Quality Management System Guidance

Transition Planning Guidance

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1 Transitioning to ISO 9001:2015

1.1 Benefits of Transitioning

Since ISO 9001 was revised to meet the needs of today's business world, we recommend that you update your quality management system to fit the new version. This section will help you get started on the journey. If your organization needs to maintain their certification to ISO 9001, you will need to upgrade your quality management system to include the requirements of ISO 9001:2015, and seek certification.

1.2 Planning the Transition

The greatest resource of any organization are its people, so strategies for managing both real and perceived change, or concerns and attitudes, should be addressed during transition planning. It is likely that during the first few months, Top management will need to regularly reinforce the benefits of the transition project to ensure that your employees maintain focus and motivation for upgrading the QMS.

Adjusting the QMS documents should also be expected as staff become accustomed to the requirements and begin to suggest improvements in usability. Instant business or quality improvements may be initially observed; however, experience suggests that there is a lag phase before consistent improvements become the norm.

The benefits to the organization of a properly functioning QMS are not just restricted to the knowledge that it complies with regulatory requirements, but that it has the discipline to manage customer requirements effectively.

1.3 How the Transition will Affect your Audits

The changes in ISO 9001:2015 will likely affect your organization's audits in many of the following ways:

1. Greater reference to organizational strategy and issues;
2. Will require more in-depth interviews with Top management;
3. More emphasis on the adoption of the process approach;
4. Requires the identification of relevant interested parties;
5. Greater focus on performance indicators;
6. Requirements to consider changes affecting organization;
7. Requires organizations to assess risks and opportunities;
8. Encourages risk-based internal auditing;
9. The need to establish and maintain the internal audit programme;
10. The need for documented information as evidence of effective audit programme implementation;
11. Approach internal audits as a risk assessment tool.

1.4 Existing ISO 9001:2008 Documentation

The extent of the documented information will differ from your organization to another because of to the size of organization and its activities, processes, products and services; the complexity of processes and their interactions, and the competence of personnel.

In ISO 9001:2008, the quality manual helped to establish and document the framework of your organization's quality management system while articulating those aspects of the QMS to any interested parties.

While there is no requirement for a quality manual or documented procedures in ISO 9001:2015, it is suggested that if they add value, then they should not simply be binned. You will be expected to maintain the integrity of the QMS during the transition process.

You do not need to renumber your existing documentation to correspond to the new clauses. It is down to each organization to determine whether the benefits gained from renumbering exceed the effort involved.

Neither do you need to restructure your management system to follow the sequence of and titles of the requirements. Providing all of the requirements contained in ISO 9001:2015 are met, your organization's quality management system will be compliant.

1. If your quality manual fits your business and your customers require it, keep it!
2. If your procedures are effective and define how your key processes operate, keep them!
3. If the quality policy and related objectives align with business strategy, and they are communicated and adding value, keep those too!

The type and extent of documented information that your organization should retain and maintain, in order to be compliant with ISO 9001:2015, clearly depends on the nature of your organization's products and processes. The following criteria can be used to assess the different types of ISO 9001:2008 documents and information that your organization should retain and maintain as documented information by determining whether the information:

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

If any of the above criteria apply to any type of document or information within your organization's domain, then it should be retained and maintained as a form of 'documented information' as per Clause 7.5 of ISO 9001:2015.

1.5 Summary of Key Changes

1.5.1 Process Approach

The process approach was promoted by ISO 9001:2008 and is now a requirement in its own right, which sets out the specific requirements for the adoption of a process approach. A process is a set of interrelated activities that transform inputs and activities into outputs.

The process approach is a management strategy that requires organizations to manage their processes and their interactions. Consider each major process with in your organization and the supporting processes that underpin and enable the processes.

Certification Auditors will likely audit your organization's processes to sufficient depth and detail to evaluate whether processes are capable of meeting planned results and performance levels, including applicable customer specific targets. Refer to Section 1.7 to understand how to audit your processes.

1.5.2 Context of the Organization

A new clause and sub clauses are introduced relating to the context of the organization. Your organization is now required to identify and asses all internal and external issues that could impact upon your quality

management system's ability to deliver its intended results. You will need to develop a methodology to understand the needs and expectations of all interested parties.

1.5.3 Scope of the Quality Management System

Greater emphasis has been placed on the definition of scope of the quality management system. The scope of quality management system should be determined in consideration to your organization's context.

1.5.4 Leadership

The previously titled Management Responsibility from ISO 9001:2008 has been replaced with 'Leadership'. Top management are now required to be actively involved in the operation of the quality management system. The removal of the role of 'management representative' reinforces a need to see the quality management system embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.

1.5.5 Risks and Opportunities

All references to preventive action have been removed from the ISO 9001:2015 and replaced with Clause 6.1 - Actions to Address Risks and Opportunities. Your organization is now required to determine, consider and, where necessary, take action to address any risks or opportunities that might impact your quality management system's ability to deliver conformance, or which might adversely impact customer satisfaction.

1.5.6 Products and Services

The term 'product' is being replaced by 'products and services'. By including specific reference to services as well as products, ISO 9001:2015 reinforces the idea that quality management systems are applicable to all types of business and not just to are manufacturing or supplying products.

1.5.7 Control of Externally Provided Products & Services

ISO 9001:2008 Clause 7.4 – Purchasing has been replaced with clause 8.4 'Control of Externally Provided Products and Services'. This clause addresses all types of external provision, purchasing from a supplier, or through the outsourcing of processes. Your organization is now required to take a risk-based approach to determine the type and extent of controls that are appropriate for each external provider and all outsourced processes.

1.5.8 Documented Information

Requirements for a documented quality manual, documented procedures and records have been removed and replaced with the term 'Documented Information'. This is the information your organization is required to control, retain and maintain.

1.5.9 Non-conforming Processes

The Control of non-conforming products now includes non-conforming processes. Your organization is now required to evaluate whether a process is not conforming to planned arrangements and, where necessary, investigate the cause and take action to prevent recurrence.

1.6 How to Make the Changes

Begin with the assumption that you are already doing most of what ISO 9001:2015 requires, you probably are! Many people talk about the high cost of implementing ISO 9001 but this is a false assumption. If you do it