ISO 9001:2015
Quality Management System Standard
Overview

By
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ISO 9000, the world’s most popular standard for quality management, is now under final review, with an updated version ISO 9001:2015 due to be available by the end of 2015.

Note:
Here are some of the important changes to be aware of:

- A greater emphasis on risk-based thinking
- More focus on achieving value for the company and its customers
- Increased flexibility regarding use of documentation
- More friendly to “service” type businesses
ISO 9001:2015 Revision

• Business has changed radically since the last major revision in 2000; technology has changed how we work, geographical boundaries are almost insignificant in today’s global economy, supply chains are increasingly complex and the information available has multiplied exponentially.

• To ensure that ISO 9001 continues to serve the business community and maintain its relevance in today’s market place, the standard is being revised to address the change in the business world.

• One thing remains constant, to be successful, businesses have to adapt to meet the growing needs of customers. ISO was originally written with the customer in mind and that remains the priority for ISO 9001:2015.
ISO 9000:2015
Final Draft International Standard (FDIS)

• The Final Draft International Standard (FDIS) of ISO 9001:2015, the world’s first quality management standard has been published.

• This is the final stage in the revision journey and means you can be confident that the information contained in the FDIS will be in line with the final version which will be published in September.

• Developed with today’s complex marketplace in mind, ISO 9001:2015 provides an integrated approach to quality management – putting quality at the heart of business.

• It’s a great time to get ahead of your competition and learn about the new standard.
Introduction to ISO 9000:2015

• Over the years ISO has published many management system standards for topics ranging from quality and environment to information security and business continuity management.

• In the past, despite sharing common elements, ISO management systems standards have all had different structures.

• This, in turn, results in some confusion and difficulties at the implementation stage.
• In order to understand the importance of structure in management system standards, we will take a step back and look at ISO’s definition of a management system and some of the benefits of implementing an effective management system.

• ISO defines a management system as a set of procedures an organization needs to follow in order to meet its objectives.

• A management system standard provides a model to follow when setting up and operating a management system.
A New High-Level Structure

• Most organizations have more than one management system standard to implement and certify.

• Doing this individually takes up a lot of extra time and resources, so there is a clear need to find a way of integrating and combining the standards in the best possible way.

• The management system standards to date each presents different structures, requirements and terminology, so integration has proved challenging.

• In order to address this problem, ISO developed Annex SL – the framework for a generic management system and the blueprint for all new and revised management system standards going forward.

• To address industry specific needs, additional requirements for individual sectors will be added to this generic framework.
How will this affect organizations?

• This high level structure will be rolled out across all new and revised management system standards to ensure consistency and compatibility.

• With Annex SL in place, management system implementers can look forward to less conflicts, duplication, confusion and the misunderstandings that took place as a result of different management system standard structures.

• Management system auditors will now use a core set of generic requirements across disciplines and industry sectors.
1. Introduction

The main changes in the new version of ISO 9001 :2015 are;
• the adoption of the HLS as set out in Annex SL of ISO Directives Part One,
• an explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach,
• fewer prescribed requirements,
• less emphasis on documents,
• improved applicability for services,
• a requirement to define the boundaries of the OMS,
• increased emphasis on organizational context,
• increased leadership requirements,
• greater emphasis on achieving desired outcomes to improve customer satisfaction.

Relevant interested parties who will benefit from this guidance include;
• organizations using ISO 9001 :2008,
• accreditation bodies (ABs),
• certification bodies (CBs),
• training bodies and consultants.
2. Transition

- The International Accreditation Forum (IAF) which monitors certifications/accreditations and the ISO Committee on Conformity Assessment (CASCO) have agreed a three year transition period from the publication date of ISO 9001:2015.

- The transition period will begin in September 2015 and end in September 2018.
3. Guidance for Transition

- For any organization the degree of change necessary will be dependent upon the:
  - maturity and effectiveness of the current management system,
  - organizational structure and practices,
  - therefore an impact assessment is strongly recommended in order to identify realistic resource and time implications.
3. Guidance for Transition
(Continued)

- 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 organization,
  - update existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness,
  - where applicable, work with your certification body for transition arrangements.
4. IAF Transition Guidance

- IAF has agreed an outline implementation plan (September 2015 – September 2018) to ensure a smooth migration of accredited certification to ISO 9001:2015 after consultation with international groupings representing quality management system or auditor certification bodies, and industry users of ISO 9001 certification services.
Introduction to the Clauses

• **Organizational Context** (Internal culture & external factors)

• **The ISO Standards for Quality Management Integration**
  – ISO 9000 Quality Management System
  – ISO 9001 Requirements for Products & Services
  – ISO 9004 Management for Sustained Success (*Is much like Baldrige*)

• **Process Approach** (Process linkage between clauses)

• **Plan-Do-Check-Act Cycle** (ISO 9001:2015 is PDCA focused)

• **Risk-based Thinking** (The impact of uncertainty)

• **Compatibility with other Management System Standards** (Aligning with other industry standards and approaches)
ISO 9004:2009

Continual Improvement of the quality management system leading to sustained success

ISO 9004
Clause 4
Managing for the sustained success of an organization

ISO 9001
Clause 6
Management responsibility

ISO 9001
Clause 6
Resource management

ISO 9001
Clause 7
Product realization

ISO 9004
Clause 7
Process management

ISO 9004
Clause 8
Measurement, analysis, and improvement

ISO 9004
Clause 9
Improvement, innovation and learning

ISO 9004
Clause 5
Strategy and policy

Note:

Organization's Environment

Interested Parties

Customers

Needs & expectations

Needs & expectations

Product

Satisfaction

Foundation: Quality management principles (ISO 9000)

Key

Information flow

Value-adding activities
ISO 9004:2009

4 Managing for the sustained success of an organization
   4.1 General
   4.2 Sustained success
   4.3 The organization's environment
   4.4 Interested parties, needs and expectations

5 Strategy and policy
   5.1 General
   5.2 Strategy and policy formulation
   5.3 Strategy and policy deployment
   5.4 Strategy and policy communication

6 Resource management
   6.1 General
   6.2 Financial resources
   6.3 People in the organization
   6.4 Suppliers and partners
   6.5 Infrastructure
   6.6 Work environment
   6.7 Knowledge, information and technology
   6.8 Natural resources

7 Process management
   7.1 General
   7.2 Process planning and control
   7.3 Process responsibility and authority

ISO 9001:2015

4 Context of the organization

5 Leadership

6 Planning for the quality management system

7 Support

8 Operations

9 Performance evaluation

10 Improvement

4.1, 4.2, 4.3 Establish context, define relevant interested parties & scope of QMS

10 Continual Improvement

5 Leadership

4.4 QMS – General & process approaches

6 Planning

9 Performance evaluation

8 Operations

7 Support processes

Customer & other relevant interested parties

Requirements

Customer Satisfaction

Products & services

 Inputs

 Outputs

Value-adding activities

Information flow
Plan-Do-Check-Act for ISO 9001:2015

Act - incorporate improvement as necessary

Plan the process - (Extent of planning on RISK)

DO - carry out the process

Check - monitor/measure process performance

Interaction with other processes

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The 10 Clauses of ISO 9001:2015
The Ten Clauses

• Clause 1: Scope
• Clause 2: Normative references
• Clause 3: Terms and definitions (any new terms)
• Clause 4: Context of the organization
• Clause 5: Leadership
• Clause 6: Planning
• Clause 7: Support
• Clause 8: Operation
• Clause 9: Performance evaluation
• Clause 10: Improvement
Clause 1: Scope

- Clause 1: Scope
  - The scope sets out the intended outcomes of the management system. The outcomes are industry specific and should be aligned with the context of the organization (clause 4).
Clause 2: Normative

• Clause 2:
  – Normative references Provides details of the reference standards or publications relevant to the particular standard.
Clause 3: Terms & Definitions

• Clause 3:
  – Terms & Definitions details terms and definition applicable to the specific standard in addition to any formal related terms and definitions standard.
Clause 4: Context of the Organization

• Clause 4 consists of four sub-clauses:
  – 4.1 Understanding the organization and its context
  – 4.2 Understanding the needs and expectations of interested parties
  – 4.3 Determining the scope of the management system
  – 4.4 The management system

As the flagstone of a management system, clause 4 determines why the organization is here.

As part of the answer to this question, the organization needs to identify internal and external issues that can impact on its intended outcomes, as well as all interested parties and their requirements.

It also needs to document its scope and set the boundaries of the management system – all in line with the business objectives.
Clause 5: Leadership

- Clause 5 comprises three sub-clauses:
  - 5.1 Leadership and commitment
  - 5.2 Policy
  - 5.3 Organizational roles, responsibilities and authorities

The new high level structure places particular emphasis on leadership, not just management as set out in previous standards.

This means top management now has greater accountability and involvement in the organization’s management system.

They need to integrate the requirements of the management system into the organization’s core business process, ensure the management system achieves its intended outcomes and allocate the necessary resources.

Top management is also responsible for communicating the importance of the management system and heighten employee awareness and involvement.
Clause 6: Planning

- Clause 6 includes two sub-clauses:
  - 6.1 Actions to address risks and opportunities
  - 6.2 Management system objectives and planning to achieve them

Clause 6 brings risk-based thinking to the front. Once the organization has highlighted risks and opportunities in clause 4, it needs to stipulate how these will be addressed through planning.

The planning phase looks at what, who, how and when these risks must be addressed. This proactive approach replaces preventative action and reduces the need for corrective actions later on.

Particular focus is also placed on the objectives of the management system. These should be measurable, monitored, communicated, aligned to the policy of the management system and updated when needed.
Clause 7: Support

• Clause 7 consists of five sub-clauses:
  – 7.1 Resources
  – 7.2 Competence
  – 7.3 Awareness 7.4 Communication
  – 7.5 Documented information

After addressing the context, commitment and planning, organizations will have to look at the support needed to meet their goals and objectives.

This includes resources, targeted internal and external communications, as well as documented information that replaces previously used terms such as documents, documentation and records.
Clause 8: Operation

• Clause 8 has one sub-clause:
  – 8.1 Operational planning and control

The bulk of the management system requirements lies within this single clause.

Clause 8 addresses both in-house and outsourced processes, while the overall process management includes adequate criteria to control these processes, as well as ways to manage planned and unintended change.
Clause 9: Performance Evaluation

- Clause 9 is formed of three sub-clauses:
  - 9.1 Monitoring, measurement, analysis and evaluation
  - 9.2 Internal audit
  - 9.3 Management review

Here organizations need to determine what, how and when things are to be monitored, measured, analyzed and evaluated.

An internal audit is also part of this process to ensure the management system conforms to the requirements of the organization as well as the standard, and is successfully implemented and maintained.

The final step, management review, looks at whether the management system is suitable, adequate and effective.
Clause 10: Improvement

- With two sub-clauses in place, Clause 10 looks at how non-conformities and corrective actions should be managed:
  - 10.1 Non-conformity and corrective action
  - 10.2 Continual improvement

In an ever-changing business world, not everything always goes according to plan. Clause 10 looks at ways to address non-conformities and corrective action, as well as strategies for improvement on a continual basis.
Additional Benefits of Using Management System Standards.
Benefits of the New Standard

• **Bringing Quality and Continuous Improvement into the heart of your business**
  The revised standard will ensure that quality management is now completely integrated and aligned with the business strategies of your organization.

• **Leadership**
  Greater involvement in the management system by the leadership team will ensure the whole organization will be motivated towards the organizations goals and objectives.

• **Introduction of Risk & Opportunity Management**
  Reinforces use of the management system as a governance tool and will help identify business opportunities that contribute to bottom line improvements.

• **An Integrated Approach**
  With the new structure applicable to all new ISO management systems standards it well be much easier to implement multiple, integrated management systems.
The New ISO 9001: 2015 Structure

• The new standard expected in September 2015, will be based on Annex SL – the new high level structure (HLS) that brings a common framework to all management system standards. This helps to keep consistency, alignment different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards.

The key changes in the standard are:

– The emphasis on leadership
– The focus on risk management
– Emphasis on objectives measurement and change
– Communication and awareness
– Fewer prescriptive requirements

• With the new standard in place, organizations will find it easier to incorporate their quality management system into the core business processes and gain greater business benefit.
Other Benefits

• **Improved Business Performance**
  – Using standards ensures all business processes are integrated and aligned with the business strategies of the organization.
  – Used as a business management tool, this will improve performance, remove complexity, drive real value and embed continual improvement.

• **Improved Risk and Opportunity Management**
  – The requirements to identify risks and opportunities affecting an organization ensures they are managed more effectively thereby improving operational efficiency, reducing duplication, saving both time and money.

• **Enhanced Reputation**
  – Adopting a standard sends a clear message to existing and prospective customers that the organization is taking a leading, innovative and proactive approach to managing the business.
Other Benefits
(Continued)

• **Increased Efficiency**
  – By providing a robust framework and focus, standards can increase operational efficiency, reducing expensive mistakes thereby saving time and money.

• **Increased Engagement**
  – By adopting a management system, an organization can ensure all employees are working to common goals driven from the business strategy.

• **Improved Integration**
  – The new common structure for all management system standards will ensure that integration of more than one system will be smoother, without investing a lot of extra time and money.
Discussion
References

• http://www.iso.org
  – ISO 9000:2008
  – ISO 9000:2015 (07-10-14 draft)

• http://www.bsigroup.com

• http://www.dnvgl.com

• http://www.saiglobal.com