

ISO 9001:2015 Update

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Presented by
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The Registrar Company

- Started in 1996 in Dallas Texas
- Accredited by ANAB
- International Certification Services purchased TRC in 2012 – Offices in Guelph
- Currently it provides registration services to the following standards:
 - ▣ ISO 9001
 - ▣ ISO 14001
 - ▣ AS 9120
 - ▣ AS 9100
 - ▣ OHSAS 18001
 - ▣ HACCP
- Over 100 auditors strategically located Globally



Overview

- The Revision of ISO 9001
- Proposed Changes to ISO 9001
- Transition Planning



THE REVISION OF ISO 9001



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The Revision of ISO 9001

- About every 5 years all standards are reviewed for necessary revisions.
 - ▣ Reasons for revision
 - ▣ How the revision process works
 - ▣ Timelines for ISO 9001:2015

Reason for Revisions

- There was a mandate from the Technical Management Board (TMB) to align multiple standards
- The need to consider changes in business practises and technology
- To allow the standard to be used in all types of businesses more effectively

Timelines for ISO 9001:2015

WD

- Working Group formed March 2012 and initial work began June 2012
- First WD was completed in November 2012

CD

- Published June 2013

DIS

- Published May 2014 – This is where we are now.

FDIS

- Estimated date for final ballot is June/July 2015

IS

- Estimated date for publication is September 2015



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PROPOSED CHANGES TO ISO 9001



Proposed Changes

- Structure – Annex SL
- More generic and less prescriptive
- Context of the Organization
- Process Approach
- More Focus on Customer
- Risk-Based Thinking
- Documented Information

Structure – Annex SL

- This is the largest change to the new revision and will be applied to all new and revised ISO management system standards
 - ▣ High level Structure
 - ▣ Identical core text
 - ▣ Common terms and core definitions

Structure – Annex SL

Annex SL

- 4 Context of Organization
- 5 Leadership Planning
- 6 Planning
- 7 Support
- 8 Operations
- 9 Performance & Evaluation
- 10 Improvement

ISO 9001:2008

- 4 Quality Management System
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realization
- 8 Measurement, Analysis, Improvement



More Generic and Less Prescriptive

- Modification of Language in Standard
 - ▣ “products and services” instead of “product” when referring to deliverables
- No mandatory documented procedures
 - ▣ This could still change based on comments
- Manufacturing focused clauses:
 - ▣ 7.3 Design and development
 - ▣ 7.6 Control of monitoring and measuring equipment

More Generic and Less Prescriptive

Changes to 7.3 Design and Development

ISO 9001:2015

- 8.3 Design and Development of Products and Services
 - 8.3.1 General
 - 8.3.2 Design and Development Planning
 - 8.3.3 Design and Development Inputs
 - 8.3.4 Design and Development Controls
 - 8.3.5 Design and Development Outputs
 - 8.3.6 Design and Development Changes

ISO 9001:2008

- 7.3.1 Design and development planning
- 7.3.2 Design and development inputs
- 7.3.3 Design and Development outputs
- 7.3.4 Design and development review
- 7.3.5 Design and development verification
- 7.3.6 Design and development validation
- 7.3.7 Control of design and development changes

More Generic and Less Prescriptive

- 7.6 is now 7.1.5 Monitoring and measuring resources
 - This has been moved to 7.1 Resources to align more effectively with other types of equipment

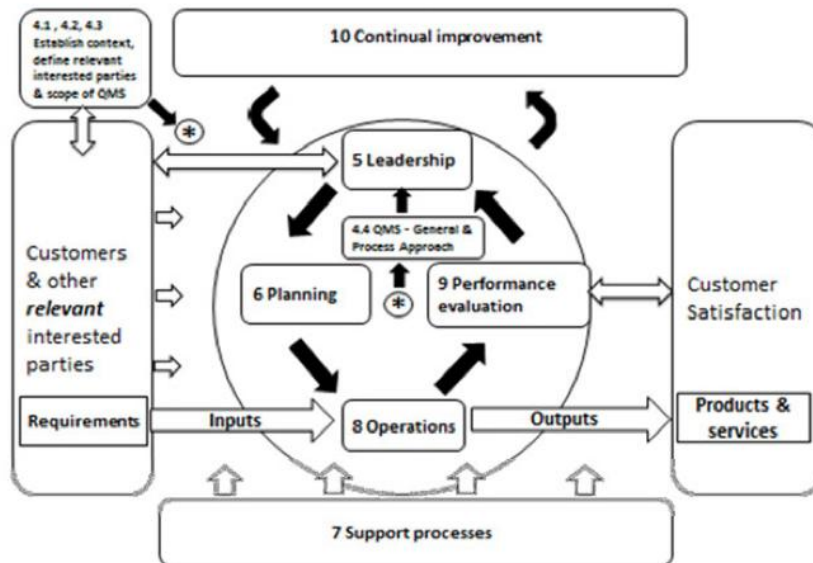
- Notes have been added to help clarify information
 - Monitoring and measurement devices can include assessment methods such as surveys

Context of the Organization

- 4.1 Understanding the organization and its context
- 4.2 Understanding the Needs and expectations of interested parties
 - “interested parties”- person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity.
- These clauses require organizations to:
 - Determine the issues and requirements that can impact their business
 - Focus on planning for these issues and requirement

Process Approach

- 4.4.2 Process approach has been added to identify more specific requirements
 - Organization who have taken a minimal approach to this requirement may need to make some changes
- Model of a process-based QMS has been changed



More Focus on Customer

- There will be more focus on the concept that ISO 9001 needs to give confidence that the products and/or services of an organization meets the requirements of the customer
- This is what the standard is all about – enhancing an organizations ability to satisfy their customer

Risk-Based Thinking

- An emphasis on risk-based thinking
 - a formal risk management program is not required – only a consideration of risks

- Preventive Action has been removed and instead 6.1 Actions to address risks and opportunities, has been added
 - Preventive action is thought to be the task of the QMS as a whole and therefore removed as a subsection

Risk-Based Thinking

- 6.1 requirements include:
 - Making sure your QMS can achieve its intended output
 - The action taken being appropriate to the potential effect of conformity on your goods and services

- This change is thought to align the standard with a more typical language used in decision making

Documented Information

- The terms “Documents” and “records” have been replaced with “documented information”
- New Definition: *information required to be controlled and maintained by an **organization (3.01)** and the medium on which it is contained*
 - ▣ No distinction is made between documents and records



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TRANSITION PLANNING



Transition Planning to ISO 9001:2015

- Transition Guidelines were published as a IAF informative document in January 2015. (IAF ID 9)
- Accreditation bodies will use this as a basis for their individual rules.

Transition Planning to ISO 9001:2015

- There will be a 3 year transition period to the new standard that will begin on date of publication
- ISO 9001:2008 certificates will no longer be valid three years after the date of publication of the 2015 version of the standard
 - ISO 9001:2008 certificates issued during the transition can not have an expiry date later than the transition deadline

Transition Planning for Registered Organizations

Organizations using ISO 9001:2008 are recommended to take the following actions:

- Identify organizational gaps which need to be addressed to meet new requirements.
- Develop an implementation plan.
- Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation.
- Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
- Where applicable, liaise with their Certification Body for transition arrangements.

NOTE: Users should be aware that at the Draft International Standard (DIS) stage technical changes may still occur, therefore it is recommended that, while preparation can be carried out at the DIS stage, significant changes should not be implemented until the Final Draft International Standard (FDIS) is issued and the technical content is finalized.



TRC ISO Revision Sessions

- With the release of the new revisions to ISO 9001, ISO 14001 and the release of ISO 45001 (replacing OHSAS 18001) TRC will be conducting revision training sessions that cover the keys changes to these standards.

- These will take place at our Guelph, ON Office (291 Woodlawn Road W. Unit #3C, Guelph, Ontario, N1H 7L6 Canada) on the following dates:
 - April 15, 2015: 3PM – 6PM
 - April 29th, 2015: 9AM – 12PM
 - May 13th, 2015: 2PM – 5PM

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THANK-YOU

