Welcome!

ISO9001:2008
Information Session
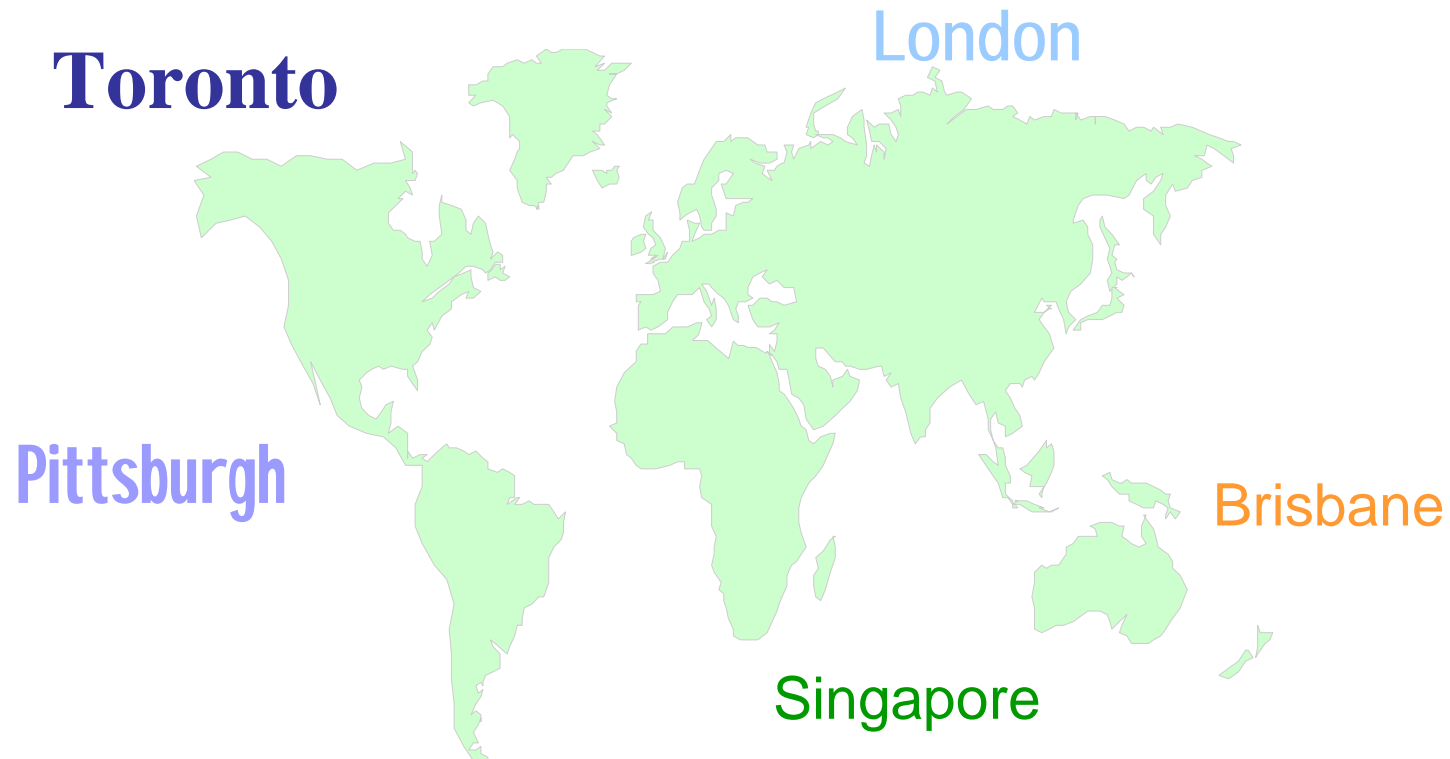
Presented by Mickey Jawa - SatiStar
2009-01-22

Outcomes

- **Who is *SatiStar*?**
- **The ISO revision process**
- **Understand the revisions in ISO9001:2008**
- **What's next?**

About SatiStar

Business Performance Improvement Consulting

Toronto

London

Pittsburgh

Brisbane

Singapore

Our mission

To experience the joy of helping our clients excel at what they do.

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Our Expertise . . .

Performance Breakthrough

Information Systems

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Management System Standards

Leadership & Cultural Tranformation

Operational Effectiveness

Some of our clients . . .

You can't beat the experience!

Manufacturing		Non-Manufacturing	
Adhesives	Mold Design & Mfg.	Architecture	Maintenance
Aerospace	Nursery Equipment	Contractors	Marketing
Agriculture	Optical	Customer Service	Medical
Appliance	Paint	Dental	Outsourcing
Automation	Pharmaceuticals	Distribution	Publishing
Automotive	Photographic	Duct Cleaning	Repair & Overhaul
Blood Products	Plastics	E-Commerce Retail	Research & Develop.
Brewing	Point of Sale Systems	Environment	Recycling
Chemicals	Porcelain	Finance	Retail
Computers	Printing	Government	Safety
Construction	Pulp & Paper	Health	Sales
Consumer Elect.	Residential Homes	Health Services	Scheduling
Defense	Robotics	Hospitality	Security
Electronics	Rolled Goods	Human Resources	Shipping
Flooring	Satellite	Information Systems	Software
Food & Ferment.	Silkscreening	Insurance	Telecommunications
Furniture	Steel	Laboratory	Transportation
Heavy Equipment	Toner Cartridges	Logistics	University
Industrial HVAC	Tool & Die	Maintenance	Warehousing
Label Manufacturing	Vision	Management Consulting	Wholesale
Machining	Wire & Cable		
Metals	Wood Products		

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We walk the talk . . .

- **SatiStar is an ISO9001:2000 registered organization**

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ISO9001 Revision Process

The ISO9000 Family of Standards (32)

- **ISO9001:2000 – Requirements**
- **ISO9000:2005 – Fundamentals and vocabulary**
- **ISO9004:2000 – Guidelines for performance improvement**
- **ISO10005:2005 – Guidelines for quality plans**
- **ISO10006:2003 – Guidelines for project management**
- **ISO10007:2003 – Guidelines for configuration management**
- **ISO10012:2003 – Requirements for measurement systems**
- **ISO10013:2001 – Guidelines for documentation**
- **ISO10014:2006 – Guidelines for realizing financial & economic benefits**
- **ISO10015:1999 – Guidelines for training**
- **ISO10017:2003 – Guidance on statistical techniques for ISO9001**
- **ISO10019:2005 – Guidance on selecting QMS consultants and using their services**
- **ISO19011:2002 – Guidelines for auditing**
- **. . . others, including many industry-specific guidelines for application**

History

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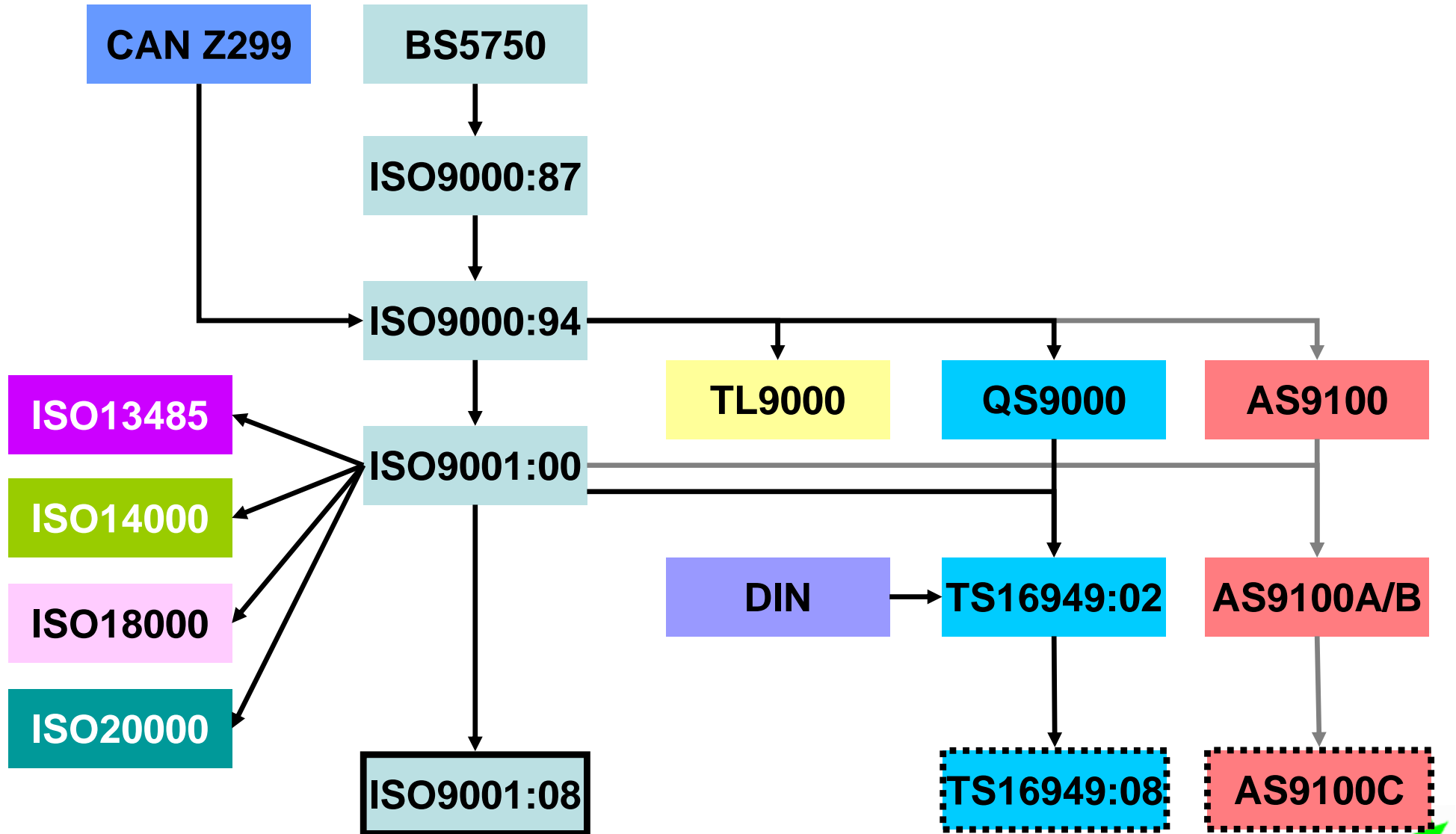
International Organization for Standardization

- **Technical Committee - TC176**
  - **Quality Management & Quality Assurance**
  - **Trevor Smith – Kodak – TC176 Chairperson**
  - **David Zimmerman – CSA – TC176 Secretary**

- **Sub-Committee - SC2:**
  - **Quality systems**
  - **Manages revisions to ISO9001, etc.**
  - **Dr. John Davies – UK – SC2 Chairperson**
  - **Charles Corrie – BSI – SC2 Secretary**

- **Reviewers:**
  - **67 Participating countries**
  - **9 Observing countries**
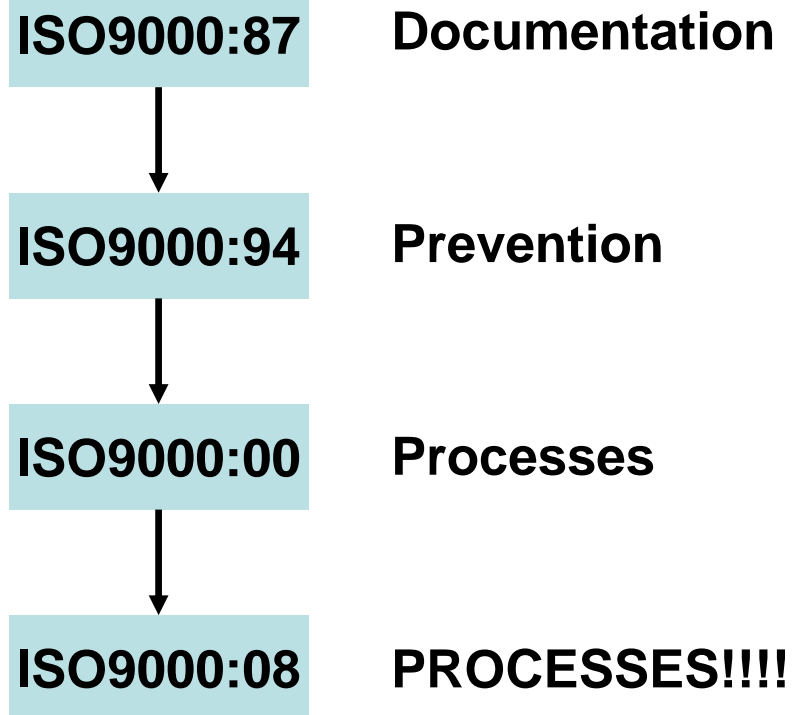 - **North America:**
    - **SCC, ANSI and DGN representatives**

ISO Standard Approval Process

Proposal

↓

Working Draft (WD)

↓

Committee Draft (CD)

↓

Draft International Standard (DIS)

↓

Final Draft International Standard (FDIS)

↓

Standard Published

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ISO Standard Approval Process

Process Stage	Date
Proposal	2005-10-05
Working Draft (WD)	
Committee Draft (CD)	
Draft International Standard (DIS)	2007-09-01 → 2008-05-15
Final Draft International Standard (FDIS)	2008-07-15 → 2 months
Standard Published	2008-11-15

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Focus

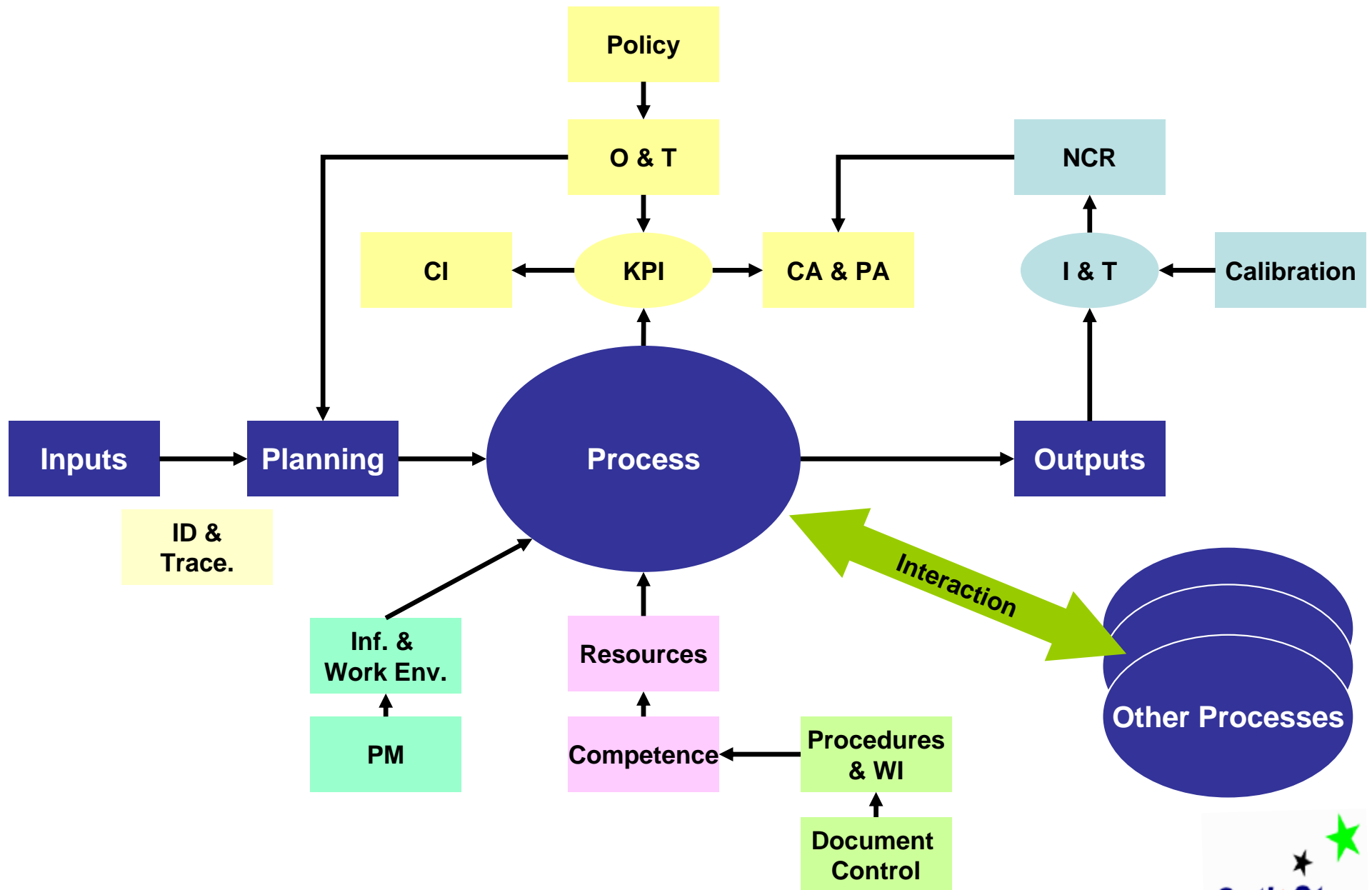|	
ISO9000:87	**Documentation**
↓	
ISO9000:94	**Prevention**
↓	
ISO9000:00	**Processes**
↓	
ISO9000:08	**PROCESSES!!!!**

Process Approach

Sales
O/E
Scheduling
Purchasing
Design & Development
Manufacturing
Warehousing
Shipping
Receiving
Customer Satisfaction
Management Review
Internal Audit
Corrective Action
Preventive Action
Continual Improvement
IM&T
NCR
MRB
Document Control
Training
Recruitment & Selection
Performance Appraisal
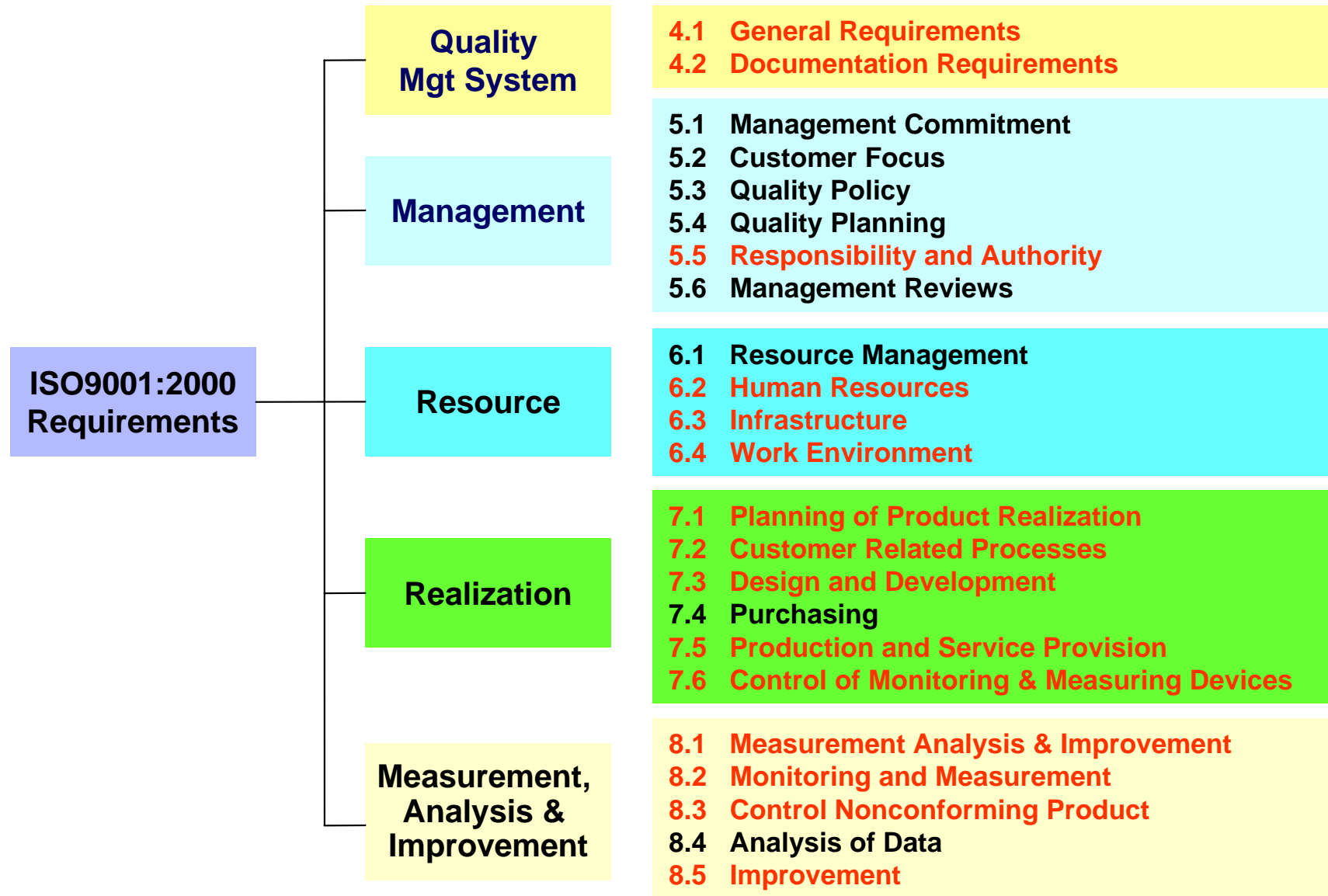Business Planning
Calibration
Preventive Maintenance

Typical processes in most companies

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Process Approach

Policy → **O & T**

O & T → **KPI**

CI ← **KPI** → **CA & PA**

CA & PA → **NCR**

NCR ← **I & T** ← **Calibration**

Inputs → **Planning** → **Process** → **Outputs**

ID & Trace.

Inf. & Work Env. → **Process**

PM → **Inf. & Work Env.**

Resources → **Process**

Competence → **Resources**

Procedures & WI → **Competence**

Document Control → **Procedures & WI**

Interaction

Other Processes

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ISO9001:2008

Overview of ISO9001:2008 changed requirements

ISO9001:2000 Requirements

Quality Mgt System
- 4.1 General Requirements
- 4.2 Documentation Requirements

Management
- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Quality Planning
- 5.5 Responsibility and Authority
- 5.6 Management Reviews

Resource
- 6.1 Resource Management
- 6.2 Human Resources
- 6.3 Infrastructure
- 6.4 Work Environment

Realization
- 7.1 Planning of Product Realization
- 7.2 Customer Related Processes
- 7.3 Design and Development
- 7.4 Purchasing
- 7.5 Production and Service Provision
- 7.6 Control of Monitoring & Measuring Devices

Measurement, Analysis & Improvement
- 8.1 Measurement Analysis & Improvement
- 8.2 Monitoring and Measurement
- 8.3 Control Nonconforming Product
- 8.4 Analysis of Data
- 8.5 Improvement

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Revision Summary

- **Changes are mostly minor in nature**
- **Clause numbering maintained**
- **Clarification of wording**
- **Consolidation of sanctioned interpretations**
- **Improved alignment with ISO9004 & ISO14001**
- **No intent to merge ISO9001 with other standards**

- **Intensified focus on process approach**

Nature of Changes

- ## 83 changes
  - ### 28 New requirements
  - ### 30 Modified requirements
  - ### 12 New notes
  - ### 3 Revised notes
  - ### 10 Deletions

- ## Analysis
  - ### Red – Big Change
  - ### Blue – Small Change

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	Introduction, 0.1 General	
Added the words "its organizational environment, changes in that environment, and the risks associated with that environment;" **No impact for most organizations**		The design and implementation of an organization's quality management system is influenced by: its organizational environment, changes in that environment, and the risks associated with that environment; its varying needs; its particular objectives; the products it provides; the processes it employs; its size and organizational structure.

Additions are "obvious" things that all companies know

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement		**Introduction, 0.1 General**
Added the word "statutory" for clarity in Europe **No impact for most organizations in NA**	…to assess the organization's ability to meet customer, regulatory requirements applicable to the product, and the organization's own requirements.	…to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

Statutory = Legislative laws
Regulatory = Lower authority laws

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement		**Introduction, 0.2 Process Approach**
Added the words "to produce the desired outcome" **Process approach applies to all business processes that produce an outcome.** **Need to know what the desired outcome is.** **Major impact for most organizations**		The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

Potential MAJOR impact – You must use the Process Approach

Inputs → Planning → Process → Outputs

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Deleted requirement **Modified requirement**	Introduction, 0.3 Relationship with ISO9004	
Revised wording **Similar meaning** **ISO9001 is related to ISO9004** **No impact for most organizations**	The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.	ISO9001 and ISO9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

Says that "9001 & 9004 are complementary" – in fewer words

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**Introduction, 0.3 Relationship with ISO9004**	
Added the word "statutory" for clarity in Europe **No impact for most organizations in NA**	It focuses on the effectiveness of the quality management system in meeting customer and applicable regulatory requirements.	It focuses on the effectiveness of the quality management system in meeting customer and applicable statutory and regulatory requirements.

Statutory = Legislative laws
Regulatory = Lower authority laws

General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
3 new requirements	**Introduction, 0.3 Relationship with ISO9004**	
Revised wording **Similar meaning** **ISO9004 is intended for improvement of and guidance on ISO9001 systems** **No impact for most organizations**	ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance.	ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly in managing for the sustainable success of an organization. ISO 9004 is recommended as a guide for organizations whose top management wishes to extend the benefits of ISO 9001 in pursuit of systematic and continual improvement of the organization's overall performance.

**Says that 9004 provides guidance for 9001
(using slightly different wording)**

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General Section Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	**Introduction, 0.4 Compatibility with other management systems**	
Revised wording **Similar meaning** **Updated standard reference** **No impact for most organizations**	This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.	During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community.

ISO14001 was revised in 2004

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 new requirements	**1 Scope, 1.1 General**	
Added the word "statutory" for clarity in Europe **No impact for most organizations in NA**	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements,… b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements,… b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Statutory = Legislative laws
Regulatory = Lower authority laws

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Revised note	1 Scope, 1.1 General - Note 1	
Clarification of term "product" **Added outputs of any realization process, including internal processes** **Major impact for most organizations**	In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.	In this International Standard, the term "product" only applies to the product intended for, or required by, a customer or the product realization processes. This applies to any intended output resulting from product realization processes.

Potential MAJOR impact – Product includes the output of all processes. You must use the Process Approach

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	1 Scope, 1.1 General - Note 2	
No impact for most organizations		Statutory and regulatory requirements can be expressed as legal requirements.

Statutory / Regulatory = Legal requirements

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**1 Scope, 1.2 Application**	
Added the word "statutory" for clarity in Europe **No impact for most organizations in NA**	Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.	Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

Statutory = Legislative laws
Regulatory = Lower authority laws

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
4 modified requirements	**2 Normative reference**	
Simplification **Dated vs non-dated references** **No impact for most organizations** **Simplified way of saying that dated references must be used as cited, undated must be most current**	The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards. ISO 9000:2000, Quality management systems — Fundamentals and vocabulary.	The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2005 *Quality management systems — Fundamentals and vocabulary.*

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Deleted requirement	**3 Term and Definitions**	
Revised wording **Deleted references to 1994 version of the standard** **No impact for most organizations**	For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used: **supplier → organization → customer** The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".	For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service". **Deleted old terminology used on 1994 version**

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	**4.1 General Requirements**	
Modified "Identify" to "Determine" **No impact for most organizations**	a) Identify the processes needed for the quality management system and their application throughout the organization (see 1.2)	a) Determine the processes needed for the quality management system and their application throughout the organization (see 1.2)

Changed "identify" to "determine" to avoid confusion about labeling processes

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**4.1 General Requirements**	
Added "where applicable" **Simplification.** **Don't have to measure all processes!** **No impact for most organizations**	e) monitor, measure and analyse these processes, and	e) monitor, measure where applicable, and analyse these processes, and

Only need to monitor / measure where applicable

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Revised Note	**4.1 General Requirements - Note 1**	
Better aligned with standard's 8th section "**8.0 Measurement, analysis and improvement**" **Removed "should"** **No impact for most organizations**	Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

Aligns with Section 8 – includes "analysis & improvement"

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**4.1 General Requirements - Note 2**	
Clarification of outsourcing vs purchasing **Potential impact for most organizations**		An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

**Outsourcing vs Purchasing
How many processes do
you outsource?**

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note		**4.1 General Requirements - Note 3 – New**
Must define all of your outsourced processes! **Significant Impact on some organizations** **Will have a SIGNIFICANT impact for anyone who outsources: (training, PM, IA, mfg, design, testing, calibration, purchasing, transport, service, customer service, etc)**		**Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced processes can be influenced by factors such as:** **a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements;** **b) the extent to which the control for the process is shared;** **c) the capability of achieving the necessary control through the application of clause 7.4.**

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 new requirements **Deleted requirement**	**4.2.1 Documentation Requirements – General**	
Revised wording for clarification **No impact for most organizations**	d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4).	c) Documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

Clarification to ensure that records are kept

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Revised note	4.2.1 Documentation Requirements – Note 1	
Greater flexibility in documentation **Nice simplification opportunity** **No impact for most organizations**	Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.	Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

Better definition of what a procedure can cover

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**4.2.3 Control of documents**	
Defines document of external origin better. **Will require access to all relevant docs, incl. 9001:2008, 9000:2005, 19011** **Minor impact for most organizations**	f) to ensure that documents of external origin are identified and their distribution controlled, and	f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

For most organizations this will be a simplification – only need to control those that are needed for your QMS

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 modified requirements	**4.2.4 Control of records**	
Revised wording for clarity **No impact for most organizations**	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

Revised wording for Control of Records

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	5.5.2 Management Representative:	
Management rep position cannot be outsourced! **No impact for most organizations**	"Top management shall appoint a member of management who,…"	"Top management shall appoint a member of the organization's management who,…"

Management Rep must be an employee

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	6.2.1 Human Resources - General	
Revised wording for clarity **No impact for most organizations**	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

Product quality = conformity to product requirements

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note		6.2.1 Human Resources - Note 1
Increases scope to all people performing any task in the QMS! **Will have an impact on most organizations**		Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

Training / Job Description scope has increased

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
No change	**6.2.2 Competence, training and awareness**	
	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken,	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken,

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**6.3 Infrastructure**	
Infrastructure includes IS (verbal, paper, IT) **Some impact across the entire organization (process approach)**	c) supporting services (such as transport or communication).	c) supporting services (such as transport, communication or information systems).

Infrastructure includes IS

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**6.4 Work Environment - Note 1**	
Better defines "work environment" **Allows auditors to investigate EHS issues – could be significant**		The term "work environment" relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).

Defines work environment more completely.

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 new requirements	**7.1 Planning of product realization**	
Revised wording to include planning of measurement activities **No impact for most organizations**	b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;	b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

Need to include measurement activities in the quality plans

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 modified requirements	**7.2.1 Determination of requirements related to the product**	
Revised wording **Clarification – more specific (not just vaguely related . . . actually applies, and necessary)** **No impact for most organizations**	c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization.

Need to determine requirements that are both applicable and necessary (vs related, and anything you can think of)

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**7.2.1 Customer Related Processes - Note 1**	
Better defines post delivery activities **Potentially significant impact on some organizations**		Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Scope includes post-delivery activities

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**7.3.1 Design & Development - Note 1**	
Greater flexibility **No impact for most organizations**		Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.

Guidance on design stages

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**7.3.3 Design & Development - Note 1**	
Guidance **No impact for most organizations**		Information for production and service provision may include details for the preservation of product.

Design output must include preservation

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**7.5.1 Control of production and service provision**	
Clarifies that "release" applies to the product **Some auditors may require evidence of this for all internal processes** **No impact for most organizations**	f) the implementation of release, delivery and post-delivery activities.	f) the implementation of product release, delivery and post-delivery activities.

Clarifies that release applies to the product

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement	**7.5.2 Validation of processes for production and service provision**	
Clarifies special process **Easier because it only focuses on consequent deficiencies** **No impact for most organizations**	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Better definition of special processes

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 new requirements	**7.5.3 Identification and traceability**	
Clarifies that identification applies throughout realization **Clarifies that traceability records must be maintained** **May have an impact on some**	The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

Identification & traceability requirements increased

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 modified requirements	**7.5.4 Customer property**	
Clarified organization's responsibility **No impact for most organizations**	If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

You are responsible for reporting issues with customer-owned property, and maintaining records

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 new requirements	**7.5.5 Preservation of product**	
Clarification of application of preservation **No impact for most organizations**	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Improved definition of preservation.

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
2 deleted requirements **Modified requirement**	**7.6 Control of monitoring and measuring devices**	
Deleted reference **Revised wording for clarity** **Deleted note** **No impact for most organizations**	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). c) be identified to enable the calibration status to be determined; NOTE See ISO 10012-1 and ISO 10012-2 for guidance.	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements c) have identification in order to determine its calibration status;

Deleted reference to 10012 for calibration

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	**8.1 Measurement, Analysis & Improvement - General**	
Clarifies conformity to requirements **No impact for most organizations**	a) to demonstrate conformity of the product,	a) to demonstrate conformity to product requirements,

Product quality = conformity to product requirements

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	**8.2.1 Monitoring & Measurement - Note 1**	
Guidance **May help some understand requirement better** **No impact for most organizations**		Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

Guidance on measuring customer satisfaction

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement **Modified requirement**	**8.2.2 Internal audit**	
Wording made more clear **Records unambiguously required** **No impact for most organizations – depends on your audit records**	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4).

Records of audits & audit results are required

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement **Modified requirement**	**8.2.2 Internal audit**	
Revised wording to include "corrections" as well as "corrective actions" per ISO9000:2005 **Revised note to reflect new standard** **No impact for most organizations**	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.	The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. NOTE See ISO 19011 for guidance.

Correction = fix
Corrective action = RCA & fix root cause
Do you have ISO19011?

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Deleted requirement	**8.2.3 Monitoring and measurement of processes**	
Removed to make application more general – Process Conformity **Potential significant impact for some organizations**	These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Removed emphasis on product conformity and replaced it with process conformity

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New note	\	
Guidance **Potential impact on some organizations**		When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.3 Monitoring and measurement of processes - Note 1

Guidance on choosing which processes to measure

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement **Modified requirement**	**8.2.4 Monitoring and measurement of product**	
Clarifies that intent is to protect the customer **No impact for most organizations**	Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Monitor & measure product in order to protect the customer

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Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
New requirement **2 modified requirements**	8.3 Control of nonconforming product	
Revised wording for clarity **No impact for most organizations** **Simplified control of non-conforming product**	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	8.5.2 Corrective action	
"Causes" **Will impact most organizations**	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.	The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. f) Reviewing the effectiveness of the corrective action taken

Will affect everybody – Improve your root causes analysis!

Requirements Revisions

Change / Rationale	ISO9001:2000	ISO9001:2008
Modified requirement	**8.5.3 Preventive action**	
"Causes" **Will impact most organizations**	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.	The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. f) Reviewing the effectiveness of the preventive action taken

Will affect everybody – Improve your root cause__s__ analysis!

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Summary of Significant Changes

- **Must use process approach to all processes**
- **Expanded scope of outsourced processes (training, mtce, IA, mfg, design, testing, calib, purch, transport, service, customer service, etc)**
- **Root Cause Analysis (Corrective Action & Preventive Action)**
- **Don't have to measure all processes**
- **Expanded definition of Work Environment**
- **Identify status throughout the entire realization process**
- **Post-delivery activities expanded to include non-contractual activities**

What's Next?

- **ISO9001:2008 - Nov, 2008**
- **New applications for registration**
  - No new ISO9001:2000 registrations in 1 year
- **Grace period for upgrades**
  - ISO9001:2000 certificates obsolete in 2 years
- **Modifying policy manual is easy**
- **Implementing process modifications relatively easy**
- **Deploying process approach might be complex**

Training Session – Feb 11-13

- **Topics:**
  - **ISO9001:2008**
  - **Process mapping and analysis**
  - **Process auditing**
- **Where:**
  - **Mississauga**
- **When:**
  - **Feb 11-13 (3 days)**
- **Cost:**
  - **$949 + GST**

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