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**How Change is addressed within ISO 9001:2015**

**Purpose of this paper:** To explain the requirements for *“Change”* in ISO 9001:2015

**Purpose of these requirements:**

One of the goals of the ISO 9001:2015 Standard is to enhance the requirements for addressing changes to the Quality Management System and its processes. The ISO 9001:2015 requirements provide a strong basis for a management system for business that supports the strategic direction of the organization. Once the organization has identified its context and relevant interested parties and their relevant requirements then identified the processes that support this linkage, addressing changes becomes an increasingly important component of continued success.

Once its processes are determined, an organization will need to identify the risks and opportunities associated with these processes. To achieve the benefits associated with the determination of risks and opportunities changes may be needed. These changes can be related to any part of the process, such as inputs, resources, people, activities, controls, measurements, outputs, etc.

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

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

* Customer feedback
* Customer complaint
* Product and service failure
* Employees and other interested parties feedback
* Innovation
* Determined risk
* Determined opportunity
* Internal or external audit results
* Management review results
* Identified nonconformity
* Identified opportunities for improvement

To achieve the benefits associated with changes, the organization should consider all types of changes that are likely to occur. For example, these changes can be generated in:

* Processes
* Documented information
* Tooling and equipment
* Supplier management

The management and control of these changes has become a core requirement within the organization’s Quality Management System.

**The change requirements specified in ISO 9001:2015 are outlined below.**

1. **6.3 Planning of changes**

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.

Examples:

* Change to a process (inputs, activities, outputs, controls, measurements, resources, information, responsibility, procedures, etc.)
* Change related to external providers
* Changes in communication with customers
* Develop documented information
* Improve employee competence

1. **8.1 Operational planning and control**

The organization shall control planned changes and review the consequences of unintended changes, taking action to prevent or mitigate any adverse effects, as necessary.

Examples:

* Additional inspection
* Outsource a process

1. **8.3.6 Design and development changes**

During design and development, changes that are identified shall be reviewed and controlled to ensure there is no adverse impact to the conformity of the product or service.

Example:

* Changes in communication with the supply chain

1. **8.5.6 Control of changes**

The organization shall review and control changes for products ~~ion~~ or service provision, to the extent necessary to ensure continuing conformity with requirements.

Examples:

* Implement a new process
* Change existing documented information

Note: Other references to change are found in clauses 4.4, 5.3, 8.2.4, 9.2.2, 9.3.2, 9.3.3, 10.2.1.

**Things to consider when implementing the requirements for “change”**

* Prior to making a change, the organization should consider how to address unintended consequences of the change
* After making a change the organization should monitor the change to determine its effectiveness and to identify any additional risks and opportunities
* Prevent risks to achieving objectives by managing the change process

Note: These recommendations are not necessarily applicable for every type of organization and every type of change

**Prioritization**

Some changes need to be carefully managed, while others may be more flexible and not need formal additional action. In order to accomplish this, the organization should consider a methodology to prioritize which changes will be managed.

To determine the priority, the organization should consider a methodology that allows them to take into account:

* Risk assessment (e.g. consequences of the change, likelihood of these consequences)
* Impact on customers
* Impact on relevant interested parties
* Impact on quality objectives
* Effectiveness of processes that are part of the Quality Management System

**Typical steps to implement changes**

* Define the specifics of what is to be changed
* Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, needed information, etc.)
* Engage people as appropriate in the change process
* Develop a communication plan that considers the appropriate people within the organization (customers, external providers, interested parties, etc.) that may need to be informed
* Use a cross functional team to review the plan to provide feedback related to the plan and associated risks
* Train people
* Implement the change
* Measure or determine the effectiveness of the change
* Lessons learned