

How do I implement ISO 9001?

A simple, methodical approach to implementing ISO 9001:2008.

This document supports our ISO 9001 Quality Manual Template
available at www.iso-9001-checklist.co.uk.

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Introduction

Where do I start?

Implementing ISO 9001 can appear daunting - that's why we've written this guide. We aim to give you a framework for the different stages of implementation and a better understanding of the scope of the project.

You might be implementing ISO 9001 in a small company or a large organization; but in all cases the stages of implementation are identical. The process is the same.

I find the ISO Standard difficult to read and confusing!

Yes, when reading the Standard it's fair to say that much of it is written in a dense, formal language - but we firmly believe that ISO 9001 is not difficult to implement once you have a good understanding of the requirements and a clear implementation plan.

We hope this document helps you move your project forward.

More help

We have written over 100 webpages explaining the ISO 9001:2008 requirements in plain English.

To learn more we recommend you start here:

<http://www.iso-9001-checklist.co.uk/iso-9001-requirements.htm>

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Where Do I Begin?

Begin with the assumption that you are already doing most of what ISO 9001 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 a copy of ISO 9000:2005 and ISO 9001:2008. 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 9001:2008 are fairly self-explanatory.

What's in Store?

At the very least, the implementation process typically opens people's eyes to what they do and why they do it. This occurs as people understand how their work affects the subsequent work of others. Often the early stages of implementation are essentially a discovery phase followed by a grand housekeeping effort.

How Long Does Implementation Take?

Generally, implementation will last between six to nine months, but this time frame varies depending on the size and complexity of the organization. There are many factors that will influence the timeline, namely:

- The state of existing management system
- How much documentation is available
- The amount of available resources

Should We Hire a Consultant?

Organizations often engage independent consultants to help plan and implement their quality management system. However, it is entirely possible to learn and implement the requirements of the standard yourself.

This resource will provide your organization with immediate access to a body of knowledge that could help your organization ensure the effectiveness of its quality management system; in short, it has the potential to save you thousands in unnecessary consultancy fees. An ISO consultant has a great deal of influence over the development of an organization's quality system and many organizations spend a great deal of money using consultants for the sole purpose of helping them achieve ISO 9001 certification.

Evaluating a Consultant

Registering an organization to ISO 9001 does not necessarily prove product quality; it proves that the organization is good at registering. All things being equal, organizations often require an ISO consultant because they want a specialist; someone who is good at 'registering'. We recommend you review ISO 10019:2005; written by Technical Committee 176, titled 'Guidelines for the Selection of Quality Management System Consultants and use of their Services'. As the name suggests, this document provides guidance on the factors to be taken into consideration when evaluating a quality management consultant.

Deciding Which Consultant to Hire

Always ask for references, these will allow you to determine how the ISO consultant handled similar implementation scenarios. References usually say a lot about a consultant's ability to deliver. You can use these references as a basis for developing your own questions when interviewing a consultant. Once all the options have been considered, ask the consultant to submit a formal proposal that outlines their implementation strategy.

Review the proposal with the consultant and resolve any queries you may have. Sections of the proposal may have to be rewritten to provide the desired level of assurance and to provide greater clarity. Accept the proposal only when you thoroughly understand and accept its implications.

Why Not Go it alone?

In order to ensure that your organization has got what it takes to build a compliant quality management system and then to achieve certification might appear to be a very daunting challenge.

Seeking the help of an ISO consultant is the most common response to this challenge, yet it is an unnecessary option to take. Once you have read through our body of knowledge you will begin to understand the requirements more thoroughly.

Can I Adapt an Existing System?

It probably is not the answer you want to hear but you may be better starting afresh; experience proves that it is harder to adapt an unsuitable existing system than it is to develop a new one. By no means should you just discard the entire system, you may want to retain the lower level forms and work instructions. Retain your old records, etc. as they will still be relevant.

Where Can I Get Training?

There are many one day courses which take you through the process of establishing an ISO 9001 compliant system by identifying what you need to do, what documentation you will need and what an ISO 9001 auditor will want to see.

The aim of these types of course help you identify the things you will need to do to get started and to clarify the parameters of the task ahead, as well as, documentation and record keeping requirements, training and competence requirements, continual improvement requirements and also the requirements for Top Management involvement.

Managing the Change

The organizational migration from a pre-ISO 9001 state to one that operates within the rigors of an ISO based system is not a casual task. There must be a tightening of how processes are managed and there are often changes in staff interactions, responsibilities and accountability. Such changes are unlikely to succeed without the dedicated support of both the executive and operational management.

The greatest resource of a quality company are its people, so strategies for managing both real and perceived change, or concerns and attitudes, should be addressed during the initial planning of the QMS. It is likely that during the first few months, top management will need to positively reinforce the QMS requirements on a routine basis to ensure that staff maintain motivation and do not lapse back into old habits.

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.

Stage 1: Learn

1.1. Find out about ISO 9001:2008

Concept

ISO 9001 is based on the following eight Quality Management Principles, whose themes are incorporated within the requirements of the standard which can be applied to any organization to improve performance:

Customer Focus:	Organizations depend on their customers and therefore should understand current and future customer needs, should meet requirements and strive to exceed customer expectations.
Leadership:	Leaders establish unity of purpose and direction of the organization. They should create and maintain an environment in which people are involved in achieving the organization's objectives.
Involvement:	People at all levels are vital to an organization; their full involvement enables their abilities to be used for the organization's benefit.
Process Approach:	A desired result is achieved more efficiently when activities and related resources are managed as a process.
Systems:	Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
Improvement:	Continual improvement of the organization's overall performance should be a permanent objective of the organization.
Decision Making:	Effective decisions are based on the analysis of data. A quality management system provides a stimulus for the production and analysis of information.
Suppliers:	An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

What you need to do

These principles are not elements against which an organization can be directly assessed or certified but their influence will be demonstrable through their impact upon the implementation of the requirements. Use the management overview presentation to brief top management.

If you do not understand what is required by the standard you may waste time and resources by doing things that are not required, which will frustrate team members and you will be certain to miss important requirements of the standard. Buy a copy of the [ISO 9001:2008 standard](#) - this is essential! Start by reviewing:

- The requirements of the standard, 'the organization shall'.
- The mandatory 'documented' procedure requirements
- The documentation and records required by ISO 9001:2008

How is ISO 9000 related to ISO 9001?

ISO 9000 explains the principles of the quality management system while ISO 9001 defines the requirements that an organization has to meet in order to gain certification. ISO 9000 is often used to refer to a family of three standards:

- ISO 9000:2005 - Fundamentals and vocabulary
- ISO 9001:2008 - Requirements
- ISO 9004:2000 - Guidelines for performance improvement

ISO 9000 contains various definitions and terminologies that are integral to developing a proper understanding of the quality management concepts used by ISO 9001. ISO 9001:2008 has five main sections:

- 4. Quality Management System
- 5. Management Responsibility
- 6. Resource Management
- 7. Product Realization (Key processes)
- 8. Measurement Analysis and Improvement

Understand how ISO 9001:2008 applies to your Company

Understand what ISO 9001 means for your organization, not all requirements of the standard will necessarily be relevant to all organizations. Under certain circumstances, an organization may exclude themselves from some specific requirements.

When initially starting to use ISO 9001, an organization should familiarize its personnel with the quality management principles, analyze the standards especially ISO 9000 and ISO 9004, and consider how their guidance and requirements may affect your activities and related processes.

ISO 9001 introduces a concept known as the process model. This means that you need to define what your organization does by developing process maps of your organizational activities, understanding how those processes inter-relate, deciding who owns those processes.

Whether your company operates internationally or simply wants to expand locally, approval to ISO 9001:2008 demonstrates that your organization has a solid commitment to achieving quality. Approval to ISO 9001 helps to improve overall performance by widening the scope of business opportunities, increasing market share and overall competitiveness. ISO 9001 certification is often a prerequisite when bidding for contracts.

1.2. Top Management Commitment

Concept

Implementation takes time, money and resources. Make sure you have top management commitment before continuing the implementation project. Be sure that top management are solidly behind implementation of the quality system because without that commitment, the implementation process becomes almost impossible. Top management should demonstrate their initial commitment to the implementation project by the ensuring that:

- The implementation mandate is communicated and understood
- Appropriate resources are made available
- An appropriate budget is made available

Top management will further demonstrate their commitment via the quality policy and through the setting of quality objectives which is covered in Stage 3.

What you need to do

Understand why your organization is implementing ISO 9001. Is it because a client or the market requires you to register? Is it for internal benefits? Is the motivation coming from Top Management? Whatever the reasons for implementation, keep them visible during the implementation project as this helps to retain commitment and to maintain focus on the end goal.

Top management should demonstrate their commitment by nominating a Quality Management Representative who will be responsible for:

- Establishing QMS processes
- Formally reporting the key QMS metrics and data to top management
- Promoting customer and quality requirements
- Actively supporting the continual development of the QMS and its processes

1.3. Choose a Registrar & Define Scope

Concept

The registrar is a third party certification auditor who will assess your quality management system and issue a certificate if it meets the requirements of ISO 9001:2008. In choosing a registrar you should consider their industry experience, geographic coverage, price and service level offered. The key is to find a registrar who can meet your requirements. For further information regarding accredited certification bodies, please see:

- www.iso.org/iso/en/info/ISODirectory/countries.html
- www.ukas.org
- www.irca.org

Different organizations look at their registrations differently; some organizations prefer to have multiple business units or locations on a single certificate. You can register one

location in an organization or you can register the entire organization. You can even, theoretically, register one part of an individual facility.

You should address this issue in your registration scope statement. You should discuss the scope of registration very early in your contact with the registrar, prior to or during the selection process.

The scope of registration and certification will need to reflect precisely and clearly the activities covered by the organization's quality management system; any exclusion to non-applicable requirements of the standard will need to be documented and justified in the quality manual. No single business related activity should exist outside of the scope.

1.4. Conduct a Gap Analysis

Concept

A gap analysis is typically performed by an auditor or by the Quality Management Representative to enable the organization to determine what is missing from the existing management system, prior to implementing the new management system.

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

The goal is to determine what processes are already in place and what processes must be implemented. From this you can prepare a task list for each section of the standard. You will also have a firm understanding of how to proceed from where you currently are.

Once you know exactly where the gaps are, you can take steps to fill them. By using this approach, you will not only comply with the standard but you will also improve the overall effectiveness of your existing management system.

What you need to do

Undertake a gap analysis to compare the requirements of the standard against your organization's existing management system. Each question in the gap analysis checklist refers to a requirement that must be met in order to comply with ISO 9001. A 'yes' answer means that your organization is already meeting one of the requirements while a 'no' answer will reveal a gap that exists between requirements of ISO 9001 and your organization's processes. A 'no' answer might indicate that a process needs to be developed further, modified or improved in some way to make it compliant.

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 standard by comparing different activities and processes with what the standard requires. At the end of this activity you will have a list of activities and processes that comply and ones that do not comply. The latter list now becomes the target of your implementation plan. Congratulations, you have just conducted your first internal audit!

1.5. Management Review

What you need to do

Use the stage 1 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

At this stage, the Quality Management Representative should also analyze the findings of the gap analysis; prepare an audit report and present recommendations to top management. Now is the time to determine opportunities for improvement and the need for amending the existing system.

The proceedings of the management review should also be documented. Management must take a close look at the data from the gap analysis, evaluate it and take action. Congratulations, you have completed your first management review!

STAGE 1 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that top management has adopted the eight leadership principles and is motivated and committed to apply them.	
<input checked="" type="checkbox"/>	Check that the contents and the philosophy of ISO 9000 and 9001 have been made clear and have been accepted.	
<input checked="" type="checkbox"/>	Check that top management has mandated the implementation project, that this is communicated to staff and understood.	
<input checked="" type="checkbox"/>	Check that top management has provided appropriate resources.	
<input checked="" type="checkbox"/>	Check that top management has provided an appropriate budget.	
<input checked="" type="checkbox"/>	Check that top management has appointed a quality management representative.	
<input checked="" type="checkbox"/>	Check that the quality management representative is a key person with the necessary authority rather than a sideline person.	
<input checked="" type="checkbox"/>	Check that a certification body has been approached for the final assessment.	
<input checked="" type="checkbox"/>	Check that the gap analysis has been carried out and study the outcome. With this analysis it should be possible to identify the gaps when it is compared with the ISO 9001 QMS.	
<input checked="" type="checkbox"/>	Check that the results of the gap analysis and the actions to bridge the gaps have been reported to top management and that management is also committed.	
<input checked="" type="checkbox"/>	Check that the result of the management review is functioning well and that all people involved know what is expected from them.	

NOTES:

Stage 2: Plan

2.1. Establish an Implementation Team

Concept Taking responsibility for your organization's management system is no easy task and seeing an implementation project through to certification is going to take a lot longer than a couple of weeks.

Ensure your organization plans for, and provides adequate resources because it will not evolve by itself. It will also require top management to support and lead the project because it will affect the function of the whole organization.

What you need to do Before you can plan effectively, you need to set up an implementation team. Top Management should identify a steering team for the project. It should be made up of managers from the different areas of the organization. The purpose of this team will be to assign resources and responsibilities for the project as well as providing leadership.

An implementation team, headed by the Quality Management Representative should also be established. The Management Representative is the coordinator and is responsible for planning and overseeing the implementation of the quality management system. He is the link between Top Management and the registrar. All departments within the organization should be represented on the implementation team.

One of the key moments in the implementation process is defining the individual responsibility of management and employees for the introduction of different quality elements into current working process. That is why the most experienced employees from the company should be involved in this process.

Following this methodology, a team of experienced and engaged key personnel should be formed at the beginning of the implementation process. The implementation team should include personnel that have the authority to devote resources to the project and to remove roadblocks.

The implementation team should meet on an 'as needed' basis according to the project timeline. When the implementation team meets they must address the items on their task list. Spread out the implementation team meetings along the implantation timeline so you do not have too many meeting at one time.

For example, you may want to have the document control team meet early in the project to establish a system to collect and control the documents that will be generated. Whereas, the internal audit team would meet later in the process because audits will not begin until the system is complete.

2.2. Develop the Implementation Plan

Concept 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 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.

What you need to do 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 into a reliable and effective 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.

2.3. Identify Key Processes

- Concept** The process approach promoted by ISO 9001 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.
- What you need to do** 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.
- Make sure you capture the work you have done for later use. Visio is great for creating process maps which can be embedded into your quality manual or procedures. Alternatively, you can use 'Auto Shapes' within Microsoft Word or Powerpoint.

2.4. Involve and Communicate with Employees

- Concept** The key to successful implementation is often through the involvement of all people within the organization; let everyone in the company know that you have started to introduce a new quality system by holding basic awareness sessions for all employees.
- Make sure you retain records of attendance as this action will contribute towards satisfying Clause 6.2.2 of the standard. If required, use the audit awareness presentation to let employees know what to expect during an audit.
- What you need to do** All well as briefing employees during introductory presentations, try using a combination of other methods to promote awareness, such as posters placed on notice boards and leaflets with pay-slips, etc. Use training sessions to inform employees of the plan, how they will be expected to contribute and how their work will be affected by the project. Communicate why the implementation is good for the company and good for the employees.
- Communication is the key; communicate goals, plans, progress and milestones. Listen first then ask for feedback. Lack of communication seems to be one of the main root causes for errors in business. Keep people informed of the progress of the project; e.g. what's been done, what's to be done next and how the project is progressing against the plan.
- Make this process transparent and visible to all concerned; for example, place progress

charts on the walls and notice boards. Employees that are not part of the implementation team may not be hearing as much about what is going on with the project and may think the project has faded away. Communicate its progress via newsletters, bulletin boards or meetings.

2.5. Management Review

What you need to do

Use the stage 2 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

At this stage, the Quality Management Representative should report to top management on the status of current planning activities. The proceedings of the management review should be documented. Make recommendations and implement solutions to address performance problems.

The need for top management to review the QMS is essential. This is the route for review and action in respect for continual improvement. Management review is one of the vehicles by which top management will become actively involved in the system and demonstrate their commitment and control.

STAGE 2 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that the implementation team is established and the objectives for the implementation team should have been made clear.	
<input checked="" type="checkbox"/>	Check that a plan has been developed to bridge the gaps found. Make sure that the plan also contains a time schedule and that the actions are realistic and can be finished in time.	
<input checked="" type="checkbox"/>	Check to see that all the processes have been identified. Have this documentation done by the process owners, the people that are responsible for these processes.	
<input checked="" type="checkbox"/>	Check that the plan is complete, including the actions to bridge the gaps, a time schedule and the allocation of the resources such as manpower, money and time.	
<input checked="" type="checkbox"/>	Check that enough effort has been made to communicate the plan and the result of it to all staff. If needed provide extra information to key people and the implementation team.	
<input checked="" type="checkbox"/>	Check that the result of the management review is functioning well and that all people involved know what is expected from them.	

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Stage 3: Define Policies, Objectives & Responsibilities

3.1. Define the Quality Policy

- Concept** The quality policy is the only true definition of quality that counts in your organization. Provided that you take into account the few important items the standard asks for, you can define and measure quality any way you choose. Make sure the quality policy builds on current corporate objectives and values; it must be fully integrated with these concepts.
- What you need to do** The quality policy is considered to be the driving force of the quality management system as it commits your organization to meeting its objectives by ensuring a focus on customer satisfaction. It is also one of the key documents against which the performance of your quality management system is measured.
- There are many formal definitions of quality but for all practical purposes you can ignore all of them since the only definition of quality that counts is the one on which top management agree and communicate via the quality policy. When devising the quality policy, ensure it builds on current corporate objectives and values by identifying measurable quality objectives that are consistent with the quality policy. Top management should now use the quality policy template to define the quality policy.

3.2. Communicate the Quality Policy

- Concept** The standard requires the quality policy is understood by staff all levels throughout the organization. This does not mean that employees must memorize the policy but it does mean they should be aware of it, know where it may be found and be able to paraphrase, or give an interpretation as it applies to their particular role. Inferred awareness through knowledge of procedures is not considered sufficient by auditors; otherwise why have the requirement in the first place?
- What you need to do** A quick and convenient way to promote and communicate the policy might be to create a shortened version of main policy; try condensing it to five key words or even a couple of short sentences. This can be posted on bulletin boards in each department. You could even add it to the reverse side of staff security passes or ID badges.
- If an auditor asks an employee whether they are aware of the policy; they can point to the bulletin board, or point to it on their badge. The employee can further elaborate to the auditor, what the policy means to them and how it influences their work.

3.3. Define the Quality Objectives

- Concept** The quality objectives are a clear requirement in their own right as opposed to being just a part of quality policy. They must be established in support of the policy and focus on meeting product requirements and achieving continual improvement.
- When your quality objectives are defined they must reflect the quality policy, be coherent, and align with the overall corporate objectives and customer expectations. Clearly defined quality objectives should also be closely linked to your key performance indicators or other pre-existing indicators; otherwise they become meaningless if they cannot be suitably measured. The objectives must be set by top management and be incorporated into regular reporting and review activities.
- What you need to do** The translation of the quality policy into practice is made by defining the supporting quality objectives. ISO 9001 does not specify how quality objectives should be documented; they may be documented in quality manual, business plans, management review output, annual budgets, etc.
- Quality objectives are a clear requirement in their own right as opposed to being just a part of the quality policy. Once you have a set of measurable quality objectives which suit you and your customers, you can drop the vague word 'quality' and focus your quality system on achieving those objectives.

3.4. Establish Roles and Responsibilities

What you need to do You need to establish the roles of various managers and staff in terms of who will be performing audits, who will maintain certain documents, who will conduct management reviews and implement improvements. If you do not currently have any job descriptions create these now, otherwise amend the existing job descriptions to include quality related responsibilities. Also, develop an organization chart that shows the lines of responsibility and authority, this will be required for the quality manual.

3.5. Management Review

What you need to do Use the stage 3 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

At this stage, the Quality Management Representative should report to top management on the status of current development activities. The proceedings of the management review should be documented. Make and implement recommendations to address any performance problems.

STAGE 3 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that an adequate quality policy has been developed. Do not continue without this policy statement.	
<input checked="" type="checkbox"/>	Check that top management is committed to achieving the quality policy. Do not continue without this commitment.	
<input checked="" type="checkbox"/>	Check that everybody in the organization has read the quality policy, understands it and can repeat it in his/her own words.	
<input checked="" type="checkbox"/>	Check that enough effort has been made to communicate the quality policy to all staff.	
<input checked="" type="checkbox"/>	Check that roles and responsibilities are established and communicated.	
<input checked="" type="checkbox"/>	Check that the result of the management review is functioning well and that all people involved know what is expected from them.	
<input checked="" type="checkbox"/>	Check that job descriptions include responsibilities for quality.	
<input checked="" type="checkbox"/>	Check that an organization chart shows responsibility and authority of staff.	
<input checked="" type="checkbox"/>	Check that the management review was undertaken and minutes were recorded.	

NOTES:

Stage 4: Build the Quality System

4.1. Develop the Quality Manual

Concept	<p>The quality manual undertakes the essential role of formalizing and communicating the relationship between the organizational processes and procedures.</p> <p>Like any high-level document, the manual must be written in such a way that it provides employees, customers, auditors and other interested parties with a sound overview of the processes that contribute to satisfying customer requirements.</p> <p>The amount of detail required in the quality manual is proportional the level of control needed to achieve product conformance and customer satisfaction.</p>
What you need to do	<p>Often, it is common to align the structure of the quality manual with that of the standard itself, but this belt and braces approach is not always necessary. Conversely, a four page quality manual may do little to inspire confidence that your quality management system has the necessary elements to be truly effective.</p> <p>Never structure the quality manual to suit an external auditor's expectations, this is the wrong approach. It is not for external auditors to 'agree' with the structure of the quality manual, instead, they should simply determine whether the manual's content complies with the requirements of the standard.</p> <p>As long as the quality manual clearly shows how the quality management system processes interact, and at the highest level, what policies and methods are established to maintain and control those processes, an auditor is less worried about the structure of the manual.</p>

4.2. Develop the Mandatory Procedures

Concept	<p>The standard requires a minimum of six documented quality procedures. You might want to implement more procedures to control other processes such as management reviews, how to approve vendors, how to process sales orders or shipping and receiving inspections. The standard requires six mandatory documented procedures:</p> <ul style="list-style-type: none"> • 4.2.3 Document control procedure • 4.2.4 Control of Records procedure • 8.2.2 Internal audit procedure • 8.3 Control of non-conforming product procedure • 8.5.2 Corrective action procedure • 8.5.3 Preventive action procedure
What you need to do	<p>It is important to maintain a clear distinction between the contents of the quality manual and the purpose and scope of the procedures. The quality manual should define top management's intention to operate an effective quality management system, while the procedures define how those intentions are implemented at an operational level.</p> <p>The approach taken many companies to avoid over-burdening their quality manual is by allowing lower-level documents, such as procedures and work instructions to contain the operational detail. Then, simple reference is made to the procedures and work instructions from within the quality manual itself. In other words, let the procedures take the strain of controlling day-to-day activities.</p>

4.3. Develop the Operational Procedures

Concept	<p>When developing your operational procedures, use the experience and expertise of those who actually carry out the tasks to help specify the content of the procedure. People who carry out tasks on a regular basis often know best but they may not know the importance or impact of what they do further down the process.</p>
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What you need to do Once you have documented the operational procedures for your key processes, conduct a review to verify effectiveness and accuracy. We suggest that clients conduct several internal implementation audits, based on the defined milestones that are established in the implementation plan. This helps to ensure effectiveness in stages and saves valuable time revising procedures. Two things you should consider are:

Not establishing document templates early on in the process.

If you do not format and distribute document templates for procedures and work instructions you will not get consistent documents. You will need to go back at the end of your project and redo documentation.

Not having central point of collection and control of the new documents.

If the document control system is not developed early in the project, you could create confusion on which documents are final, what has been approved, what is the final revision, where the electronic file is and was it distributed

4.4. Select and Train Internal Auditors

Concept Internal auditors should be selected from candidates from across the organization. They should be inquisitive and open-minded. The internal auditors need to understand how the clause structure and requirements will affect their audit plans. Instead of auditing by clause, your organization may decide to audit by functional area. Developing human resources is one of the keys to organizational success and demonstrates an ability to plan for the development of human resources.

What you need to do Formal training in internal auditing will provide your auditors with a broad understanding of the various organizational processes that comprise the quality management system and how it has been implemented.

The aim of such training is to provide participants, who intend on performing internal audits, with the knowledge and skills needed to assess and report on the conformance and implementation of processes, and to contribute to the continual improvement of the quality management system. Internal auditor courses are normally two-days in duration and topics include:

- An introduction to ISO 9001
- The key requirements of ISO 9001
- Auditing guidelines based on ISO 19011
- Audit planning and preparation
- Conducting the audit
- Audit reporting and follow-up

For more information on internal auditor qualifications and training, please visit the International Register of Certified Auditors website: www.irca.org/auditortraining. Use the internal auditor training presentation to familiarize the internal auditors with their responsibilities.

4.5. Management Review

What you need to do Use the stage 4 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

After the documentation has been developed, top management should review the documentation and determine its effectiveness and provide resources for corrective actions and improvements. It is important at this stage to have a formal management review that shows the commitment of all levels. The recommendations from this review have to be carried out.

STAGE 4 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that the QMS manual is ready. Don't continue without an approved manual.	
<input checked="" type="checkbox"/>	Check that the requirements from the standards are fulfilled and that reference is made to the mandatory and operational procedures.	
<input checked="" type="checkbox"/>	Check that all the operational procedures have been developed and that the work instructions have been written.	
<input checked="" type="checkbox"/>	Check that the process owners are involved in the development of the procedures.	
<input checked="" type="checkbox"/>	Check that the QMS is designed around business processes and not around ISO 9001 or any other standard.	
<input checked="" type="checkbox"/>	Check that the responsible people have been trained for the internal auditor function. Record their training results and data.	
<input checked="" type="checkbox"/>	Check that the result of the management review is functioning well and that all people involved know what is expected from them.	

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Stage 5: Launch the Quality System

5.1. Provide Employee System Training

- Concept** Awareness training should be given to all employees about the different elements of the quality management system and how it might affect their work.
- After training, employees should be comfortable using the system and be able to demonstrate their knowledge by being able locate and use documents that are required for their work. Use the employee awareness presentation to promote the quality system. Employees should know:
- Which procedures apply to their work
 - Which forms to use, how to complete and process them
 - Where the quality policy is and how it relates to their work
 - How to report non-conformances and issues for preventive action
 - Where to find the quality manual, procedures and forms (e.g. network/intranet)
- What you need to do** Training should never be performed as a knee-jerk reaction with no real objectives, but instead, it should be geared toward empowering each employee with the skills and knowledge they need to move the organization forward.

5.2. Implement the Quality System

- Concept** Begin implementation and monitor the status of each item on the implementation plan. Monitor and measure process performance and start internal audits. Check that the necessary elements of the standard are implemented in the organization and that elements such as continual improvement, leadership principles and customer satisfaction are evident.
- What you need to do** Keep implementation team on schedule. The Quality Management Representative should review the task checklist during team meetings. Watch out for problems and delays and provide assistance as soon as problems arise. Have each member of Steering Team manage the local implementation teams.
- Check that the required procedures have been developed and that forms and work instructions have been written. Check that the process owners are involved in the development of forms and work instructions.

5.3. Audit the Quality System

- Concept** Auditing relies on a number of principles whose intent is to make the audit become an effective and reliable tool that supports your company's management policies and procedures whilst providing suitable objective information that your company can act upon to continually improve its performance.
- During the launch phase of the implementation process, perhaps six months after the documentation has been written and deployed, the auditors should carry out one or two internal audits covering all activities that are in the scope of the quality management system.
- Management should take corrective action on the audit findings without delay. Where required, revise the quality manual, procedures and objectives.
- What you need to do** Once you have implemented the documented procedures for each key process, conduct an implementation (internal) audit to verify effectiveness and accuracy. It is suggested that clients conduct at least one internal implementation audit, based on the defined milestones established in the implementation plan, to ensure effectiveness in stages and save valuable time revising procedures.
- The auditor will verify that processes are documented, implemented and understood. He will also seek confirmation that each process complies with the necessary requirements, that the process is effective and demonstrates continual improvement.

Finally, quality management system audits are not surprise audits! They are planned and everyone should know when they happen and what processes or departments will be audited. There should be no surprises, as this tends to foster mistrust towards the audit process, and a feeling of 'them versus us'.

5.4. Management Review

What you need to do

Use the stage 5 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

After the internal audit, top management should review the effectiveness of the system and provide resources for corrective actions and improvements. Management should take corrective action on the audit findings without delay and where required, revise the quality manual, procedures and objectives. The proceedings of the management review should be documented. Management must take a close look at data from the quality system, evaluate it and take action to improve it.

Stage 6: Review Performance

6.1. Begin Process Auditing

Concept Once the quality management system is complete and everyone is following the documented procedures, conduct an audit of each key process.

What you need to do Begin by selecting a key process and identifying the inputs needed by the process and the outputs that are generated by the process. Select the appropriate process audit checklist and interrogate the process by completing the audit questions for that 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 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:

- Is the process planned?
- Is there is an appropriate review to verify output?
- Is there confirmation that the output meets the input requirements?
- Is the process is verified for effectiveness? (measured)
- Is there validation to ensure that the process meets intended results?
- Is there continuity between the various processes in the organization?
- Is the task done consistently on a person-to-person or day-to-day basis?
- Do the interfaces between the departments operate smoothly?
- Are corrective/preventive actions being used adequately in this process?
- Does product information flow?
- How are changes controlled?
- Is the procedure right, does it meet the Standard?
- Is it helping the organization effectively?

Ensure that internal auditors do not audit their own department or work area and that the results of the internal audits are fed back into the quality management system to facilitate process improvement. Check that the results of the internal audits are reviewed by top management and that appropriate action is taken to correct non-conformances. Check that there is a schedule for internal audits and that it is maintained.

6.2. Implement System Changes

What you need to do 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.

6.3. Refine the System

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

Demonstrate your commitment to continual improvement by focusing on the next improvement and by taking it seriously. Show that the 'quality' approach is becoming instituted into the organization by integrating management reviews into normal management cycles and reporting. Ensure that records are turned visibly into management information so that people keeping them understand their importance.

6.4. Management Review

What you need to do

Use the stage 6 management review checklist to ensure that all tasks from this stage have been completed. If there any outstanding items, make sure these are completed before progressing to the next stage.

Top management now need to review the quality management system in order to determine opportunities for improvement and the need for amending the system. The proceedings of the reviews should be documented. The management review is your final check to ensure that everyone is happy therefore you should review the business, not just 'quality'.

ISO 9001:2008 requires that the management review generates decision on key matters such as process improvement, resource allocation, product improvement driven by customer requirements and the establishment of new improvement objectives. Bearing in mind the importance of these sorts of topics, it is best not to hold a separate review, knowing that this sends signals to people in the organization that quality is outside the normal activities of management.

STAGE 6 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that internal auditors do not audit their own department or work area.	
<input checked="" type="checkbox"/>	Check that the results of the internal audits are fed back into the system and lead to improvement of the QMS, the processes and the documents.	
<input checked="" type="checkbox"/>	Check that the results of the internal audits are reviewed on top management level and that appropriate action has been taken.	
<input checked="" type="checkbox"/>	Check that there is a time schedule for internal audits and that it is maintained.	
<input checked="" type="checkbox"/>	Check that the result of the management review is functioning well and that all people involved know what is expected from them.	
<input checked="" type="checkbox"/>	Check that actions are taken and decisions are made.	

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Stage 7: Assessment & Certification

7.1. Certification Body Preliminaries

Concept The documentation audit is a desk-based exercise carried out by registration auditors either in their own offices or at the company being audited. The audit is restricted to the quality manual and related systems.

The aim is to ensure that the documentation addresses the elements of ISO 9001. If the auditors identify major gaps in your QMS, there is little point in proceeding with the assessment until these are rectified.

7.2. Pre-assessment Audit

Concept The pre-assessment audit (optional, also known as the ISO 9001 pre accreditation audit) is a mock audit in preparation for the real thing. A pre-assessment identifies problems and enables the company to benefit from the advice of the auditor on how to eliminate those problems. You are likely to pay extra, but it is often worthwhile to arrange a pre-assessment visit. Make sure you understand and agree any corrective actions and arrange certification date.

Pre-assessment by your registrar normally takes place about six weeks before registration. The purpose of the pre-assessment audit is to identify areas where you may not be operating in accordance with the standard. This allows you to correct any deficiencies before registration.

What you need to do Prior to registration, you should arrange an initial assessment with your registrar. At this point the registrar will review your quality management system (by interviewing staff, observing activities and checking records) to decide whether you should be recommended for registration.

7.3. Correct Non-conformances & Corrective Actions

Concept Common non-conformances raised by Registrars during assessment audits:

1. The audit plan/schedule does not address all the requirements of ISO 9001:2008
2. The audit plan/schedule does not address multiple facility locations
3. The audit plan/schedule is not approved
4. Audits are not completed as scheduled
5. Audits are performed by personnel who audited their own work
6. Audits were not conducted in an effective manner
7. Audit reports not completed
8. Audit records not managed
9. Internal auditors are not trained

Make sure you don't get caught out!

7.4. Management Review

What you need to do Use the management review checklist to ensure that all tasks from this stage have been completed before certification day arrives. If there any outstanding items, make sure these are completed before the Registrar arrives.

7.5. Certification Day

Concept This is an on-site audit. It involves a systematic examination of the organization's quality management system against the ISO 9001 standard. The emphasis is placed on finding objective evidence that the system demonstrates conformance with the standard, has been implemented effectively and that the procedures are being followed.

What you need to do

The first area to be scrutinized is often management commitment (quality policy and communication), management reviews, corrective actions taken, quality objectives, continual improvement and changes made as the result of the pre-assessment audit. Make sure you understand and agree any non-conformances. If not, ask for a second opinion. The Registrar will:

- Undertake audits of processes and activities defined in the scope of assessment
- Document how the system complies with the standard
- Report any non-compliances
- Determine potential for non-compliances
- Produce a surveillance plan
- Confirm a date for the first surveillance visit

7.6. Surveillance Audits

Concept

Remember, gaining certification is not the end. Your registrar will perform a surveillance audit once or twice a year to verify continued compliance. The Registrar will produce a surveillance audit plan and confirm the date for the first surveillance audit.

Your ISO 9001 based quality management system is designed to continually improve itself. Make sure it remains fully implemented, continue auditing, and we are convinced you will see performance improvements right down to the bottom line!

STAGE 7 – MANAGEMENT REVIEW CHECKLIST

<input checked="" type="checkbox"/>	Check that a certification body has been engaged for the final assessment.	
<input checked="" type="checkbox"/>	Carry out a pre-assessment audit to win trust and confidence among the people involved in the certification process.	
<input checked="" type="checkbox"/>	Check that actions are taken and decisions are made based on the results of the pre-assessment.	
<input checked="" type="checkbox"/>	Check that the non-conformities from the pre-assessment will be solved as soon as possible.	
<input checked="" type="checkbox"/>	Check that management reviews are planned and conducted periodically.	
<input checked="" type="checkbox"/>	Keep up with regular internal audits and management reviews.	

NOTES:

Stage 8: Continual Improvement

8.1. Maintain & Improve the QMS

Concept

Clause 8.5.1 of ISO 9001:2008 requires organizations to 'continually improve the effectiveness of the quality management system'. 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.

Corrective action requirements include development of the means to stop a problem from re-occurring while preventive action requirements include ways to stop a problem arising in the first place. It is the proactive analysis of a process, whereas corrective action is the reaction to a problem after it arises. Preventive action can be achieved by an assignment of the risk of something going wrong.

What you need to do

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 for introducing continual improvement. Each step to improvement can be defined in the four sub steps, plan, do, check and act:

Plan Establish a timetable for internal audits and management reviews. Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the 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.

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.

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.

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.