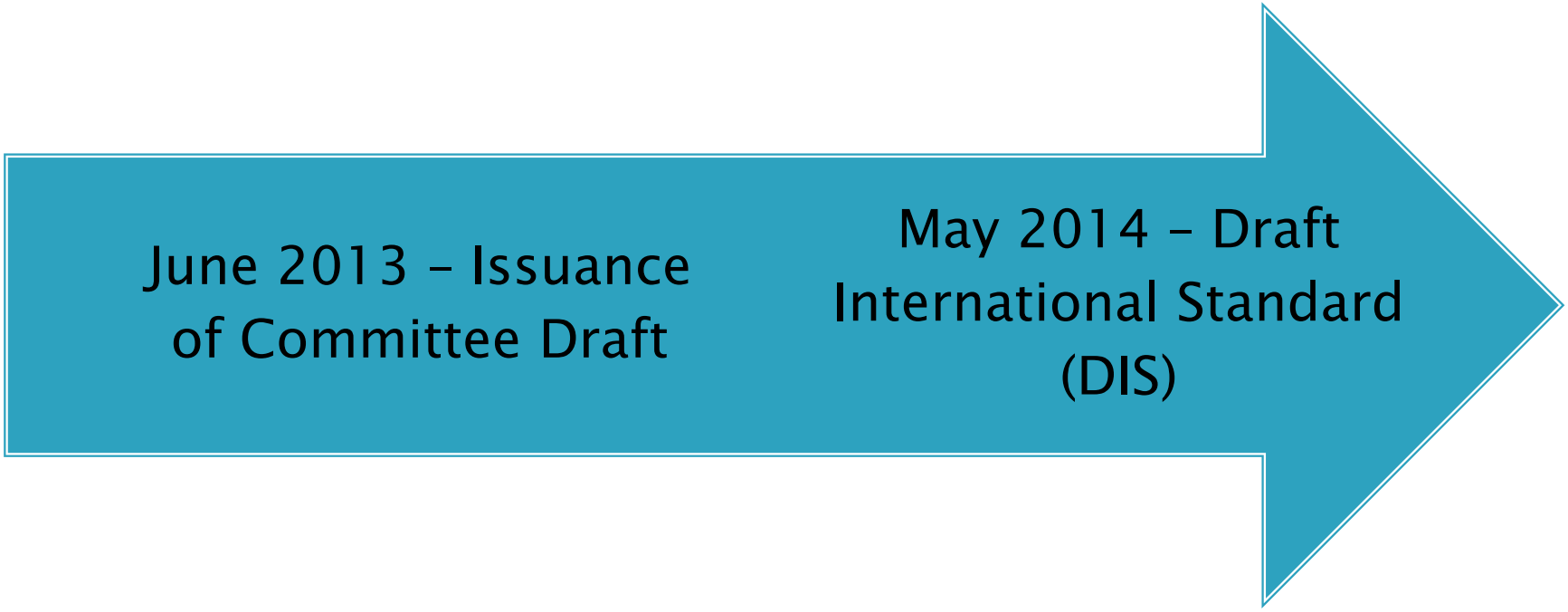
The three goals most important to TC 176 and the ISO at large

- Nigel Croft (the TC 176 chairperson) recently expressed the following as the three key features that TC 176 wants the ISO 9001 standard to have:
  - Foster a Process Approach (systematic, management, results based, consistency)
  - Foster a cycle of Plan-Do-Check-Act (both at the process and system level)
  - Foster Risk Based Thinking (preventing undesirable outcomes)
- Of these, the first two are familiar from ISO 9001:2000 and ISO 9001:2008. The third is new.

What is the timeline for transition?

- The development of the ISO 9001 standard is in the midst of a long term process with several key dates as shown on the next two slides.

Transition timeline (past dates)



Transition timeline (planned dates)

Current stage – DIS comment integration

- The DIS 9001:2014 received an overwhelming approval of 90% when the TC 176 members voted on it.
- This approval meant that progression to FDIS should proceed according to the planned timeline (July 2015.)
- Current work includes incorporation of all comments (from all voting members including those that approved and rejected the DIS.)
- The hope is that the careful “tweaking” being done will ensure a swift and decisive approval vote on the FDIS to proceed to full publication as ISO 9001:2015 in September 2015.

Key things to keep in mind

- The transition timeline does not take hold until the standard is published.
- It is not yet clear whether it will be necessary to add additional audit time for transition audits.
- The September 2018 cut-off likely means that registrars like PJR will have to establish a cutoff date for clients to perform a transition audit. Such provisions will vary from case to case.

What are the key changes?

- ISO 9001:2015 will be among the first ISO standards to make use of the standardized structure represented by “Annex SL.”
- Annex SL has also been referred to as the “High Level Outline” or “Annex XL.”
- Annex SL is part of a larger ISO publication called “ISO/IEC Directives Part 1 – Consolidated ISO Supplement – Procedures Specific to ISO.”
- ISO/IEC Directives Part 1 (and Annex SL therein) can be found here:
- http://www.iso.org/sites/directives/directives.html#toc_marker-76

More details about Annex SL

- Annex SL was first published in 2012 and represented the output of a special committee of the ISO called the Joint Technical Coordination Group (JTCG.)
- 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.
- Eventual plan calls for full transition of all ISO standards to Annex SL structure by 2016 or 2017.

Annex SL's 10 section structure (1-4)

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Context of the organization
  - context
  - interested parties
  - scope of QMS
  - quality management system

Annex SL's 10 section structure (5-6)

- 5 Leadership
  - general
  - management commitment
  - policy
  - roles, responsibility and authority
- 6 Planning
  - actions to address risks and opportunities
  - objectives and plans to achieve them
  - planning of changes

Annex SL's 10 section structure (7-8)

- 7 Support
  - resources
  - competence
  - awareness
  - communication
  - documented information
- 8 Operation
  - operational planning and control
  - determination of market needs and interaction with customers
  - operational planning process
  - control of external provisions of goods and services
  - development of goods and services
  - production of goods and provision of services
  - release of goods and services
  - non conforming goods and services

Annex SL's 10 section structure (9-10)

- 9 Performance evaluation
  - monitoring, measurement, analysis and evaluation
  - internal audit
  - management review
- 10 Improvement
  - Non-conformity and corrective action
  - improvement

What are the key changes?

- The following pages provide insight into the primary “new” content areas represented by ISO 9001:2015.

Combining content found in ISO 9000, 9001, and 9004

- Among the items now found in a single ISO 9001 document are the following:
  - Terms and definitions (many of which were formerly found in ISO 9000:2005.)
  - Quality Management Principles (formerly found in ISO 9004:2009) – 7 now (combining two of the former 8) – each with a sanctioned "rationale" to aid in understanding intent.

- This has greatly increased the size of the ISO 9001 standard – the DIS numbers over 50 pages (17 auditable/certifiable content.)

- ISO 9000 and ISO 9004 will both be updated in the near future, but their planned content is not fully known at this time.

Risk (the scary new requirement)

- The term “risk” is used 18 times in the current Draft standard;
- 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.

Risk

- Clause 6.1.1 of the DIS 9001 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) prevent, or reduce, undesired effects;*
    - *c) achieve continual improvement.*

Risk

- Clause 6.1.2 of the DIS 9001 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.*

What ISO 9001:2008 requirements most directly correlate to 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),
  - 8.5.3 Preventive Action (an assessment of potential problems with actions taken to avoid those issues in the first place), and
  - 6.2.2 Training (an assessment of competency needs with steps taken to ensure that personnel are fully qualified and competent.)

Key changes in terminology

- “Procedures”, “Records”, and “Documents” have all been eliminated in favor of “Documented Information.”
  - The standard is trying to be more inclusive in accepting alternative approaches to these areas.

- All references to “Product” will 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.)
- Suppliers are now referred to as "External Providers"
  - This is intended to better accommodate service organizations.

Elimination of required content

- ISO 9001:2015 will 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.

- If this can be accomplished without a procedure/quality manual, it will be accepted.

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 still claim certain items under a “Non-Applicable” designation.
- This means that the validity of such designations will continue to be verified at each audit.
- In practice – not terribly different from current approach. Your current method for documenting these very likely will not change.

Let's look at some key new questions posed by the ISO 9001:2015 standard:

Most key changes are found in Sections 4, 5, and 6

Section by Section

- Sections 1-3 – Not specifically auditable (as before)
- Section 4 – Context of the Organization
  - Similar to ISO 9001:2008 4.0 – Quality Management System
- Key new questions:
  - *What purpose does the organization serve?*
  - *Who does it exist for?*

Section by Section (cont.)

- Section 5 – Leadership
  - Uses strong language related to top management's involvement in the quality management system.

- Key new questions:
  - *Has management made itself accountable for the effectiveness (or lack thereof) of the QMS?*
  - *Has management ensured that the Quality Policy/Objectives are consistent with the strategic direction of the company?*
  - *Has the QMS been integrated into the business processes?*

- Please note that this does NOT mean that your financial records will be subject to audit.

Section by Section (cont.)

- Section 6 – Planning for the quality management system
  - Planning is viewed in a whole new light – taking into account the new concept of risk.

- Key new questions:
  - *Have all risks (and opportunities) been considered?*
  - *Have actions been taken or planned for said risks?*
  - *With regards to Quality Objectives –*
    - *Who will be responsible?*
    - *What is the target date?*
    - *What is to be accomplished?*

Section by Section (cont.)

- Section 7 – Support
  - Borrows heavily from ISO 9001:2008 Section 6.0 – Resource Management, as well as bits and pieces from Section 4 and 5.

- One very slightly new area of content is provided in clause 7.1.6 that asks the following key question:

  - *"Has the organization considered changing needs and trends against its current competency base and determined what is needed for the future?"*

  - No other significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 8 – Operation
  - Very similar to ISO 9001:2008 Section 7.0 – Product Realization, as well as bits and pieces of Section 8.0
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 9 – Monitoring, Measurement, Analysis, and Evaluation
  - Very similar to ISO 9001:2008 Section 8.0 – Measurement, Analysis, and Improvement, while also using content from Section 5.0 – this is now where Management Review (5.6) is found.
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 10 – Improvement
  - Very similar to ISO 9001:2008 Sections 8.5.1–8.5.2– Continual Improvement and Corrective Action.
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

As you can hopefully see!

- The changes to the ISO 9001 standard are actually minimal and quite manageable.

- Even the “new” idea of risk is not so new if one considers the fact that Preventive Action has been a part of the ISO 9001 standard since it was first published.

Do we have to overhaul our current system?

- Certainly not!
- As previously mentioned, one of the goals of the TC176 committee in writing the new standard was to improve its inclusiveness.
- Telling over 1,000,000 world-wide registered firms that they have to overhaul their system doesn't seem terribly inclusive, does it?

If it works, keep it!

- Your quality manual fits your business?
  - Keep it!
- Your procedures are effective at defining your key processes and how they operate?
  - Keep them!
- Quality Policy, Quality Objectives, etc. are all well known and adding value?
  - Keep those too!

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.

Will the other standards (AS9100, TS16949, etc.) be updated also?

- All of the major sector specific standards, including TS 16949 (automotive), AS9100 (aerospace), and TL9000 (telecommunications) have indicated their intentions to transition and continue their alignment with ISO 9001.

- The timelines for these other standard updates are not fully known at this time, but a 2016 publication date seems likely for all three.

- At present the only major standard that is not planning to continue its alignment to ISO 9001 is ISO 13485 (medical devices,) which is in the midst of its own update with a targeted publication of early 2016.

Should we get certified now or wait?

- There are many companies at various stages of implementing a new quality management system in accordance with ISO 9001:2008 that may be wondering if there is still value in registering to ISO 9001:2008.
- While PJR cannot make the final decision for you, it is important to bear in mind that ISO 9001:2008 still has at least 3.5 years of usability left in it.
- It is also important to bear in mind that the very first audits later this year to ISO 9001:2015 will be a bit more difficult for both auditee and auditor.
- With the passage of time, auditors will be more comfortable auditing ISO 9001:2015, ensuring an even smoother transition.

What steps can we take right now?

- 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.

Final point on document transition

- Make sure that your existing documentation (Quality Manual, Procedures, etc.) works for you first and foremost.

- If a re-numbering enables the documentation to work better for you, than do so, but it will not be required.

Work with your auditor

- Particularly in times of transition, auditors provide expert analyses of a quality management system against audit criteria.
- Your auditor will be a valuable resource in your transition process.

Looking ahead

- This is an exciting time for quality system certification. ISO 9001:2015 promises to be a beneficial update to a standard with a long track record of contribution to the world.

- PJR will continue to provide timely updates on the transition process and will endeavor to enable our clients as smooth a transition as possible.

Helpful links:

- An side by side comparison between ISO 9001:2008 and the DIS 9001:2014 can be found here:
  - http://www.pjr.com/downloads/ISO%209001%20CRM.pdf
- PJR has prepared an FAQ report that can be accessed here:
  - http://www.pjr.com/downloads/WSR_Spring_2015.pdf

Thank you!