QUALITY SYSTEMS IN THE SMALL OR MEDIUM SIZED ENTERPRISE [SME]

A guide to the adoption of the ISO 9001:2000 standard

This workbook has been written for Small or Medium Sized Enterprises [SMEs] who are either considering seeking initial registration to ISO 9001:2000 or who are already registered to, or are familiar with, the ISO 9000:1994 series of standards and intend to update to ISO 9001:2000. SMEs are generally described as those that employ less than 250 staff and have a turnover of less than £25M.

It has been prepared by a small working group comprising representatives of the Institute of Quality Assurance, [IQA], Federation of Small Businesses, [FSB], and the Association of British Certification Bodies, [ABCB], under the chairmanship of ABCB.

The workbook is for public information and may be downloaded from the websites of the working group members. It does not replace the ISO 9000:2000 series and should be read in conjunction with the standards.

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The document is in eight parts:

Foreword

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 300,000 organisations world-wide. It specifies minimum requirements for a quality management system where an organisation needs to:

- Demonstrate its ability to provide consistently a product that meets customer and applicable regulatory requirements and to:
- 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].

Certification

If you are thinking about implementing the ISO 9001:2000 standard in your organisation, third party certification is an option available to you. Part 6 provides advice on the selection of a suitable certification body.

There are both advantages and disadvantages in implementing ISO 9001:2000 and achieving certification. In summary, these are:

Perceived benefits/advantages of ISO 9001:2000 certification

- Improvement in "bottom line" profit through:
  - Better efficiency
  - Continual improvement
  - Less waste
- Consistent control of key processes
- Possible reduction in insurance premiums
- Promotion and standardisation of good working practices
- Greater marketing appeal and improved public relations
- Meeting the requirements for inclusion on some tender lists.
- Provision of a vehicle for training new employees
- The effective management of risk
- Provision of a vehicle for introducing a culture for opportunity
- Increasing the potential for world-wide recognition

Perceived disadvantages of ISO 9000:2000 certification

- Costly to obtain and maintain
- Lengthy time-scale to obtain certification
- Time-consuming development
- Difficult to implement
- Organisational resistance to change
- Staff resistance to change
- Hard to maintain enthusiasm for the system
- More documentation

Accreditation

Most certification bodies have been accredited by their national accreditation body. In the UK, this is the United Kingdom Accreditation Service, [UKAS], [see Part 6]. Accreditation is part of a hierarchy of assurance. It is granted to a certification 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 certification 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.

PART 1 - THE INTRODUCTION OF ISO 9001:2000

Why the ISO 9000:1994 series of standards is changing

It is normal practice to revise a standard every few years. The world moves on, and standards have to keep up. The revision of the ISO 9000:1994 series of standards in year 2000 has been planned since before the 1994 versions were issued.

Few standards have had more impact around the world than the ISO 9000:1994 series and the interest it has generated has inevitably led to many suggestions for its improvement. Before embarking upon the revision process, the responsible committee carried out extensive surveys, to determine what issues should be addressed by the revised standard. Some of the concerns with the ISO 9000:1994 series of standards are:

- too much emphasis on documentation rather than results
- customer satisfaction and improvement are not specifically addressed
- the standard is now used globally and universally [not just in manufacturing]
- the '20 elements' is not the best structure
- too many standards in the series
- duplication and/or incompatibility with other standards [e.g. ISO 14001].

The revised standard seeks to address these shortcomings, having evolved to meet the changing needs and expectations of users.

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

Organisations will be assessed and awarded certification against ISO 9001:2000, whether or not they are involved in design. Further explanation of how this will work in practice is in Part 4.

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 certification or contractual purposes.

Differences from the ISO 9000:1994 series of standards

It is important to recognise 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 realisation
  - measurement, analysis and improvement
- 'Continual improvement' [see "Improvement"]
- the move to 'customer satisfaction' [rather than 'customer complaints']

Benefits of the revised standard

There seems little doubt that the revision is beneficial in terms of making the standard relevant both to the organisations that adopt it and to their clients.

The move towards process management and the removal of the 20 elements will help organisations implement a quality management system that moulds itself to their business, and should avoid the pitfalls of re-designing the business to suit the standard. The emphasis on product/service realisation and customer satisfaction, rather than documentation, is a response to criticisms that the old standard concentrated on the wrong things. The need to address continual improvement is something that most responsible organisations had already recognised and this is now brought into the revised standard.

In addition to the major changes, there are a whole host of minor improvements which combine to make the revised standard more user-friendly.

Timescale for introduction

The revised standard was published towards the end of 2000. From that date onwards, certification bodies are able to certificate organisations to ISO 9001:2000, provided that the organisation's quality management system is in compliance.

However, if your organisation is already registered to the 1994 series of standards and you wish to adopt the year 2000 revision, there is no immediate need to change. There will be a 3-year transition period from the date of publication of the revised standard, i.e. until late 2003. During this time, you can continue to be assessed and certificated against the 1994 standard. You can decide when you are ready to be assessed against ISO 9001:2000. You should notify your certification body when you are ready for this. It is unlikely that the certification body will need appreciably more or less time to audit to the revised standard.

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, certification to these standards will no longer be possible and 1994 certificates will become invalid. This means that any organisation holding an ISO 9000:1994 series certificate, issued with a Government recognised accreditation and who has not updated to ISO 9001:2000, will have its certificate withdrawn.

PART 2 - 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 organisation. 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.

Product/Service realisation: 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 organisation, this may be the process of converting iron ore to steel via a blast furnace for example. For a service organisation, 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. Analysing 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 recognised 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 organisation'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 organisation 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 organisation'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.

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 organisation 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 organisation and the process for obtaining them was operating under the controlled conditions that the organisation had defined.

Auditing of processes should result in a logical audit of the activities of organisations 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.

PART 3 - 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 [Clause 0]

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 emphasises that the adoption of a formal management system is a strategic decision of the organisation. 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 [Clause 1]

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 organisation, together with an explanation of the reasons for this.

See Part 4 of this document for a more detailed explanation of scope.

Normative Reference [Clause 2]

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

Terms and Definitions [Clause 3]

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] [Clause 4]

The qms is the means by which you manage and control your organisation. 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 organisation and deliver the organisation's products or services to either internal or external customers.

Processes are what needs to be done, who 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 organisation and this had led to cases of severe over-documentation. See Part 5 - Implementing the Quality Management System, for guidance on the extent to which the details of activities should be specified.

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. See the qms requirements in Clause 4.

The standard requires control of records and documents.

Management Responsibility [Clause 5]

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

> "person or group of people who direct and control an organisation 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 organisation has to determine the customer's needs and expectations for their organisation. This is aimed not only at individual customers but also at the market in which the organisation operates.

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 organisation 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 organisation of the system.
- Internal communications, covering the need for there to be managed communication within the organisation.

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]

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 organisations' 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 Realisation [Clause 7]

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

Planning of realisation 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 realisation 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 organisation knows that the requirement is needed to satisfy the customer and also comply with regulatory or legal requirements.

For example, ordering a meal in a restaurant involves a number of implied needs. If you order soup. it is not normal for you to specify that the soup be served in a bowl. However, if it is not, then it will be difficult to eat. This is an implied need. Also, all food prepared for public consumption in the UK has to be in accordance with the Food Safety Act. This is a statutory implied need. The standard requires that the known or intended use of the product or service is determined before the order is accepted. There is also a specific requirement for clear communications between the organisation and the customer.

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.

Production and service provision [Clause 7.5]

This clause sets out the requirements for the actual production of the product and/or providing the service. It requires the product and/or service to be provided under controlled conditions and lists a number of conditions that may be applicable, e.g. availability of work instructions and necessary equipment. It also covers the situation where the final product and/or service cannot be checked or tested without damage or where problems may arise only after the product and/or service has been taken into use. To ensure that the product and/or service is delivered as planned, the processes involved should be validated to maximise confidence in the output.

The identification of products is covered but it should be noted that traceability is only necessary if it is a stated requirement e.g. contractual. If the product is required to be monitored and measured during production, its status is to be capable of identification.

An organisation shall have procedures to manage customer property whilst under its control and the product or its constituent parts are to be protected within the organisation and during delivery.

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.

Measurement Analysis and Improvement [Clause 8]

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]

A 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.

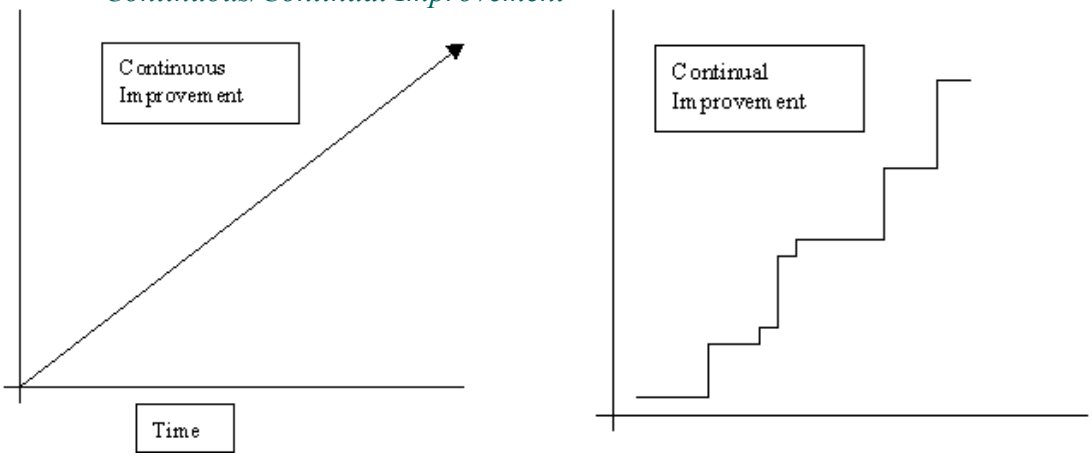
Analysis of data [Clause 8.4]

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.

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 organisation'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.

Annexes A and B

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

PART 4 - SCOPE DESCRIPTION AND APPLICATION

General

To accommodate the differences between different organisations' activities, ISO 9001:2000 allows for "Application". This only applies to the requirements of clause 7, "Product Realisation" [i.e. the clause that asks an organisation 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 certification that indicates which clauses or sub clauses of section 7 are included or excluded. It also indicates any other specific elements of the organisation's business. Exclusions are only allowed within section 7. You must comply with all the requirements of sections 4, 5, 6 and 8.

Some examples of scope description are:

> A solicitor, with no measurement instruments, can justify that ISO 9001 clause 7.6, Control of measuring and monitoring devices, has no bearing on meeting customer requirements and can therefore exclude it.

Similarly, many manufacturing industries simply manufacture to set specifications without themselves designing the product. There is therefore a valid justification to exclude ISO 9001:2000 clause 7.3 Design and/or development.
Scopes of Certification will appropriately reflect these different descriptions of a businesses' activities. An architect may indicate a scope of:

> "The design of houses and the project management of their construction"

Whereas a builder using these designs would perhaps indicate:

> "The building of houses".

A training organisation may have the scope:

> "The development and running of training courses"

Or, if it only runs the courses:

> "The running of training courses".

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/TC176/SC2 website http://www.bsi.org.uk/iso-tc176-sc2]. The following example is drawn from this document.

The "DEF Bottling Organisation" has a manufacturing facility that produces soft drinks according to product and packaging specifications provided by its parent organisation. It also manufactures products under license according to full product and packaging specifications provided by another independent organisation. The two sets of specifications meet all regulatory requirements and have not changed for years.

The manufacturing plant of DEF Bottling Organisation excludes from its QMS Clause 7.3 of ISO 9001:2000 [Design & Development], because this clause is not applicable to the manufacturing plant's operations. Full justification for this decision is provided in DEF's Quality Manual, nor do any publicity materials imply that the manufacturing plant has any design activity relating to its products.

Note: The fact that the design has not changed for years is irrelevant to the exclusion of clause 7.3 for DEF's QMS. Changing regulatory requirements may necessitate changes to the product design and the application of clause 7.3 by the organisation responsible for the design, which in this case is not DEF Bottling organisation.

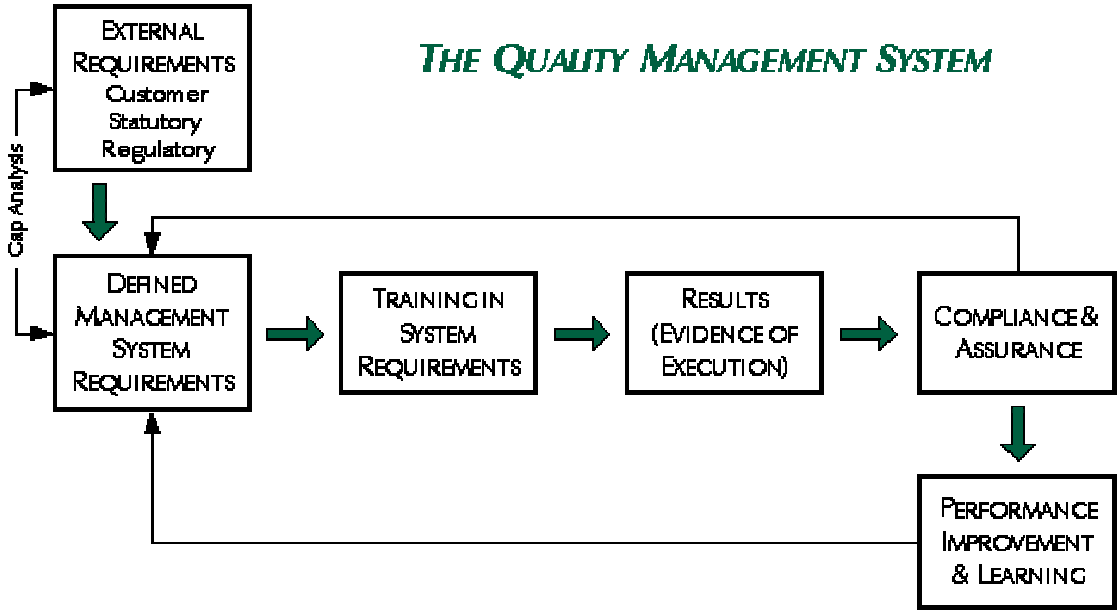
The corporate purchasing division of DEF's parent organisation negotiates all raw material and packaging purchases, in order to negotiate better prices.

The organisation 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 certification and any possible "Application" of your systems with your assessment body, consultant, independent adviser or customer.

PART 5 - IMPLEMENTING THE QUALITY MANAGEMENT SYSTEM

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



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 Licences 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 organisation'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 organisation assigned the responsibility of implementation, the implementer, should have an understanding of the organisation'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 organisation's resources. If you develop the system based on the following aims of implementation, the result should be a satisfactory and useful system.

Aims of Implementation

The aims and goals of implementation are usually based on a organisation'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 organisation 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 figure 1 below sets out the basic stages that should be followed.

The Process of Implementation and Certification of a Quality Management System (qms)

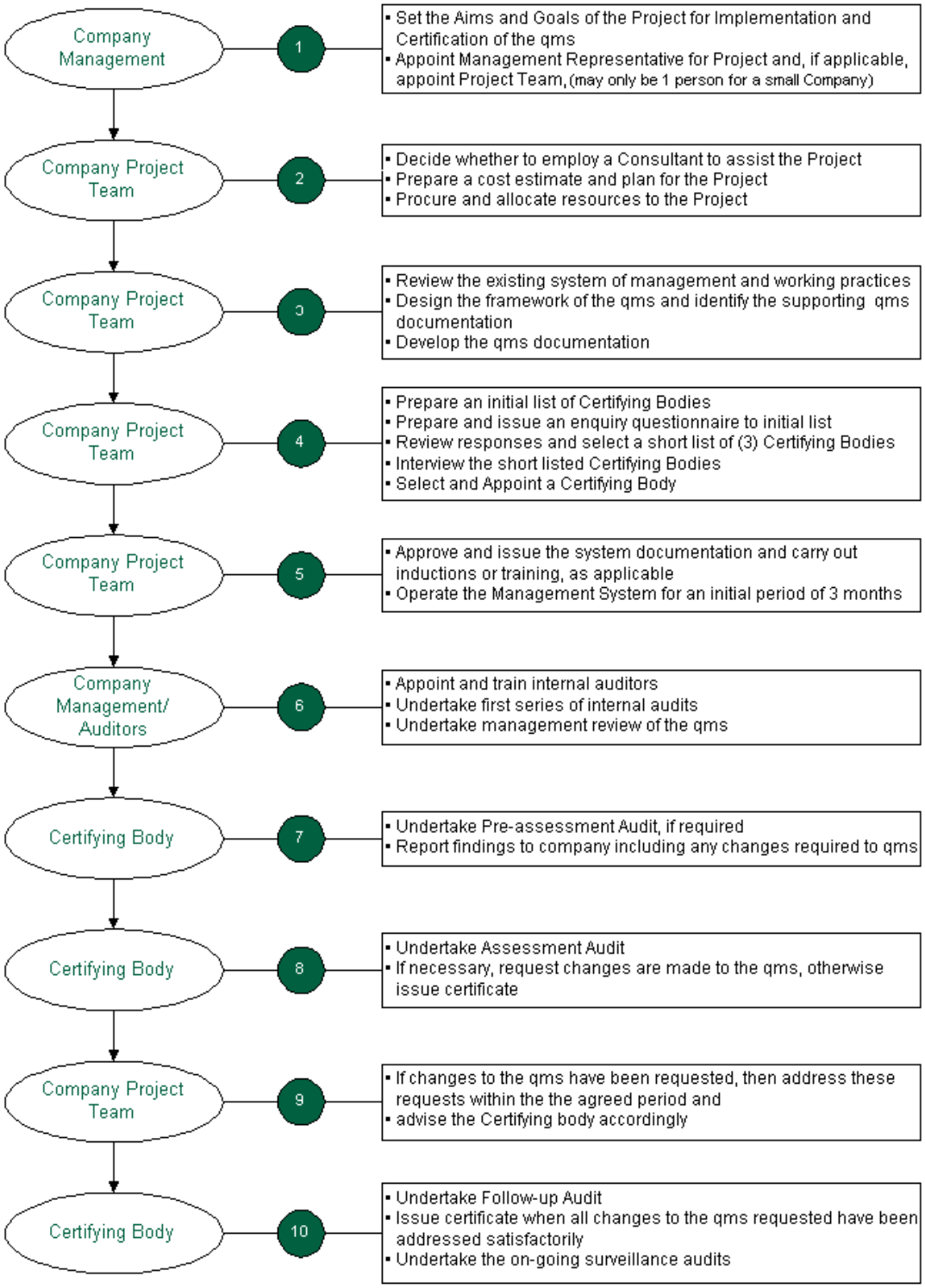


Figure 1

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 organisation'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.

Developing the System Documentation

To ensure that procedures are maintained as current documents and to reinforce the concept of ownership, "custodians" should be assigned to all system documentation.

The easiest way to prepare process definitions and procedures is during a series of half-day workshops supervised by the custodian and attended by the people who are stakeholders in the process or procedure under development. The workshop will generally take the form of a 'brain-storming' session and during or following the workshop the custodian will prepare the draft process definitions and/or procedures and competencies.

System process and procedures should reflect, as far as possible, existing working practices and identify the interfaces with the function's internal and/or external customers and suppliers.

The draft processes and procedures are then circulated to interested parties, i.e. customer/supplier interfaces. They are invited to submit comment within a given time and/or attend a finalisation meeting at which the process or procedure is approved for issue.
It is vital that qms documentation is prepared and issued swiftly and the practice of endless 'circulation for comment' is not recommended.

To repeat what has been said elsewhere in this publication, processes are essentially what needs to be done, who needs to do it and what is the result or evidence that it has been done. Either procedures and/or competencies will support processes. Procedures and other instructional documents [work/operating instructions, etc.] will define how an activity is required to be done.

The extent to which you will detail this in your instructional documentation will depend on the following:

- What is required to limit your organisation's exposure to risk to a predefined and acceptable level
- The extent at which clarity of instruction becomes over prescription
- The size and type of the organisation
- The complexity of the processes
- The defined levels of competencies required to support the processes

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 organisation's management. It should also ensure that the system does not become too demanding for the organisation 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 Execution

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 certification 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 certification audit.

Certification

You need to exercise care when selecting the a certification body. Refer to Part 6 for more information on this topic.

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:

- Top 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, ie qms documentation is clear, concise and readable. The documentation is easily maintained by document custodians
- The organisation has a culture for opportunity, focussed around continual improvement, rather than a "person-to-blame" culture
- Quality management representatives are key organisation personnel rather than side-lined personnel
- Internal audit is seen as adding value and part of continual improvement of the qms

Selecting and Working with a Consultant

Quality management is a task that needs continuing commitment and dedicated attention. It can be provided from within an enterprise, but external help from a consultant specialising in quality management may be valuable. Medium and large sized organisations generally utilise middle management staff that can be deployed on special assignments such as quality system development. Small organisations cannot always do this.

The development of the management system must aim at meeting the needs of the organisation and its customers, not a certification body. Regard the quality management system as a business improvement exercise. Determining its overall strategy, its quality objectives and practices must reside with the organisation itself. Therefore, it is preferable to choose a consultant with direct experience of your industry. However, it is probably more important that the consultant has had experience of a small business either as an employee or as a consultant and that he or she has such referees as to his/her success rate. Ensure that your consultant has the resources and back up to see your project through to a timely conclusion

How to select a consultant

It is a difficult task to choose a consultant to ensure the selection produces a properly qualified and appropriate individual. The following steps provide a systematic approach to help you through such an important selection decision:

1. Prepare a statement outlining the nature, scope and objectives of the assignment.

2. Circulate this written statement to the key people in your organisation inviting them to comment by a specific date in terms of whether it defines the need accurately and whether the assignment should be tackled internally or external help sought.
3. Define the expertise you will need.
4. Invite an agreed shortlist of not more than three consultants for a preliminary interview. The use of a consultant certified by IQA or another government-recognised body is recommended practice.
5. Brief the staff who will be involved in the selection process.
6. Avoid organisation jargon.
7. Ask each consultant to describe how the assignment will be approached.
8. Request references, in confidence, from each of the short listed consultants to provide precise examples of previous assignments carried out and check with the referees how successfully the assignment was carried out. Do not buy on price alone.
9. Request the short listed consultants to submit proposals in which they should define and even refine the objectives you have stated
10. Express the assignment you wish carried out in terms of the end results, i.e. outputs, that you want to achieve.
11. Provide resources and executive commitment to implement the quality management system. There is no point in seeking consultancy help unless you have the will and organisation resolve to implement the advice you get.

Working with a Consultant

Once you have confidence in your choice, regard your consultant as an adjunct to your management team. This should include participation in the selection of and negotiation with any certification body and in negotiations with key clients.

PART 6 - SELECTING A CERTIFICATION BODY

"Buyer Beware"

Some readers may be in possession of an ISO 9000:1994 series certificate issued by a non-accredited or non-UKAS accredited certification body. This Part provides advice on how to proceed initially towards ISO 9001:2000 registration. It explains the factors to be considered and pitfalls to be avoided by an SME when selecting a certification body either for the first time or in order to replace a certificate not accredited by UKAS.

United Kingdom Accreditation Service [UKAS]

UKAS is the only United Kingdom accreditation body recognised by Government and it operates in strict accordance with agreed international standards and under a Memorandum of Understanding with the Department of Trade and Industry. It is also subject to peer assessment by other recognised international accreditation bodies under the terms of a Multinational Recognition Agreement known as a MLA. Most importantly, companies who are certified by a UKAS accredited certification body are the only ones who may display the "Tick & Crown" logo on their certificate and on their publicity material. The "Tick & Crown" logo provides visual assurance to the many purchasers who require their suppliers to hold a UKAS accredited ISO 9000:1994 series or ISO 9001:2000 certificate.

Non Accredited Certification

Some readers may hold ISO 9000:1994 series certificates issued by certification bodies who are either non-accredited or accredited by an accreditor who is not recognised by the UK Government. These bodies offer a cheaper service than a UKAS accredited certification body and usually offer a package that combines consultancy with certification. Many offer to provide their services on a "no certificate - no fee" basis, but, this offer should be viewed against the fact that a certificate is rarely, if ever, refused. It is invariably received together with a quality manual which may, or may not, reflect the operations of the SME. This practice is contrary to the requirements of the international standard with which UKAS accredited certification bodies are required to comply. Some of these certification bodies claim to be accredited but, if they do, their accreditation will not have been granted by a UK Government recognised accreditor. Such accreditors are not subject to any regulatory constraints and provide little assurance of integrity, impartiality or accountability. Also they are not legally entitled to award the "Tick & Crown" logo for display by their clients.

Making the Selection

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

- Obtain a list of UKAS accredited certification bodies. [ABCB or UKAS can provide on request]
- Contact at least three, describing your business and asking whether or not the certification body is accredited to provide certification services in your specific area of operations
- Prepare a shortlist and ask for quotations
- Make the choice

APPENDIX 1 - USEFUL ADDRESSES

Association of British Certification Bodies [ABCB]
SIRA, South Hill, Chislehurst, Kent BR7 5EH
Tel: 0208 2951128 Fax: 0208 467 8091
e-mail: tinman@abcb.demon.co.uk
website: www.abcb.demon.co.uk

The British Quality Foundation [BQF]
32-34 Great Peter Street, London SW1P 2QX
Tel: 0207 654 5000 Fax: 0207 654 5001
e-mail: mail@quality-foundation.co.uk
website: www.quality-foundation.co.uk

Federation of Small Businesses [FSB]
2 Catherine Place, Westminster, London SW1E 6HF
Tel: 0207 592 8100 Fax: 0207 233 7899
e-mail: london@fsb.org.uk
website: www.fsb.org.uk

Customer Services, BSI Publications
British Standards Institution, 389 High Road, London W4 4AL
Tel: 0208 996 7000 Fax: 0208 996 7001
e-mail: info@bsi-global.com
website: www.bsi-global.com

Independent International Organisation for Certification [IIOC]
c/o Mr Sandy Sutherland, LRQA Ltd, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ
Tel: 02476 882375 Fax: 02476 639493
e-mail: sandy.sutherland@lrqa.com

Institute of Quality Assurance [IQA]
12 Grosvenor Crescent, London SW1X 7EE
Tel: 0207 245 6722 Fax: 0207 245 6788
e-mail: iqa@iqa.org
website: www.iqa.org

International Registration of Certification Auditors [IRCA]
12 Grosvenor Crescent, London SW1X 7EE
Tel: 0207 245 6833 Fax: 0207 245 6844
e-mail: irca@irca.org
website: www.irca.org

United Kingdom Accreditation Service [UKAS]
21-47 High Street, Feltham, Middlesex TW13 4UN
Tel: 0208 917 8400 Fax: 0208 917 8500
e-mail: ikc@ukas.com
website: www.ukas.com