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REPORT

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What is ISO 9001:2015 and Why Is It Important?

TABLE OF CONTENTS

Tables

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Note to the Reader

Much of the information provided here is rendered in a table format to provide the reader with easy-to-use job aids and reference material.

INTRODUCTION

What is ISO 9001:2015?

ISO 9001:2015 is an international standard dedicated to Quality Management Systems (QMS). It outlines a framework for improving quality and a vocabulary of understanding for any organization looking to provide products and services that consistently meet the requirements and expectations of customers and other relevant interested parties in the most efficient manner possible.[i] The QMS is the aggregate of all the processes, resources, assets, and cultural values that support the goal of customer satisfaction and organizational efficiency. First published in 1987, the latest iteration (ISO 9001:2015) replaces ISO 9001:2008.

ISO 9001:2015 doesn't dictate what an organization's objectives should be or how to achieve them. In other words, it doesn't tell anyone how to run their business. It's a flexible standard that allows each organization to define for itself what its objectives and adherence to the standard ought to be. ISO 9001:2015 defines the guiding principles that can be used to create efficiencies by aligning and streamlining processes throughout the organization, in an effort to bring down costs, create new opportunities, meet regulatory requirements, and help organizations expand into new markets in which clients demand ISO 9001 certification (the last of which is increasingly crucial for businesses working in or with the public sector or serving as suppliers in automotive or private OEM (Original Equipment Manufacturer) scenarios).

ISO does not perform certifications to ISO 9001:2015. Instead, organizations engage an independent certification body to audit their QMS implementation against the ISO requirements. Organizations of any size can certify to this standard, including smaller ones with no dedicated Quality resources.

Why a new version?

ISO regularly reviews all standards to ensure they are up-to-date and continue to be relevant for the needs of organizations around the world. The last major revision of ISO 9001 was in 2008. While that might not seem like such a long time ago, the exponential increase in the availability of technology, products, and services for consumers, as well as the size and complexity of the global supply chain, have meant that ISO needed to make 9001 meet several new requirements. Customer demands on products and services, and the impact on the brand reputations of those companies that can meet them, grow each day, and ISO 9001 needed to meet these enhanced expectations.

Important dates

ISO 9001:2015 was published in September 2015 and is already the most widely adopted standard in the history of standards. To help the more than 1 million companies that have certified to ISO 9001:2008 move to the new standard, ISO has set in place a three-year transition period during which ISO 9001:2008 certification will remain valid. This transition will expire in September 2018. It is important to note that after 2018, those companies that were certified ISO 9001:2008 and have not certified to ISO 9001:2015 will lose their ISO 9001 certification until they recertify to the new standard.

OVERVIEW OF ISO

Many people have heard the term "ISO standard" and wondered what ISO is and how it became the guardian of standardization. ISO (from Greek *isos* meaning "equal") is the "International Organization for Standardization," a non-governmental organization based in Geneva, Switzerland. It is dedicated to developing voluntary standards that ensure product safety and quality while encouraging innovation in a global marketplace. ISO dates from 1947, after a meeting at the Institute of Civil Engineers in London at which delegates from 25 countries met to coordinate international standards for industrial manufacturing.[ii]

ISOs fundamental mission is to provide common specifications, terms, standards, and units of measurement to organizations around the world. ISO does not provide certification or conformity assessment. Rather, it facilitates global trade and innovation to allow every organization in every sector from around the world to have a common language and common expectations for everything from technology and manufacturing to food safety, healthcare, and agriculture. ISO standards benefit organizations at the environmental, economic, and societal level and help developing countries meet the United Nations Sustainable Development Goals through the ISO Action Plan for Developing Countries, a program that provides technical courses to assist developing countries in meeting international standards. ISO has published more than 22,000 standards since its first published standard in 1951.

ISOs overall mission is built on the following core initiatives for its members:

- Strengthening the links between standardization and public policy by providing thought leadership and promoting awareness of best practices.
- Identifying and building national standardization strategies by applying best practices.
- Ensuring the efficient operation of their organizations while managing financial sustainability and risk.
- Ensuring participation of, and collaboration with, key stakeholders in all standardization projects.
- Increasing adherence to Good Standardization Practices (GSP) among standards experts in every national organization and evaluating all processes to determine their alignment with the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.

ISO consists of 161 standards bodies from around the world, with 776 technical committees and subcommittees. The annual General Assembly is the overall authority for the Principal Officers, Development Committees, Technical Management Board, and various other committees and subcommittees. ISO works in partnership with the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU) as part of the World Standards Cooperation (WSC), and with the World Trade Organization

to use international standards to reduce trade barriers. ISO collaborates with over 700 international, regional, and national organizations and provides pedagogical material to educational institutions around the world from primary to university levels.

ISO technical committees determine the strategy for creating standards in accordance with the needs of specific markets. The technical committee creates the initial draft and then shares it with other members for comments, discussion, and revision. Developing a new standard from proposal to publication typically takes about three years and adheres to the following key principles:

- ISO develops standards in response to requests from industry stakeholders or to meet clear market demands.
- ISO develops standards based on the opinions of international experts. The technical committee then decides the scope and content for the standards.
- ISO develops standards according to a process that includes multiple stakeholders including consumer associations, academics, NGOs, and the public sector.
- ISO develops standards based on consensus and accounts for all feedback and requests for revisions.

WHAT IS IN ISO 9001:2015 AND HOW IS IT DIFFERENT FROM ISO 9001:2008?

ISO 9001:2015 and its complementary management standards are based on the following seven Quality principles.[iii]

Table 1 - Seven Quality Principles

Principle	Description
Customer Focus	Customer focus means exceeding customer expectations and providing satisfaction and value with every customer interaction. It requires an organization to link every business objective to customer needs and to recognize that customers are those that have both direct and indirect relationships with an organization.
Leadership	Leadership must commit to ensuring the availability of all resources for Quality projects and to providing positive role models through active participation, proactive communication of vision and strategy, and an organization-wide engagement with a Culture of Quality.
Engagement of People	Organizations must engage and empower competent and motivated workers while encouraging everyone to contribute and collaborate.
Process Approach	A process approach recognizes that processes must be part of a unified and consistent system that produces predictable results, illuminates elements that require improvement, and addresses all risks that have an impact on process outcomes.
Improvement	An ongoing dedication to improvement reacts to changes in external and internal conditions to create new opportunities by focusing on root-cause determination and preventative and corrective actions.
Evidence-Based Decision Making	Making decisions based on statistical evidence provides greater objectivity, effectiveness, and efficiency to an organization and makes it easier to review results for ongoing improvement.
Relationship Management	Organizations must account for and manage relationships with all vendors, partners, and suppliers to understand the constraints, opportunities, and risks for each.

These principles are the strategic basis for all decisions relating to Quality Management in the organization and are infused within all aspects of the ISO 9001:2015 language. Every organization will prioritize each principle in a different way at various stages of their development.

ISO 9001:2015 contains a subset of tactical elements that complement the strategic principles provided above. These five elements, which represent a significant advance on ISO 9001:2008, are:

- The Plan-Do-Check-Act cycle
- Risk-based thinking
- Leadership participation
- Unified structure, and
- Clarified documentation requirements.

These elements are complementary and are highly integrated into the fabric of ISO 9001:2015. As such, discussing them in isolation from one another is somewhat artificial and carries the danger of misrepresenting the organic quality of the standard. To accommodate this, we will look at a brief background of each element and summarize the structure in a table format to highlight their overall integration.

Plan-Do-Check-Act

Plan-Do-Check-Act (PDCA) is a process approach that manages processes and systems to create a cycle of continuous improvement. It considers the QMS as an entire system and provides systematic management of the QMS from planning and implementation through to checks and improvement. PDCA helps organizations achieve better customer satisfaction and, consequently, higher levels of customer confidence in an organization's abilities to meet customer requirements.[iv]

The stages of PDCA are as follows:[v]

Table 2 - The Plan-Do-Check-Act Cycle

Stage	Description
Plan	The organization: • determines the objectives of the QMS and maps all processes that will be within its scope • provides all resources necessary for meeting customer requirements and all internal and external interests, and • identifies and addresses all risks and opportunities.
Do	The organization implements the QMS according to the parameters determined during the planning stage.
Check	The organization measures the processes and outputs against the objectives and requirements
Act	The organization implements remedies to correct any deviations or inefficiencies and to improve overall performance of the QMS.

Risk-Based Approach and Context of the Organization

Clause 4 in ISO 9001:2015 is "Context of the organization," which deals with understanding the priorities of the organization and its stakeholders, as well as the risks involved with impending change. Context refers to all issues (internal and external, negative and positive) that impact an organization and that are impacted by the opportunities and risks at hand, such as:[vi]

Table 3 - Context of the Organization

External Issues	Internal Issues
Legal	Values of the organization
Technological	Culture of the organization
Competitive	Knowledge of the organization
Market	Performance of the organization
Cultural	
Social	
Economic	

Since the understanding of these issues arises from strategic planning at the executive level, "Context of the organization" ensures that leadership becomes aware of the importance of the integrated QMS in the organization's strategic priorities, which also complements the priorities of Section 5 on Leadership Responsibilities.[vii] Organizations must also consider the scope of the QMS to ensure that its applicability and boundaries serve the requirements of interested parties (both internal and external) and the products and services that form the core of the organization's business. "Context" also covers an audit of existing processes and the requirements for new processes, as well as the resources and inputs needed to support them, that the QMS might require.

Risk-based thinking has always been part of ISO 9001, but the 2015 standard has made this approach more explicit. While ISO 9001:2015 sometimes seems to present "risk" as the opposite of "opportunity," it actually provides a more nuanced concept of risk as it applies to an organization. In this approach, opportunities arise from favourable situations intended to achieve a positive result, such as developing a new product or enhancing an old one to attract new customers or enter a new market. Such opportunities can also carry risks associated with change. For example, enhancing an older product could alienate existing customers or create supply chain problems when sourcing parts to repair older models.[viii] ISO 9001:2015 therefore defines risk not as the probability of loss or damage, but as "the effect of uncertainty."[ix] Risk carries a possibility of loss, but also the possibility of opportunity. Not all risks result in loss, nor in opportunities, but an awareness of the circumstances in which each of them can arise results in a more effective QMS that facilitates positive results and mitigates negative ones.

ISO 9001:2015 does not provide prescriptive methods for implementing or documenting risk management in an organization. As with other sections of the standard, it is up to each organization to determine their own approach to managing risk and the level of risk with which they are comfortable.

Leadership Participation

ISO 9001:2015 requires leadership to move from a position of supporting the QMS to participating in its success. Leadership is responsible for ensuring that the QMS remains focused on customer requirements and for establishing and communicating the overall QMS policy for the organization. Leadership also has the following requirements for demonstrating

its commitment to the QMS:[x]

- Taking accountability for the effectiveness of the QMS.
- Ensuring that the QMS is aligned to the context and strategy of the organization.
- Integrating the QMS into the organization's existing processes.
- Promoting the QMS and risk-based thinking.
- Acquiring required resources for the QMS.
- Communicating the importance of adhering to the QMS.
- Ensuring the success of the QMS.
- Supporting the staff who maintain the QMS.
- Promoting continual improvement of the QMS.
- Supporting leadership in other areas that support the QMS.

For the leadership of many organizations, even those certified to ISO 9001:2008 or other standards, these new responsibilities could be new territory, so Quality professionals should prepare to take on the role of introducing and teaching these principles to their leadership.

Unified High-Level Structure

ISO has been developing a unified structure for Management System Standards (MSS) since the early 1990s. The ISO Technical Management Board created a technical advisory group to develop these requirements and in 2011 published them as Annex SL in the ISO/IEC directives.

The fundamental impact of Annex SL is that all ISO standards dedicated to management system requirements, including ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018, will now have the following identical elements:[xi]

- Clause titles
- Sequence of clause titles
- Text, and
- Terms and definitions.

Table 4 (as outlined on the following page) shows the high-level structure for all MSS standards as defined by Annex SL:[xii]

Table 4 - High-Level Structure of ISO 9001:2015

Section	Description
1. Scope	ISO 9001:2015 applies to organizations that want to show their ability to meet customer requirements and regulatory obligations through the development of consistent products and services.
2. Normative Reference	ISO 9000:2015 Quality management systems – Fundamentals and vocabulary is the primary supporting document outlining the principles and methodology of ISO 9001:2015.
3. Terms and Definitions	The controlled vocabulary of ISO 9001:2015 is contained in the document ISO 9000: 2015 Quality management systems - Fundamentals and vocabulary.
4. Context of the Organization	Organizations should identify all issues, requirements, and priorities that are relevant to their objectives for their QMS, including those of any third-parties. They should also determine and document the scope of the QMS and the processes that will contribute to the creation, maintenance, and continuous improvement of the QMS.
5. Leadership	Organizational leadership should demonstrate its commitment to the QMS by ensuring alignment with strategic objectives and processes, providing resources as necessary, and ensuring the achievement of the intended results of customer satisfaction. The organization must establish regular channels to communicate Quality values to all employees and delegate responsibilities for maintaining the QMS to well-trained subject matter experts.
6. Planning	Organizations should consider the context and requirements of all parties to enhance desired effects, prevent undesired effects, and improve Quality processes. They can then address the risks and opportunities, integrate actions into the QMS processes, and evaluate those actions to determine their impact. They should establish realistic Quality objectives and the means for measuring their impact, and then implement any required changes to the QMS that are within the scope of the resources available.
7. Support	Organizations should determine the resources (people, infrastructure, and environment) required for the implementation and maintenance of the QMS. They should ensure that all QMS professionals understand and are trained on their responsibilities and that the principles of the QMS are communicated widely. They should also create and maintain all required QMS documentation.
8. Operation	Organizations should implement the QMS according to the scope that was determined in the planning stage, ensuring that it is sufficiently documented and meets the requirements of customers, regulators, and stakeholders. They should also ensure that all suppliers and vendors conform to these same standards. Products and services that are not ready to meet QMS standards should not be released to the public, and all nonconformities should be documented and addressed.
9. Performance Evaluation	Organizations should use internal audits to measure, analyze, and evaluate the effectiveness of the QMS to ensure that it is meeting customer requirements for consistent products and services. They must identify and take corrective action on any non-conformity and should review the QMS regularly to ensure that it aligns with the overall QMS strategy.
10. Improvement	Organizations should identify opportunities for continual improvement, take immediate corrective actions for nonconformities, and retain controlled documentation of all improvement activities on a continuing basis.

Table 5 shows an application example of the high-level structure across ISO 9001:2015 and ISO 14001:2015 for environmental management systems, with minor differences to accommodate the specific requirements of each.

Table 5 - Comparison of High-Level Structure in ISO 9001:2015 and ISO 14001:2015

ISO 9001:2015	ISO 14001:2015
Forward Introduction 1. Scope 2. Normative references 3. Terms and definitions 4. Context of the organization 4.1. Understanding the organization and its context 4.2. Understanding the needs and expectations of the interested parties 4.3. Determining the scope of the quality management system 4.4. Quality management system and its processes 5. Leadership 5.1. Leadership and commitment 5.2. Policy 5.3. Organization roles, responsibilities and authorities 6. Planning 6.1. Actions to address risks and opportunities 6.2. Quality objectives and planning to achieve them 6.3. Planning of changes 7. Support 7.1. Resources 7.2. Competence 7.3. Awareness 7.4. Communication 7.5. Documented information 8. Operation 8.1. Operational planning and control 8.2. Requirements for products and services 8.3. Design and development of products and services 8.4. Control of externally provided processes, products and services 8.5. Production and service provision 8.6. Release of products and services 8.7. Control of nonconforming outputs 9. Performance evaluation 9.1. Monitoring, measurement, analysis and evaluation 9.2. Internal audit 9.3. Management review 10. Improvement 10.1. General 10.2. Nonconformity and corrective action 10.3. Continual improvement	Forward Introduction 1. Scope 2. Normative references 3. Terms and definitions 3.1. Terms related to organization and leadership 3.2. Terms related to planning 3.3. Terms related to support and operation 3.4. Terms related to performance evaluation and improvement 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 environmental management system 4.4. Environmental management system 5. Leadership 5.1. Leadership and commitment 5.2. Environmental policy 5.3. Organizational roles, responsibilities and authorities 6. Planning 6.1. Actions to address risks and opportunities 6.2. Environmental objectives and planning to achieve them 7. Support 7.1. Resources 7.2. Competence 7.3. Awareness 7.4. Communication 7.5. Documented information 8. Operation 8.1. Operational planning and control 8.2. Emergency preparedness and response 9. Performance evaluation 9.1. Monitoring, measurement, analysis and evaluation 9.2. Internal audit 9.3. Management review 10. Improvement 10.1. General 10.2. Nonconformity and corrective action 10.3. Continual improvement

The fact that the language of PDCA and risk-based thinking is entwined throughout the standard, combined with ISOs approach of providing standards without prescriptively telling organizations how to operate, means that it can be difficult for organizations to create a detailed roadmap to ISO 9001:2015 certification. In fact, there are multiple paths to

certification depending on the type of organization and its priorities. Table 6 shows one possible approach to mapping the elements of PDCA, risk-based thinking, and leadership involvement to the high-level structure prescribed by Annex SL, as well as some of the complementary ISO standards that can assist with each stage of the implementation as defined in Annex B of ISO 9001:2015.[xiii]

Table 6 - High-Level Structure, PDCA, and Complementary Standards

Chapter	Element	Complementary Standards for Guidance
1. Scope	N/A	N/A
2. Normative References	N/A	
3. Terms and Definitions	N/A	ISO 9000:2015 – Quality management systems – Fundamentals and vocabulary.
4. Context of the Organization	Risk	ISO 9000:2015 ISO 9004:2018 – Quality management – Quality of an organization – Guidance to achieve sustained success ISO 18091:2014 – Quality management systems – Guidelines for the application of ISO 9001:2008 in local government ISO 10006:2003 – Quality management systems – Guidelines for quality management in projects ISO 10008:2013 – Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions ISO 10014:2006 – Quality management – Guidelines for realizing financial and economic bene-fits ISO 10018:2012 – Quality management – Guidelines on people involvement and competence ISO 31000:2018 – Risk management – Guidelines IEC 31010:2009 – Risk management – Risk assessment techniques ISO Guide 73:2009 – Risk management – Vocabulary
5. Leadership	Leadership Involvement	ISO 9000:2015 ISO 9004:2018 ISO 10005:2005 – Quality management systems – Guidelines for quality plans ISO 10006:2003 ISO 10008:2013 ISO 10014:2006 ISO 10018:2012
6. Planning	Plan	ISO 9000:2015 ISO 9004:2018 ISO 10005:2005 ISO 10006:2003 ISO 10008:2013 ISO 10014:2006 ISO/TR 10017:2003 – Guidance on statistical techniques for ISO 9001:2000 ISO 10018:2012 ISO 21500:2012 – Guidance on project management ISO 10019:2005 – Guidelines for the selection of quality management system consultants and use of their services
7. Support	Do	ISO 9000:2015 ISO 9004:2018 ISO 10005:2005 ISO 10006:2003 ISO 10008:2013 ISO 10012:2003 – Measurement management systems – Requirements for measurement pro-cesses and measuring equipment ISO/TR 10013:2001 – Guidelines for quality management system documentation ISO 10014: 2006 ISO 10015:1999 – Quality management – Guidelines for training ISO/TR 10017:2013 ISO 10018:2012
8. Operation		ISO 9000:2015 ISO 9004:2018 ISO 10001:2007 – Quality management – Customer satisfaction – Guidelines for codes of conduct ISO 10002:2014 – Quality management – Customer satisfaction – Guidelines for complaints handling in organizations ISO 10005:2005 ISO 10006:2003 ISO 10007:2017 – Quality management - Guidelines for configuration management ISO 10008:2013 ISO 10014:2006 ISO 10018:2012 ISO 10019:2005
9. Performance Evaluation	Check	ISO 9000:2015 ISO 9004:2018 ISO 10001:2007 ISO 10002:2014 ISO 10003:2007– Quality management – Customer satisfaction – Guidelines for dispute resolu-tion external to organizations ISO 10004:2012 – Quality management – Customer satisfaction – Guidelines for monitoring and measuring ISO 10005:2005 ISO 10006:2003 ISO 10008:2013 ISO 10014:2006 ISO/TR 10017:2013 ISO 10018:2012 ISO 19011:2011 – Guidelines for auditing management systems
10. Improvement	Act	ISO 9000:2015 ISO 9004:2018 ISO 10002:2014 ISO 10005:2005 ISO 10006:2003 ISO 10008:2013 ISO 10014:2006 ISO 10018:2012

This approach to aligning the structure with the basic elements of PDCA, risk-based thinking, leadership involvement, and complementary standards can help organizations understand the details of the standard and how to apply them to their own priorities. A more detailed map could highlight all those places in which elements overlap and complement one another in the same section, which would provide a more nuanced and sophisticated approach that might benefit more complex organizations.

Documentation

Previous iterations of ISO 9001 have received criticism for placing an excessive burden for documentation on organizations.[xiv] To meet this criticism, ISO 9001:2015 does not prescribe specific approaches to the governance of documentation. It is up to each organization to determine its approach to maintenance, retention, and disposition of all documentation.

ISO 9001:2008 adhered to the guidelines for QMS documentation outlined in ISO/TR 10013:2001, which distinguished between records, processes, and Quality manuals in a much more defined way.[xv] ISO 9001:2015 has simplified these categories to one overarching category of "documented information." ISO 9001:2015 uses the phrase "maintain documented information" to suggest working documentation that requires updating, such as procedures and work instructions, and uses "retain documented information" to suggest records, which are completed and archived documents that provide evidence of past conformity with requirements. While ISO 9001:2015 does not explicitly state categories of documentation such as procedures, work instructions, Quality manuals, and records, organizations should still look to the definitions and categories provided in ISO/TR 10013 for guidance on what the options for documentation should be. It is, however, the responsibility of the organization to determine the best media or type for its documentation. Organizations can also look for guidance on documentation from their technical writers and business analysts. Where the term "information" is not preceded by "documentation," ISO 9001:2015 does not require that the information be documented.

This less prescriptive approach allows organizations to determine their own scope for documentation and to scale the requirements to their resources. It is important to note, however, that the lack of prescriptive direction is not the same as reduced responsibilities for documentation. Section 7.5 lays out the general responsibilities for documentation that ensures the effectiveness of the QMS.[xvi] Organizations must ensure that all documentation has adequate identifying information, is in a media format that facilitates easy and efficient interaction, and that it is regularly reviewed and approved by appropriate subject matter experts. Organizations must also ensure that documentation is subject to governance that addresses control, distribution, storage, retention, security, and disposition.

The inclusion of risk-based thinking in ISO 9001:2015 has a direct influence on the complexity of documentation required for each organization. Essentially, the greater the risk of uncertainty, the greater the requirements for documentation that effectively captures the complexity of that risk and the full extent of the actions the organization takes to mitigate it.

ISO 9001:2015 is prescriptive regarding the processes that require documentation. This information is located throughout the standard and is not located in a single section, which makes it difficult for the reader to quantify exactly what they need to do. Table 7 shows all the information that requires documentation in ISO 9001:2015:

Table 7 - Required Documentation for ISO 9001:2015

Clause	Document Information	Description
4.3	Scope of the QMS	Describe products and services covered and justify anything the organization decides is out of scope for ISO 9001:2015.
4.4.2	Operation of QMS processes	Maintain documents that support the operation of the QMS and retain documents that provide confidence and evidence that processes are being carried out correctly.
5.2.2	Communicating Quality policy	Distribute and facilitate interaction with the Quality policy.
6.2.1	Quanitity Objectives	Maintain documentation of the Quality objectives and their relevance to the QMS.
7.1.5.1	Resources	Maintain documentation that provides evidence of the suitability of monitoring and measuring resources for the QMS.
7.1.5.2	Measurement traceability	Maintain the basis for calibration or verification as documented information when no standards for these activities exist.
7.2	Competence	Retain documentation as evidence of the competence of all human resources supporting the QMS.
7.5.1	Documented Information	Maintain documentation required by ISO 9001:2015 for the effectiveness of the QMS.
7.5.2	Creating and updating	Ensure that all documentation has appropriate identification, description, format, and review policies.
7.5.3	Control of documented information	Ensure documentation is available for use and adequately protected by effective information governance policies.
8.1	Operational planning and control	Provide governance of documentation to demonstrate that processes, products and services have met all requirements and expectations.
8.2.3.2	Requirements for products and services	Retain documentation to demonstrate reviews of the requirements for products and services and of any new or additional requirements.
8.2.4	Changes to requirements for products and services	Amend documentation to reflect changes to the requirements for products and services.
8.3.3	Design and development inputs	Retain documentation relating to design and development inputs.
8.3.4	Design and development controls	Retain documentation of the controls relating to the design and development process.
8.3.5	Design and development outputs	Retain documentation relating to the design and development outputs.
8.3.6	Design and development changes	Retain documentation relating to any changes to the design and development controls.
8.4.1	Control of external processes, products and services	Retain documentation relating to externally provided processes, products and services.
8.5.1	Control of production and service provision	Ensure the availability of documentation that defines the characteristics of the product, services, and activities, as well as the results of each.
8.5.2	Identification and traceability	Maintain documentation to ensure traceability of outputs and conformity of products and services.
8.5.3	Property belonging to customers or external providers.	Retain documentation relating to any incident involving customer or external provider property while in the care of the organization.
8.5.6	Control of changes	Retain documentation relating to any incident involving customer or external provider property while in the care of the organization.
8.6	Release of products and services	Retain documentation of: • the conformity of the release of products and services with acceptance criteria, and • traceability relating to the authorization of the release.
8.7.2	Control of nonconforming outputs	Retain documentation relating to nonconforming outputs.
9.1.1	Monitoring, measurement, analysis and evaluation	Retain documentation relating to the monitoring, measurement, analysis and evaluation of the QMS.
9.2.2	Internal audit	Retain documentation relating to audits of the QMS.
9.3.3	Management review outputs	Retain documentation of results of management reviews of required changes and improvements.
10.2.2	Nonconformity and corrective action	Retain documentation on nonconformities and corrective actions taken.

As noted above, organizations are not required to amend their numbering system for their documentation to meet the structural changes from ISO 9001:2008, but doing so could certainly ease the transition to ISO 9001:2015 and add significant efficiency to the QMS administration.

HOW DO YOU BECOME CERTIFIED ISO 9001:2015?

Organizations looking to become certified in ISO 9001:2015 will likely fit into one of two groups: those who have never been certified to ISO 9001, and; those who are already certified to ISO 9001:2008 and need to update to ISO 9001:2015. While organizations that have already done the work of certifying to the 2008 standard are in a good position to make the transition, those that have yet to tackle ISO 9001 might be intimidated by the mass of information that confronts them. In this section, we'll look at how organizations from each of these groups might tackle their certification to the 2015 standard.

Starting your certification to ISO 9001:2015

Table 4 in this article provides a detailed breakdown of the structure of ISO 9001:2015, the way in which that structure maps to the Plan-Do-Check-Act approach, the responsibilities at each stage, and the complementary standards an organization can use to guide them at each stage. It synthesizes guidance from various ISO documents and represents a high-level map of the journey to certification.

It is important to again note that ISO does not perform certifications. The International Accreditation Forum (IAF) evaluates assessment organizations all over the world and ensures they can suitably and uniformly accredit certification bodies to ISO standards. Table 8 shows the current IAF members in North America and the European Union.

Table 8 - Accreditation Organizations in North America and the EU

Country	Accreditation Organization
Canada	Standards Council of Canada
United States of America	American Association for Laboratory Accreditation (A2LA)
	American National Standards Institute – American Society for Quality National Accreditation board LLC (ANAB)
	American National Standards Institute (ANSI)
	International Accreditation Service (IAS)
	United Accreditation Foundation (UAF)
	IOAS Inc.
Austria	Akkreditierung Austria
Belgiu,	BELAC
Czech Republic	Czech Accreditation Institute, (Český institut pro akreditaci, o.p.s.) (CAI)
Denmark	Danish Accreditation (DANAK)
France	Comite Francais d'Accreditation (COFRAC)
Germany	Deutsche Akkreditierungsstelle GmbH (DAkkS)
Greece	Hellenic Accreditation System (ESYD)
Hungary	National Accreditation Authority (NAH)
Ireland	The Irish National Accreditation Board (INAB)
Italy	ACCREDIA (Italian National Accreditation Body)

Luxembourg	Luxembourg Office of Accreditation (OLAS)
Netherlands	Dutch Accreditation Council (Raad Voor Accreditatie) (RvA)
Poland	Polish Centre for Accreditation (PCA)
Portugal	Portuguese Institute for Accreditation (IPAC)
Romania	Romanian Accreditation Association (Asociatia de Acreditare din Romania) (RENAR)
Slovakia	Slovak National Accreditation Service (Slovakia) (SNAS)
Slovenia	Slovenska Akreditacija (SA
Spain	Entidad Nacional de Acreditacion (ENAC)
Switzerland	State Secretariat for Economic Affairs, Swiss Accreditation Service (SAS)
United Kingdom	United Kingdom Accreditation Service (UKAS)

Table 9 shows ISOs additional general guidance on certifying to ISO 9001:2015:[xvii]

Table 9 - General Guidance for Certifying to ISO 9001:2015

Guidance	Description
Engaging Top Management	Leadership engagement is a crucial component of the certification project and should be integrated into it from the outset. Leadership should first consult ISO 9000 to become familiar with the principles and vocabulary of ISO 9001:2015, the fundamentals of a QMS, and risk-based thinking, as well as whether a certification project is feasible. Leadership should then determine whether certification is the right goal for which to aim. In some industries, certifying could be either a requirement for doing business or an industry best practice, in which case achieving certification is not optional. Other industries, however, could achieve considerable benefit by applying all or even portions of the standard without becoming certified.[xviii] Leadership needs to make this determination early so that the project has the necessary scope and resources for success. Leadership should then determine its Quality objectives, strategic objectives, and customer requirements as it defines the policy that will provide the scope of the certification plan.
Identifying Key Processes	Determining business processes that are within scope for ISO 9001:2015 can be arduous, if rewarding, work. Every organization, regardless of size, has elements that are opaque to the observation of leadership or that lack effective processes, and engaging in a process analysis can often turn up some unpleasant surprises. Project readers should work with different parts of the organization to uncover those areas and processes that are within the QMS scope.
Planning the QMS	QMS planning requires the organization to determine the gap between where it is and where it wants to be when it reaches certification. It needs to consider how to control the business processes that will be in scope for the QMS and what the project requirements will be, including human and technology resources. Although the documentation requirements for ISO 9001:2015 are reduced from 2008, they remain extensive and may still prove onerous for organizations that don't have extensive documentation practices. Organizations new to documentation might look to the assistance of business process analysts and technical writers to document the processes and activities of the QMS to meet ISO 9001:2015 standards.
Documenting the QMS	Implementing the QMS isn't an isolated event. Organizations won't throw a switch, watch lights come on, and bask in the glory of processes that are suddenly efficient. What they will do is reach a point at which processes are documented, resources are in place to manage the processes and verify their efficacy, and all employees will have been effectively trained on their responsibilities for ensuring customer satisfaction. Organizations shouldn't underestimate the change management that might be required to train employees on the QMS. Many employees, especially those who have created their own workflows to accommodate a lack of processes, will resist the change to a QMS that could have a serious impact on the way they are used to doing their jobs. Organizations should focus on working with employees throughout the change by making training fun and interactive and by focusing on face-to-face communications instead of impersonal digital channels.
Implementing the QMS	Audits, reviews, and measurements occur during the management of the QMS. This is the analysis stage, at which the organization should determine if the QMS is having its intended impact of enhancing customer satisfaction and reducing process waste. This is the stress-test of the QMS that determines whether it's ready for certification. The result should be a deeper insight into the impact of the QMS on the organization. The organization will then take this result as a new standard against which to measure its ideal implementation of the QMS and engage in its continuous improvement.
Managing the QMS	Audits, reviews, and measurements occur during the management of the QMS. This is the analysis stage, at which the organization should determine if the QMS is having its intended impact of enhancing customer satisfaction and reducing process waste. This is the stress-test of the QMS that determines whether it's ready for certification. The result should be a deeper insight into the impact of the QMS on the organization. The organization will then take this result as a new standard against which to measure its ideal implementation of the QMS and engage in its continuous improvement.
Improving the QMS	If the QMS passes the stress-test, it's ready for third-party certification. This, however, is not the end of continuous improvement. While some organizations look to certification to maintain an industry best-practice or fulfill an industry requirement, certification doesn't need to be the end-goal of the process. As new processes, products, resources, or services are introduced, organizations may find inefficiencies cropping up that need to be brought within the scope of the QMS and managed effectively. Organizations might also consider expanding the scope of the QMS to improve processes in other parts of the business.

The Seven Basic Quality Tools

Quality professionals have a dedicated set of tools for process analysis. These versatile tools can be useful at any stage of the QMS, from the initial gap analysis and internal audit to the cycle of continuous improvement. Table 10 shows a brief description of each tool:

Table 10 - Seven Basic Quality Tools

Tool	Description
Cause-and-Effect Diagram	This is also known as the "Ishikawa" or "fishbone chart" and can be used to identify the possible causes of a problem.
Check Sheet	This is a generic tool for capturing the frequencies and patterns of events such as defects or problems.
Control Chart	This is a graph that tracks how processes change over time.
Histogram	This is a tool for frequency distribution that shows how often different values occur.
Pareto Chart	This is a bar graph that shows the frequency of events in a process and determines which are the most significant.
Scatter Diagram	This is a graph that pairs variables and looks for relationships between them.
Stratification	This is a technique for separating and analyzing data from different sources to uncover patterns.

We'll look at these tools in greater depth in an upcoming Intelex Insights Report. In the meantime, readers should become familiar with Nancy R. Tague's *The Quality Toolbox* to learn more about these important resources.[xix]

Transitioning from ISO 9001:2008 to ISO 9001:2015

Organizations that are moving from ISO 9001:2008 to ISO 9001:2015 have the advantage of an existing QMS as a starting point. That should not, however, lull them into thinking that the transition can be completed in the few days before the auditor is scheduled to appear. Here are a few things to keep in mind about the transition.

Familiarity with the new standard

It might seem like an obvious point, but the first step is to read and become familiar with ISO 9001:2015. Table 6, or the more detailed correlation matrices from ISO,[xx] can help organizations determine the extent to which the changes from ISO 9001:2008 have an impact on the scope and implementation of their QMS.

Audit internal resources

Organizations should consult with internal teams like IT and Human Resources to assess the current tools and training required for the QMS and determine if there are new processes that should come within the scope of the QMS. IT can help assess the current tools available on the market to manage the QMS processes, while Human Resources can ensure all employees have sufficient training to manage the QMS.

Consult Resources

Organizations moving to the 2015 standard should consult the resources by ISO/TC 176/SC2, the Subcommittee for Quality Systems. This committee not only developsISO 9001:2015, but also maintains learning resources and products to help organizations implement the standard. Organizations should also consult with their certification body to provide expert guidance in what to expect when preparing to make the transition to the 2015 standard.

CONCLUSION

ISO 9001:2015 sets a global standard for Quality Management Systems and ensures their efficiency for products, services, and international supply chains. Whether an organization is starting down the path of a QMS or transitioning to the 2015 standard, ISO 9001:2015 embodies the best practices of Quality Management and Quality certification.

ABOUT INTELEX

Intelex Technologies is a Toronto, Canada-based provider of Environmental, Health & Safety, and Quality (EHSQ) Management and workflow software for organizations of all sizes. The company is a leader in software-as-a-service solutions and serves customers from across a wide range of industries, located around the world. The Intelex platform is a mobile solution and provides integrated tools for front-line EHSQ professionals. We can be found at www.intelex.com.

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