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Introduction to ISO 9001:2015

Quality Management Systems

June 23, 2015

National Arts Centre, Ottawa, ON

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HUMAN

Today's Agenda

- Welcome and Introductions
- What is ISO
- What is ISO 9001
- Upcoming changes in 2015
- Why implement ISO 9001
- Costs and benefits of implementation
- Steps to implement
- The registration process
- Questions & answers
- Feedback

Canadian Public Sector Excellence Network

Member-based non-profit volunteer organization dedicated to supporting Canadian public sector professionals in implementing organizational excellence.

Membership is free. Go to www.cpsen.ca and click on the membership tab in the top menu.

4 free NCR member morning networking events annually.

Annual NCR Canadian Public Sector Excellence Fair.



**Canadian Public Sector Excellence Network /
Réseau de l'excellence dans le secteur public du Canada**

(Formerly the Canadian Public Sector Quality Association /
auparavant Association canadienne de la qualité dans le secteur public)

Canadian General Standards Board



Mandate

- The CGSB is mandated by an Order in Council and accredited by the Standards Council of Canada (SCC) to provide standards development and conformity assessment services, including programs for certification of personnel, products and services, registration of quality (ISO 9001) and environmental management systems (ISO 14001), as well as advisory services.
- These services are provided in support of socio-economic, regulatory, procurement, health, safety, trade and environmental interests of Canada.

History



Timeline

1934	The Canadian Government Purchasing Standards Committee (CGPSC) established in the National Research Council
1965	CGPSC transferred by order in council to the former Department of Defence Production (<i>now PWGSC</i>)
1980	CGPSC renamed the Canadian General Standards Board (CGSB)
1996	CGSB becomes a registrar for ISO 9001 and ISO 14001
1998	Re-confirmation of role and mandate through an order in council to provide services to the public and private sectors, nationally and internationally.
2012	Mandate shifts to focus service provision to public sector clients.

CGSB - Key Facts



- Staff on Strength : currently 30 FTE Indeterminate
- Network of more than 4,000 volunteers, providing subject matter technical expertise on active CGSB committees and review panels
- Charter participant of the National Standards System (NSS)
- CGSB is the only Federal Standards Development organization Accredited by the Standards Council of Canada (SCC)
- CGSB is the only Federal ISO 9001 and 14001 registrar Accredited by the Standards Council of Canada (SCC)
- CGSB is a unique centre of expertise within the Government of Canada on standards and certification of personnel, products and organizations

HUMAN

Located in the National Capital Region

- ISO 9001 Implementation
- Internal QMS Audit team training
- Integrated Management Systems
- Business Excellence Programs
- Strategic Planning
- Process Improvements
- Assessments and Evaluations
- Customized Quality Workshops

A woman with a stressed expression is the central focus of the image. She is wearing a dark blazer over a striped top. The background is a light-colored wall covered with numerous colorful sticky notes (orange, green, blue, white) and a round analog clock. The overall scene suggests a busy, overwhelming work environment.

New job stressing you out?

Coming this Fall
The ISO 9001 Club
www.iso9001club.com

Awesome start to finish
implementation guidance
at group rates



What Is ISO



International Organization
for Standardization

® Registered Trademark of ISO



ISO 9000 family of standards

- ISO 9000:2005 – Quality Management Systems- Fundamentals & Vocabulary – ISO 9000:2015 to be published same time as ISO 9001
- ISO 9001:2015 - Quality Management Systems– Requirements
- ISO 9004:2009 – Managing for the sustained success of an organization — A quality management approach

Friend of the family

ISO 19011:2011 - Guidelines for auditing management systems



What is a Management System?

A management system represents the policies, procedures and practices that define an organization.

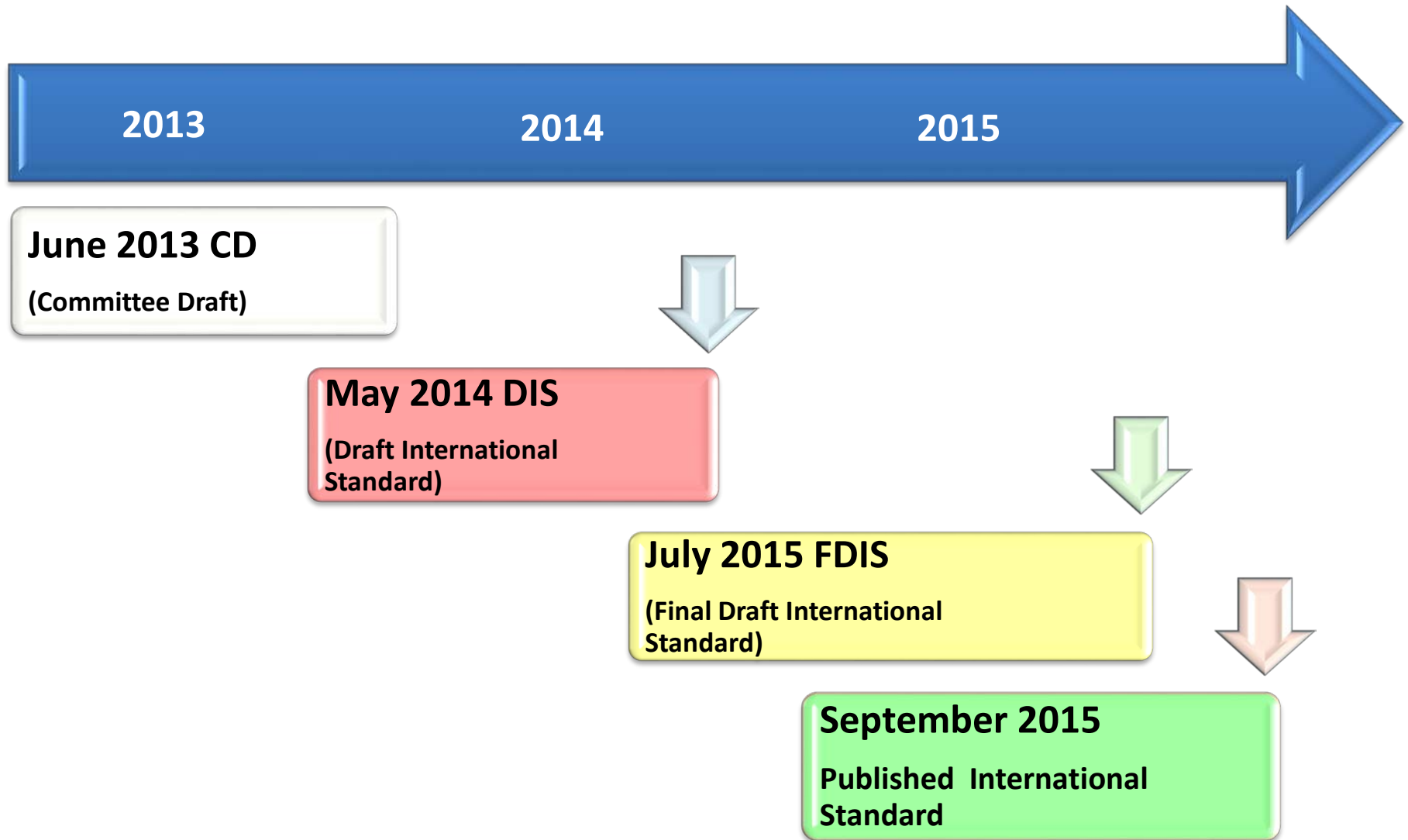
A **quality management** system provides focus on the quality of the product/service and the satisfaction of the customer/client.



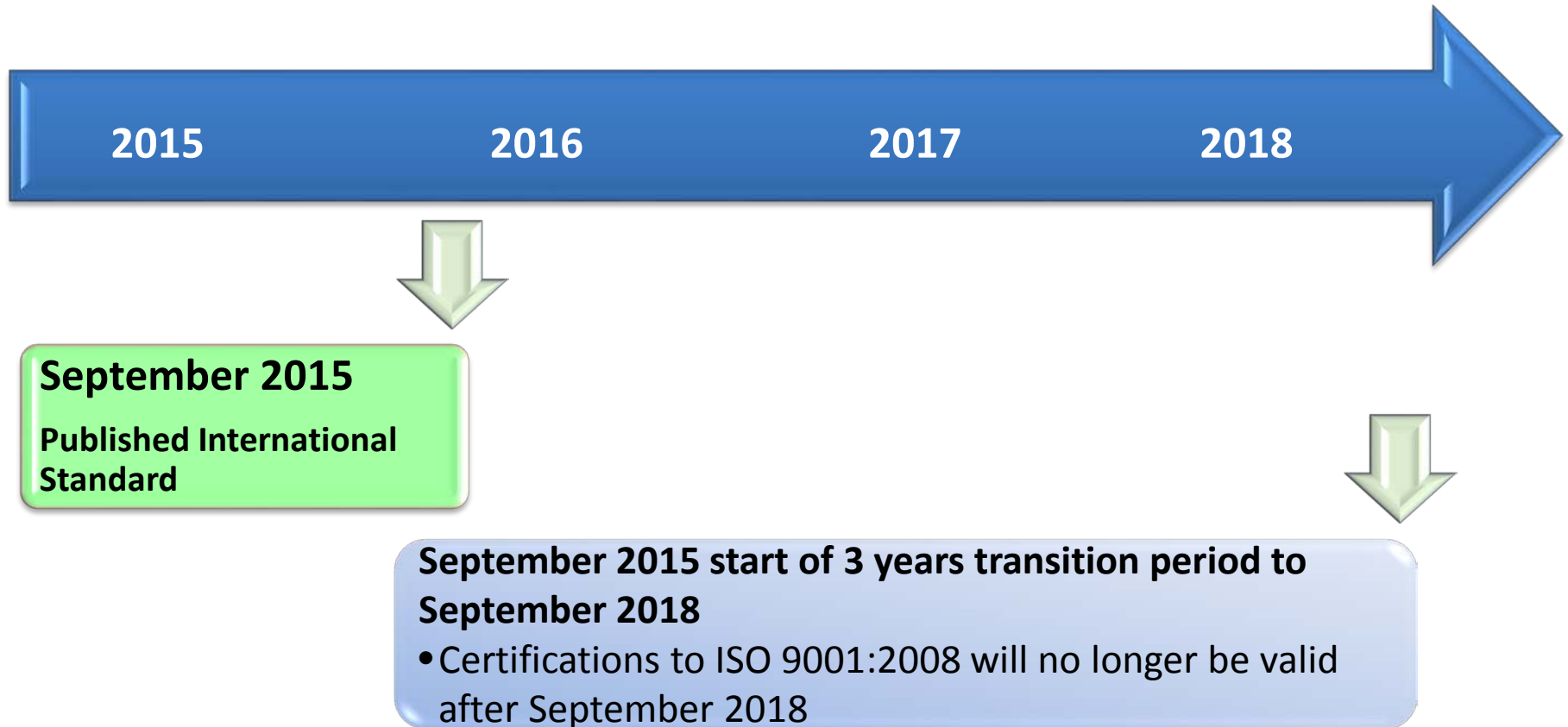
ISO 9001 Standard

- International consensus on good management practices
- Focus on quality on the products or services delivered
- Focus on the customer
- Available to use with all organizations, all sectors, all sizes, anywhere in the world
- Compliance audits
- First published in 1987. Revised in 1994, 2000, 2008, and now 2015.

ISO 9001:2015 Development Timeline



ISO 9001:2015 Certification Transition Timeline



ISO 9001 - Requirements

2008 Version

1. Scope
2. Normative reference
3. Terms and Definitions
4. Quality Management System
5. Management responsibility
6. Resource Management
7. Product realization
8. Measurement, analysis and improvement

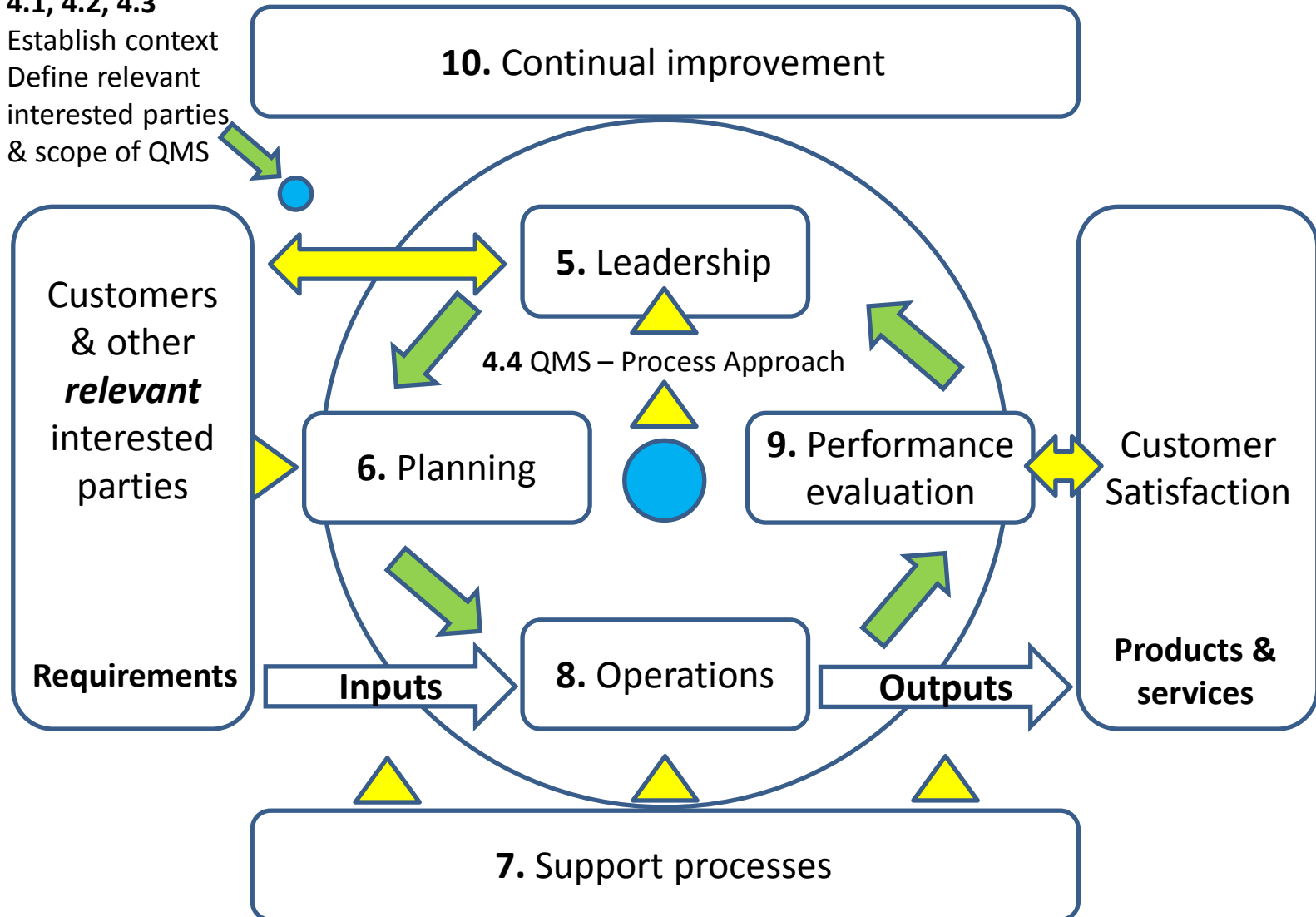
2015 Version

1. Scope
2. Normative reference
3. Terms and Definitions
4. Context of the organization
5. Leadership
6. Planning for the QMS
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Process approach

4.1, 4.2, 4.3

Establish context
Define relevant
interested parties
& scope of QMS





4. Context of the organization

4 Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of QMS

4.4 Quality management system and its processes

Includes “*justification* for any instance where a requirement of (ISO 9001) cannot be applied”.



5. Leadership

5 Leadership

5.1 Leadership and commitment

5.2 Quality policy

5.3 Organizational roles, responsibilities and authorities



6. Planning for the QMS

6 Planning for the QMS

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes



7. Support

7 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information



8. Operation

8 Operation

8.1 Operational planning and control

8.2 Determination of requirements for products and services

8.3 Design and development of products and services

8.4 Control of externally provided products and services

8.5 Production and service provision

8.6 Release of products and services

8.7 Control of non conforming process outputs, products and services



9. Performance evaluation

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review



10. Improvement

10 Improvement

10.1 General

10.2 Non-conformity and corrective action

10.3 Continual improvement

Changes in 2015 – Structure and terminology

ISO 9001:2008	ISO 9001:2015
8 sections	10 sections
Products	Products and services
Exclusions	Not used
Documentation and records	Documented information
Work environment	Environment for the operation of processes
Purchased product	Externally provided products and services
Supplier	External provider

Changes in 2015 – Products and Services

“Products and services include all output categories such as hardware, services, software and processed materials”.

“The organization needs to take into account where a tangible product has some associated intangible service, or an intangible service has some associated tangible product”.

Changes in 2015 – Context of the organization

“4.1 Understanding the organization and its context”.

“4.2 Understanding the needs and expectations of interested parties”.

“...no requirement to consider interested parties....not relevant to the (QMS)....”



Changes in 2015 – Risk-based approach

Risk-based approach replaces Preventative Action.

“Although risks and opportunities have to be determined and addressed, there is no requirement for formal risk management or a documented risk management process”.

Changes in 2015 – Exclusions and Applicability

“...no longer makes specific reference to *exclusions*....”.

Where a requirement can be applied, it is applicable – where it cannot be applied, it is not applicable, but justification has to be stated.



Changes in 2015 – Documented information

“terms *documented procedure* and *record* have both been replaced by *documented information*”.

“...now expressed as a requirement to **maintain** *documented information*”.



Changes in 2015 – Organizational knowledge

“*Organizational knowledge* addresses the need to determine and maintain the knowledge obtained by the organization....to ensure that it can achieve conformity of products and services”.

“The balance between knowledge held....and knowledge made available....is at the discretion of the organization....”.



Changes in 2015 – Control of externally provided products and services

- Purchasing from a supplier
- Arrangement with an associate organization
- Outsourcing of processes and functions
- Any other means

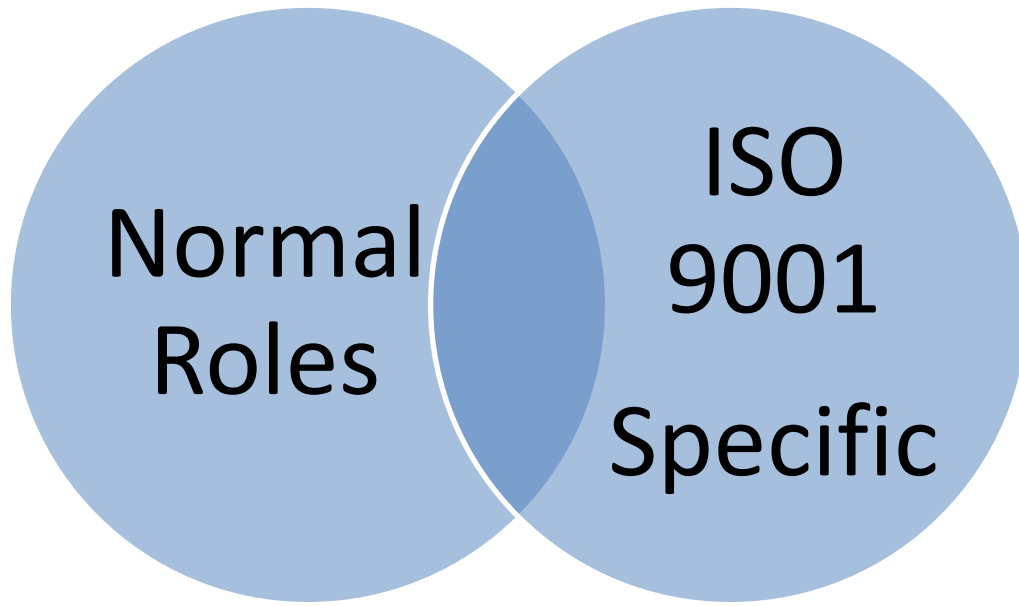
“The organization is required to take a risk-based approach to determine the type and extent of controls appropriate....”.

Why Implement ISO

1. Make organization more efficient and effective
2. Provide perceptible value to current and potential customers (promotion)

Why did (or does) your organization want to implement ISO 9001?

Cost To Implement ISO



Internal Costs

- Management Representative
- Administration
- Implementation Team
- Management Team
- All Staff

External Costs

- External Guide – if required, may reduce internal times
- Registrar – if decision to become certified
- Additional training – if required, ISO 9001 related, job related

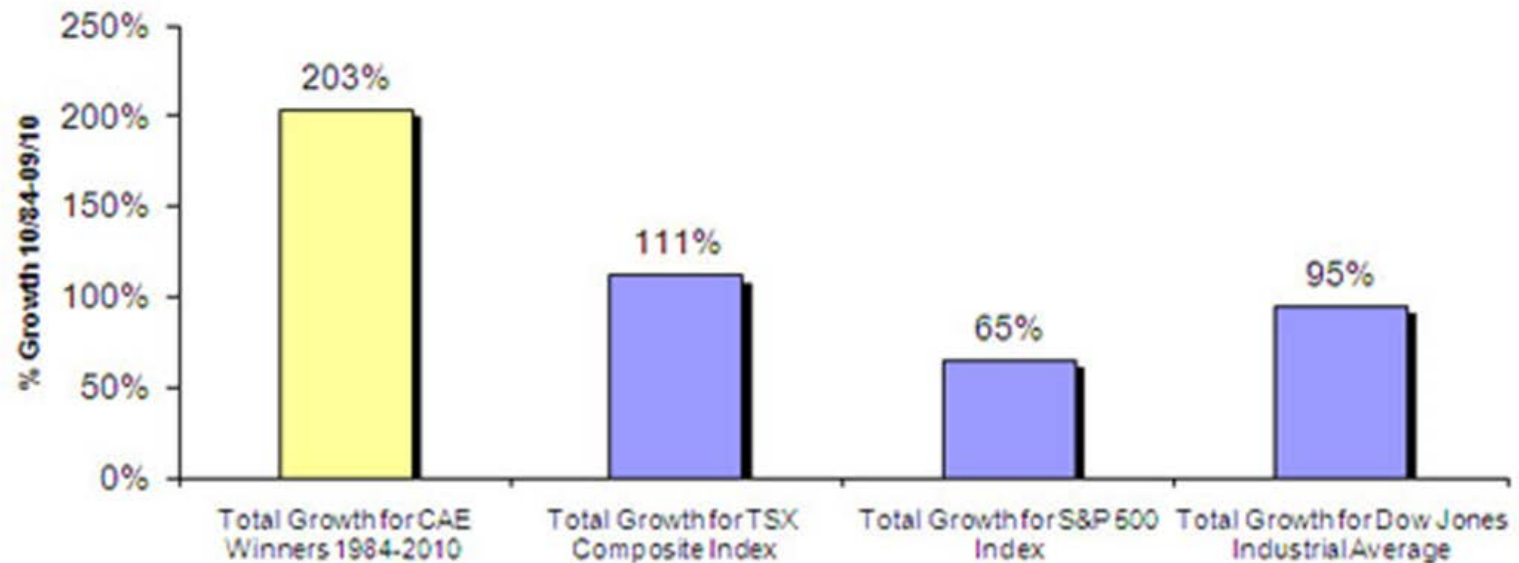
Benefits of implementing ISO 9001

- More structured and discipline
- Proactive rather than reactive
- Opportunities to do more with less
- Increased process efficiencies
- Increased employee morale
- Increased confidence from your market

Benefits of Implementing ISO 9001

Quality Award Winners perform better

Comparison of Investment Growth for
CAE Award Winners 1984-2010
(as at September 1, 2010)



Steps to Implement

1. Planning

- Gap analysis
- Implementation team setup
- Management team setup
- Find your registrar

2. Documentation and Development

- Quality policy manual
- Procedures
- Instructions
- Forms and templates

3. Training & Implementation

- Train employees
- Follow your documented system
- Develop what's not there

4. Assessment & Monitoring

- Departmental monitoring
- Management reviews
- Internal audits
- Certification audit



The Registration Process

1. Organization selects a registrar and completes a profile
2. Nature of registration services are selected for a 3 year period, initial dates are agreed upon, and a contract for services signed
3. Registration is a two stage process:
 - 1.Document Review (on-site or off-site)
 - 2.Implementation Audit (on-site)

The Registration Process

4. Depending upon results:

- a) If minor nonconformities found, organization is asked to email acceptable corrective actions
- b) If major nonconformities found, organization asked to correct and schedule a follow-up visit

5. When nonconformities corrected and/or acceptable corrective actions sent, organization is recommended for registration

The Registration Process

6. Sample maintenance audits completed annually or semi-annually
7. Re-registration audit re-applied every 3 years

Note: Registrars are themselves accredited by standard making bodies around the world and bound by an international accreditation process. In other words, even the auditor is audited.

Questions & Answers



Ask Us – we'll stick around

Want to know more about **CGSB** and certification to ISO 9001?

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Website: <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/index-eng.html>



Want to know more about **HUMAN** and implementation guidance for ISO 9001?

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President

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E-mail: mhart@human.ca

Website: www.human.ca

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Thank you for coming

- Please fill out the CPSEN feedback form before you leave.
- You're welcome to stick around and network.
- Don't forget – the best way to learn about future CPSEN events is to sign up as a member at www.cpsen.ca.



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