# ISO 9001:2015

# Are you ready?


SoftExpert
Software for Performance Excellence

The International Organization for Standardization (ISO) is at work on a major revision to its standard ISO 9001; an internationally-recognized standard that outlines the principles for quality management systems.

The revision is currently scheduled for publication in **September 2015**, and is expected to include a number of important changes for organizations currently holding ISO 9001 certification, as well as those contemplating the development and implementation of a quality management system.

# Why is a revision of ISO 9001 being undertaken?

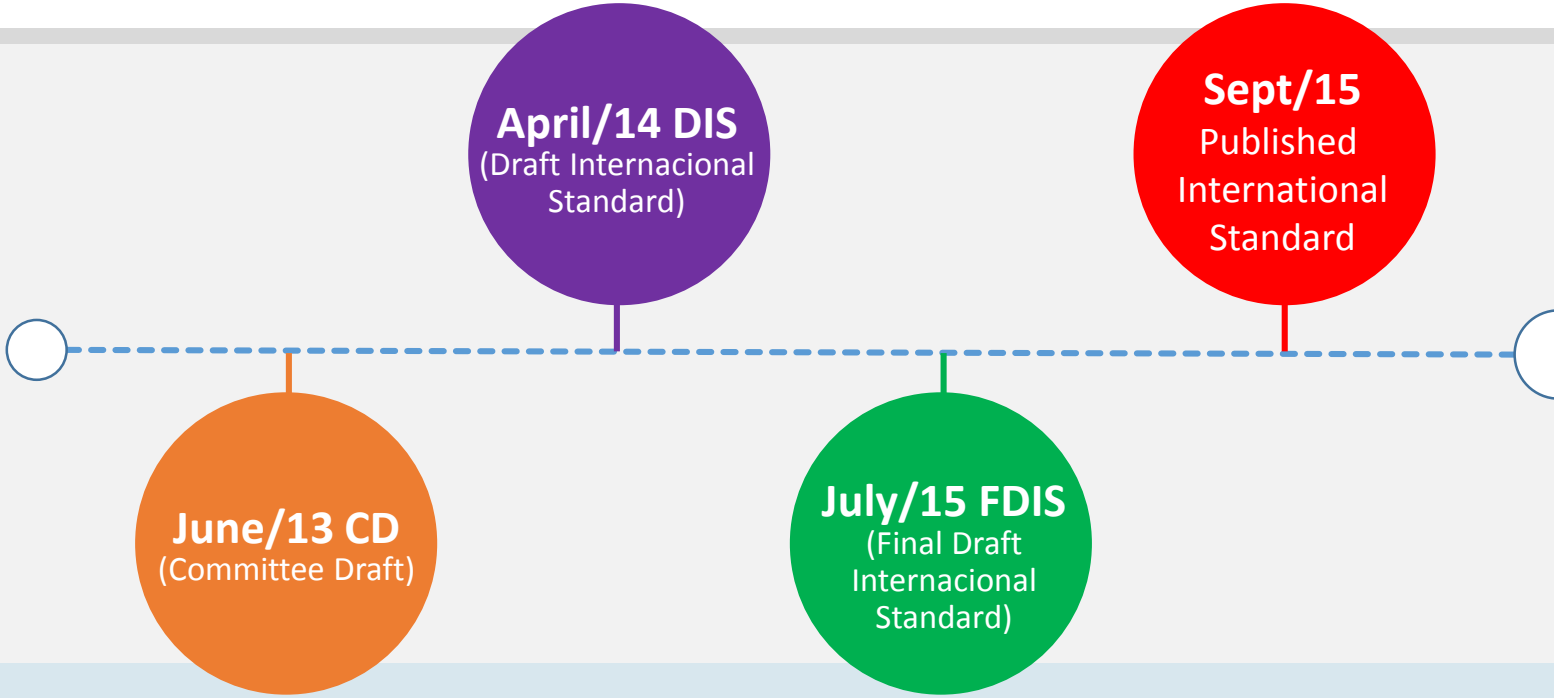
The ISO Technical Committee 176, responsible for ISO 9001, determined that a fundamental review of the standard and its underlying quality management principles was required due that the basis for ISO 9001 had undergone considerable evolution during the 25-years since the standard's original publication.

The standard needed to evolve to remain relevant to modern quality management practices.

## How long will ISO 9001:2008 continue to be recognized and audited to?

The current standard will be recognized and can be audited to until the end of the three-year transition period for ISO 9001:2015 (expected September 2018). All organizations must transition to the new standard by the transition deadline at which point certificates for ISO 9001:2008 will no longer be valid.

# What is the timeline for publication and implementation of ISO 9001:2015?




July - October 2014: Comments on DIS submitted

July 2015: Final Draft International Standard FDIS issued

September 2015 (estimate): ISO 9001:2015 issued

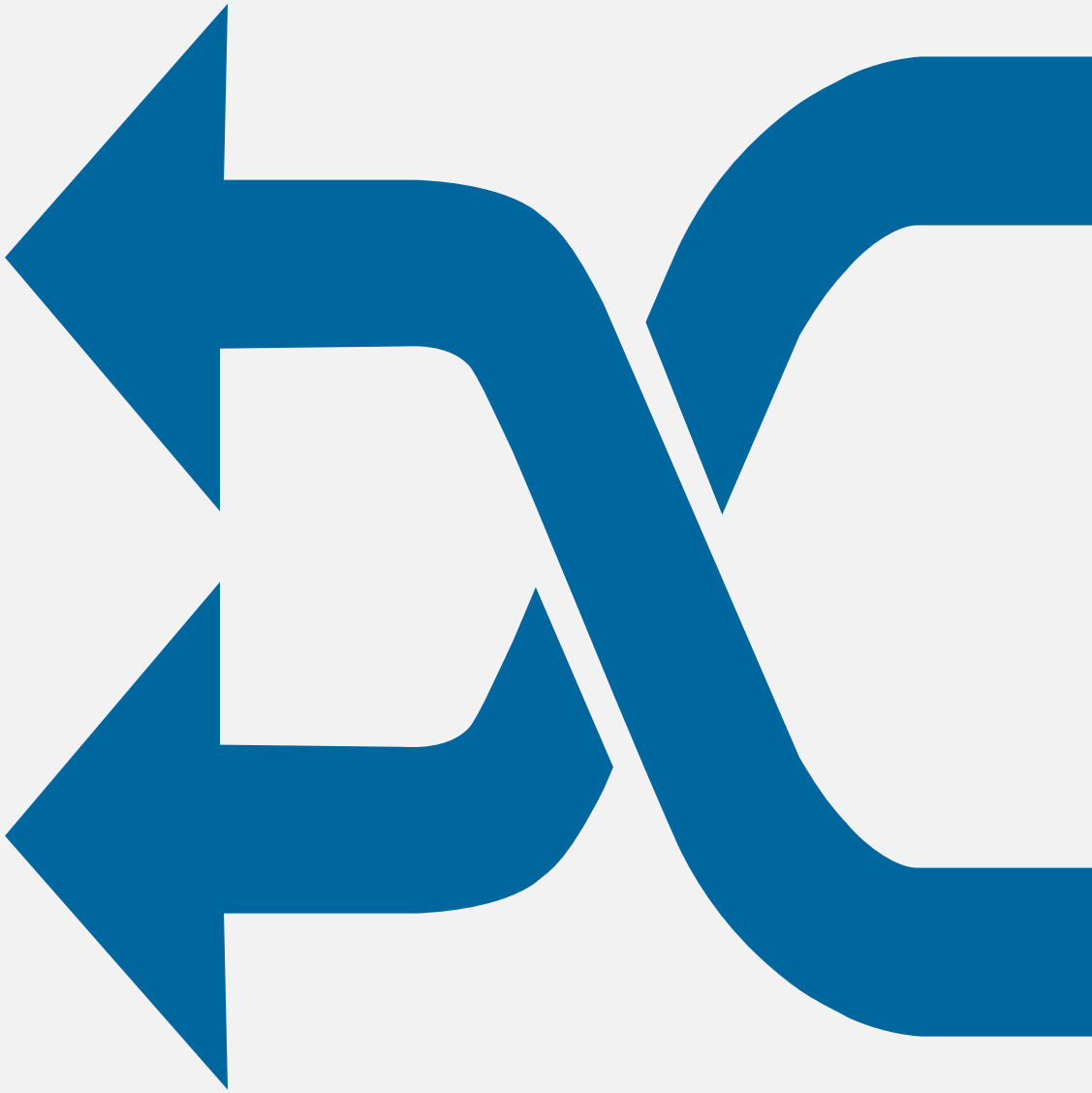
September 2015 - September 2018: Transition period. All current registrations to ISO 9001:2008 must be transitioned to the 2015 revision by this time, or they will lapse.

# How will organizations currently holding ISO 9001 certification be affected by the standard's changes?

Currently holding ISO 9001 certification should track the progress of the revision process. Organizations may also want to consider beginning the process of reviewing their existing quality management system for possible areas of change under the new requirements. Once the revised standard has been published, certified organizations will need to carefully review changes in the standard and map out a process for implementing modifications to their existing quality management system to meet the new requirements.

# Should organizations considering ISO 9001 certification delay until the new version of the standard has been released?

Implementing an effective quality management system and achieving ISO 9001 certification is an important step in an organization's commitment to quality, and the benefits will typically out weigh any challenges associated with the introduction of revised requirements. However, given the amount of time usually necessary for implementation and certification, organizations beginning that process now may want to consider the prospective changes in the standard as they develop their quality management plan.



## My integrated system also includes the use of ISO 14001 and OHSAS 18001. Will the changes that are being made to ISO 9001 affect my system and how I will need to transition to the new requirements?

All three standards are undergoing their own revisions over the next 2 years. The proposed changes to each standard have considered those who use more than one standard. With greater alignment between the standards, organizations will find the integration process much easier in future. However, each standards projected publication date is not the same.

# ISO 14001 is also being revised along with ISO 9001. How will the changes affect organizations using both standards?


ISO 9001:2015 and ISO 14001:2015 will be more closely aligned than ever. Both standards will be utilizing the same high-level structure defined in Annex SL.

Approximately 30% of the language in the two management system standards will be the same. ISO 14001:2015 FDIS is scheduled for issue in April - May, 2015 which represents a delay in the original scheduling. The standard ISO 14001:2015 should be issued in October 2015 if everything goes according to plan.

# Changes to the Standard

# Will there be a requirement for a quality manual in ISO 9001:2015?

ISO 9001:2015 does not require a quality manual. The question each organization should consider is whether or not having one is beneficial to the organization. If it is used as intended in 9001:2008 - an introduction to the management system that acts as a guide or roadmap to the overall system - then by all means have one.

# What is Annex SL?

Annex SL is a high-level structure created by ISO in order to provide a universal high-level structure, identical core text, and common terms and definitions for all management system standards. It was designed to make it easier for organizations that have to comply with more than one management system standard.

Annex SL has a total of 45 “shall” statements resulting in 84 requirements. By the way, the “SL” in Annex SL doesn’t mean anything. It’s just part of ISO’s numbering scheme.

# Does the impending arrival of ISO 9001:2015 mean that most management representatives will shortly be out of work?

The management system still needs a champion and a spokesperson, but it does not automatically mean that this is the quality manager - or any one person. Optimally, these responsibilities would be shared by a member(s) of the leadership team. Once the management system has been implemented, this person's role should transform into being a facilitator of continual improvement. It should be noted that while the requirement for a designated Management Representative has been removed from the DIS, the responsibilities that were attributed to this position are still retained in the standard.

# What is “Risk based Thinking”?

Risk based Thinking is a common sense that we do apply in our daily life automatically and sub-consciously while doing any work to get the best results. And, this thinking approach is made a part of the whole quality management system as per new revised ISO/DIS: 9001-2015 standard.

# Why should an organization adopt “Risk based Thinking”?

**Three main reasons to adopt “risk based thinking”:**

- To improve customer confidence and satisfaction
- To assure consistency of quality of goods and services
- To establish a proactive culture of prevention and improvement

# Would meeting the risk management requirements in ISO 31000 satisfy the risk management requirements in ISO 9001:2015?

An organization could certainly apply the full requirements of a risk management system as defined in ISO 31000 and more than meet the requirements for risk based thinking in ISO 9001:2015. The standard does not require a full risk management approach but rather the organization must identify, understand and consider their business environment in a broad sense and the potential risks they face. Equipped with this information, the organization should then design and implement a management system to eliminate, minimize and control these risks.

## Is Plan-Do-Check-Act (PDCA) still a part of the ISO 9001 structure in the new version?

The new standard is still built around the PDCA cycle, which is featured on page 8 of the Draft International Standard, published in May 2014. Additionally the new version is more explicit about the meaning of the process approach.

## Can you summarize the new approach to Preventative Action in ISO 9001:2015 DIS?

One of the key purposes of a quality management system is to act as a preventive tool. The concept of preventive action is expressed through a risk-based approach to formulating quality management system requirements. Although risks and opportunities have to be determined and addressed, there is no requirement for formal risk management or a documented risk management process. The implication is the entire management system, properly implemented, should function as a preventive tool.

# Will FMEA's and Control Plans be required under ISO 9001:2015?

Although very valuable tools, FMEA's and Control Plans are not required by ISO 9001:2015. The organizations could apply these tools as their approach to meet the requirements. Properly developed Control Plans would satisfy many of the requirements for section 8. FMEA's are a useful tool to identify areas of risk required in section 6. However, the organizations will need to broaden the approach to cover all aspects of the business, not just the manufacturing processes.

# Key changes in terminology

"**Procedures**", "**Records**", and "**Documents**" have all been eliminated in favor of "**Documented Information**". The standard is trying to be more inclusive in accepting alternative approaches to these areas.

All references to "**Product**" will now read "**Products and Services**". This has long been the case already, as clause 3 of ISO 9001:2008 stated "Wherever the term "Product" appears it can also mean Service.".

"**Management Responsibility**" has become "**Leadership**". Pushes further the concept that Management must lead by example and involvement, rather than simply directing that activities are performed.

"**Continual Improvement**" has evolved into a larger section called "**Improvement**". Promotes the concept that Continual Improvement is not the only aspect of improvement strived for in a quality system (improvement can also be characterized by breakthroughs, reactive changes, and reorganizations.)

"**Suppliers**" are now referred to as "**External Providers**". This is intended to better accommodate service organizations.

# Where technology fits

**Clause 4 - "Context of the Organization":** *a process-based quality management system*

Technology considerations: The QMS provides a centralized, common, and collaborative environment to maintain all policies and procedures. This is where flexibility becomes an important component:

- Flexibility to adapt to the various processes, and match the outlined commitments to quality and to customers
- Builds in the functionality that will support business needs and the needs/requirements of the standard

## **Clause 5 - “Building Leadership”:** no longer a single management representative

Technology considerations: The solution should give the entire company visibility into and control over the quality effort by ensuring that all data related to processes and procedures is kept in a centralized location accessible by all necessary parties:

- A centralized system, one holistic place for quality policy that provides transparency of information
- Document and communicate the policy—control and disseminate information in a consistent manner

## **Clause 6 - “Planning”:** the risk management

Technology considerations: Having a way to not only define the measurement of risks, but also to align them with the quality objective and then assess them from an operational perspective, is critical. This is done through a risk matrix, which enables to calculate risk by quantifying hazards by plotting them on a graph. The resulting calculation of severity and frequency becomes the risk factor:

- Risk matrixes, built into the operational processes, not only calculate risk but enable immediate remediation of high-risk events.
- A solution should have the ability to set up a risk assessment calculation, benchmarked against the requirements/objectives, and provide a way to take action on high-risk events.

## **Clause 7 - “Supporting your QMS”:** the people and the infrastructure to support the quality initiatives

Technology considerations: A technology solution will build in functionality around the process of review and approval, integrated with training, change and revision control processes, and periodic reviews. Collaboration on documentation improvement is key to this element:

• An integrated document control and training system.

• The process includes the training of people and communication, by which new information is disseminated and consumed. Being able to automate much of this is key, especially when the target is to create a more seamless, collaborative, and companywide perspective on quality.

## **Clause 8 - “Operational Processes”:** the framework for how you design, source, produce, and monitor your operations

Technology considerations: The processes are the biggest component, and creating a design plan, a supplier evaluation, or establishing nonconforming material criteria, it’s important to ensure that information is transferred from one process to the next:

• A technology solution that will take design information, such as a bill of materials, and communicate to production and suppliers, and include potential nonconforming criteria to be assessed, rests in the ability of the system to provide traceability, visibility, and control.

## **Clause 9 - “Evaluation”:** the importance of feedback and regular assessment

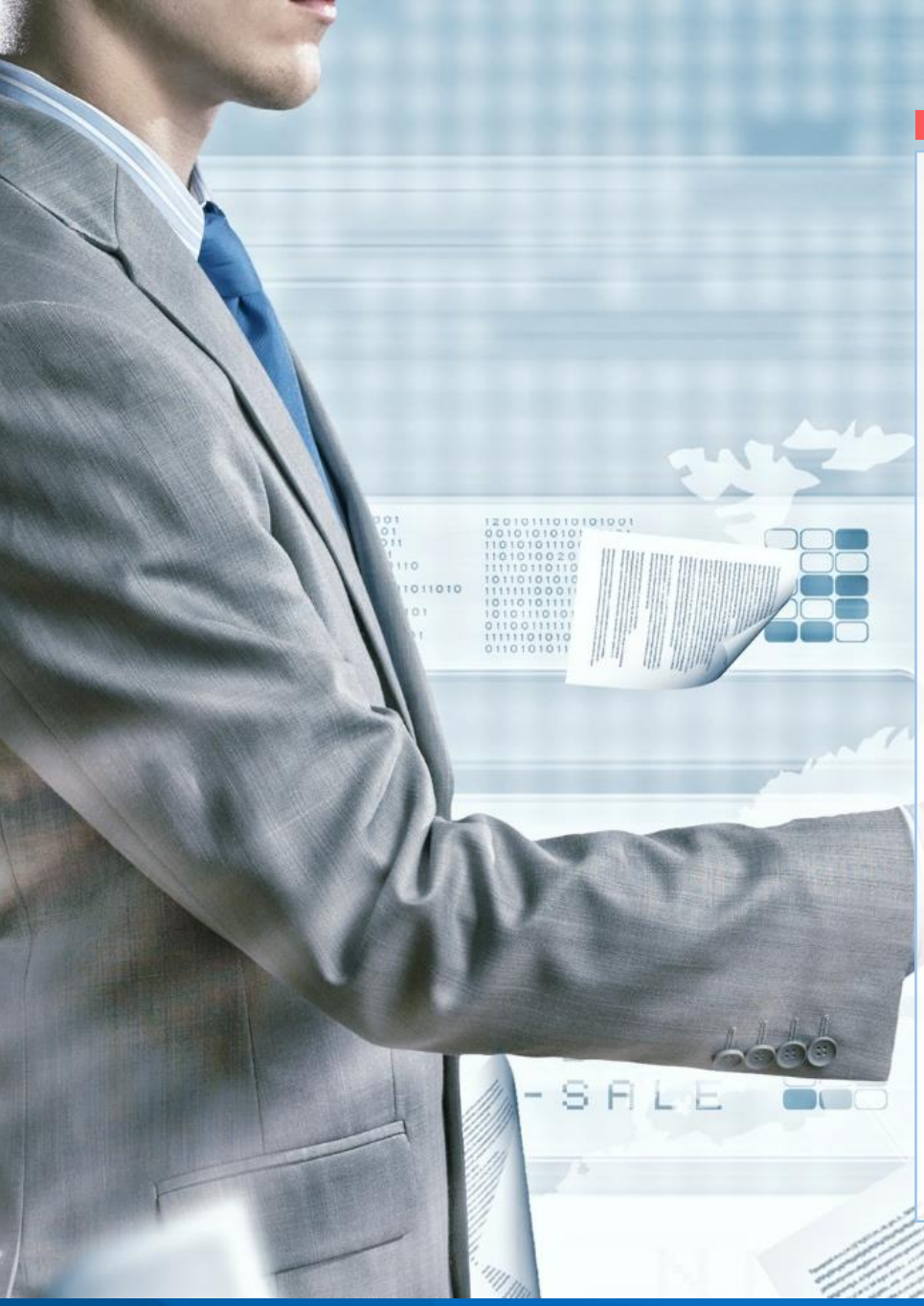
Technology considerations: A solution that can collect customer data via feedback such as complaints and adverse events, and allows to take action on that data, is vitally important to understanding if the quality commitment to customers is reached. Having a centralized and aggregated way to organize the feedback data is essential, and an automated QMS will provide:

- Auditing solutions: a solution that not only manages and standardizes the auditing process, but also the scheduling process.
- Measuring effectiveness with collaborative reporting: a solution that provides data from design, production, documentation, training, feedback, audits, and beyond

## **Clause 10 - “Improvement”:** Fostering overall improvements

Technology considerations: Being able to record information in a single location is critical. If the organization is going to issue a corrective action, it should be traceable back to the nonconformance. Linking a nonconformity to a corrective and preventive action, and being able to create a seamless closed loop on the process, will ensure that data is not lost or entered incorrectly.

- Lastly, the organization want to build reporting and data collection to look for improvement areas. Having a robust reporting system on the entire QMS is critically important to make informed decisions.



# SoftExpert EQM Suite

## Enterprise Quality Management

SoftExpert EQM Suite helps organizations establish, document, implement and maintain a quality management system and continually improve its effectiveness.

+ Ensure management responsibility
+ Effective resource management
+ Advanced product planning and realization
+ Continually improve data measurement and analysis

SoftExpert EQM Suite is the most comprehensive enterprise quality management software (EQMS) to implement and simplify enterprise-wide quality and compliance management programs, through automated, highly interactive quality processes tailored to align with each organization's specific products, operations and business practices.

SoftExpert EQM solution easily manage, track and report all quality metrics in real-time, comply with multiple regulations and standards such as ISO 9000 , FDA, Lean, Six Sigma, etc., focus on customer requirements and satisfaction, and drive continuous improvement processes up, down and across the organization.

Learn More at:
www.softexpert.com/enterprise-quality-management.php

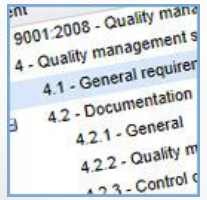
Process mapping


Quality performance indicators

Document control

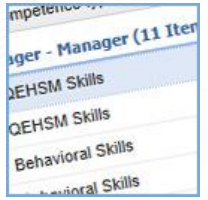
NCR

CAPA Management



Audit Control

Problem analysis (Ishikawa)



Competence management

Supplier performance evaluation


**Take your business to the next level**

www.softexpert.com | sales@softexpert.com