Background to the changes

– ISO survey 2013  1.1m of 1.5m certificates were ISO 9001.

– The last major revision was in 2000 (minor changes in 2008)

– Multiple management system standard certifications

– Changes in the business environment

– Provide a core and stable set of requirements for the next 10 years.
– Remain generic and relevant to all sizes and types of organization operating in any sector.
– Maintain the current focus on effective process management to produce desired outcomes.
– Take account of changes in quality management systems practices and technology since the last major revision in 2000.
– Reflect changes in the increasingly complex, demanding and dynamic environments in which organizations operate.
– Enhance compatibility and alignment with other ISO management system standards.
– Facilitate effective organizational implementation and effective conformity assessment by first, second and third parties.
ISO 9001:2015 transition timeline

- **June 2012**: Draft design spec. and WD0
- **December 2012**: Approved design spec. and WD1
- **April 2013**: CD for comment and ballot
- **May 2014**: ISO/DIS 9001:2015 published for comment (3 months)
- **July 2015**: ISO/FDIS 9001:2015 publication
- **September 2015**: Proposed ISO 9001:2015 publication
- **Proposed Transition Period**: 3 years from standard publication

**Improving performance, reducing risk**
Overview of Annex SL

Annex SL - a framework for a generic management system. However, it requires the addition of discipline-specific requirements to make a fully functional standard.
The major clause numbers and titles of all management system standards will be identical. They are:

Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement.
Management system standards

Common structure for management system standards

PLAN
4. CONTEXT OF THE ORGANIZATION
5. LEADERSHIP
6. PLANNING
7. SUPPORT

DO
8. OPERATION

CHECK
9. PERFORMANCE EVALUATION

ACT
10. IMPROVEMENT
ISO 9001:2015 – Structure and content

PLAN

4. CONTEXT OF THE ORGANIZATION
   - Understanding of the organization and its context
   - Needs and expectations of interested parties
   - Scope of management system
   - QMS and its processes

5. LEADERSHIP
   - Leadership and commitment
   - Policy
   - Roles, responsibilities and authorities

6. PLANNING
   - Actions to address risk and opportunities
   - Quality objectives & planning to achieve them
   - Planning of changes

7. SUPPORT
   - Resources
   - Competence
   - Awareness
   - Communication

8. OPERATION
   - Operational planning and control
   - Requirements for products and services
   - Design and development of products and services
   - Control of externally provided processes, products and services
   - Production and service provision
   - Release of products and services
   - Control of nonconforming outputs

DO

CHECK

ACT

9. PERFORMANCE EVALUATION
   - Monitoring, measurement, analysis and evaluation
   - Internal audit
   - Management review

10. IMPROVEMENT
    - General
    - Nonconformity and corrective action
    - Continual improvement
## ISO 9001:2015
### Key areas of change to requirements

<table>
<thead>
<tr>
<th>Clause number: Title</th>
<th>Item</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Scope</td>
<td>Scope</td>
<td>Some clarification stating all requirements in the standard relate to all organizations</td>
</tr>
<tr>
<td>2: Normative references</td>
<td>Normative references</td>
<td>ISO 9000 remains as the normative reference</td>
</tr>
<tr>
<td>3: Terms and definitions</td>
<td>Terms and definitions</td>
<td>Refer to ISO 9000:2015</td>
</tr>
<tr>
<td>4: Context of the organization</td>
<td>Context of the organization</td>
<td>New requirements</td>
</tr>
<tr>
<td>5: Leadership</td>
<td>Leadership</td>
<td>Greater area of focus, integral to business processes and accountability</td>
</tr>
<tr>
<td>6: Planning</td>
<td>Risks/Opportunities Planning of changes</td>
<td>New requirement Greater area of focus</td>
</tr>
<tr>
<td>7: Support</td>
<td>Knowledge Documented Information</td>
<td>New requirement New terminology</td>
</tr>
<tr>
<td>8: Operation</td>
<td>Outsourcing Design and development Post-delivery activities</td>
<td>New requirement Requirements made clearer Greater area of focus</td>
</tr>
<tr>
<td>9: Performance evaluation</td>
<td>Analysis and evaluation Management review</td>
<td>Greater area of focus especially on performance Greater area of focus on risk(s) and performance</td>
</tr>
<tr>
<td>10: Improvement</td>
<td>Continual improvement</td>
<td>Clarification on approach and structure, removal of preventive action</td>
</tr>
</tbody>
</table>
Improving performance, reducing risk

**4. CONTEXT OF THE ORGANIZATION**
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**7. SUPPORT**
- Resources
- Competence
- Awareness
- Communication
- Documented information
Context of the Organisation

- External issues
- Internal issues

**determine:**
- Interested parties and their requirements
- Monitor
- Review

**understand:**
- Purpose
- Strategic direction

Improving performance, reducing risk
PESTLE

Example:

<table>
<thead>
<tr>
<th>Political</th>
<th>Economic</th>
<th>Social</th>
<th>Technology</th>
<th>Legal</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>New tax rules</td>
<td>Economic growth rates</td>
<td>Changing population demographics</td>
<td>Process automation</td>
<td>Labour laws</td>
<td>Changes in weather and climate</td>
</tr>
<tr>
<td>Government funding</td>
<td>Unemployment rates</td>
<td>Changing social attitudes</td>
<td>Rate of innovation</td>
<td>Discrimination laws</td>
<td>Waste management</td>
</tr>
<tr>
<td>Pending elections</td>
<td></td>
<td></td>
<td>New materials</td>
<td>H&amp;S Regulatory requirements</td>
<td></td>
</tr>
</tbody>
</table>

- Used to assess the external factors in relation to the organization’s business environment.
Interested Parties – stakeholder map

- Providers
- Users/Beneficiaries
- Influencers
- Governance
- Stakeholder identification
- Suppliers
- Partners
- Staff
- Consumers
- Customers
- Local interest groups
- Media
- Trades union
- Suppliers
- Regulatory
- Steering groups
- Boards
Risks and opportunities – New requirement

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ISO 9001:2015 requirements

- Determine external and internal issues (4.1)
- Determine relevant interested parties and their requirements (4.2)

- Consider the issues and requirements and determine the risks and opportunities that need to be addressed (6.1.1)

- Plan actions to address these risks and opportunities and integrate and implement the actions into the QMS processes (6.1.2) (8.1)
- Plan how to evaluate the effectiveness of these actions (6.1.2)

- Evaluate performance (9.1)
- Review information, including trends and indicators on the effectiveness of actions taken to address risks and opportunities (9.3)
ISO 9001:2015 does not require formal risk management, but it states that “Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services”.

Risk assessment matrix

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Critical</th>
<th>Significant</th>
<th>Marginal</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>High</td>
<td>High</td>
<td>Serious</td>
<td>Medium</td>
</tr>
<tr>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Serious</td>
<td>Medium</td>
</tr>
<tr>
<td>Significant</td>
<td>High</td>
<td>Serious</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Low</td>
<td>Serious</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Very low</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Almost impossible</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>
Leadership
Top management....

by taking accountability for ..... ensuring that .... promoting the use of .... by engaging, directing and supporting persons to ...
ensuring ... risks and opportunities .. are determined and addressed

........... shall establish, implement and maintain ...
shall assign the responsibility and authority for: ....
 ........ shall review the organization's QMS
Leadership - Greater focus

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   - Communication
   - Documented information
Leadership Overview

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles, responsibilities and authorities

Examples of key Requirements:

• Demonstrate leadership and commitment to QMS & to Customer Focus
• Establish & Link policy and objectives to organizational strategy and context
• Promote awareness of the process approach and risk based thinking
• Ensure risks are determined and addressed
• Be accountable for the effectiveness of the QMS, review its performance and ensure it achieves its intended results
Summary

- Considerable change to the business environment
- Extensive changes to structure and contents to ISO 9001:2015
- The introduction of the new high-level structure and identical core text from Annex SL
- Most ISO 9001:2008 requirements carried forward to 2015 revision and substantially unchanged.
- ISO 9001:2015 introduces a number of new requirements.
- These changes are the next step in the evolution of ISO 9001 and aim to truly integrate quality management into the organization’s business management system.
There are a range of resources available to help you understand what the revised ISO 9001 will mean to your organisation.

www.lrqa.com/isostandardsupdate
LRQA website featuring news, technical information and interviews about all of the major ISO standard revisions

www.iso.org
International Organization for Standardization

www.iioc.org
Independent International Organisation for Certification

www.irca.org
International Register of Certified Auditors

www.iaf.nu
International Accreditation Forum

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