

ISO 9000: Keys to Success

Welcome

Thank you for downloading our 'Keys to Success' white paper which will get you on the road to understanding the requirements for implementing a Quality Management System.

In this paper, we aim show you the intent behind the Standards and what the requirements really are. It includes a detailed introduction to ISO 9000:2005, provides an extensive list of tips including links to free information and our proven project plan.

With our knowledge you can avoid complicating an otherwise simple tool. Only by ensuring a minimal amount of time is spent on administrative tasks, can the true power of your quality system deliver real business benefits.

To your success!

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ISO 9000 Series Overview

- ISO 9000 is a series of quality management systems standards created by the International Organization for Standardisation (ISO), a federation of 132 national standards bodies.
- The ISO 9000 quality management systems (QMS) Standards are not specific to products or services, but apply to the processes that create them.
- The Standards are generic in nature so that they can be used by both manufacturing and service industries. First released in 1987 and revised in a limited manner in 1994, they underwent a major revision in 2000.
- The approval Standard, ISO 9001:2008, uses a simple process-based structure, which fits easily the process management structure of most businesses.

ISO 9000 Introduction

ISO 9000 has evolved into a Standard designed to assist organisations in achieving 'quality' whilst helping to assure customers that quality will be achieved. Whatever definition you choose to use for quality, and there are many, it is essential that your customers are happy with the product/service being supplied.

ISO 9000 is intended to assist that aim by helping to ensure that the product or service is right - for both the organisation itself and its customers.

The poor implementation of the 1994 series resulted in many people claiming that the Standards did not prevent organisations producing sub-standard product. The 2000 edition clearly requires organisations to satisfy their customers and undertake continual

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improvement of their quality management systems therefore compliance with ISO 9001:2008 should result in significant benefits for organisations and their customers.

The ISO 9000 series consists of:

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

ISO 9000:2005 Fundamentals and Vocabulary

ISO 9000 is an introduction to the philosophy of quality management and also contains the definitions used in ISO 9001 and ISO 9004. It also contains the 8 management principles which provide the foundation for the ISO 9000 series of Standards. These are:

1. Customer focus
2. Leadership
3. The involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. A factual approach to decision making
8. Mutually beneficial supplier relationships

These principles are NOT elements against which the organisation can be directly assessed but their influence can be seen throughout the Standard. They should be considered by any organisation wishing to comply with the spirit, as well as the text of ISO 9001.

ISO 9001 is the only part of the ISO 9000 family against which an organisation can become certified.

ISO 9001:2008 Requirements

ISO 9001 contains all of the requirements which an organisation must address within their Quality Management System (QMS) if they wish to be certified against the Standard. The majority of these requirements would be identified by many organisations as 'common sense' topics which they would want to address in order to run their business well e.g. sales, design, purchasing, training, calibration of test equipment, control of records.

ISO 9001 is written by a committee (TC 176) and is designed for use in any type of organisation. This inevitably means that there are compromises in the wording of the Standard and some interpretation is often needed.

There are 8 sections in ISO 9001:

1. Scope
2. References
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realisation
8. Measurement, analysis and improvement

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It is sections 4, 5, 6, 7 & 8 which contain the Requirements themselves and organisations wishing to be certified against ISO 9001 will need to demonstrate that they have addressed all of these requirements.

There are over 250 individual requirements in ISO 9001 that can be condensed into five key statements.

The organisation shall:

1. Determine the needs and expectations of customers
2. Establish policies, objectives and a work environment necessary to motivate people to satisfy these needs
3. Design, resource and manage a system of inter-related processes to implement the policy and attain the objectives
4. Measure and analyse the effectiveness of each process in fulfilling its objectives
5. Pursue the continual improvement of the system from an objective evaluation of its performance.

ISO 9001:2008 Approval

ISO 9001:2008 registration gives the organisation the benefit of an objectively evaluated and enforced quality management system. It is a tangible expression of a firm's commitment to quality that is internationally understood and accepted.

ISO 9001:2008 registration is carried out by certification bodies (registrars), accredited organisations that review the organisation's quality manual and working practices to ensure that they meet the Standard.

Using ISO 9001:2008

It is important that when an organisation is certified to ISO 9001, it is clear which aspects of the organisation are covered by the certificate. This is addressed through the Scope of Registration, and this must clearly identify what is included so as not to mislead.

It is a requirement that all elements of ISO 9001 must be addressed by the organisation. However, there are specific circumstances under which certain requirements of the Standard can be excluded, yet compliance with ISO 9001 still be claimed:

- Any excluded requirements do not affect the ability of the organisation to meet customer and regulatory requirements
- Any excluded requirements do not affect the ability of the organisation to provide conforming products or services
- Any excluded requirements must only come from section 7 (Product realisation) of ISO 9001. An example may be customer property. Clearly if a company never deals with such property then the requirement would not be applicable

The company's quality manual must also clearly identify why specific requirements of ISO 9001 have been excluded and the justification for that exclusion.

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What 9001 is not

ISO 9001 is NOT a product Standard - it contains no product requirements. It is a series of generic requirements for quality management systems. Approval to ISO 9001 does not guarantee product or service quality. Customer focused leadership, not standards produce satisfied customers.

Approval to ISO 9001 demonstrates that you meet the minimum requirements of quality management.

ISO 9004:2000 Guidelines for performance improvement

ISO 9004 is not a guide on how to implement ISO 9001, rather a guide on how to improve on the basic requirements that ISO 9001 specifies.

The requirements statements in ISO 9001 may be seen sometimes as a little brief and it rarely, if ever, tells the user 'how' to achieve compliance with it. ISO 9004 takes the basic requirement and expands on it. It gives options for the organisation to consider if they wish to progress beyond basic compliance and into excellence.

Given that 'Continual Improvement' is a requirement of ISO 9001; it is strongly recommended that you consider using ISO 9004 as a way forward in the journey of continual improvement.

Certification bodies cannot certify organisations against ISO 9004 but auditors may use it for guidance. You should consider using ISO 9004 to assist internal auditors when seeking improvement of the more mature processes.

ISO 9004 reproduces the full requirement of ISO 9001. It may also be that some of the guidance contained in ISO 9004 may one day become part of the requirements of ISO 9001 when the Standard is updated again in the future.

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Thirteen Step Project Plan

Step 1: Find out about ISO 9001:2008.

Understand what ISO 9001:2008 means for your organisation:

- ISO 9001:2008 is intended to be generic and therefore applicable to all organisations, regardless of type, size and product category. However, not all requirements in the new Standard will necessarily be relevant to all organisations. Under certain circumstances, an organisation may exclude some specific requirements.
- ISO 9001:2008 Clause 1.2, Application, states that requirements can be excluded only if they're limited to clause 7, Product realization. Exclusions are acceptable only if they don't affect an organisation's ability, or responsibility, to provide products that meet customer and applicable regulatory requirements.
- Do a gap analysis - you are probably doing most of what ISO 9001 requires already as part of your normal business practice.
- Get the backing of your Top Management. Every sub-clause of ISO 9001 Section 5, Management Responsibility, begins with the phrase, "Top management shall." Top management must provide evidence of its commitment to developing and implementing the quality management system, as well as continually improving its effectiveness.
- Develop your project plan based on your gap analysis and decide how much or how little documentation you need to demonstrate control.
- To get information on potential certification bodies refer to www.ukas.org or see www.iso.org/iso/en/info/ISODirectory/countries.html which lists national Accreditation Bodies, followed by national Certification Bodies.
- NOTE: **Accreditation Bodies** audit and "accredit" the **Certification Bodies** who audit and "certify" you.

Step 2: Top Management to define Quality Policy

- The reason you need to define 'quality' is simply that, if you don't know what it is, you'll never know whether or not you are achieving it.
- Not knowing where you want to get to also makes it difficult to communicate to other people what is to be achieved and why, let alone to motivate them to act.
- The only definition of quality that counts is the one on which you and your senior management colleagues are agreed. Clearly if you have a definition that clashes with what your customers, your suppliers, your partners, or the people in your organisation believe, that would be a problem. So you will no doubt listen carefully to these stakeholders before you decide. But - the decision is yours.
- ISO 9001 helps you make this key decision by requiring top management to establish measurable quality objectives. These measurable objectives define what you mean by 'quality'.
- The standard also helps by requiring objectives that improve the degree to which your products and services meet requirements, the effectiveness of your processes and the perceptions of your customers.

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Step 3: Define the processes

- A process is a system of activities that uses resources to transform inputs into outputs. The process approach promoted by ISO 9001:2008 systematically identifies and manages these processes and their interaction within a quality management system. For example - how do Sales relate to Design, Design to Purchasing, Purchasing to Manufacturing, etc.

Step 4: Select internal auditors

- Internal auditors should be people chosen from across the organisation that are inquisitive and open-minded.
- Most certification bodies require at least three months history between the formal implementation date of the quality system and the certification audit.
- Typically, they require that at least one internal audit covering all elements of the quality system is completed and followed by a management review before the certification audit. This enables the company itself to identify problems and to resolve them prior to assessment by the certification body.

Step 5: Train internal auditors

- They need to understand how the new clause structure and requirements will affect their audit plans. Instead of auditing by clause, your organisation may decide to audit by functional area.
- Develop internal audit schedule Management review of progress against plan.

Step 6: Implement Management systems

- Monitor and measure process performance and start internal audits.

Step 7: Select Certification Body

- Agree Scope of Registration and pay fees and continue the implementation plan.

Step 8: Continue implementation plan

- Make any necessary changes, from 7, above. Most certification bodies wish to see at least 3 months of history.

Step 9: Management review

- This your final check to ensure that everyone is happy therefore you should review the business, not just "quality". This vital step is traditionally represented by a minimal, typically annual, senior management review of the QMS. ISO 9001:2008 now requires that the 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 organisation that quality is outside the normal activities of management.

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Summary of management actions and benefits:

1. Define 'quality' in the form of objectives to help internal communication of what is to be achieved (product and service requirements, process effectiveness and efficiency, customer perception etc.)
2. Show that the business is central to the system: use your normal business language, not 'quality' or ISO 9001 terms.
3. Produce a simple top-level, "big picture" of your business processes to show how the system improves results by focusing on the improvement of processes.
4. Demonstrate your commitment to continual improvement by focusing on the next improvement and by taking it seriously.
5. Show that the 'quality' approach is becoming instituted by integrating reviews into normal management cycles.
6. Ensure that records are turned visibly into management information so that people keeping them understand their importance.

Step 10: Implement any system changes

- Implement any changes to the Quality System that might have arisen from the outputs of previous steps.

Step 11: Certification Body preliminaries

- The Documentation Audit is a desk-based exercise, carried out by auditors either in their own offices or at the company being audited. The audit is restricted to the quality manual and related systems. Its aim is to ensure that the documentation addresses the elements of ISO 9001. If the auditors identify major gaps in your QMS, there is no point in proceeding with the assessment until these are rectified.
- Pre-Assessment Audit (optional) - A pre-assessment 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 have to pay extra but it is often worthwhile to arrange a pre-assessment visit and have the certification body to do a preliminary assessment. Make sure you understand and agree any non-conformances. If not, ask for a second opinion.
- Arrange certification date.

Step 12: Certification Day

- Implementation Audit - This is an on-site audit. It involves a systematic examination of the company's quality system against the ISO 9001 standard.
- The emphasis is placed on finding objective evidence that demonstrates it has been implemented effectively and that any procedures are being followed.

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- The first areas generally examined are 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.

Step 13: Maintain and improve your management system

- Processes can always be more efficient and effective, even when they're producing conforming products. The aim of a continual improvement program is to increase the odds of satisfying customers by identifying areas needing improvement. After setting improvement objectives, an organisation searches for possible solutions, selects and implements the appropriate one and evaluates results to confirm that objectives are met.
- Generally, Certification Bodies audit small companies for 1 day, once per year. Bigger organisations are audited twice per year.

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ISO 9000 Top Tips

Top Tip 1: Get free information

Start with our [FAQ page](#)

Get a work book (PDF format) from [Association of British Certification Bodies](#)

Follow this link for some limited interpretations (PDF format) on the ISO Committee's site www.tc176.org/Interpre.asp

NOTE: you will need Acrobat Reader to open these files. [Click here](#) for free Acrobat Reader download.

Take a look at the public documents on the [ISO 9000 committee](#) site

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Follow this link to the [ISO 9001 Audit Practices Group](#) and learn more about modern audit techniques.

The leading UK Certification Bodies [NQA](#) and [Lloyds Register Quality Assurance](#) both provide free, and useful information on 21st Century quality thinking.

Identify any gaps - typical gaps: no process map (Para 4.1), no [policy or objectives](#) (Para 5.3, 5.4), no [internal audits](#) (Para 8.2.2) misunderstanding [Preventive Action](#) (Para 8.5.3)

Top Tip 2: What the standard doesn't tell you:

What the Standard doesn't tell you is how all this information should be documented. As a rule, you should avoid creating overly complex or burdensome documentation.

You may decide to merely "Define" simpler processes (by giving an overview in the Quality Manual) rather than "Document" them in detailed Procedures. Rely instead on the skills, training and experience of the people doing the work. Balance lightweight procedures with heavyweight Training records.

Top Tip 3: Assume you're already DOING most of what ISO 9001 requires:

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 9000 but I believe this is a false assumption. If you do it right and understand the Standard then implementation should not be that big a problem: as 75% of your quality system is already in place.

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Top Tip 4: Process Control:

The traditional method of controlling a process is to write a procedure. The typical procedure will be 'text based', comprise a number of pages broken down into paragraphs of information which direct the reader to perform certain activities.

Alternatively, they may be in the form of flowcharts which generally contain less specific information but are easier for the reader to obtain a quick 'snapshot' of what is happening in the process. Flowcharts may be backed up by text if the process is complex.

An equally valid method for controlling a process is the use of software e.g. the sales department may have a piece of software which 'drives' the order system and provides the necessary control. For example, the software helps the staff to enter the correct information by prompting inputs in appropriate fields, and throws up an error message when incorrect data has been entered, why have a documented procedure defining how to perform the task? It may be more appropriate to train people in its use and then evaluate their competence by reviewing performance.

Smart Forms are another alternative. Smart forms which contain enough information to help ensure that the activity is performed correctly can be used to provide the necessary control.

Top Tip 5: How to define a business process:

There is more to a process than just the tasks and decisions which define the flow of information or material. You also need to define the materials, hardware and skills required and the environmental influences (e.g. light, hygiene, humidity) which could affect the operation of the process.

Top Tip 6: Defining the appropriate level of detail:

Use as little detail as you need to. Be clear about why are you doing it and who will use the resultant definitions. But do it for yourself and your staff - a Quality Management System is not solely for your external auditor.

Two pages of a flowchart should be sufficient for a process. Assume your people are competent - or train them if they're not.

Too many 'quality systems' have tonnes of documentation. They are *Quantity* Systems NOT *Quality* Systems.

Quality Manuals are NOT full of weird words and convoluted language that no one can even understand much less use.

Top Tip 7: Production process:

Production processes (or as ISO 9001:2008 calls it, "product realisation processes") are just a subset of your normal business processes.

Think of "production" as "creation". If your organisation designs training courses or provides cleaning services, your production processes are how you develop a course or how you plan and deliver your service – it's all just part of "running the business".