
ISO 9001:2015

Preparing for the next revision of the ISO 9001 standard
on quality management systems



Agenda—Countdown to 2015

- ISO 9001 Facts
- ISO 9001 Timeline
- Standards Development Process
- ISO 9001 What to Expect
- Transition from 2008 to 2015

References

- *ISO/IEC Directives, Part 1, Consolidated ISO Supplement—Procedures Specific to ISO*, fourth edition, 2013 <http://bit.ly/ISOdirectives> refer to Annex SL
- Hay Hampton, Debra **A Step Forward** <http://rube.asq.org/quality-progress/2014/03/standards/a-step-forward.pdf>
- Liebesman, Sandford **Brought into Focus** <http://rube.asq.org/quality-progress/2014/09/iso-9000/brought-into-focus.pdf>
- Paul Palmes A New Look <http://rube.asq.org/quality-progress/2014/09/standards/a-new-look.pdf>
- West, Jack and Cianfrani, Charles **Managing the System** <http://asq.org/quality-progress/2014/08/standards-outlook/managing-the-system.html>
- West, Jack, Hunt, Lorri and Cianfrani, Charles **Changes Ahead** <http://asq.org/quality-progress/2014/02/standards-outlook/change-ahead.html>

Disclaimer

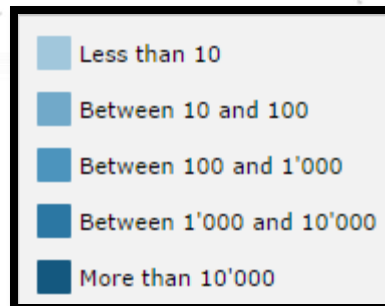
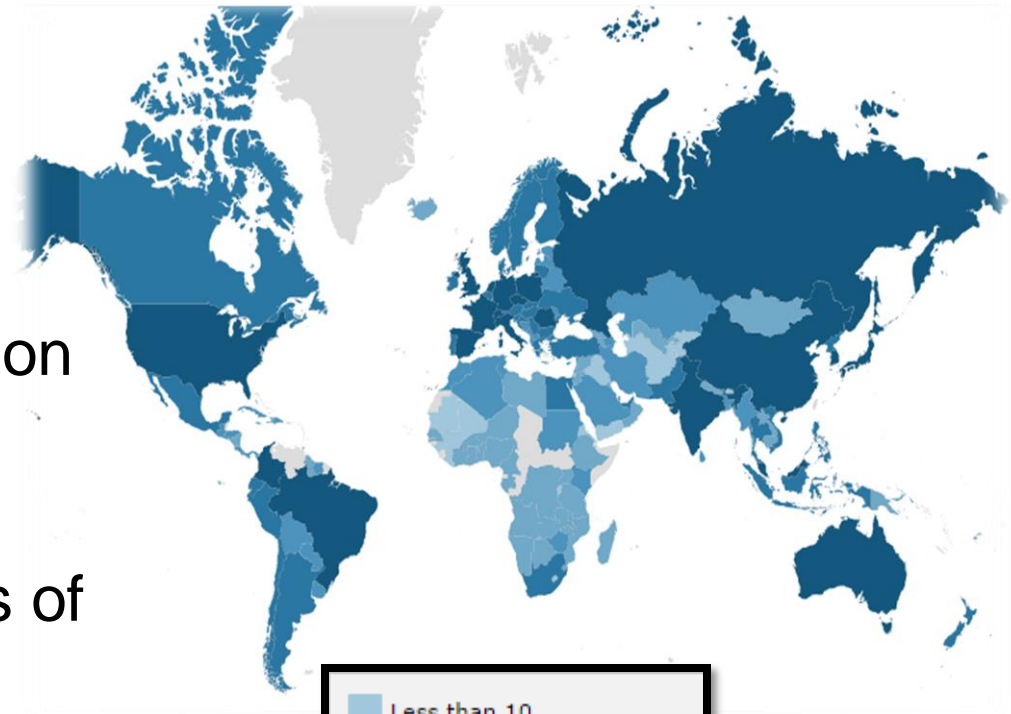
- Revisions are still underway, this presentation does not represent final decisions regarding ISO9001-2015 or should content of this presentation be used in making changes to your existing quality systems.

ISO 9001 Facts

<http://videos.asq.org/standards-and-auditing>

International standard for quality management systems (QMS)

- Originally published in 1987
- Underwent major revision in 2000
- Applies to any organization regardless of size or industry
- 1,541,983 certificates issued in over 170 countries (2013)



Reasons for 2015 Revision

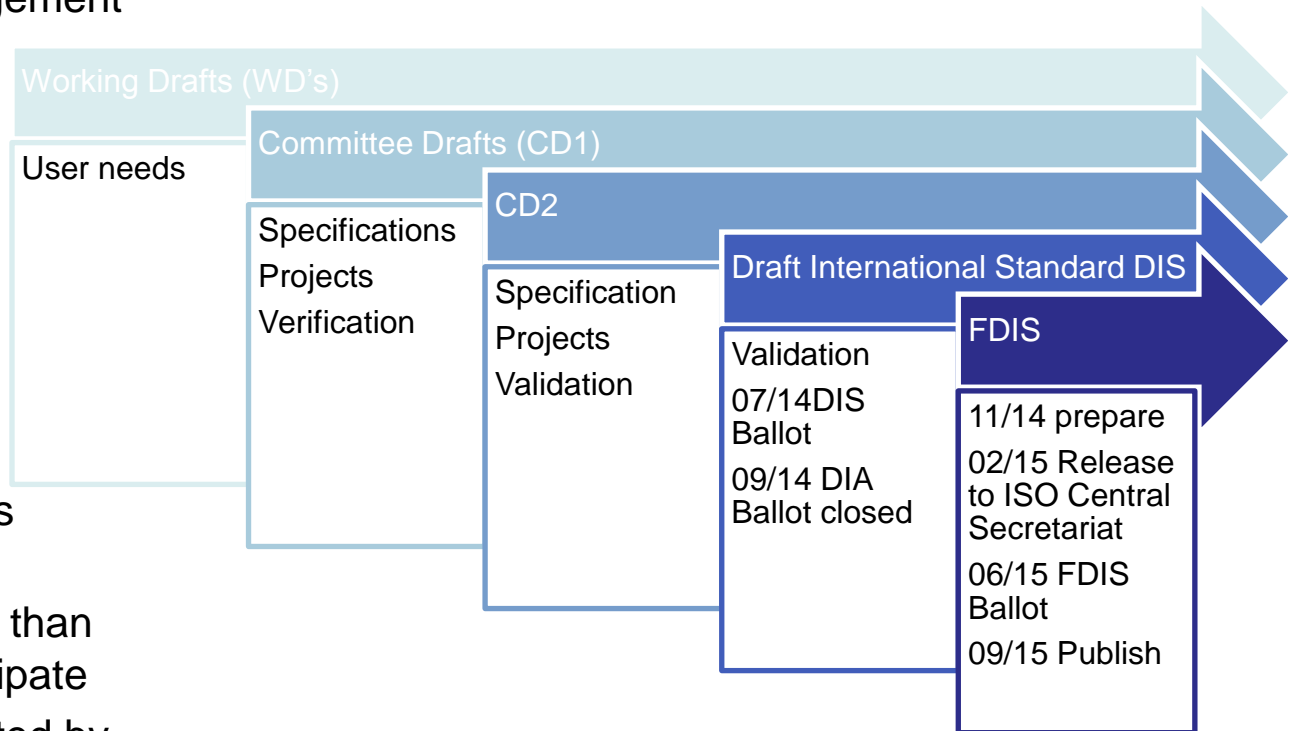
- Adapt to a changing world – online versus paper
- Maintain relevance for increasing diversity of 9001 users
 - Increased service organizations
 - Globalization and complex supply chains
 - Greater information availability
- Facilitate integration with other management system standards – ISO9001
 - ISO14001 Environmental
 - OHSAS 18001 Health and safety
 - ISO27001 Information Systems
 - ISO22301 Societal Security
 - ISO39001 Road Safety Mgmt.
 - ISO13485 Medical Devices
 - ISO50001 Energy Management
 - ISO30301 Records Management
 - ISO20121 Sustainable Event Mgmt.
 - ISO22000 FSMS

The Standards Development Process

1. Annex SL is a structure applied to all Management System Standards

- Common terms
- Core text and definitions
- High-level structure

2. ISO standards are based on consensus
3. National standards institutes from more than 160 countries participate
4. Experts are nominated by these standards bodies to work on technical committees (TCs), subcommittees, or project committees



ISO is an acronym derived from the Greek word "isos," which means "equal."

www.iso.org



The 2015 Revision: What to expect

- More emphasis on
 - Increased focus on customer satisfaction
 - Risk-based thinking (replaces preventive action)
 - QMS policy alignment with company strategies
 - Leadership engagement replaces management representative
- More flexibility around documentation
- Improved applicability for service organizations
- Terminology changes
 - “Documented information” replaces “documents and records”
 - “Outsourcing” is replaced by “external provision”

<http://asq.org/standards-iso-9001-2015.html>



The 2015 revision: what to expect

- Annex SL <http://bit.ly/ISOdirectives> refer to Annex SL
 - No requirement to change QMS documentation to match new numbering scheme
 - Reference Annex A.1 Structure and Terminology
 - Use of new common structure for management system standards for smoother integration
 - Standardized core text, structure, and definitions (30% of standards will be identical text)

Annex SL

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

Increase from 8 clauses to 10

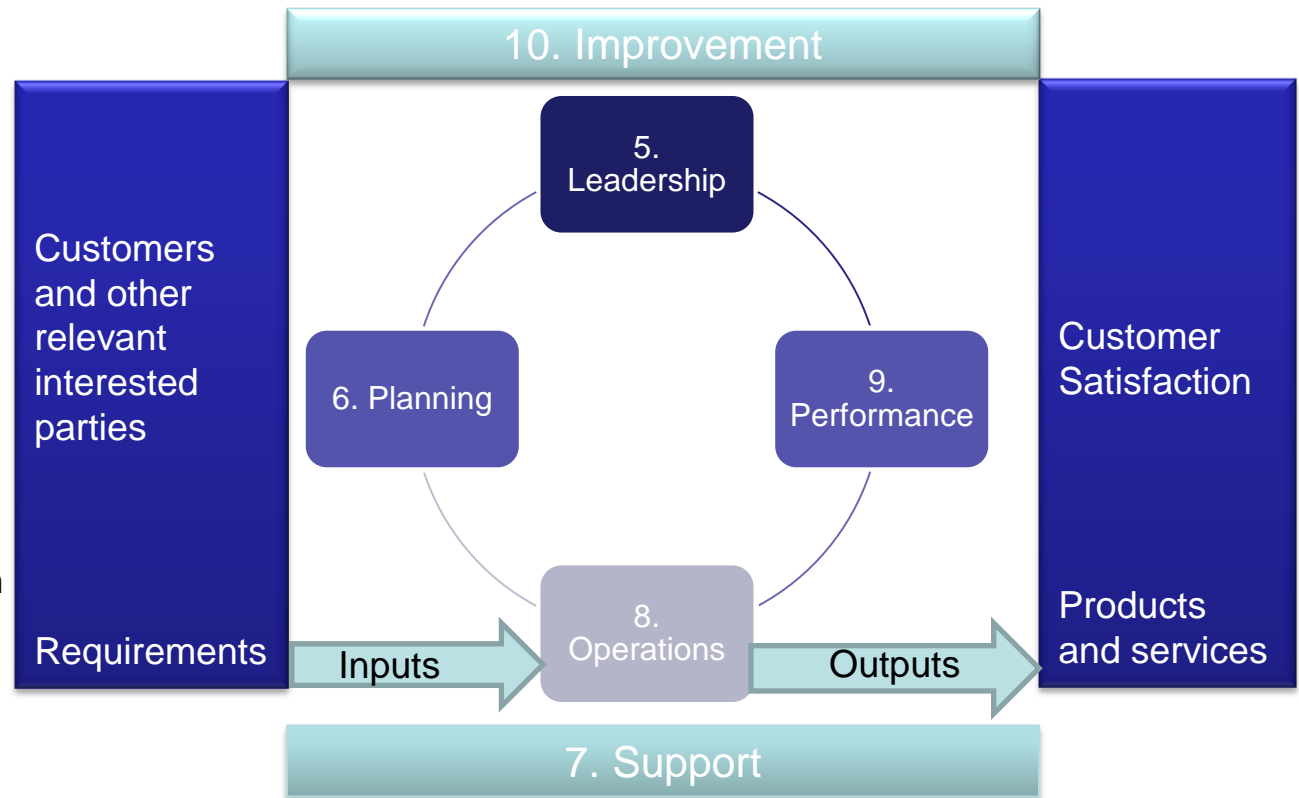
ISO9001:2008

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

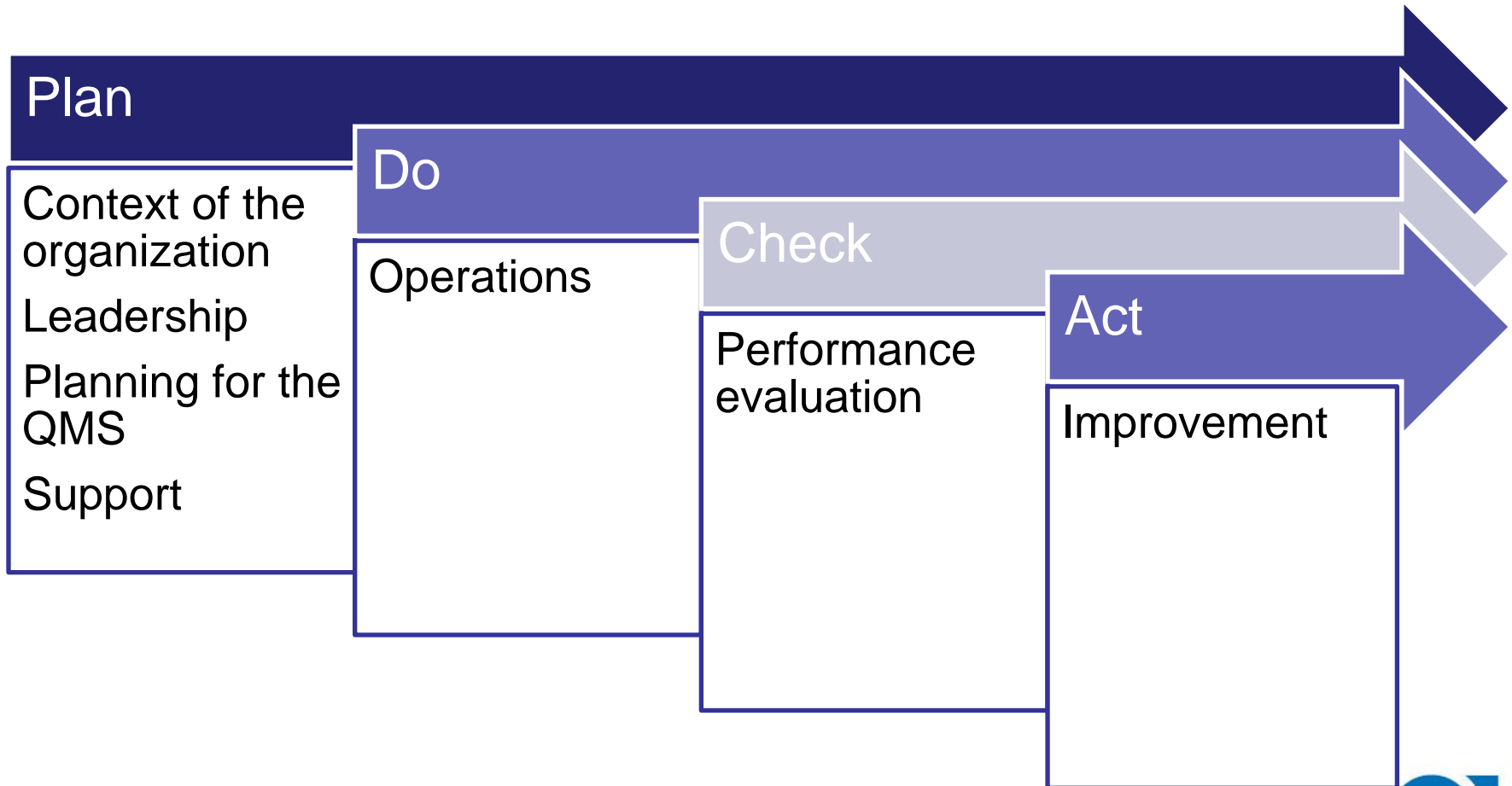
ISO9001:2015 High level structure

ISO9001:2015 Structure

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



PDCA and ISO9001:2015



4. Context of the organization

ISO/DIS 9001

- 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 the quality management system
- 4.4 Quality management system and its processes



Changes

- Relevant interested parties could include external sources
- No Quality Manual required
- Scope maintained as “documented evidence”
- Process approach made explicit

5. Leadership

ISO/DIS 9001

- 5.1 Leadership and commitment
- 5.2 Quality policy
- 5.3 Organizational roles, responsibilities and authorities



Changes

- No Mgmt. Representative
- Leaders ensure quality policy is applied and quality objectives are achieved
- QMS is integral to the business processes

6. Planning for the quality mgmt. system

ISO/DIS 9001

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes



Changes

- New requirements to determine risks and opportunities and plans to address them
 - A.4 Risk-based approach (Annex SL)
- Quality objectives for relevant functions, levels and processes
- Planning and implementation of changes



7. Support

ISO/DIS 9001

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information
 - 7.5.1 General
 - 7.5.2 Creating and updating



Changes

- Resources are external and internal
- Organizational knowledge is a resource
- Emphasis on competency
- No procedure for documented information
 - Annex A.6 Documented Information
- Loss of confidentiality

8. Operation

ISO/DIS 9001

- 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 nonconforming process outputs, products and services

Changes

- Product realization is now “operation”
- Planning and control is emphasized
- Potential consequences of design or development failure
- Post delivery activities
- No exclusions; instead prove not applicable

Product Planning

Contract Review

Design and Development

Supplier Management

Process Control

Supply Chain Mgmt.

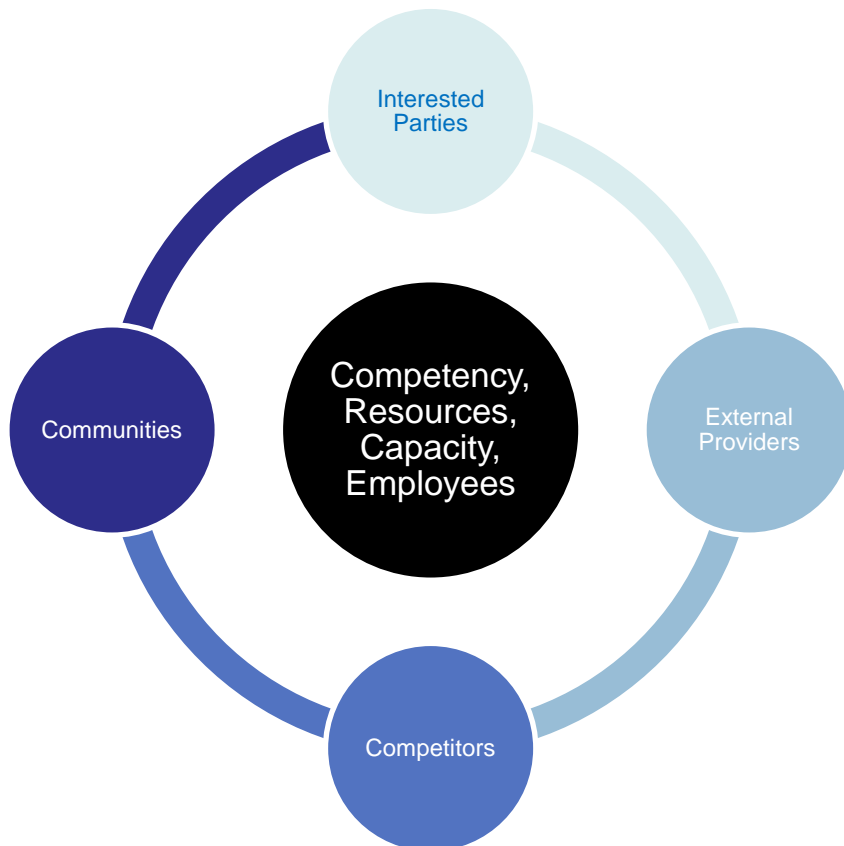
Non-conforming Product



9. Performance evaluation

ISO/DIS 9001

- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review



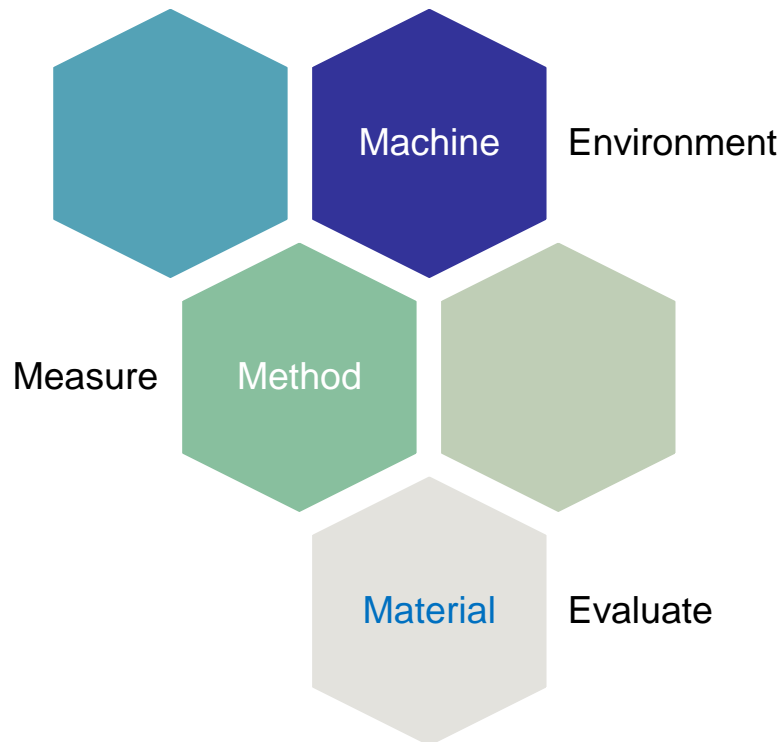
Changes

- Evaluation is added
- Preventive action is removed
- No documented procedure for internal audit
- Context, risk and opportunities added to management review

10. Improvement

ISO/DIS 9001

- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual Improvement



Changes

- Preventive action is removed
- Address “predicted requirements”
- Record the nature of nonconformities
- Analysis and evaluation is used to identify underperformance and opportunities

Currently certified to ISO 9001:2008?

- Transition period begins when new revision is published
- Expect to have three years before ISO 9001:2008 becomes obsolete
- Certify to ISO 9001:2015 before transition period ends (expected late 2018)



Resources from ASQ

Knowledge Center

asq.org/standards-iso-9001-2015.html

ISO 9001:2015

The next revision to **ISO 9001**, the international standard specifying requirements for quality management systems, is in development and currently planned for publication by the end of 2015. Organizations that seek to maintain certification to ISO 9001 can start preparing now for the transition.



(0) Member
Reviews

ISO 9001 TIMELINE

Originally published in 1987, ISO 9001 underwent revision in 2000 and again in 2008. Until the next revision is finalized, organizations can still purchase and certify to the current (2008) version.

ISO 9001:2008

ASQ is the only place to get ANSI/ISO/ASQ Q9001-2008, the American National Standard version of ISO 9001:2008. Available formats include:

- **Published hard copy**
- **E-standard** for immediate download and viewing (please note, e-standards cannot be printed)
- **Site license** for posting an electronic version to your network or Intranet

ISO 9001:2015 Development Timeline

- June 2013: **Committee Draft (CD)** published; countries participating in the development process form national positions on the draft

Knowledge Center

Topics

Tools

Publications

Case Studies

Webcasts

Video

Research

Most popular

- [ANSI/ASQ Z1.4 and Z1.9](#)
- [ISO 9001](#)
- [Six Sigma](#)

More topics A to Z

Also browse the [online glossary](#)

ISO 9000

[About ISO 9000](#)

[Quality management principles](#)

[ISO 9000 quotes](#)

[Other standards](#)

ISO 9000 Resources

[Articles and more](#)

[Books](#)

[Case studies](#)

[Jobs](#)

[Standards Central](#)

[Training](#)

Related Topics

[Knowledge Center](#) > [Learn About Quality](#) > [ISO 9000](#)

Quality Glossary Definition: ISO 9000 series standards

A set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system.

The ISO 9000 Series is a set of international standards for quality management and quality assurance. standards were developed to help companies effectively document the elements they need to maintain efficient quality system. They are not specific to any one industry.

ISO 9000 can help a company satisfy its customers, meet regulatory requirements, and achieve continuous improvement. But it's a first step, many quality professionals will tell you, the base level of a quality system complete guarantee of quality.

ISO 9000 Facts

FREE ISO 9000 RESOURCES

- [Introduction to the ISO 9000 Standards \(article\)](#)
- [Standards Outlook: Change Ahead \(article\)](#)
- [Geometrica Builds ISO 9001 QMS on Water study\)](#)



The Global Voice of Quality™

Portland Section 0607

Serving You and All of Oregon



www.asqpdx.com

Volunteer opportunities

- The Portland Section always welcomes volunteers to help with leadership roles, events, and activities. If interested, please contact chair@asqpdx.com.
- Recertification Units (RU's) can be earned through volunteering
- Dinner Meetings
 - Live Broadcasting
 - Networking
- Brown Bag Webinars
- Tours
- Certification preparation training resources
- Certification Testing facilitation
- ASQPDX LinkedIn Group
- Monthly Newsletter

