



## ARE YOU PREPARED FOR RECENT CHANGES TO ISO 9001?

Change, it happens. Whether it is driving your car to work and anticipating the road conditions and hazards, or maneuvering and positioning your company in today's expanding global markets.

### History of Change to ISO 9001

Since its inception in 1987, ISO 9001 has outlined the requirements for creating and managing the system of change within organizations, large, small, and anywhere in between. Each successive revision to ISO 9001 has only served to improve upon these requirements and how they are communicated to organizations.

The 1994 version of the standard placed a distinct emphasis on product requirements using preventive actions, instead of relying solely on final product inspection. That version also sought for organizations to implement documented procedures to manage the quality control aspects of organizations. In 2000, ISO 9001 strengthened its core by placing quality and process management as the focus. It asked organizations to understand their client's requirements and needs before they designed processes. The intent was to help organizations to deliver on the client's requirements through continual improvement and customer satisfaction. This version focused much more on managing quality throughout the organization rather than quality control.

The changes made in ISO 9001:2008 served only to clarify the existing requirements of 2000. It also began the process of aligning the standard with other international standards.

### ISO 9001:2015

In September 2015, the international community adopted the latest version of ISO 9001, Quality management systems – Requirements. This version includes key changes that incorporate many new concepts and expand on concepts already accepted by quality professionals. A short synopsis of these changes is discussed below.

#### Clause 4- Context of the organization

This clause is a new requirement that features the need for senior managers to understand the expectations of all relevant parties. Senior managers will also be expected to analyze the internal and external challenges to meet these expectations. This clause is very closely linked to clause 5 – Leadership which means the management system must enter the boardroom. This clause challenges the organizational leadership to embrace the management system and to actively lead it. Additionally, clause 4 deals with process management. Once implemented, clause 4 requires organizations to determine process risks and have measures prepared to ensure effective operation. The organization will need to allocate resources for processes.

## Clause 5 - Leadership

This requirement has been implemented to ensure organizational policies are aligned with strategic direction. This will assist organizations in identifying, assessing, and managing all risks that could prevent an organization from meeting product requirements or customer requirements. The clause also emphasizes the need for defining responsibility for process management.

## Clause 6 – Planning

This clause replaces the requirement for preventive action and emphasizes risk and opportunities related to product conformity and customer satisfaction. This is a significant change from previous versions where the focus was on preventive actions. However, by focusing on risk and opportunities, the organization will, in essence, prevent the occurrence of deficiencies within the management system. Additionally, clause 6 implements requirements to assist organizations in change management in a systematic way.

## Clause 7 – Support

Clause 7 focuses on how organizations manage changing resources more effectively. It also adds new requirements to determine, present and maintain knowledge to continually meet customer requirements and improve overall customer satisfaction.

## Clause 8 – Operation

This clause adds two new requirements. The first of which is contingency planning to improve customer communication. The second sets out to assess methods to determine suitability of a design before it reaches operations. Clause 8 also stipulates the control of all outsourced activities through utilization of risk management.

## Clause 9 – Performance Evaluation

This clause incorporates more stringent requirements for monitoring, measurement, analysis and evaluation of the management system. It also presents how monitoring and measurement work in relation to risk and the effectiveness of an organizations management system.

## Clause 10 – Improvement

Clause 10 requires organizations to establish and maintain processes to correct errors and improve the management system. These requirements allow for “find and fix” improvements as well as a structured corrective action process.

As you can see from the above summarization of the clauses of ISO 9001:2015, many changes have been implemented to assist organizations in the improvement of their management system. This is a systematic approach many quality professionals can equate to the Shewhart/Deming Cycle of Plan, Do, Check, and Act. Clauses 4 through 7 would be the Plan stage of the cycle; Clause 8 the Do stage of the cycle; Clause 9 Check stage of the cycle; and Clause 10 the Act stage of the cycle. If you follow these clauses you will complete one cycle of the Shewhart/Deming Cycle for each process under analysis.

If you are currently certified to ISO 9001:2008, your certification will no longer be valid after September 2018. What can you do in preparation of the transition to ISO 9001:2015?

The following is a list of actions you can take to begin the transition process:

- Identify gaps in your system in accordance with the new requirements. Use the new standard as the basis to compare your current system to the new requirements.
- Develop an implementation plan.
- Ensure training and awareness across your organization to all parties influencing the performance of your organization.
- Provide information to all participants in the management system process about the new requirements of ISO 9001 and the impact the new changes will have on them
- Systematically update your quality management system to meet the additional and/or modified requirements.
- Verify the performance of the management system.

How QAI can help:

Just a few short years ago, QAI was previously known as Quality Auditing Institute. Auditing process and product compliance is at the heart of what we do. Our focus continues to be on ensuring process and product compliance. Whether you are currently certified to ISO 9001:2008 or seeking to gain certification from scratch, QAI can help you along the path of change in your organization.

### 1. GAP Analysis

The International Accreditation Forum (IAF) recommends a GAP analysis as the first step in the transition process. This is the best way to analyze your current system and ensure compliance of your current system to the new requirements. This will also pinpoint needed improvements in your current system. QAI can come onsite to your facility to perform an overall GAP analysis of your system and processes or review your documentation to perform a GAP Analysis of documentation only.

### 2. Consult and Train

QAI offers one-on-one training and consultation on the improvements to your system. Your organization will be partnered with an expert in auditing and management system implementation. This expert will guide you through the process of implementing change and understanding the requirements of ISO 9001:2015.

### 3. Auditing

QAI can perform audits of your quality management system throughout the implementation period to ensure your system is meeting the requirements of ISO 9001:2015. The auditing provided by QAI will assist you in identifying corrections which must be made to your system before your clients or certifiers could identify them.

### 4. Risk Management

QAI can train your personnel in identifying the risks to your processes. This will assist your organization in mitigating these risks through the implementation of effective process changes.

For more information on ISO 9001 related services QAI offers please contact us at [info@qai.org](mailto:info@qai.org) or phone 888.540.4024 and ask to speak to Jarred Johnson.