

Change in ISO 9001:2015

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In this article we give basic guidelines regarding the implementation of the change process in the company and their relationship to the QMS defined by ISO 9001:2015 standard.
Keywords: Change, ISO 9001:2015, Change process, implementation, steps to Implement changes.

Introduction

ISO 9001:2015 focuses on change management at many places. Any change, whether in the process, manpower, machinery, instruments, technology, raw materials, suppliers, customer requirements, legal requirements etc. shall go through a defined change management process.

One of the goals of the ISO 9001:2015 is to enhance the requirements for addressing changes at system and operational levels.

The ISO 9001:2015 requirements provide a strong basis for a management system of a business that supports the strategic direction of the organization.

Once the organization has identified its context and interested parties, and then identified the processes that support this linkage, addressing changes becomes an increasingly important component of a continued success.

Once processes are determined, an organization will need to identify the risks and opportunities associated with them. Changes may be necessary to achieve the benefits associated with the determination of risks and opportunities.

They can be related to any element of the process, such as inputs, resources, personnel, activities, controls, measurements, outputs, etc.

The change process in ISO 9001:2015

The change process would include:

- the change to be implemented
- changes initiated by the reason for change
- changes reviewed by the evaluation of change for consequences / effects on an overall performance of quality system and further actions to be taken to resolve such effects
- resources required to make the change
- skills required to make the change
- the final decision for change approval; the change in the documentation as per change to be implemented.

Changes are intended to be beneficial for the organization, and need to be carried out as determined. In addition, the consideration of new, introduced, risks and opportunities need to be taken into account.

To achieve the benefits associated with changes, the organization should consider all types of changes that may need to occur. These changes may be generated, for example, in:

- The processes
- The documented information
- The Tools
- The equipment
- The employee training
- The supplier selection
- The supplier management
- and many others

The successful management and control of these changes has become a core requirement within the organizations QMS.

Things to consider when implementing the new requirements for Change

There are many triggers that can cause a change to the Quality Management System:

- Customer feedback
- Customer complaint
- Product failure
- Employee feedback
- Innovation
- Determined risk
- Determined opportunity
- Internal audit results
- Management review results
- Identified nonconformity
- Many others

These recommendations are not necessarily applicable for every type of organization. Some changes need to be carefully managed, while others can be safely ignored. In order to sort through this, the organization should consider a method to prioritize. To determine the priority, the organization should consider a methodology that allows them to take into account:

- The consequences of the change
- The likelihood of the consequence
- The impact on customers
- The impact on interested parties
- The impact on quality objectives
- The effectiveness of processes that are a part of the QMS
- others

Typical steps to Implement changes

- Define the specifics of what is to be changed
- Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, the necessary information, others)
- Engage other people, as appropriate, in the change process
- Develop a communication plan (appropriate people within the organization, customers, suppliers, interested parties, etc. may need to be informed)
- Use a cross functional team to review the plan and provide feedback related to it and the associated risks
- Train people
- Measure the effectiveness

What changes need to be made?

- The change in the process (inputs, activities, outputs, controls, etc.)
- Communication with customers
- Communication with the supply chain
- Additional controls for processes
- Inspection
- Employee training
- Implement a new process
- Provide documented information
- Change existing documented information
- Improve employee competence
- Outsource a process
- Many others
- Other considerations.

Prior to making a change, the organization should consider unintended consequences. After making a change, the organization should monitor it to determine its effectiveness and identify any additional problems that might occur. The records of some changes may be needed as a part of the Quality Management System.

Here are some tips and techniques to help plan and implement changes in an effective, efficient and timely manner:

- The change must be realistic, achievable and measurable
- Start at the top but involve every layer
- Risk thinking through change management
- Risk management will be included in the change management!
- Make change management integrated

Conclusion

There are different internal and external sources initiating the change throughout the organization. The Change management tool, as a platform, enables you to plan, control and manage every change needed in the organization.

Implementing The Change Management tool will help you with every single change suggested in ISO 9001:2015 and will be a good practice for any other change such as business needs and daily decisions. An effective change management will support a smooth transition from the old Quality Management system to the new one and will be a good practice to manage all the other changes of your organization in the future.

References

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Promjene u ISO 9001:2015

SAŽETAK

U ovom članku ćemo dati osnovne smjernice o provedbi procesa promjene u društvu i njihov odnos prema QMS definiranog normom ISO 9001: 2015

Ključne riječi: Promjena, ISO 9001: 2015, proces promjene, implementacija, korake za provedbu promjena.