ISO 9001:2015
Quality Management Systems (QMS)

What is ISO 9001 and why was it revised?

ISO 9001:2015 key objectives:

- *Provides financial – cost saving – benefits*

- *Improves the efficiency of existing processes, quality awareness and improved consistency & traceability*

- *Sets a framework for continual improvement and addresses risks and opportunities in a structured manner*

- *Creates satisfied customers, management and employees by improving the products and services offered*

ISO 9001 is the international standard that specifies requirements for a quality management system (QMS). In 2015 a new version of ISO 9001 was released, but companies certified under the previous standard of ISO 9001:2008 will still be recognized as compliant until September 2018. Many of the ISO standard elements are performed by companies who already follow a similar approach by using the plan-do-check-act cycle, making ISO integration a straightforward next step. ISO 9001:2015 formalizes and standardizes QMS activities on an international scale for today's multinational companies.

Who should use the ISO 9001:2015 revision?

The standard provides guidance and tools for organizations who want to consistently improve the quality of their products and services, and ensure they consistently meet customer and regulatory requirements. ISO 9001:2015 applies to any organization, regardless of size or industry, that would like to improve its overall performance. It is expected to have a significant impact on trainers, consultants, certification and accreditation bodies, auditors and standards writers.

What are the key changes to the standard?

Easier integration with other ISO management standards – using Annex SL, ISO 9001:2015 makes it easier for organizations to follow the same structure as other ISO management standards – improving integration and simplifying audit processes with industry quality standards to meet regulatory requirements.

Emphasis on risk-based thinking – even though the 2008 version of ISO 9001 included risk-based thinking, the prominence is highlighted more in the latest version of the standard. Risk-based thinking helps address organizational risks and opportunities in a structured manner to identify, consider and control the risks inherent in systems, processes and functions at every step of the plan-do-check-act cycle.

Define your QMS and processes – while the ISO 9001:2015 standard does not provide a list of core QMS plans, it suggests that organizations focus on core processes and assign responsibility for these processes.

Emphasizes leadership engagement and focus – puts accountability for quality on leadership to define clear and specific quality objectives that recognize organizational context; and monitor, measure, track and communicate progress to employees.

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Evidence-based quality performance focus – the new standard is less concentrated on quality documentation procedures and how to achieve it. Instead, the new standard focuses on what must be achieved to ensure that product and service quality meet the expectations of all interested parties, including client and regulatory.

Takeaways

1. **Start identifying operational risks** – survey for potential risks in your core processes and categorize them.

2. **Perform a gap analysis** – identify any organizational gaps which need to be addressed to meet the new requirements.

3. **Calculate your risk** – quantify the risks and their likelihood of occurrence.

4. **Create a risk approach** – determine what to do if there is a risk and develop a corrective or preventative action.

5. **Educate** – provide appropriate training and awareness for all parties that have an impact on organizational effectiveness.

6. **Refresh your QMS** – update the existing QMS to meet the revised requirements.

7. **Prepare for transitioning** – if you are certified to the standard, talk to your certification body about transitioning to the new version.

8. **Integration with ISO 14001** – there are common elements between ISO 9001:2015 and ISO 14001:2015, so you can combine documentation to support the same processes.

To find out more about how ComplyWorks can help you manage your compliance to ISO standards contact:

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