



International Organization for Standardization

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How Change is addressed within ISO 9001:2015

Purpose of this paper: To explain the new requirement for Change (6.3 *Planning of changes*, 8.1 *Operational planning and control*, 8.3.6 *Design and development changes* and 8.5.6 *Control of changes* in ISO 9001:2015).

Purpose of this new requirement:

One of the goals of the ISO 9001:2015 revision 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 for 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 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 element of the process, such as inputs, resources, persons, 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.

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:

- Processes
- Documented information
- Tooling
- Equipment
- employee training
- supplier selection
- supplier management
- and many others

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

These new requirements are referenced in ISO 9001:2015 as 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 and systematic manner (see 4.4).

The organization shall consider the:

- a) purpose of the changes and their potential consequences;
- b) integrity of the quality management system;
- c) availability of resources;
- d) allocation or reallocation of responsibilities and authorities.

2. 8.1 Operational planning

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

3. 8.3.6 Design and development changes

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

4. 8.5.6 Control of changes

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

The organization shall retain documented information describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.

Footnote: Other references to change are found in clauses; 4.4, 5.3, 9.2, 9.3, 10.2)

Things to consider when implementing the new requirement 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
- NOTE: These recommendations not necessarily applicable for every type of organization.
- Background: 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:
 - Consequences of the change
 - Likelihood of the consequence
 - Impact on customers
 - Impact on interested parties
 - Impact on quality objectives
 - Effectiveness of processes that are 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, needed 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 review the plan to provide feedback related to the plan and associated risks
 - Train people
 - Measure the effectiveness

What changes may need to be made?

- Change to a 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 the change to determine its effectiveness and to identify any additional problems that might be created
- Records of some changes may be needed as part of the Quality Management System