# ISO 9001:2015 – Preparing For A Successful Transition

Presented by:
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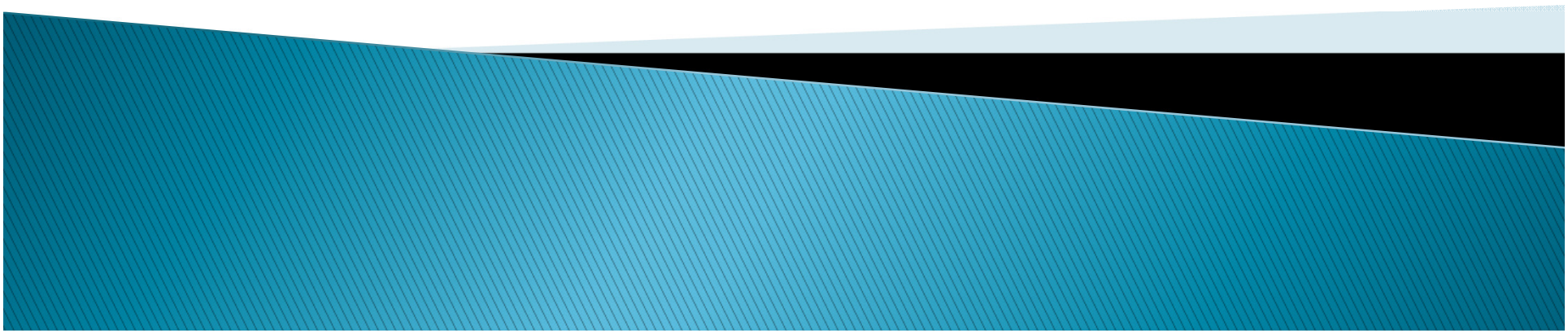
Technical Director

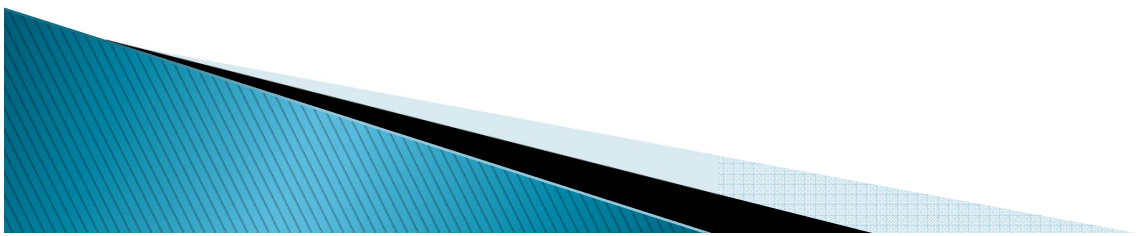


# Please note:

- 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?
- Questions

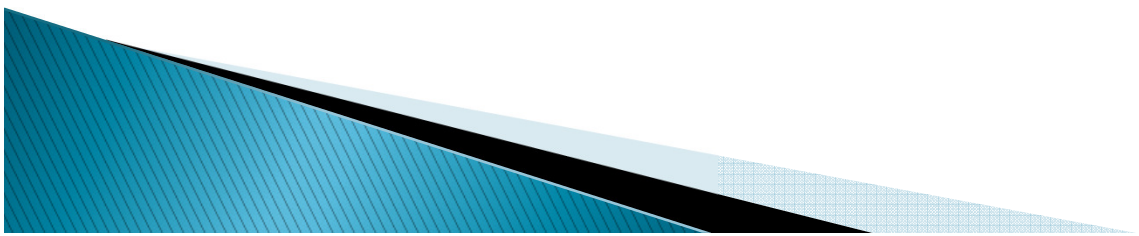


# Where do these standards come from?

- 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)

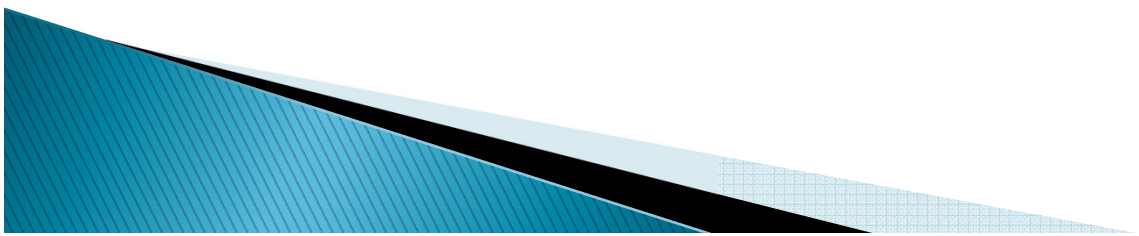
# Why are things changing (again!)

- 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.)

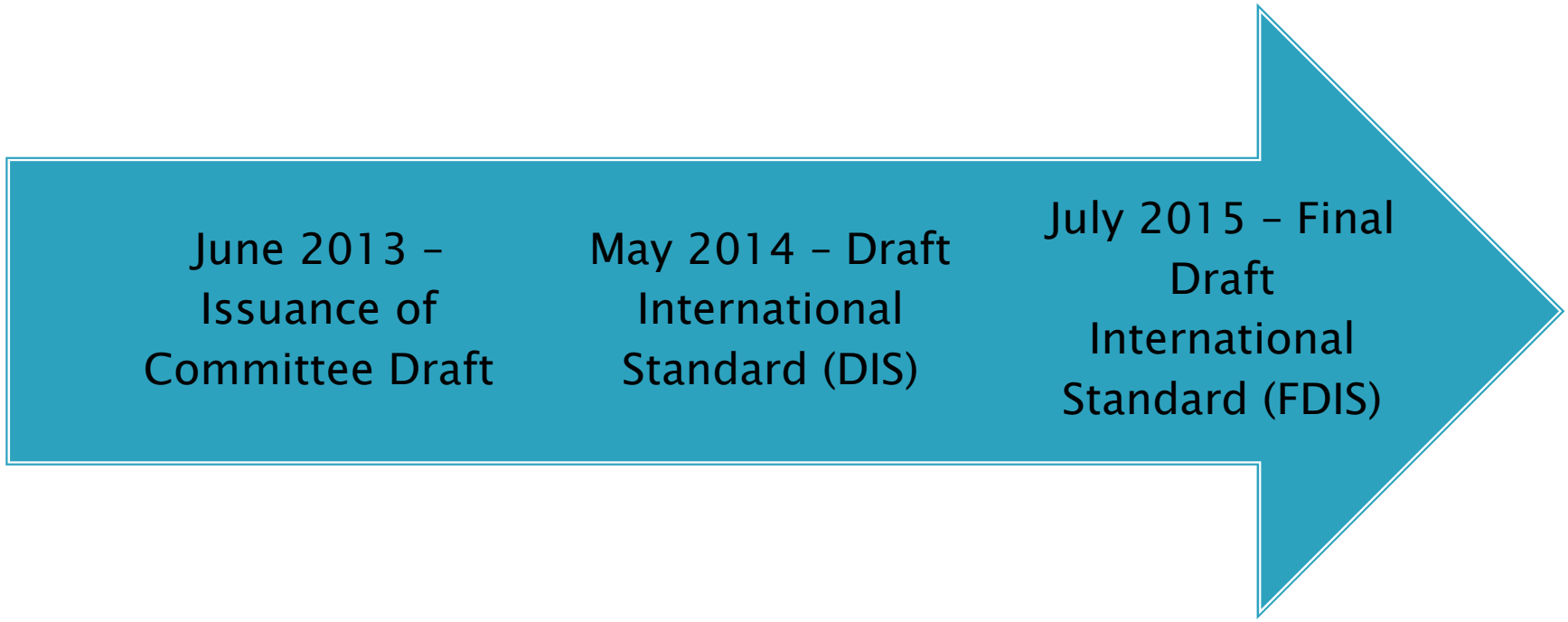


# What is the timeline for transition?

- 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 part one



# Transition timeline part two

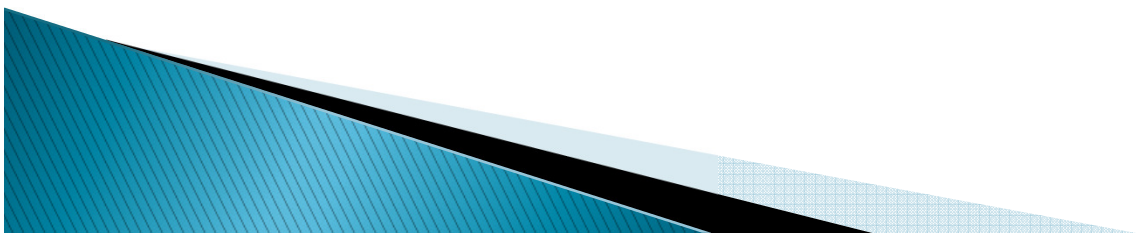
# Key things to keep in mind

- The September 2015publication date is probable, even likely, but not (at the moment) definite.  The refusal of the automotive industry to adopt the new ISO 9001:2015 standard may (but probably will not) delay its publication.
- 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 means that registrars like PJR will probably establish May or June 2018 as the last date a client can have a transition audit.  This would mean, for example, if a company has an August audit schedule, then they would likely transition in August 2017.

# 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.”

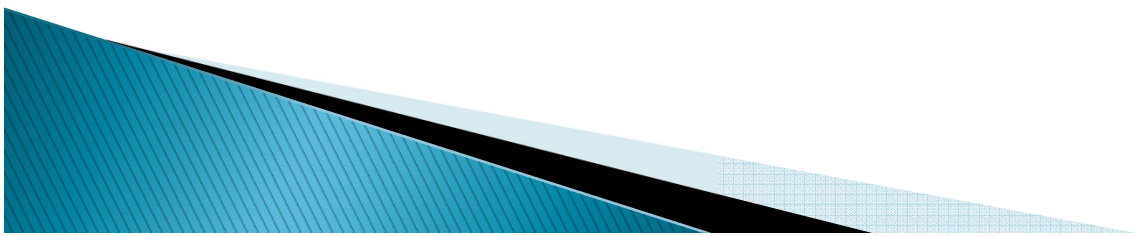


# What is Annex SL?

- 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.
- Eventual plan calls for full transition of all ISO standards to Annex SL structure by 2016 or 2017.

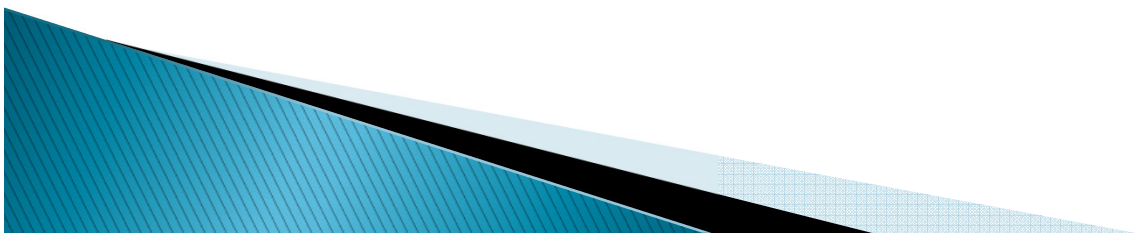
# Annex SL's 10 section structure (1-4)

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



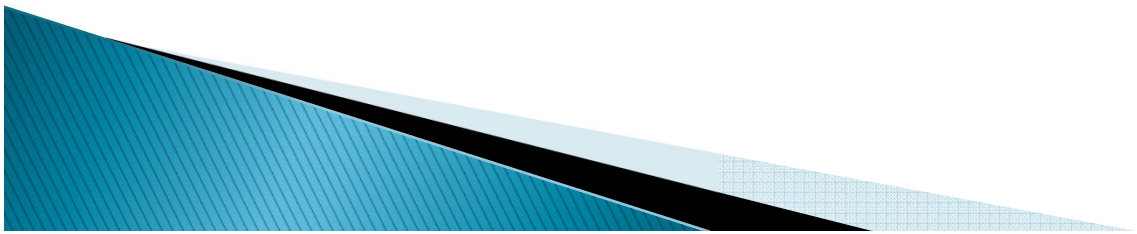
# Annex SL's 10 section structure (5-6)

- 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



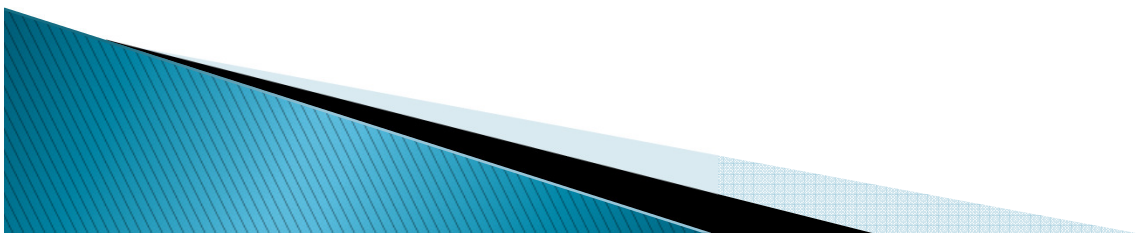
# Annex SL's 10 section structure (7–8)

- 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



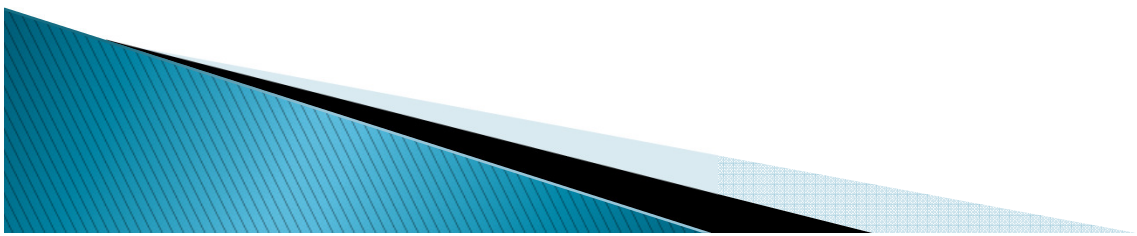
# Annex SL's 10 section structure (9-10)

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



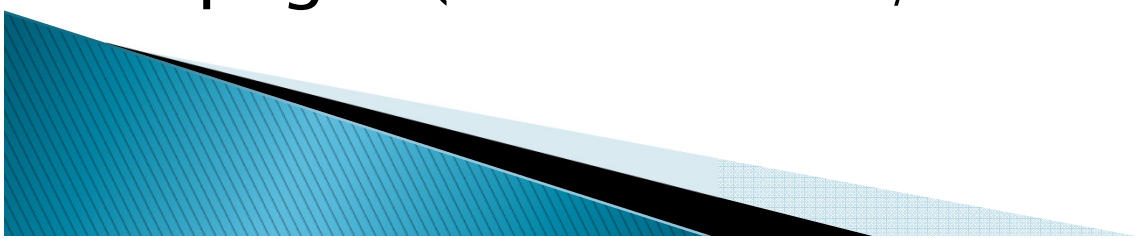
# What are the key changes?

- 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.)

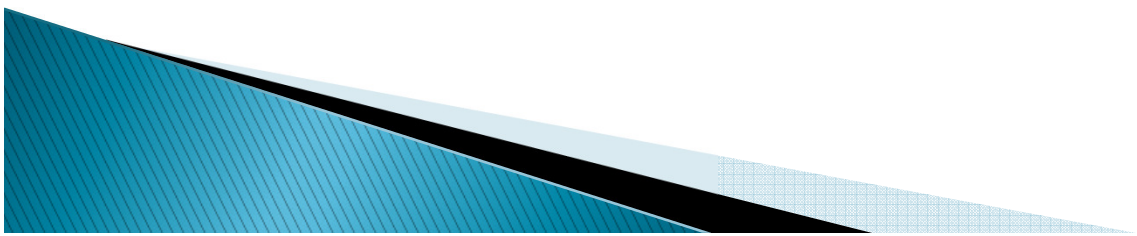


# Risk (the scary new requirement)

- 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.

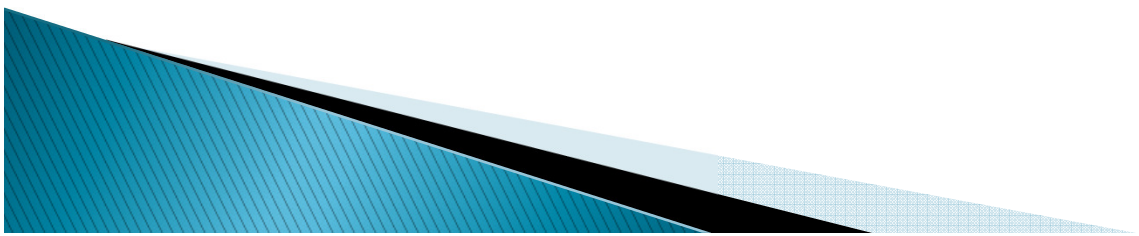
# Risk

- 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.*



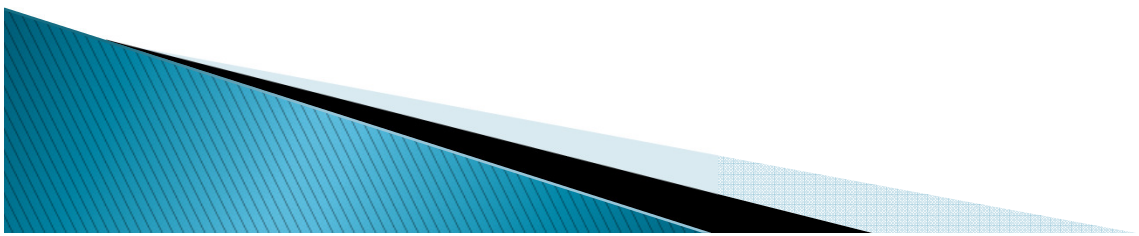
# Risk

- 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.*



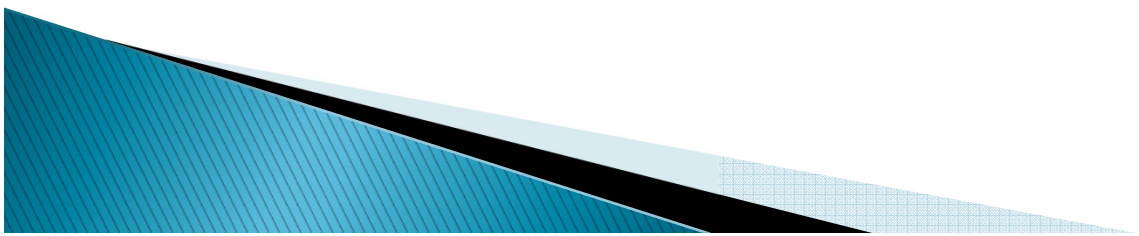
# Risk

- Borrows heavily from the concept of Preventive Action (clause 8.5.3 in ISO 9001:2008.)
- Preventive Action isn't going anywhere!
- Expands the idea of Risk aversion to one that affects all of the various areas of the Quality Management System.



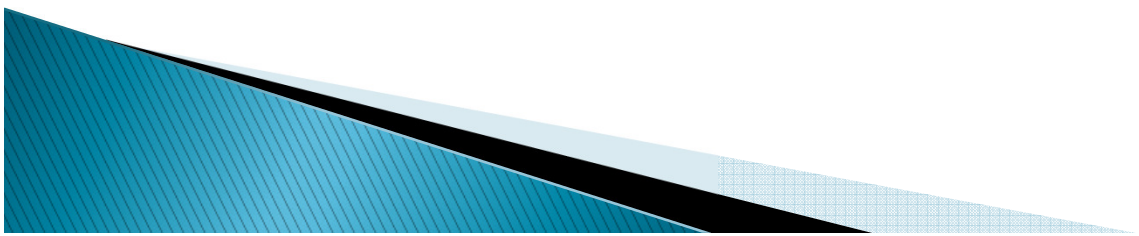
# Key changes in terminology

- “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.

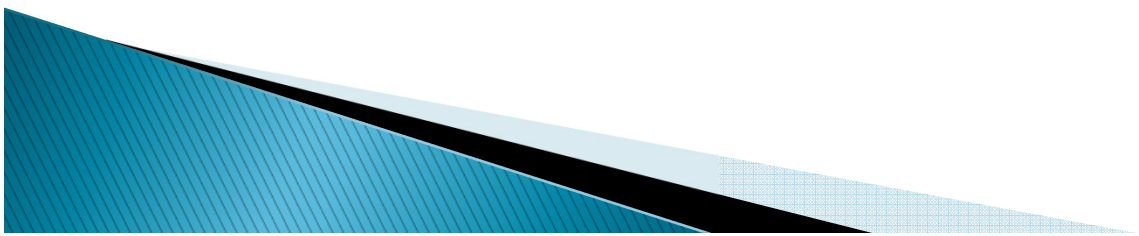


# Elimination of required content

- 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.

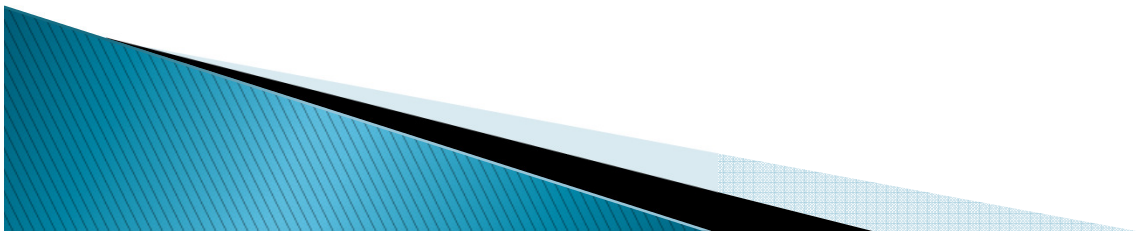


# Elimination of the Management Representative

- 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.
- This reflects the current “in practice” arrangement for many of the companies already certified.

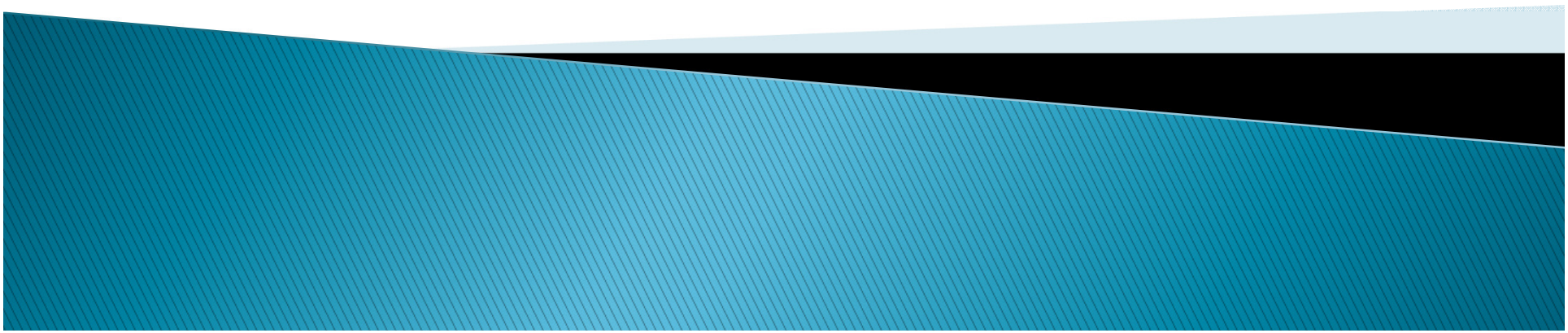
# Elimination of Permissible Exclusions

- 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.



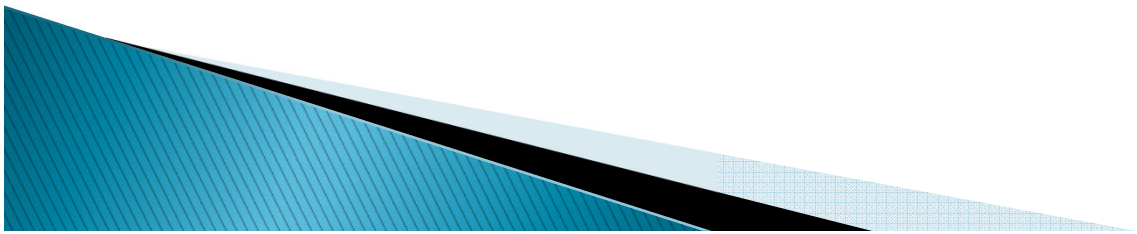
# Let's look at some key new questions posed by the ISO 9001:2015 standard:

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



# Section by Section

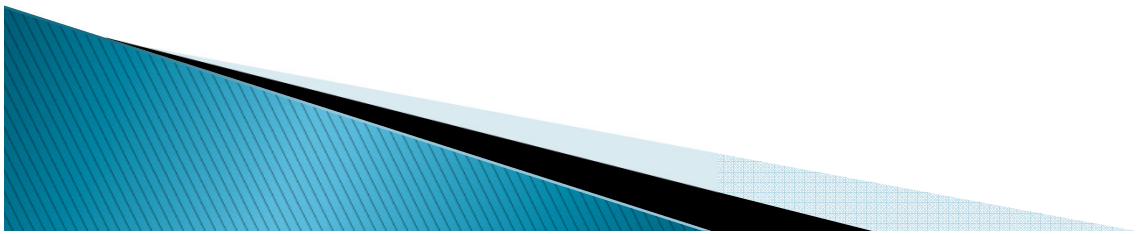
- Sections 1-3 – Not specifically auditable (as before)
- Section 4 – Context of the Organization
  - Similar to ISO 9001:2008 4.0 – Quality Management System
- Key new questions:
  - *What purpose does the organization serve?*
  - *Who does it exist for?*



# 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?*



# 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.

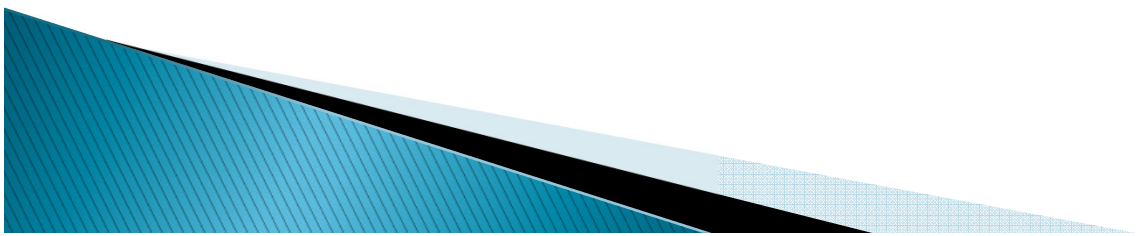
- Key new questions:
  - *Have all risks (and opportunities) been considered?*
  - *Have actions been taken or planned for said risks?*
  - *With regards to Quality Objectives –*
    - *Who will be responsible?*
    - *What is the target date?*
    - *What is to be accomplished?*

# 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.

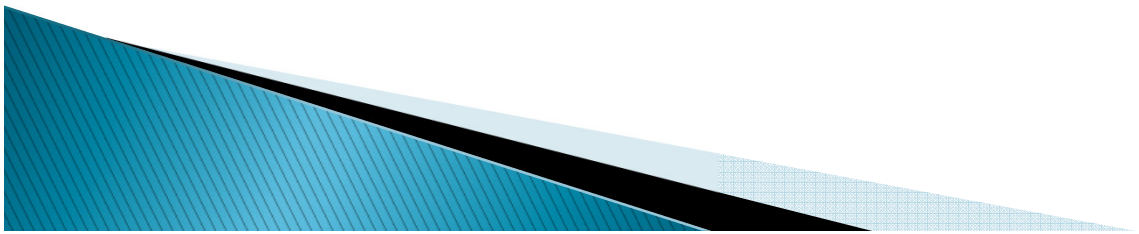
# Section by Section (cont.)

- 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.



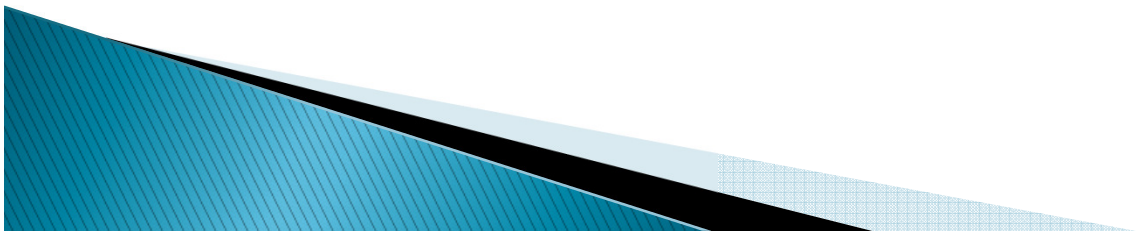
# Section by Section (cont.)

- 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.



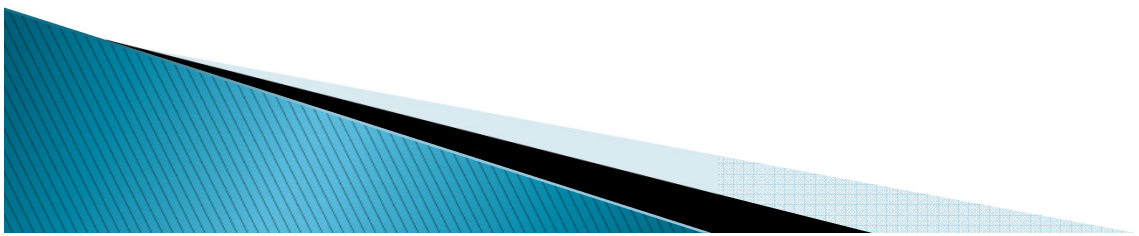
# Section by Section (cont.)

- 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.



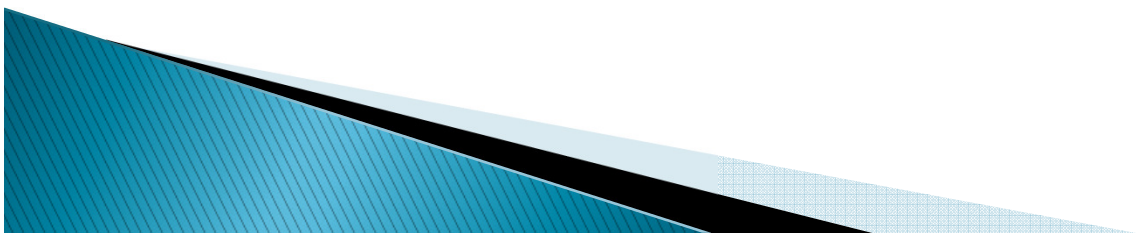
# As you can hopefully see!

- 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.



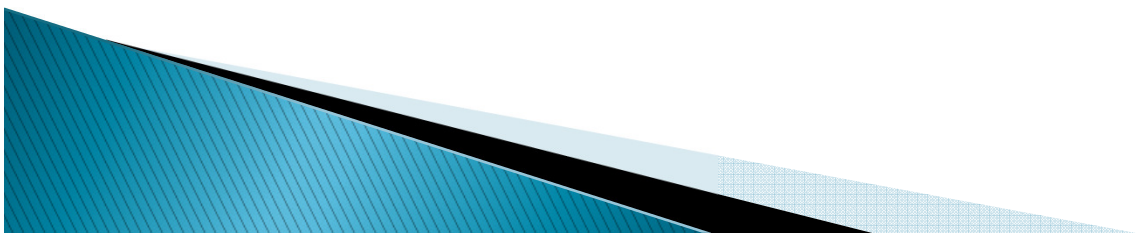
# Do we have to overhaul our current system?

- 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!



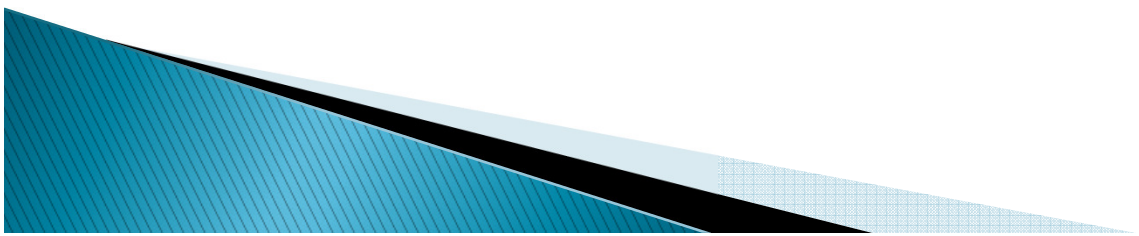
# Begin with a review of the new standard

- Organizations should plan a careful review of the new standard upon its publication.
- Identify gaps that exist within their current system
  - It is entirely conceivable that there won't be any!
- Determine strategies for gaps that do exist.
- 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.

# Continue with the natural cycle of the audit process

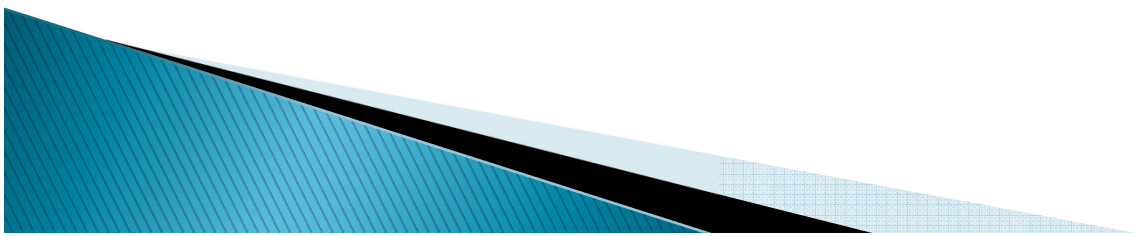
- Particularly in times of transition, auditors provide expert analyses of a quality management system against audit criteria.

- Your auditor will be a valuable resource in your transition process.



# What's next?

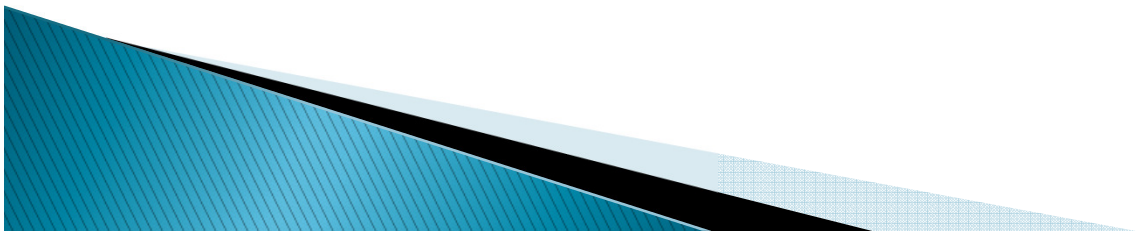
- Look to PJR to continue to provide timely information in this transition process.
- The final published standard will likely bear some further revisions to ensure that all interested parties are as satisfied as possible.
- Stay in close contact with PJR to be sure you are aware of these developments.



# Corrections

- Please note that Slide 6 was corrected to reflect the revised dates of publication for the DIS and FDIS versions of the ISO 9001:2015 standard.

- Please note that Slide 8 was corrected to reflect that a few other standards have already been published under Annex SL.



# Thank you!

Thanks to Jim Johnson for his review of this presentation and his invaluable comments.