Management System Guidance

ISO 9001:2015 & ISO 14001:2015

Contents

8 Operations

8.1 Operational Planning & Control

8.1.1 Quality Operational Planning & Control

You should seek and record evidence that your organization has determined the design and its processes to meet the requirements of your customers and the requirements of your EQMS. Evidence that the process, including all inputs, outputs, resources, controls, criteria, process measurement, and performance indicators being planned, should be sought.

For those risks and opportunities that your organization has identified, you should seek evidence that these actions have been integrated into the management system; as such, these actions should be verifiable at the process level – for example, evidence of controls, acceptance criteria, and resources to address the risks and opportunities.

Review the acceptability criteria; this may include targets, measures, values, KPIs, specifications, and other criteria relevant to the output.

You should ensure that the implemented processes are controlled as planned and that there is evidence that your organization has evaluated the effectiveness of actions taken when addressing risks and opportunities. Evaluate and record any evidence pertaining to planned and unintended changes.

Operational planning is about controlling the design and development process. The organization must ensure that all related activities take place under controlled conditions. The final product or service is the culmination of events that transfer customer requirements and expectations into a tangible product or effective service that conforms to specified requirements and expectations.

Control product planning by:

1. Determining quality and environmental objectives for the product;
2. Determining requirements for the product;
3. Identifying processes required to achieve conformance;
4. Establishing processes required to achieve conformance;
5. Identifying documents to demonstrate conformance;
6. Identifying resources required to achieve conformance;
7. Maintaining and retaining documented information.

Your organization needs to plan in advance for how they will manufacture their product or deliver their service. The plans need to take into account the product requirements and any quality objectives that might be appropriate, resources and documents that may be necessary, and what type of monitoring and/or inspection activities should be put in place to ensure the product or service will meet the requirements, and what types of records should be kept.

ISO 9001:20015 and ISO 14001:2015 both introduce the concept of controlling change, whether it is a 'planned change to be controlled' or an 'unintended change to be reviewed for their consequences'. Controls can include engineering controls, procedures, documented procedures, etc. They can be implemented following a hierarchy (e.g., elimination, substitution, administrative) and can be used singly or in combination.

All operational factors must be determined, and risks associated with the environment must be managed in a way that conforms to the EQMS policies. There should be a process for developing work instructions that detail standard practice for performing tasks that comply with all EQMS requirements, as well as a process for identifying hazards and controlling tasks for all non-routine tasks and ensuring all environmental requirements are met.

8.1.2 Environmental Operational Planning & Control

You should seek and record evidence that your organization has determined the design and its processes to meet the requirements of your customers and the requirements of your EQMS.

Evidence that the process, including all inputs, outputs, resources, controls, criteria, process measurement, and performance indicators being planned, should be sought. ISO 14001:2015 introduces three new issues that open up the scope of this whole clause:

1. **Changes**: Planned changes to be controlled or unintended changes to be reviewed for their consequences. Controls can include engineering controls, procedures, documented procedures, etc. They can be implemented following a hierarchy (e.g., elimination, substitution, administrative) and can be used singly or in combination.
2. **Life cycle perspective**: To design and develop products and services taking into account the environmental impact throughout their life cycle. Include environmental requirements in the purchasing specifications of products and services, and communicate these environmental requirements to external providers. When necessary, provide information on potential environmental impacts related to the transportation, use, end-of-life treatment, and final disposal of its products and services.
3. **Out-sourced Processes**: Outsourced processes affecting EQMS compliance must be controlled or influenced. Auditors will be alert and identify instances of outsourcing highly pollutant processes with the intention of dropping them out of EQMS.

Considering that some of your organization's environmental impacts can occur once the products and services have been delivered to the customers, organizations need to provide information to those that will transport, use, treat, or dispose of the products and services in order to prevent adverse environmental impacts. The Life cycle perspective means that your organization must also:

1. Design and develop products taking into account environmental impacts throughout the life cycle;
2. Include environmental requirements in the purchasing specifications of products and services;
3. Communicate these environmental requirements to external providers;
4. When necessary, provide information on potential environmental impacts related to the transportation, use, end-of-life treatment, and final disposal of its products and services.

Ensure that those with responsibility for each stage of the lifecycle, for example, procurement, design, logistics, operations, sales, and after-sales, are represented in environmental aspects identification and evaluation.

Again, a workshop scenario works well. Where significant aspects related to other stages of the lifecycle can be managed or coordinated through the EQMS, for example, by operational control and environmental objectives.

Certification Auditors will not expect to see a fully developed life-cycle analysis. This is not a requirement of the new standard. All operational factors must be determined, and risks associated with health, safety, and the environment must be managed in a way that conforms to the EQMS policies.