

Quality Management System **ISO 9001 - 2000**



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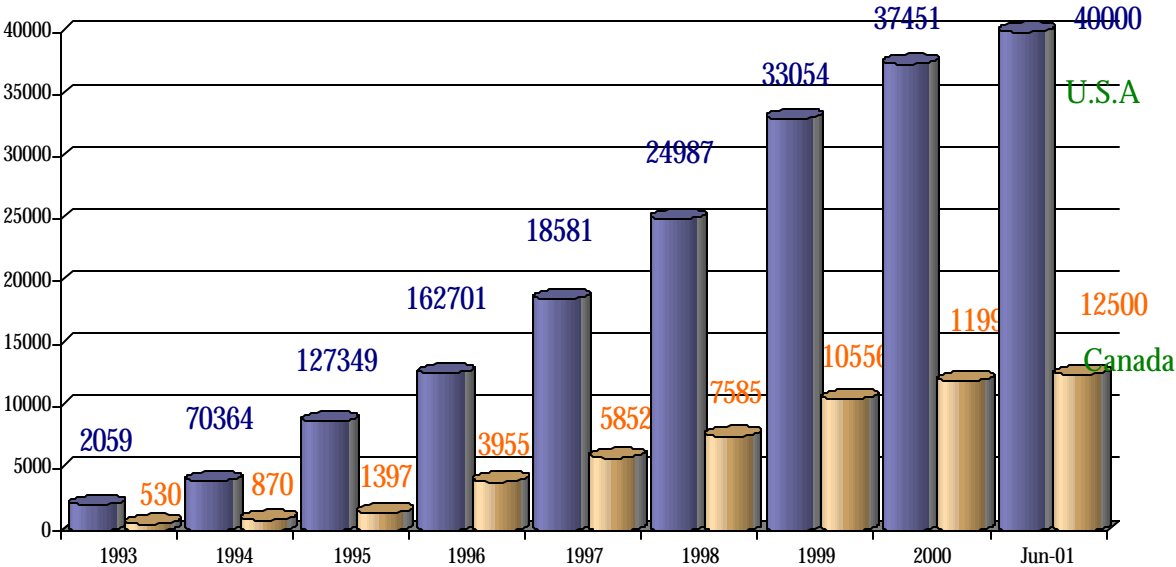
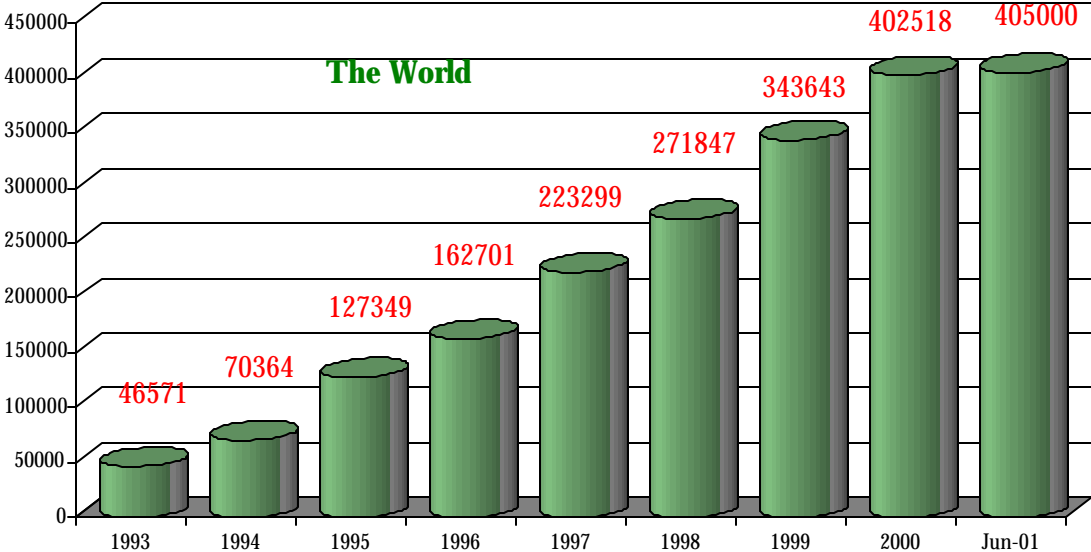
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ISO Registrations



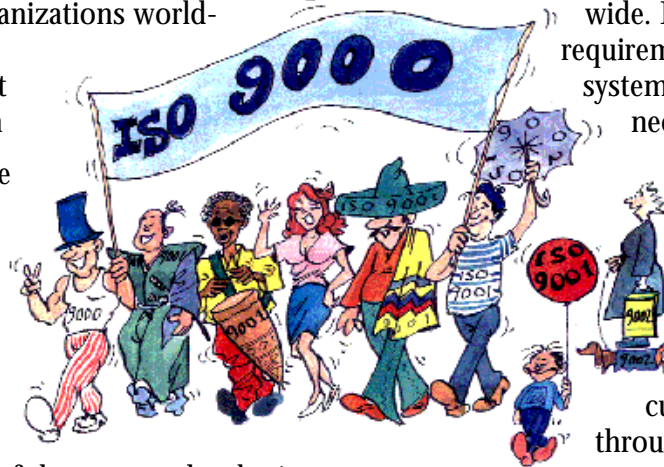
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What is ISO 9001:2000?

ISO 9001:2000 is the latest version of a quality management standard which has been in existence for many years and which has been applied by more than 400,000 organizations world-wide. It specifies requirements for a quality management system where an organization needs to:

Demonstrate its ability to consistently provide product that meets customer regulatory and to:

Address customer satisfaction through the effective application of the system, developing processes for continual improvement and the prevention of errors and mistakes.



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Address customer satisfaction through the effective application of the system, developing processes for continual improvement and the prevention of errors and mistakes.

ISO 9001:2000 and the SME

A successful SME needs to:

Identify and meet the needs and expectations of its customers and other interested parties, i.e. employees, suppliers, owners, society, to achieve competitive advantage and to do this in an effective and efficient manner. Achieve, maintain, and improve overall performance and capabilities.

The application of the ISO 9001:2000 standard can help you achieve these objectives. SMEs wishing to implement the standard may wish to seek the services of a consultant [see Part 5 - Implementing the Quality Management System].

Accreditation

Their national accreditation body has accredited most registration bodies.

Accreditation is part of a hierarchy of assurance. It is granted to a registration body as recognition that it meets and continues to meet internationally accepted criteria. These criteria cover integrity and technical competence, and the capability of staff to assess companies to the ISO 9000:1994 series of standards and to ISO 9001:2000 in specific business areas to a consistent level of quality. The accrediting authority ensures that the registration body conforms to these criteria, which include the qualification and experience of auditors, the time spent on auditing and surveillance and the need for impartiality.

A most important aspect of impartiality is the requirement that registration bodies should not have provided consultancy to their clients. Where the same organization has both advised an organization on the development and implementation of its

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quality system and then assessed it as satisfactory, the objectivity of the registration is seriously impaired.

The Year 2000 revision

The revision comprises a family of standards:

ISO 9000:2000 - Quality Management Systems: Concepts and Vocabulary

ISO 9001:2000 - Quality Management Systems: Requirements

ISO 9004:2000 - Quality Management Systems: Guidance for Performance Improvement

Organizations will be assessed and awarded registration against ISO 9001:2000, whether or not they are involved in design.

ISO 9004:2000 offers guidance on implementing a quality management system and although it is consistent with ISO 9001:2000 it is not intended for use for registration or contractual purposes.

Differences from the ISO 9000:1994 series of standards

It is important to recognize that the revised standard does not represent a radical change and that large sections of the revised standard have not significantly altered from the 1994 series.

However, the new standard does introduce the following conceptual changes:

The most significant is the movement away from a procedurally based approach to management, i.e. stating 'how' you control your activities, to a 'process' based approach, which is more about 'what' you do the standard is now much simpler in its structure and approach, which makes it easier to use and understand there is now considerable flexibility within the standard, which requires a balance between documenting an activity and the competence of the staff involved

Its presentation is also different and it introduces certain aspects that were not directly addressed previously. We discuss these aspects in more detail later but some of the more notable ones are:

- The replacement of the somewhat artificial '20 elements' by 5 broad headings:
- Quality management system
- Management responsibility
- Resource management
- Product/service realization
- Measurement, analysis and improvement
- 'Continual improvement'
- The move to 'customer satisfaction'

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Benefits of ISO 9000:2000

ISO 9000:2000 builds upon the 13 years track record of ISO 9000 and makes a good product even better. Some of the principal benefits of the new standards series include:

- The ISO 9000:2000 series is restructured on a business process model, which more closely corresponds to the way organizations actually operate and should result in quality management systems that are more effective, easier to implement and audit.
- The language of the ISO 9000:2000 version has been crafted to make the standards easier to understand and implement by organizations large and small, manufacturing or service, in public or private sectors.
- The reinforced requirement for customer satisfaction and the inclusion of requirements for monitoring customer satisfaction and for continual improvement will ensure that user organizations not only "do things well" (efficiency), but also "do the right things" (effectiveness).
- The ISO 9000:2000 series goes beyond meeting customer requirements to enhancing customer satisfaction. The revised standards can be used as a stepping-stone for achieving Total Quality Management (TQM). They are based on eight Quality Management Principles, which are clearly spelled out in ISO 9000 and ISO 9004. These principles cover the basic concepts of many quality awards.
- The design and development of ISO 9001:2000 and ISO 9004:2000 as a strongly linked "consistent pair" providing organizations with a structured approach to progress beyond certification to the achievement of Total Quality Management. (e.g. satisfaction not just of customers, but of all interested parties - shareholders, employees, suppliers, the local community, society as a whole).
- ISO 9001:2000 has been designed to have maximum compatibility with ISO 14001, the environmental management system standard. ISO 19011, to be published in 2002, will allow joint and/or combined audits of quality and environmental management systems.
- ISO 9000:2000 has reduced the requirements for documented procedures. Draft guidance on documentation requirements of ISO 9001:2000 has been drawn up to help users in this regard.

What happens to the old standard?

When the 3-year transition period expires towards the end of 2003, the 1994 series of standards will be withdrawn, registration to these standards will no longer be possible, and 1994 certificates will become invalid. This means that any organization holding an ISO 9000:1994 series certificate, issued with a Government recognized accreditation and who has not updated to ISO 9001:2000, will have its certificate withdrawn.

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Quality Management Principles

This document introduces the eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based. Senior management as their a framework to guide their improved performance can use these principles. The from the collective experience of the international and knowledge experts who participate in ISO Technical responsible for developing and maintaining the ISO 9000 standards.

The eight quality management principles are defined in ISO 9000:2000, Quality management systems Fundamentals and vocabulary,

Quality management systems Guidelines for performance improvements.



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management principles 9000:2000, Quality management systems Fundamentals and in ISO 9004:2000,

This document gives the standardized descriptions of the principles as they appear in ISO 9000:2000 and ISO 9004:2000. In addition, it provides examples of the benefits derived from their use and of actions those managers typically take in applying the principles to improve their organizations' performance.

Principle 1 Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.
- Applying the principle of customer focus typically leads to:
 - Researching and understanding customer needs and expectations.
 - Ensuring that the objectives of the organization are linked to customer needs and expectations.

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- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

Principle 2 Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Key benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

Applying the principle of leadership typically leads to:

- Considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole.
- Establishing a clear vision of the organization's future.
- Setting challenging goals and targets.
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization.
- Establishing trust and eliminating fear.
- Providing people with the required resources, training and freedom to act with responsibility and accountability.
- Inspiring, encouraging and recognizing people's contributions.

Principle 3 Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.

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- People eager to participate in and contribute to continual improvement.

Applying the principle of involvement of people typically leads to:

- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and their responsibility for solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues.

Principle 4 Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.

Applying the principle of process approach typically leads to:

- Systematically defining the activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities.
- Analyzing and measuring of the capability of key activities.
- Identifying the interfaces of key activities within and between the functions of the organization.
- Focusing on the factors such as resources, methods, and materials that will improve key activities of the organization.
- Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

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Principle 5 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Key benefits:

- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

Applying the principle of system approach to management typically leads to:

- Structuring a system to achieve the organization's objectives in the most effective and efficient way.
- Understanding the interdependencies between the processes of the system.
- Structured approaches that harmonize and integrate processes.
- Providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.
- Understanding organizational capabilities and establishing resource constraints prior to action.
- Targeting and defining how specific activities within a system should operate.
- Continually improving the system through measurement and evaluation.

Principle 6 Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Key benefits:

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

- Employing a consistent organization-wide approach to continual improvement of the organization's performance.

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- Providing people with training in the methods and tools of continual improvement.
- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Establishing goals to guide, and measures to track, continual improvement.
- Recognizing and acknowledging improvements.

Principle 7 Factual approach to decision making

Effective decisions are based on the analysis of data and information

Key benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Applying the principle of factual approach to decision making typically leads to:

- Ensuring that data and information are sufficiently accurate and reliable.
- Making data accessible to those who need it.
- Analyzing data and information using valid methods.
- Making decisions and taking action based on factual analysis, balanced with experience and intuition.

Principle 8 Mutually Beneficial Supplier Relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Key benefits:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Applying the principles of mutually beneficial supplier relationships typically leads to:

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.

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- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers

Overview of the Standard

The year 2000 revision contains five requirements sections, each dealing with one of the fundamental building blocks required by any process. These are:

Quality management system:

This section details the general and documentation requirements that are the foundation of the management system. The general requirements ask you to look at the processes of the management system, how they interact with each other, what resources you need to run the processes; and how you will measure and monitor the processes. The second part of the section then sets out the requirements for the documentation needed to operate the system effectively and how the documentation should be controlled.

Management responsibility:

The management of the systems is the responsibility of the "top management" at a strategic level in the organization. The "top management" must know customers' requirements at a strategic level and make a commitment to meeting these as well as statutory and regulatory requirements. "Top management" must also set policies; and to achieve these policies set objectives through planning how the objectives will be met. "Top management" should also ensure that there are clear internal communications and that the management system is regularly reviewed.

Resource Management:

This covers the people and physical resources needed to carry out the process. People should be competent to carry out their tasks and the physical resources and work environment need to be capable of ensuring that the customers' requirements are met.

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Product/Service realization:

These are the processes necessary to produce the product or to provide the service. This is the act of converting the input of the process to the output. For a manufacturing organization, this may be the process of converting iron ore to steel via a blast furnace for example.

For a service organization, this may be the process of moving a product or person from one place to another, for example, a taxi journey.

Measurement, analysis And improvement:

These are the measurements to enable the systems to be monitored to provide information on how the systems are performing with respect to the customer, the management systems themselves through internal audits, the processes and the product. Analyzing these, including any defect or shortfall in performance, will provide valuable information for use in improving the systems and products where this is required.

Each of these five fundamental building blocks is required for any process because, if one is missing, a controlled process does not occur. This is recognized in the new standard and represents a shift to viewing the quality system as a series of processes.

This shift will require an internal or external auditor to look at the organization's processes and audit them and their output as they occur, rather than audit compliance with the requirements of the ISO 9000:1994 series of standards. The new standard will require significant changes in auditing methods for both internal and external auditors. Auditing will become more subjective and less objective, relying more upon questioning than hard evidence.

In order to carry out a "process audit" the auditor will start with the inputs, follow the process through its various stages to examine how it is controlled and verify that the output meet what is required.

Such a process may be, for example, the actions required by the organization on receipt of a customer order, and the steps taken to convert that order into something that will allow a product ordered to be manufactured. The input here would be the customer order, and the output, the organization's internal documents, resources and materials that allow the manufacture of the product.

Another example of a process could be those steps that a dry cleaner would take to procure the chemicals required by the cleaning process itself. The input would be the need to buy chemicals; the output would be the receipt of the chemicals from the supplier.

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Thus the auditor will need to look at the process, determine the inputs, examine how it is controlled, and look at the outputs. The way the process is controlled may require an examination of mechanisms other than documented procedures.

Such control mechanisms could be by, for example, control charts, process flow diagrams or by training of operatives to ensure they are competent. Whatever the means by which the organization decides to control the process, the auditor will seek evidence that the control mechanism is indeed effective. The ultimate test of effectiveness is an examination of whether the end result of the process is in accordance with the inputs.

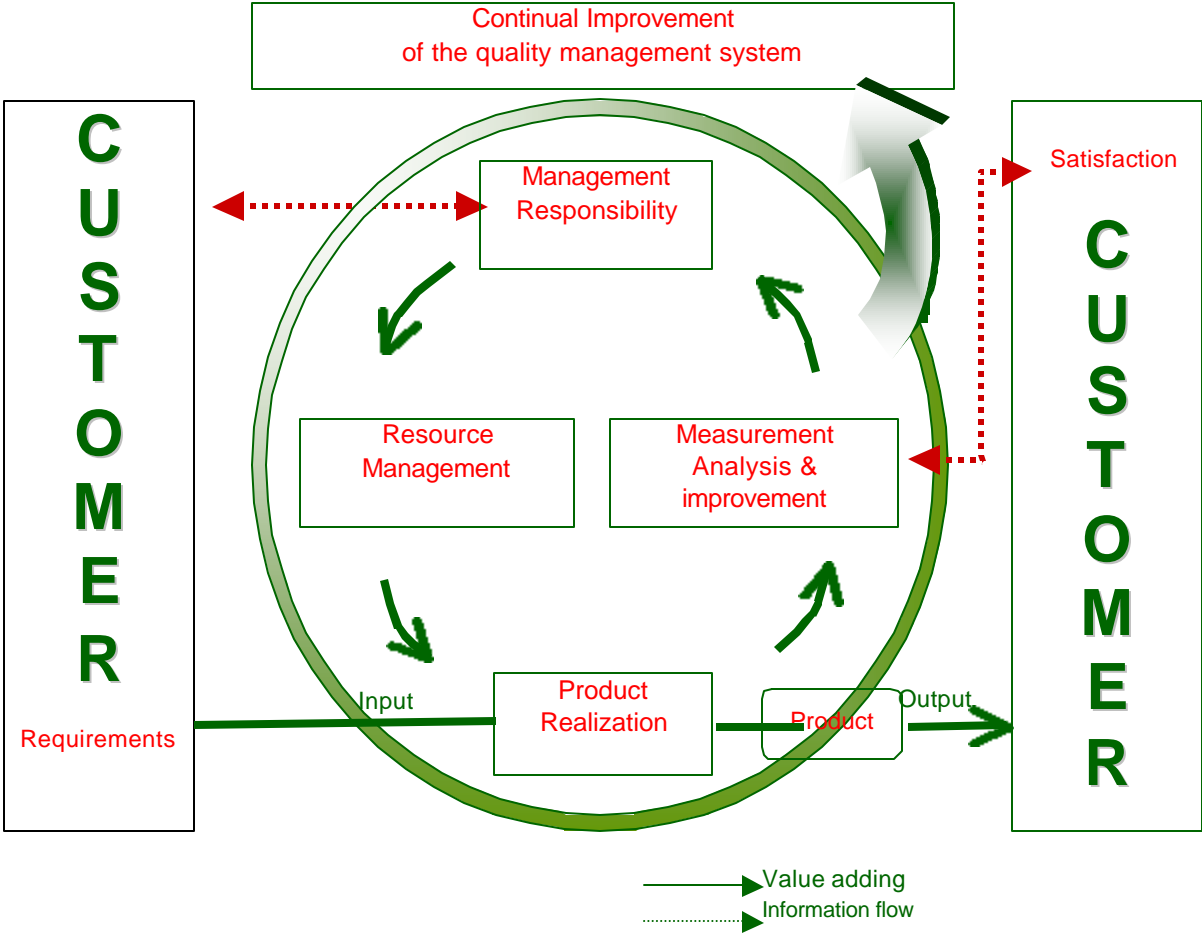
An example of a buying process end result could be receipt of chemicals. If the purchase order did not contain sufficient information to allow the correct product to be supplied or was deficient in some way, then the output would not be acceptable. The customer may not get the chemicals that were required. Thus the process would not be giving the output required. Some change to the process would need to occur in order that the chemicals required were received, thereby making the process output acceptable. Thus, during an audit of the process, the auditor would need to determine if the process output, i.e. the chemicals received, met the requirements of the organization and the process for obtaining them was operating under the controlled conditions that the organization had defined.

Auditing of processes should result in a logical audit of the activities of organizations in carrying out the various functions required to supply customers with a product or service, which meets their needs.

This change should therefore be viewed very positively.

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Model of a process-based quality management system



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Structure and Content of the Standard

General

You should read ISO 9000:2000 before ISO 9001:2000 so that you can understand the concepts and meaning of the terms used in the standard. The new standard has models that can be used to illustrate the concepts of the standard's structure and to help in the understanding of how the standard should be used. ISO 9004:2000 contains the requirements of ISO 9001:2000 in order to help the user to understand how to use the standard.

Main Elements of the Standard

The main elements of ISO 9001:2000 are outlined below and cross-referenced to the relevant Clause of the standard.

Introduction

The introduction includes a process model and an explanation of how to interpret it. It also places emphasis on the customer, addressing customer satisfaction. It emphasizes that the adoption of a formal management system is a strategic decision of the organization. There is an explanation of the relationship between ISO 9001:2000 and ISO 9004:2000. It also covers compatibility with ISO 14000:1996. The introduction explains that the standard does not address other areas such as finance and health and safety.

Scope

The standard gives a clear indication of its process nature and that:

- You need to take into account the regulatory requirements of your products
- You need to have processes in place for continual improvement.

"Application" requires you to state clearly if any areas of the standard do not apply to your organization, together with an explanation of the reasons for this.

Normative Reference

This clause states that the definitions of ISO 9000:2000 apply.

Terms and Definitions

The three parties involved in the requirements are clearly shown. The terminology has been brought into line with general usage in industry and commerce.

Quality Management System [QMS]

The QMS is the means by which you manage and control your organization. How you do this is entirely up to you. However, your system should use processes to achieve this. Those processes should consist of a balance between procedures and competencies.

Your current systems for control may already have much of the detail that is needed for the revised standard. There is an all embracing requirement for you to identify your processes, determine their interaction, ensure that there is enough information to monitor them and to document them where they are needed to maintain control.

A process is described in the standard as a 'set of interrelated or interacting activities which transform inputs into outputs'. Put more simply they are those chains of activities that take place across an organization and deliver the organization's products or services to either internal or external customers.

Processes are what need to be done, which needs to do it and what is the result. Either procedures and/or competencies will support processes. Procedures and other documents [work/operating instructions, etc.] define how an activity is required to be done.

In the past there has been a perception that the standard requires a detailed description of every activity undertaken by an organization and this had led to cases of severe over-documentation.

You need a Quality Manual. The standard allows flexibility in respect of its status and structure. It can be part of the overall system, and need only contain the scope of the QMS, processes and any related procedures. You need to detail system processes.

The standard requires control of records and documents.

Management Responsibility [Clause 5.6]

You need to be aware of the role played by the "top management" of the organization. ISO 9000:2000 section 3.2.7 defines "top management" as:

"Person or group of people who direct and control an organization at the highest level".

There is a requirement for "top management" to show a commitment to the development and improvement of the QMS. It can demonstrate its commitment through leadership and active participation.

The top management also needs to ensure that it understands and meets the regulatory and legal requirements with respect to the products and services it supplies. The organization has to determine the customer's needs and expectations for their organization. This is aimed not only at individual customers but also at the market in which the organization operates.

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Planning [Clause 5.4]

Objectives are the targets that you set yourself to achieve your policies. To meet your objectives you need to plan the actions you take. This clause clarifies the requirement for objectives and includes continual improvement. Planning includes the use of resources, how processes are used, and the requirement to maintain the system whilst the organization is undergoing change.

Responsibility, authority and communication [Clause 5.5]

For your management system to operate effectively you need to have control over how it is administered. This is achieved through:

- Responsibility and authority, which includes the communication of responsibility and authority.
- A management representative who plays a pivotal role in the running and organization of the system.
- Internal communications, covering the need for there to be managed communication within the organization.

Management Review [Clause 5.6]

The need for the "top management" to review the QMS is pivotal. This is the route for review and action in respect of 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. Management Review shows the inputs and outputs required.

Resource Management [Clause 6.0]

The requirements of this clause cover training needs, training itself, infrastructure, and the work environment. There are also requirements dealing with competencies of personnel and the evaluation of training effectiveness, together with staff awareness of the relevance and importance of their role and how it contributes to the achievement of the organizations' objectives. The clause requires you to identify and provide company infrastructure. You need to take into account the working environment for personnel and product to ensure that the product conforms to customer requirements. For further

Guidance on this subject see clause 6.4 of ISO 9004:2000.

Product Realization [Clause 7.0]

"Product Realization" is the process of making a product and/or delivering a service.

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Planning of realization process [Clause 7.1]

The planning requirements relate to objectives concerning the product, project, or contract. You need to determine what processes you require and how you will control them for the realization of the product or service provided. The clause refers to objectives and how the processes will help you to meet them. Note the sub paragraphs a-d, as these lay down the requirements for what should be taken into account when planning the processes. Also note the reference made to the development of the processes and note 2, which suggests that the requirements of design may be used to develop the processes needed for the product or service.

Customer-related processes [Clause 7.2]

This clause includes specific requirements concerned with taking into account legal and regulatory requirements relating to the product or service provided. An implied need is one where the customer does not specify a requirement but the organization knows that the requirement is needed to satisfy the customer and also comply with regulatory or legal requirements.

Design and/or development [Clause 7.3]

This clause provides a comprehensive description of design and/or development requirements. It covers both design to customer specifications and off-the-shelf designs. It is as applicable to design of services, as it is to design of products. It requires you to plan activities, agree inputs and for outputs to meet the inputs. The design should be reviewed against the inputs and verified as it progresses. Once the design is complete its validation is required to ensure that it meets the input requirements regardless of whether or not the output is a tangible product or a service. Also, design changes require a control system.

Purchasing [Clause 7.4]

This clause deals with purchasing in relation to the selection of suppliers. It requires you to exercise control over suppliers in proportion to the effect that a purchased product has upon the final product to the customer. It also requires you to evaluate your suppliers both initially and periodically. Purchasing information is a requirement as is verification of purchased product.

Control of measuring and monitoring devices [Clause 7.6]

This clause explains the monitoring devices that you can use to control processes. It also deals with the validation of software.

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Measurement Analysis and Improvement [Clause 8.0]

General [Clause 8.1]

This clause requires you to plan how you will measure and monitor systems, processes and products. It also refers to the statistical techniques you may use in measurement and monitoring.

Measurement and Monitoring [Clause 8.2]

The standard contains a customer satisfaction requirement. You need to have a way of measuring customer perception of your company and thus customer confidence. When you have this information you can consider actions for improvement.

The requirement for internal audits includes a consideration of the results of previous audits. It is made clear that auditors should not audit their own work.

You should have methods for measuring your processes to check that they are capable of ensuring that the product or service meets requirements, both stated and implied.

Control of non-conformity [Clause 8.3]

Non-conformity is anything that does not conform to what has been specified. The last paragraph of this clause deals with the detection of a non-conformity after the product has been released or delivered.

Analysis of data [Clause 8.4]

Analysis of data is an important aspect of the system. It requires all the information from the measurement section to be brought together with a view to effecting improvement.

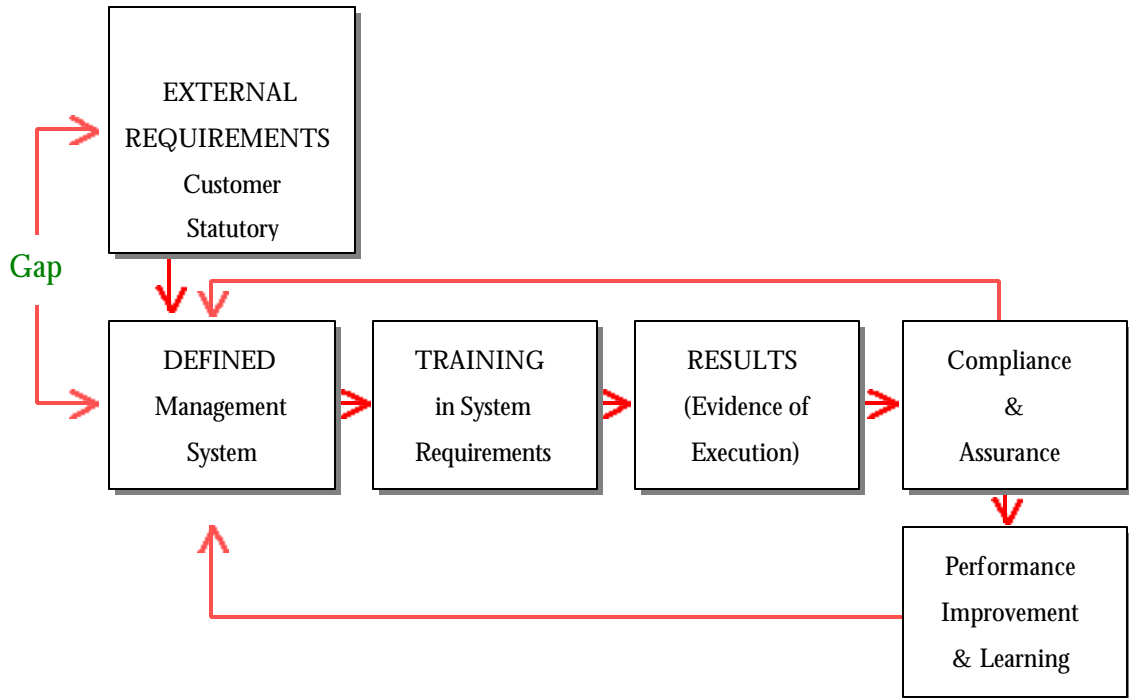
Improvement [Clause 8.5]

Continual improvement looks for the improvement of the QMS. It requires you to plan improvement systems and to take into account many other activities that you can use in the improvement process.

Typically, these will be the results from the analysis of data. Corrective action requirements include development of the means to stop a problem from happening again. Preventive action requirements include ways to stop problems arising in the first place. It is the proactive analysis of the processes, whereas corrective action is the re-action to problems when they arise. Preventive action can be achieved by an assessment of the risk of something going wrong.

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Continuous/Continual Improvement



The above diagrams illustrate the differences between "Continuous" and "Continual" improvement.

Continual improvement is a step-by-step process of carrying out improvements and then looking to see how effective they have been.

You need to look at your organization's overall systems performance and decide when and where you can make the most effective improvements. You then need to set objectives for those improvements and conduct periodic evaluation to monitor achievement.

Improvements may be the reduction of cycle time within a process or the economic effectiveness and improvement of changes to the systems.

PDCA Cycle

From problem-faced to problem-solved

The PDCA Cycle is a checklist of the four stages, which you must go through to get from 'problem-faced' to 'problem solved'. The four stages are Plan-Do-Check-Act, and they are carried out in the cycle illustrated below.

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Walter Shewhart, the pioneering statistician who developed statistical process control in the Bell Laboratories in the US during the 1930's, originally developed the concept of the PDCA Cycle. It is often referred to as 'the Shewhart Cycle'. It was taken up and promoted very effectively from the 1950s on by the famous Quality Management authority, W. Edwards Deming, and is consequently known by many as 'the Deming Wheel'.

Use the PDCA Cycle to coordinate your continuous improvement efforts. It both emphasizes and demonstrates that improvement programs must start with careful planning, must result in effective action, and must move on again to careful planning in a continuous cycle.

Also use the PDCA Cycle diagram in team meetings to take stock of what stage improvement initiatives are at, and to choose the appropriate tools to see each stage through to successful completion.

How to use the PDCA Cycle diagram to choose the appropriate tool is explained in detail in the 'How to use it' section below.

Plan-Do-Check-Act

Here is what you do for each stage of the Cycle:

- PLAN** to improve your operations first by finding out what things are going wrong (that is identify the problems faced), and come up with ideas for solving these problems.
- DO** changes designed to solve the problems on a small or experimental scale first. This minimizes disruption to routine activity while testing whether the changes will work or not.
- CHECK** whether the small scale or experimental changes are achieving the desired result or not. Also, continuously check nominated key activities (regardless of any experimentation going on) to ensure that you know what the quality of the output is at all times to identify any new problems when they crop up.
- ACT** to implement changes on a larger scale if the experiment is successful. This means making the changes a routine part of your activity. Also Act to involve other persons (other departments, suppliers, or customers) affected by the changes and whose cooperation you need to implement them on a larger scale, or those who may simply benefit from what you have learned (you may, of course, already have involved these people in the Do or trial stage).

You have now completed the cycle to arrive at 'problem solved'. Go back to the Plan stage to identify the next 'problem faced'.

If the experiment was not successful, skip the Act stage and go back to the Plan stage to come up with some new ideas for solving the problem and go through the cycle again. Plan-Do-Check-Act describes the overall stages of improvement activity, but how is each stage carried out? This is where other specific quality management, or continuous improvement, tools and techniques come into play.



The diagram below lists the tools and techniques, which can be used to complete each stage. of the PDCA Cycle

This classification of tools into sections of the PDCA Cycle is not meant to be strictly applied, but it is a useful prompt to help you choose what to do at each critical stage of your improvement efforts.

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Annexes

Please note these annexes can be used for the comparison between the new standard and ISO 14001:1996 and ISO 9001:1994 respectively.

Scope Description And Application

General

To accommodate the differences between different organizations' activities, ISO 9001:2000 allows for "Application". This only applies to the requirements of clause 7, "Product Realization" [i.e. the clause that asks an organization to describe the processes of producing its products or providing its services].

ISO 9001:2000, Clause 1.2 explains the concept of "Application" and, at Clause 4.2.2 requires the Quality Manual to include details and justification for exclusions.

This then allows for a description in the scope of the QMS that will differentiate those businesses that supply design and development services, and/or manufacturing services and/or process services and/or service provision. It is the scope of registration that indicates which clauses or sub clauses of section 7 are included or excluded. It also indicates any other specific elements of the organization's business. Exclusions are only allowed within section 7. You must comply with all the requirements of sections 4, 5, 6, and 8.

The ISO committee responsible for the development of ISO 9000:2000 has issued Guidance on "Application" that may be referred to for further help [look at the ISO web site www.iso.ch].

The organization recognizes that, even though the manufacturing unit does not carry out the operational part of purchasing, it has an important input into the process, particularly the specification and verification of the purchased product. It therefore does not exclude Clause 7.4 ["Purchasing"] from its QMS, and explains in its documented QMS the way in which the purchasing process operates, including a description of the interfaces between the manufacturing plant and the corporate purchasing division. It also applies the requirements of clause 7.4 to other purchased products and services, which are managed locally.

At all times you are advised to discuss your scope of registration and any possible "Application" of your systems with your assessment body, consultant, independent adviser or customer.

Implementing The Quality Management System

As a rule, all organizations operate a management system and virtually all employ a 'formal' management system of some sort. Few organizations do not issue documented invoices, retain accounts, and issue contracts of employment and job descriptions/specifications to their employees.

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Implementing quality management amounts to building the eight quality management principles of ISO 9000 onto this foundation. The following illustration sets out the quality management system model in its simplest form.

- Set Goals and Objectives of the QMS project for Implementation and Registration
- Appoint Quality Management Representative
- Appoint ISO Team (*if necessary*)
- Decide if a Consultant is required
- Plan the QMS Project. Prepare Cost Estimate
- Allocate Resources for the QMS Project
- Conduct Gap Analysis by reviewing existing Management System & Working Procedures and Practices
- Flowchart the process
- Develop Quality Management System documentation
- Prepare a list of accredited Registrars
- Interview and Select a Registrar
- Review and approve QMS documentation
- Introduce and Train employees to QMS
- Implement QMS for at least 3 months
- Identify and train Internal Auditors (*Quality Improvement Team*)
- Conduct 1st series of Internal Audit
- Conduct 1st management Review meeting
- Initiate Corrective and Preventive Actions
- Conduct 2nd Management Review meeting

The Concept of Quality Management

The Quality Management System is simple in its basic concept. It seeks to:

- Identify external quality related input requirements specified in Licenses to Trade, regulations, specified customer requirements and the chosen management system standard(s);
- Ensure that all these input requirements have been addressed within the management system at the appropriate location in terms of defined specific system requirements;
- Ensure that personnel receive applicable training in system requirements; define performance measures, as applicable, to the system requirements;
- Generate the result or evidence that system requirements have been executed;
- Measure, monitor and report extent of compliance with these performance measures; continually monitor changes to input requirements and ensure that these changes are reflected in changes to the specific system requirements when applicable;
- Audit and evaluate the system processes and correct them when applicable;
- Provide a culture and process for continually improving the system and feeding back lessons learned into the system.

There are two ways of undertaking the programme of implementation. The first is to use in-house resources and the second is to employ a quality management consultant. Bear in mind that even if you decide to use a consultant, you will still have to devote a significant amount of time to his/her support.

This time must be allocated if the quality management system is to be effective and ownership by the organization's personnel is to be ensured. Before embarking on the process of implementation, you should carefully weigh up the advantages and disadvantages of the alternatives.

If you decide to use in-house resources, then the member of the organization assigned the responsibility of implementation, the implementer, should have an understanding of the organization's activities, an in-depth understanding of basic management principles and should have undertaken some training in the requirements of ISO 9001. A guide to selecting and working with a quality management consultant is provided later in this chapter.

The first and most important task for an SME undertaking the implementation of a quality management system is to establish why you are doing so. If the sole driver is to obtain an ISO 9001 certificate to get on customers' tender lists, there is a danger that the system will simply focus on the ISO standard. The result may not serve any useful purpose and simply act as a drain on organization's resources. If you develop

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the system based on the following aims of implementation, the result should be a satisfactory and useful system.

Goals and Objectives of Implementation

The objectives and goals of implementation are usually based on a organization's need for:

“Performance improvement and an increase in bottom line profit the effective management of risk assurance of quality of product or service to the customer the basis for implementing a culture for opportunity if required, the acquisition of a symbol of international recognition (ISO 9001)”

Measurement Criterion for the Process of Implementation

It is also important to agree a criterion for the process of implementation with all those involved in it.

Typically, the following criterion might be adopted:

“All aspects of the management system must add value to the activities of the organization in relation to the resources required to implement and maintain each aspect.”

Definition of Added Value

Similarly it is important to agree the definition or understanding of what it means to add value. Some examples are listed below.

- Reduction of the risk of occurrence of a safety incident or accident
- Reduction of the risk of occurrence of an environmental incident or accident
- Improved assurance of specified product or service quality
- Improved actual product or service quality
- Reduction of product or service delivery cost
- Reduction of the delivery time for product or service
- Improved management of resources, (human, facilities and financial)

A detailed explanation of how to implement a quality management system is outside the scope of this publication but the figure below sets out the basic stages that should be

The Process of Implementation

The implementation of a formal management system is best handled as a specific project with a Project Manager, who should be a key member of the organization's management team and appointed at the outset of the project.

It is important that none of the stages detailed in the flowchart in figure 1. are omitted. The existing system of management and working practices must be known in some detail before the framework of the formal management system documentation can be designed. The system is best designed around existing processes as the development of new systems that require additional resources may simply delay the implementation process.

Designing the System Framework

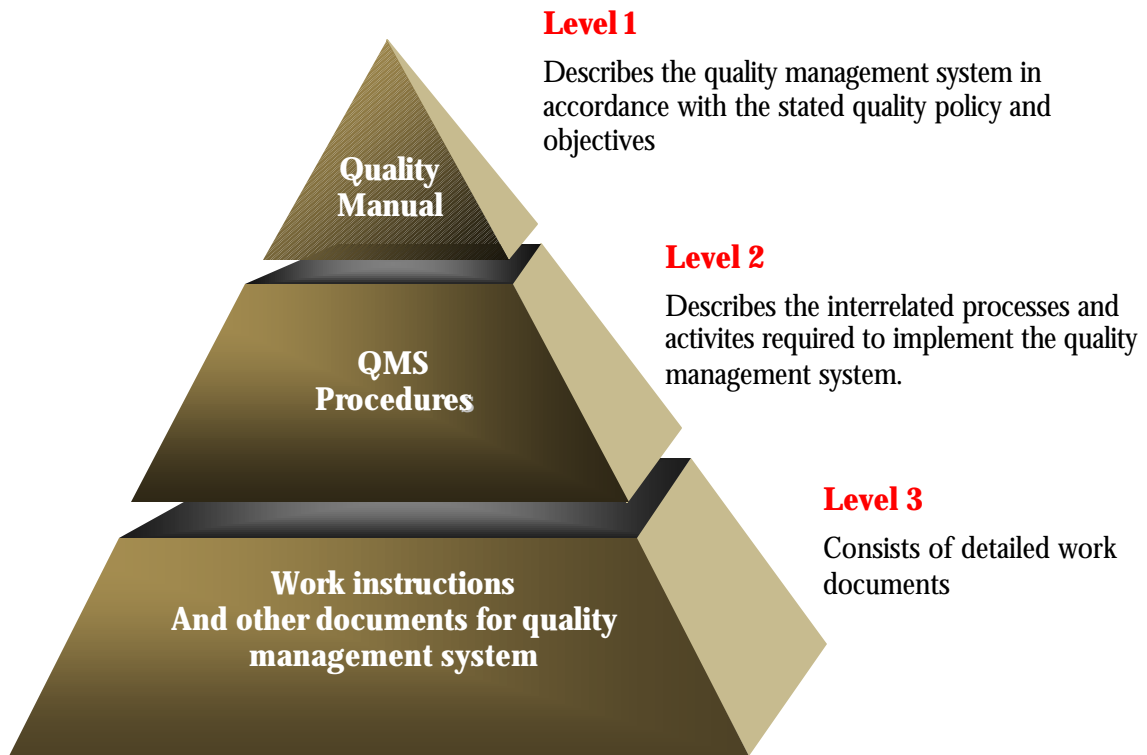
The first task is to develop the initial framework of the QMS, identifying the various processes that are used to deliver the products or services to the customer, [either an external or internal customer]. From the framework of the management system the project team will identify the required supporting documentation, firstly in terms of defined processes and then in terms of the supporting competencies and procedures that will underpin these processes.

Once the full framework of the QMS has been designed and the supporting documentation identified, it is important to prepare a plan for implementation so that all participants understand their responsibilities. The plan will detail the authors of the various documents, the personnel responsible for the later stages of implementation and will include the associated deadlines for completion.

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Document Structure

The documentation structure of a quality management system consists of three levels



Quality manual

Contents

A quality manual is unique to each organization. A small organization may find it appropriate to include the description of its entire quality management system within a single manual, including all the documented procedures required by ISO 9001.

The quality manual should include the scope of the quality management system, the details of and justification for any exclusion, the documented procedures or reference to them, and a description of the processes of the quality management system and their interactions.

Information about the organization, such as name, location and means of communication, should be included in the quality manual. Additional information such as its line of business, a brief description of its background, history and size may also be included.

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Title and scope

The title and/or scope of the quality manual should define the organization to which the manual applies. The manual should make reference to the specific quality management system standard on which the quality management system is based.

Table of contents

The table of contents of the quality manual should list the number and title of each section and its location.

Review, approval and revision

Evidence of the review, approval, revision status and date of the quality manual should be clearly indicated in the manual.

Quality policy and objectives

Where the organization elects to include the quality policy in the quality manual, the quality manual may include a statement of the quality policy and the objectives for quality. The actual quality goals to meet these objectives may be specified in another part of the quality management system documentation as determined by the organization.

The quality policy should include a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

Objectives are typically derived from the organization's quality policy and are to be achieved. When the objectives are quantified they become goals and are measurable.

Organization, responsibility and authority

The quality manual should provide a description of the structure of the organization. Responsibility, authority and interrelation may be indicated by such means as organization charts, flow charts and/or job descriptions. These may be included or referenced in the quality manual.

References

The quality manual should contain a list of documents referred to but not included in the manual.

Quality management system description

The quality manual should provide a description of the quality management system and its implementation in the organization. Descriptions of the processes and their interactions should be included in the quality manual.

Documented procedures or references to them should be included in the quality manual.

The organization should document its specific quality management system following the sequence of the process flow or the structure of the selected standard or any sequencing appropriate to the organization. Cross-referencing between the selected standard and the quality manual may be useful.

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The quality manual should reflect the methods used by the organization to satisfy its policy and objectives.

Appendices

Appendices containing information supportive to the manual may be included.

Documented procedures

Structure and format

The structure and format of the documented procedures (hard copy or electronic media) should be defined by the organization in the following ways: text, flow charts, tables, a combination of the above, or any other suitable method in accordance with the needs of the organization.

Documented procedures may make reference to work instructions that define how an activity is performed.

Documented procedures generally describe activities that cross different functions, while work instructions generally apply to tasks within one function.

Contents

Title The title should clearly identify the documented procedure.

Purpose The purpose of the documented procedure should be defined.

Scope The scope of the documented procedure, including the areas to be covered and areas not to be covered, should be described.

Responsibility and authority The responsibility and authority of people and/or organizational functions.

Description of activities The level of detail may vary depending on the complexity of the activities, the methods used, and the levels of skills and training of people that is necessary in order for them to accomplish the activities. Irrespective of the level of detail, the following aspects should be considered as applicable:

- a. defining the needs of the organization, its customers and suppliers;
- b. describing the processes in terms of text and/or flow charts related to the required activities;
- c. establishing what is to be done, by whom or by which organizational function; why, when, where and how;
- d. describing process controls and controls of the identified activities;
- e. defining the necessary resources for the accomplishment of the activities (in terms of personnel, training, equipment and materials);
- f. defining the appropriate documentation related to the required activities;
- g. defining the input and output of the process;

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- h. defining the measurements to be taken.

Records

The records related to the activities in the documented procedure should be defined in this section of the documented procedure or in other related section(s). The forms to be used for these records should be identified as applicable. The method required to complete, file and keep the records should be stated.

Appendices

Appendices containing information supportive to the documented procedure may be included, such as tables, graphs, flow charts and forms.

Review, approval and revision

Evidence of review and approval, status and date of revision of the documented procedure should be indicated.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

Work instructions

Structure and format

Work instructions should be developed and maintained to describe the performance of all work that would be adversely affected by lack of such instructions. There are many ways of preparing and presenting instructions.

Work instructions should contain the title and a unique identification.

The structure, format and level of detail used in the work instructions should be tailored to the needs of the organization's personnel and depends on the complexity of the work, the methods used, training undertaken, and the skills and qualifications of such personnel.

The structure of the work instructions may vary from that of documented procedures.

The work instructions may be included in the documented procedures or referenced in them.

Contents

Work instructions should describe critical activities. Details which do not give more control of the activity should be avoided. Training can reduce the need for detailed instructions, provided the persons concerned have the information necessary to do their jobs correctly.

Types of work instructions

Although there is no required structure or format for work instructions, they generally should convey the purpose and scope of the work and the objectives, and make reference to the pertinent documented procedures.

Whichever format or combination is chosen, the work instructions should be in the order or sequence of the operations, accurately reflecting the requirements and relevant activities. To reduce confusion and uncertainty, a consistent format or structure should be established and maintained.

Review, approval and revision

The organization should provide clear evidence of review and approval of work instructions and their revision level and date of revision.

Records

Where applicable, the records specified in the work instruction should be defined in this section or in other related section(s). The minimum records required are identified in ISO 9001. The method required to complete, file and keep the records should be stated. The forms to be used for these records should be identified as applicable.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

Forms

Forms are developed and maintained to record the data demonstrating compliance to the requirements of the quality management system.

Forms should contain a title, identification number, revision level and date of revision. Forms should be referenced in, or attached to, the quality manual, documented procedures and/or work instructions.

Quality plans

A quality plan is a part of quality management system documentation.

The quality plan needs to refer only to the documented quality management system, showing how it is to be applied to the specific situation in question, and identify and document how the organization will achieve those requirements that are unique to the particular product, process, project or contract.

The scope of the quality plan should be defined. The quality plan may include unique procedures, work instructions, and/or records.

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Specifications

Specifications are documents stating requirements. Specifications are not further detailed in this Technical Report because they are unique to the product/organization.

External documents

The organization should address external documents and their control in its documented quality management system. External documents can include customer drawings, specifications, statutory and regulatory requirements, standards, codes and maintenance manuals.

Records

Quality management system records state results achieved or provide evidence indicating that the activities indicated in the documented procedures and work instructions are performed. The records should indicate the compliance with the requirements of the quality management system and the specified requirements for the product. The responsibilities for preparation of records should be addressed in the quality management system documentation.

NOTE Records are not generally under revision control as records are not subject to change.

The Quality Department

You are unlikely to need to appoint a full-time Quality Manager or full-time auditors as you can generally assign these responsibilities to existing personnel as part of their overall duties. This will help to ensure that the system does not become the property of a Quality Department rather than remaining the tool of the organization's management. It should also ensure that the system does not become too demanding for the organization in terms of additional expenses.

Training in System Requirements

You can provide training in system requirements through a series of induction or training workshops for the people who have not been involved in the writing of procedures and who will be required to work to them. In addition to developing a full understanding of the system requirements, the training will extend ownership of the procedures to those who work to them. New employees will also require induction or training in the QMS.

Evidence of Implementation

You will usually work to the system documentation for three to six months. During this time you will generate the required evidence of execution. Following this, you can undertake the first series of internal audits.

Internal Auditing

Selecting and training internal auditors are important aspects of the process of implementation. It is essential that you select internal auditors carefully. It is recommended that you choose people to train in auditing from a broad spectrum of the company, rather than employing a specific internal audit department. This helps to create a good understanding of formal systems management throughout the company, avoids the impression that internal auditing is a policing activity and provides the opportunity for suppliers to audit customers and vice versa.

Additionally, it is best that, if possible, you do not select auditors from management. This will ensure that internal audit is perceived as a system evaluation rather than an appraisal of personnel. The training of internal auditors will focus on conveying the message that the aim of internal audit is to add value rather than to find fault with the function being audited.

Performance Improvement and Learning

You need to have implemented the system of performance improvement and learning [continual improvement] before the registration audit. Performance improvement may be based on the regular meeting of performance improvement teams. In practice these teams must have been established, held meetings and kept minutes of these meetings before the registration audit.

Measuring the Success of the Process of Implementation

It is important that the project team and those involved measure the success of the implementation process either at predefined stages during or at the conclusion of the process. Measurement should be against the original aims and goals and the key indicators of an effective QMS described below:

- Senior management is fully committed to the QMS and owns the appropriate processes
- The QMS is designed around the business processes and not ISO 9001 or any other management system standard
- Staff know how to access QMS documentation
- Visibility of process and clarity of instruction, i.e. QMS documentation is clear, concise, and readable. Document custodians easily maintain the documentation
- The organization has a culture for opportunity, focused around continual improvement, rather than a "person-to-blame" culture
- Quality management representative is a key organization person rather than side-lined person
- Internal audit is seen as adding value and part of continual improvement of the QMS

Selection of a Registrar

We recommend that when you are ready to seek accredited registration you should:

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- Obtain a list of accredited registration bodies.
- Contact at least three, describing your business and asking whether or not the registrar is accredited to provide registration services in your specific area of operations
- Prepare a shortlist and ask for quotations
- Make the choice