

We're committed to helping you and your organization understand the updated requirements. This guidance document identifies the steps you should take to achieve compliance to ISO 9001:2015, and more importantly; what you don't need to do!

Transition Planning Guidance

9 Step Project Plan for Implementing
ISO 9001:2015

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Transitioning to ISO 9001:2015

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 to it by September 2018.

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.

How the Transition will affect your Audits

The changes in ISO 9001:2015 will likely affect your organization's internal 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 establish and maintain the internal audit programme;
10. Includes the need for documented information as evidence of effective audit programme implementation;
11. Approach internal audits as a risk assessment tool.

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.

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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 will 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.

Summary of Key Changes

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.

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 assess 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.

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.

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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.

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.

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.

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.

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.

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.

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 right and understand the standard, then implementation should not be a problem since 75% of your quality system is already in place.

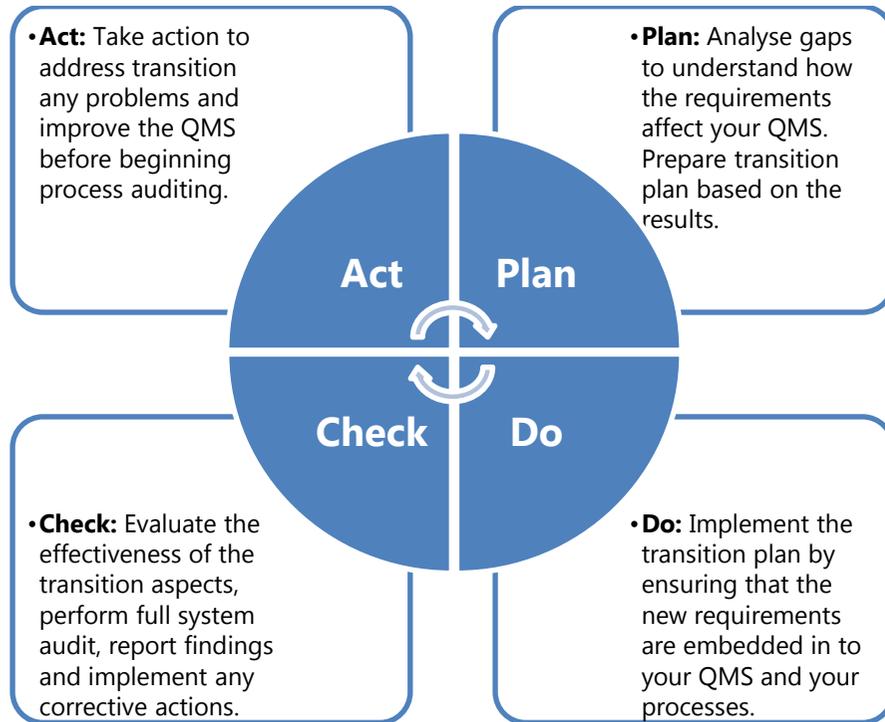
Purchase copies of ISO 9000:2015 and ISO 9001:2015. Read them both and make yourself familiar with their language and concepts. Although it is written in a dense, formal language, the clause titles in ISO 9001:2015 are fairly self-explanatory.

We suggest that you use the familiar Plan-Do-Check-Act (PDCA) methodology to manage your organization's transition from the old to the

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new requirements. The following transition methodology provides nine simple steps to make the transition, using the PDCA approach:



Transition Methodology

Plan – Identify System Deficiencies & Develop a Plan

Step 1 – Perform the Gap Analysis

The generalized audit questions in the gap analysis checklist will help you to highlight new requirements contained in ISO 9001:2015 and where they need to be implemented when compared with ISO 9001:2008.

The unique knowledge obtained about the status your existing quality management system will be the key driver of the subsequent implementation approach. Armed with this knowledge, it allows you to establish accurate budgets, resources, timelines and expectations which are proportional to the state of your current management system when directly compared to the requirements of the new standard.

Your organization may already have in place an ISO 9001:2008 compliant quality management system or you might be running an uncertified system. If this is the case, you will want to determine how closely your system conforms to the requirements of ISO 9001:2015.

The results of a gap analysis exercise will help to determine the differences, or gaps, between your existing management system and the new requirements. Not only will this analysis template help you to identify the gaps, it will also allow you to recommend how those gaps should be filled.

The gap analysis output also provides a valuable baseline for the implementation process as a whole and for measuring progress. Try to understand each business process in context of each of the requirements of the standards by comparing different activities and processes with what the standards requires. At the end of this activity you will have a list of activities and processes that comply with the requirements and ones that do not comply. The latter list now becomes the target of your implementation plan in Step 2.

Step 2 – Develop the Implementation Plan

Once you have identified the gaps in the system and have a committed implementation team, it is now possible to develop an achievable and manageable implementation plan that identifies the necessary resources

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needed to fill the gaps. The implementation plan should focus on the results of the gap analysis by prioritizing the correction of non-compliant processes.

Ensure that the implementation plan has clear milestones and is supported by Top Management. Implementation planning is about controlling the development process. The organization must ensure that all related activities take place under controlled conditions. The implementation plan is a culmination of events that transfer the requirements of ISO 9001:2015 into quality management system.

A good plan is often the key to any successful project and without a plan; projects tend to run indefinitely and without showing measurable progress. By having a plan, you have specific deadlines to meet. You can show progress as you meet the deadlines and take action if you are not meeting deadlines. If the implementation team is not expected to meet deadlines, other tasks will take precedence, the project will drag on and lose momentum. The implementation team must be watching the timeline and milestones while coordinating and implementing the plan.

Do – Implement Changes & Promote Awareness

Step 3 – Implement Key Requirements

The process approach promoted by ISO 9001:2015 requires that each business process is defined along with its interaction within the quality management system model. A good process model will reflect your business and be unique to how your organization functions. Use the process approach presentation to brief relevant staff about this concept.

Identify the processes that comprise your management system, there are two main types of process that you should focus on. Key processes are

steps that you go through to give the customer what they want, e.g. from order acceptance to design through to delivery while support processes are those processes that do not contribute directly to what the customer wants but do help the key processes to achieve it. Support processes include human resources, training and facilities maintenance, etc.

A good way to do this is to think about how workflows through your organization. Consider how the inputs and outputs to the key processes flow from one process to the next, what sub-processes might exist within it and how the support processes link in. For now, ignore the standard, in fact put it in a draw and forget it exists. Instead focus on your key processes and how the departments interface with each other.

Once you have defined the processes and interfaces; go back to the standard and determine which processes are responsible for meeting which requirements. When defining your organization's processes, think about each process and department and assign try to define those processes around the current organizational model and not around the requirements of the standard.

The simplest tools are often the best; try to capture this information using process maps and/or flowcharts ensuring you use the terms and language of your organization to describe what happens where. Another technique is to use a large clear wall and a pack of sticky notes. Write on the sticky those activities that happen in your organization and then organise the notes into a logical chain of events.

Step 4 – Provide Awareness Training

Awareness training should be given to all employees about the new elements of the quality management system and how it might affect their

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work. Employees should be made of the quality policy and its objectives. After training, employees should be comfortable with using the revised QMS and will demonstrate their knowledge by being able to locate and use the documented information that relates to their work. Employees should know:

1. Types of documented information that applies to their work;
2. Which forms to use, how to complete and process them;
3. Know the quality policy and how objectives relate to their work;
4. How to report non-conformances and issues for corrective action;
5. Understand the context of the organization;
6. Understand the risk and opportunities that affect their work.

Check – Ensure the changes are Implemented

Step 5 – Begin System Auditing

During the implementation phase, you should carry out one or two system audits covering all of the requirements that are relevant to your quality management system. Enter the audit findings into the Audit Findings Tracker.

Prepare the narrative for each section of the internal audit report and copy and paste the trend tables and charts to summarize your findings. Ensure the audit report is reviewed and approved. Submit the audit report to Top management for review and action.

Step 6 – Review Findings

Top management should ensure that corrective action is undertaken on any adverse audit findings without delay. Make any necessary changes to

the quality management system and the documentation information. Certification bodies will wish to see at least three months of records. The new system will likely generate numerous corrective actions; if they are not investigated and completed, your quality management system will not be ready for a registration audit.

Once you have implemented the new key requirements and have dealt with any corrective actions, it is suggested that clients conduct at least one other internal (element) audit as per the defined milestones that were established by the implementation plan. After this internal audit, Top management should again review the effectiveness of the system as whole and provide resources for corrective actions and improvements.

Act – Take action on the Audit Findings

Step 7 – Implement System Changes

Implement any changes to the quality management system processes that might have arisen from the outputs of previous step. Once the whole system is implemented, conduct a full system internal audit. Look for areas to streamline and improve.

Step 8 – Begin Process Auditing

Once the quality management system is complete and everyone is following the new system, you should conduct an audit of each key process. Begin by selecting a key process and identifying the inputs needed by the process and the outputs that are generated by the process.

Each process audit checklist is divided into two sections. The first section of the checklist deals with general questions that relate to the supporting processes that impact upon the functioning of the key process. The second

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section of the checklist deals with questions whose answers will reveal whether the key process itself is meeting the requirements of the standard. You may want to add other questions to the checklists that relate to assessing how well the process satisfies customer requirements.

Once the questions from the checklist are answered, you will be able to quickly identify and summarize the process by determining its performance level against the requirements of the standard or customer specifications. Consider these points:

1. Is the process planned?
2. Is there is an appropriate review to verify output?
3. Is there confirmation that the output meets the input requirements?
4. Is the process is verified for effectiveness? (measured)
5. Is there validation to ensure that the process meets intended results?
6. Is there continuity between the various processes in the organization?
7. Is the task done consistently on a person-to-person basis
8. Is the task done consistently on a day-to-day basis?
9. Do the interfaces between the departments operate smoothly?
10. Are corrective actions being used adequately in this process?
11. Does product information flow freely?
12. How are changes controlled?

Ensure that the results of the internal audits are reported to Top management and that appropriate action is taken to correct non-conformances.

Step 9 – Continual Improvement

Clause 10.3 of ISO 9001:2015 requires organizations to 'continually improve the effectiveness of the quality management system and its process'. Most auditors would expect you to revise the quality system documentation and processes as the quality management system matures or when a new process is implemented.

Processes can always be made more efficient and effective, even when they are producing conforming products. The aim of a continual improvement program is to increase the odds of satisfying customers by identifying areas that need improvement. It requires the organization to plan improvement systems and to take into account many other activities that can be used in the improvement process. Typically, these will be the results from the data analysis.

You will be required to ensure that you continually improve the degree to which your products and services meet customer requirements and to measure effectiveness of your processes. To this end the continual improvement principle implies that you should adopt the attitude that improvement is always possible and that organizations should develop the skills and tools necessary to drive improvement.

The PDCA cycle is a perfect way of introducing continual improvement to your organization's activities. Each step to improvement can be defined by four sub steps, Plan, Do, Check and Act:

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1. **Plan:** Establish a timetable for internal audits and management reviews. Establish the objectives and processes necessary to deliver results in accordance with your customer's requirements and your organization's policy. To improve the operation by finding what is going wrong (customer complaints, internal complaints, rework etc.) and come up with ideas for solving the problem.
2. **Do:** Implement changes designed to solve the problems on a small scale first to see the effect. This minimizes disruption to routine activity while testing whether the changes will work or not.
3. **Check:** Monitor and measure processes and product against policies, objectives and requirements and report the results. Also check on key activities to ensure that the quality of the output is conforming and not influenced by the changes.
4. **Act:** Take actions to continually improve process performance. Implement the changes on a larger scale, if the experimental changes have proven to be successful. This means making the changes a routine part of the activity.

Also act to involve other people, departments or suppliers affected by the changes and whose co-operation is needed to implement them on a larger scale. Make sure that changes are documented properly according to the documentation requirements.

All management reviews must be documented. Observations, conclusions, and recommendations for further necessary action from the review must be recorded. If any corrective action must be taken, top management should follow up to ensure that the action was effectively implemented. The purpose and final outcome of the management review should be

continual improvement of the QMS. As your organization's QMS increases in its effectiveness and efficiency, your environmental performance will likewise increase.

Here's what ISO 9001:2015 is really all about: defining a policy, creating a plan devising with relevant objectives. You then implement the system according to the plan. You then begin auditing, monitoring and measuring performance against the plan and reacting to your findings. Bi-annual management reviews are insufficient in frequency to be able react to any issues effectively.

Performance metrics should be monitored with varying frequencies, some hourly, some daily, some weekly and some monthly. Management cannot wait for six months to respond, if they do, it will be too late. Every time management convenes to review and react to performance, it is considered as a management review. Whether they are reviewing an individual's performance, departmental programmes and projects, etc., this should be considered as valid management review.

Some companies have multiple review levels, whereby, each review may require multiple subjects and rely upon multiple metrics as inputs. Sometimes subjects are reviewed at more than one level, e.g. production numbers might be reviewed by the Production teams during daily production meetings and then by senior management, possibly weekly. Top management might conduct weekly meetings in which they review metrics and objectives to determine if any corrective action is required. The process owner is then responsible for reporting close out progress in the meeting a week later.