An Introduction to
ISO 9000: 2000

Contents

The ISO 9000 family of standards  2
Major changes  6
Transitional period  7
Specific versions of ISO 9000  8
Costs and benefits  10
Implementation  11
Certification  14
Annex  17
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. The ISO 9000 family of standards</td>
<td>2</td>
</tr>
<tr>
<td>1. Four primary standards and several guides</td>
<td>2</td>
</tr>
<tr>
<td>2. ISO 9000 family of standards and SMEs</td>
<td>4</td>
</tr>
<tr>
<td>3. Management principles</td>
<td>5</td>
</tr>
<tr>
<td>II. Major changes between the 1994 and 2000 versions of the ISO 9001 standard</td>
<td>6</td>
</tr>
<tr>
<td>III. ISO 9000 transitional period between the 1994 and 2000 version</td>
<td>7</td>
</tr>
<tr>
<td>IV. Specific versions of ISO 9000 quality management system standard</td>
<td>8</td>
</tr>
<tr>
<td>1. Two sector-specific standards</td>
<td>8</td>
</tr>
<tr>
<td>2. Other sector-specific standards</td>
<td>9</td>
</tr>
<tr>
<td>V. Costs and benefits of setting up a quality management system</td>
<td>10</td>
</tr>
<tr>
<td>1. Costs...</td>
<td>10</td>
</tr>
<tr>
<td>2. ...and benefits of obtaining ISO 9000 certification</td>
<td>11</td>
</tr>
<tr>
<td>VI. Implementing a quality management system</td>
<td>11</td>
</tr>
<tr>
<td>VII. Certification</td>
<td>14</td>
</tr>
<tr>
<td>1. How to select a certification body</td>
<td>14</td>
</tr>
<tr>
<td>2. Preparing for assessment</td>
<td>14</td>
</tr>
<tr>
<td>3. Auditing</td>
<td>15</td>
</tr>
<tr>
<td>4. Nonconformities</td>
<td>15</td>
</tr>
<tr>
<td>5. Award of the ISO 9000 certificate</td>
<td>16</td>
</tr>
<tr>
<td>6. Surveillance audits</td>
<td>16</td>
</tr>
<tr>
<td>ANNEX</td>
<td>17</td>
</tr>
<tr>
<td>A. List of selected websites where information about ISO 9000 can be obtained</td>
<td>17</td>
</tr>
<tr>
<td>B. List of selected documents on ISO 9000</td>
<td>17</td>
</tr>
<tr>
<td>1. Documents downloadable free from the Internet</td>
<td>17</td>
</tr>
<tr>
<td>2. Books</td>
<td>18</td>
</tr>
<tr>
<td>3. CD-ROM</td>
<td>20</td>
</tr>
</tbody>
</table>
I. The ISO 9000 family of standards

1. Four primary standards and several guides
   The ISO 9000 series consists of four primary standards supported by several other documents.

This standard describes the concepts of a quality management system (QMS) and defines the fundamental terms used in the ISO 9000 family. The standard also includes the eight quality management principles which were used to develop ISO 9001 and ISO 9004. This standard replaces ISO 8402:1994 and ISO 9000-1:1994.

This standard specifies the requirements for a QMS, whereby an organization needs to assess and demonstrate its ability to provide products that meet customer and applicable regulatory requirements, and thereby enhance customer satisfaction. This standard replaces ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994.

This standard provides guidance for continual improvement and can be used for performance improvement of an organization. While ISO 9001 aims to give quality assurance to the manufacturing processes for products and to enhance customer satisfaction, ISO 9004 takes in a broader perspective of quality management and gives guidance for future improvement. This standard replaces ISO 9004-1:1994. Guidelines for self-assessment have been included in Annex A of ISO 9004:2000. This annex provides a simple, easy-to-use approach to determine the relative degree of maturity of an organization’s QMS and to identify the main areas for improvement.

ISO/DIS 19011, *Guidelines on quality and/or environmental management systems auditing*
This future international standard, currently under development, provides guidance on conducting internal or external quality and/or environmental management system audits to verify a system’s ability to meet defined objectives. On its publication, anticipated for 2002, it will replace three guidelines on auditing quality systems (ISO 10011-1, ISO 10011-2 and ISO 10011-3) and three guidelines for auditing environmental management systems (ISO 14010, ISO 14011 and ISO 14012).

In addition to the above, the ISO 9000 family includes the following guidelines, technical reports (TR) and technical specifications (TS):
ISO 10006:1997, *Quality management–Guidelines to quality in project management*
ISO/TR 10014:1998, *Guidelines for managing the economics of quality*
ISO 10015:1999, *Guidelines for training*

All these standards and guides are obtainable from the International Organization for Standardization (ISO), Case postale 56, CH-1211, Geneva 20, or from National Standards Bodies in countries which are members of ISO. They cannot be obtained from the International Trade Centre.

The ISO 9000 standards were first published in 1987, revised for the first time in 1994, and revised for the second time in 2000. Standards are reviewed every five years to ensure that they are current and satisfy the needs of users. The *ISO 9000 + 14000 News* magazine enables you to keep abreast of information about standards (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO’s management system standards, obtainable from ISO).

ISO 9000 is a starting point for understanding the standards, as it defines the fundamental terms used in the ISO 9000 “family”, or set of standards relating to quality management. ISO 9001 specifies requirements for a quality management system whereby you can demonstrate ability to provide products that fulfil customer requirements as well as applicable regulatory requirements; it also aims to enhance customer satisfaction. ISO 9004 provides you with guidance on continual improvement of your quality management system so that the needs and expectations of all interested parties are met. These interested parties include customers and end-users; directors and staff in the organization; owners/ investors; suppliers and partners; and society at large.

ISO 9001 and ISO 9004 are a “consistent pair” of standards that relate modern quality management to the processes and activities of an organization, and emphasize the promotion of continual improvement and achievement of customer satisfaction. ISO 9001, which focuses on the effectiveness of the quality management system in meeting customer requirements, is used for certification or for contractual agreements between suppliers and buyers. On the other hand, ISO 9004 cannot be used for certification as it does not prescribe requirements but provides guidance for the continual improvement of an organization’s performance. ISO 9001 focuses on “effectiveness”, i.e. doing the right things, whereas ISO 9004 emphasizes both “effectiveness” and “efficiency”, i.e. doing the right thing in the right way.

There is sometimes a misconception that ISO 9000 is mandatory for export to the European Union. This is not correct. When exporting products covered by the New Approach and the Global Approach to the European Union, manufacturers have a choice between various alternatives to satisfy the regulator. Where the module chosen by the manufacturer requires a quality system, compliance with ISO 9001 gives a presumption of conformity, provided that the quality system takes into account, as necessary, the specific requirements of the products for which they are
implemented. Compliance with the module does not require a certified quality system, although the latter provides a useful means of establishing compliance. Manufacturers should implement an ISO 9001 system if that is a requirement imposed upon them by their buyers in their purchasing contract.

In a number of fields, such as that of medical devices, compliance to quality systems, often ISO 9001, can be important in some countries. In the United States, for instance, lack of attention to quality systems can result in hefty fines and some big indirect costs. The US FDA (Food and Drug Administration) requirements for medical device quality systems are found in the Quality System Regulation, known as the QSR. The QSR was the first revision of the FDA's medical devices original good manufacturing practice (GMP) regulation issued in December 1978. The revision achieved the primary purpose of incorporating many of the quality system concepts of ISO 9001:1994 into the GMPs.

Japan's approach to regulating the design and manufacturing of medical devices is similar to that of the FDA. ISO 9000 requirements are embedded within their country's regulations.

2. ISO 9000 family of standards and SMEs

The ISO 9000 quality management system is generic in nature and applicable to all companies, regardless of the type and size of the business, including small and medium enterprises (SMEs), and they are applicable to all categories of products, whether hardware, software, processed materials or services.

ISO 9001:2000 specifies what is required to be done by an organization but does not indicate how it should be done, thus giving the enterprise a lot of flexibility to run its business.

It is simple to use, clear in language and easily understandable. The new standard is also appropriate for small companies, as it does not demand the type of paper bureaucracy needed for the implementation of the 1994 version. Only six documented procedures are now required and need for other procedures/documents can be decided by the company. Companies will, however, be required to provide objective evidence that the QMS has been effectively implemented. A small company may find it appropriate to include the description of its entire QMS within a single Quality Manual, including all the documented procedures required by the standard.

The process-based approach given in the new standard will tend to ensure that systems are documented and implemented in a manner that suits a SME’s own way of doing business. This approach makes it easier for SMEs to implement, instead of just taking over an artificial structure of QMS imposed from outside. It will also be easier for SMEs managed by their owners to demonstrate “top management commitment” towards QMS. Furthermore, in a SME, it is easier to ensure effective internal communication, better utilization of resources, people clearly understanding their roles and responsibilities, etc.

The new standard has included a provision for deciding on the applicability of certain product realization processes included in section 7 of the standard. For example, if the SME has no responsibility for the design and development of the product it provides, the SME may say so, giving the reasoning behind it, in the Quality Manual; the certification body, being satisfied that this corresponds, would
then award it certification to ISO 9001:2000. Similarly, other product realization processes such as purchasing, product identification and traceability, control of measuring devices may also be excluded if these are not applicable for the type of products or services being provided by the company.

It is also possible that SMEs may not have adequate in-house expertise or there may be other constraints to perform all processes on their own. In such cases, the new standard also permits the outsourcing of any of the QMS processes, providing the company has control over such processes. The nature of this control will depend on the nature of the outsourced or subcontracted processes and the risk involved. For example, the design and development process may be subcontracted to an expert or a specialized agency, inspection/verification of goods purchased may be subcontracted to an inspection agency, internal audit of QMS can be outsourced, etc. However, overall responsibility for ensuring control on all outsourced processes as per requirements of the standard would remain with the company’s management.

Further information can be obtained from the document “Quality Systems in the Small and Medium Enterprises” which is available free of charge from http://www.iqa.org (Institute of Quality Assurance website). It explains what is ISO 9001:2000 and how to implement a quality management system in SMEs.

3. Management principles

ISO 9000 is based on eight management principles (see www.iso.org):

- **Customer focus**, resulting in meeting customer requirements and striving to exceed them;
- **Leadership**, aiming to create an internal environment in which people are fully involved;
- **Involvement of people** who are the essence of an organization;
- **Process approach**, resulting in improved efficiency to obtain desired results;
- **System approach to management**, leading to improved effectiveness and efficiency through identification, understanding and management of interrelated processes;
- **Continual improvement**, which becomes a permanent objective of the organization;
- **Factual approach to decision-making**, based on the analysis of data and information; and
- **Mutually beneficial supplier relationships**, based on an understanding of their interdependence.

ISO 9000 encourages the adoption of the process approach to manage an organization. There are five main areas considered for the revised process model in ISO 9000:

- Quality management system
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement.
The process model used in the standards is fully compatible with the well-known PLAN-DO-CHECK-ACT cycle.

Quality management has to include the processes required to achieve quality and highlight their interaction with each other. Top management must take responsibility for leadership, commitment and active involvement for developing and maintaining the quality system. It should provide adequate resources so that customers get what was mutually agreed. It is necessary to have well-defined processes, operational and support, to be able to realize the product. Customer satisfaction has to be measured and analyzed so that the organization can be improved continually.

II. Major changes between the 1994 and 2000 versions of the ISO 9001 standard

The new standard is less biased towards the manufacturing sector and thus more generic. It can be used by all organizations, regardless of type, size and product category.

All the requirements of this new standard may not be applicable to all organizations. As the distinction between ISO 9001, ISO 9002 and ISO 9003 has been removed, an “application clause” (clause 1.2) in the new standard allows companies to exclude certain requirements of section 7 (Product realization) that are not relevant to them. For example, an organization that was certified to ISO 9002:1994 and does not carry out design activities may seek exclusion for clause 7.3 of ISO 9001:2000, relating to “design and development”, so long as it states the reasons for exclusion in its Quality Manual.

A new “process-oriented” structure and more logical sequence of the contents differentiates the new standard from the 1994 version, which was “clause-oriented”. The standard retains a large part of ISO 9001:1994, but the 20 requirements have been grouped in five sections: quality management system; management responsibility; resource management; product realization; and measurement, analysis and improvement.

The new standard has also reduced significantly the amount of documentation required. Documented procedures have been reduced from eighteen to six, although the organization, if required, may document other procedures, instructions, etc.

The new requirements in ISO 9001:2000 include:

• increased emphasis on the role of top management;
• “customer focus” to ensure “involvement of top management for determining customer requirements”;
• consideration of statutory and regulatory requirements;
• establishment of measurable quality objectives at relevant functions and levels;
• establishment of internal communication processes to ensure effective communication of QMS objectives within the organization;
• increased attention on resource availability, by adding separate requirements for “infrastructure” and “work environment”;
• determination of training effectiveness;
• monitoring of information on customer satisfaction as a measure of system effectiveness;
• analysis of collected data to demonstrate the suitability and effectiveness of QMS;
• “continual improvement” of the effectiveness of the QMS.

III. ISO 9000 transitional period between the 1994 and 2000 versions

ISO 9001:2000 has retained a large part of the 1994 version of the standards. Thus, it may not be necessary for a company that is already certified to any of the three standards of the 1994 version to change the whole structure of its existing quality management system, or to rewrite all its procedures.

The revised standard includes some new requirements such as increased commitment of top management to the development and improvement of a QMS; consideration of statutory and regulatory requirements; the establishment of measurable quality objectives; the monitoring of information on customer satisfaction; and pursuing continual improvements, etc. The company needs to understand these new requirements, and should consider addressing them in the existing system at an appropriate opportunity.

The first step in implementing QMS requirements is to obtain the necessary information and guidance on the changes. The eight quality management principles and fundamentals of the ISO 9001:2000 QMS, including new vocabulary, are given in ISO 9000:2000. Further information and clarification on the subject can be obtained from the national standards body in your country; industry and trade associations; quality institutes/societies; or certification bodies in the country. The ISO Central Secretariat and its technical committee have developed many guidance documents that can be obtained free of charge from their web sites.

ISO 9001:2000 has revised and integrated ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. The replacement of ISO 9002 and ISO 9003 does not mean that companies that were certified to these standards have now also to demonstrate capability for “design and development” of their product which was not covered in ISO 9002, or other requirements such as servicing and purchasing which were not covered in ISO 9003. In fact, the new standard includes a provision allowing companies to exclude certain product realization processes like design and development, purchasing, customer property, calibration, process validation, etc., which are not applicable to them. Companies will continue therefore to have the flexibility for implementing ISO 9001:2000 which was earlier possible through use of ISO 9002 or ISO 9003. Companies will, however, need to provide justifications for exclusion of certain processes and state them in their Quality Manual.

If a company has structured its present QMS around the way it operates, i.e., using a process approach, it may not need to rewrite all the documentation in order to
meet the requirements of the new standard. In this case, the existing documentation may be referenced in the Quality Manual, which should also be updated to take account of the new requirements of the standard.

If a company has not used the process approach in the past, it will need to pay particular attention to describing its processes, their sequence and interaction.

In order to claim conformity to ISO 9001:2000, there is now more emphasis on the need to provide objective evidence of the effectiveness of an organization’s processes and QMS. The evidence need not depend on documented procedures or records, except where these are specifically required by ISO 9001:2000. The new standard enables a company to streamline and/or consolidate its existing documents, which leads ultimately to a simplified QMS.

A changeover period of three years (i.e., up to mid-December 2003) is available to organizations to implement the new standard. The 1994 versions of ISO 9001, ISO 9002 and ISO 9003 will remain in use in this period for organizations certified up to mid-December 2000, and organizations will have to shift to ISO 9001:2000 in a planned manner in consultation with their certification bodies.

In order to reduce the cost of certification to the new standard, certification bodies will audit companies to the new standard during their routine surveillance audits, depending upon the preparedness of the companies.

IV. Specific versions of ISO 9000 quality management system standard

“Sector specific” standards are quality management standards that are meant for a specific industry, product or group of products. For example there are quality management standards specific to the automotive industry, to the food and drink industry, to the telecommunications industry, etc.

The ISO 9000 family of standards, being generic in nature, is applicable to any type of product or service and can be implemented by any industry. This being the case, ISO (the International Organization for Standardization) seeks to limit the proliferation of standards in the field of quality management. ISO’s Technical Committee 176 (ISO/TC 176), responsible for developing the ISO 9000 family of standards, supports the development of sector-specific standards once it is established that there is a need for them.

1. Two sector-specific standards
   • ISO/TS 16949:1999, Technical specification for Quality system, particular requirements for the application of ISO 9001:1994 for automobile suppliers. This technical specification (TS) was issued by ISO for provisional application in the automotive sector to gather information and experience in its use.
   To obtain recognition of certification to this TS by the customers members of International Automotive Task Force (IATF), a common global certification scheme has been developed and must be followed. All participating IATF original
equipment manufacturers (OEMs) and suppliers have customer-specific requirements in addition to this TS.


2. **Other sector-specific standards**

Following are other frequently found sector-specific quality management system standards, which are based on the requirements of ISO 9001:1994 or ISO 9001:2000. These standards have not been published by ISO:

- **QS 9000** is a set of quality system requirements that defines the quality system expectations of Chrysler, Ford, General Motors, Truck Manufacturers and other subscribing companies. QS 9000 is fast becoming the accepted quality management system for the automotive industry. Suppliers worldwide are implementing its requirements. Automotive Industry Action Group (AIAG) published the latest edition of QS 9000 in March 1998. QS 9000 is applicable to all suppliers of production materials; parts and accessories, including parts used for replacement; heat-treating; painting; plating; or other finishing processes. Implementation of QS 9000 is a precondition for supplying materials or parts and for providing finishing services to the above OEMs.

- **TL 9000** is a set of telecommunications-specific quality management system requirements, published by QuEST (The Quality Excellence for Suppliers of Telecommunications) Forum. This Forum provides its members with a set of performance-based materials useful for determining the “best in class” for every product or service provided by the suppliers. TL 9000 was revised in March 2001 to align it with ISO 9001:2001.

- **TickIT** is a guide to software quality systems. TickIT was designed by the United Kingdom information technology industry for use in areas such as software production and services. It can only be used in combination with ISO 9001. TickIT covers the assessment and certification of an organization’s software quality management system to ISO 9000. It also includes a guide on how to apply ISO 9000-3:1997; Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software.

- **AS 9001**, is the aerospace version of ISO 9000. The Society of Automotive Engineers has released its aerospace standard AS 9100, Revision A, still referred to as AS 9001 in August 2001. This standard now includes the aerospace unique requirements and ASQ Q9001:2000 and the original AS 9110 based on the Q9001:1994 quality system requirements. The quality system requirements specified in this standard are complementary to the contractual and applicable law and regulatory requirements for the aerospace industry. Standard AS 9100 contains approximately 80 unique requirements and 18 amplifications of the ISO 9000 requirements.

- **EN 46001** is a set of quality system requirements for medical devices. The EN 46001 standard (soon to be EN ISO 13485), provides particular requirements relating to the design/development, production, installation and servicing of medical devices. The standard embraces the principles of good manufacturing practice (GMP), and is widely used in the manufacture of medical devices. It can only be used in combination with ISO 9001:1994.
The above documents are fully compatible with ISO 9001:1994 or ISO 9001:2000. They have not “diluted” or modified the requirements of the generic standard, but have added some sector-specific requirements, guidelines and clarifications.

Many of these sector specific documents are now being revised or have been revised to reflect ISO 9001:2000.

Third party certification by accredited certification bodies is available for all the above quality management system standards. Further details of the schemes can be obtained directly from the certification bodies or from their websites.

V. Costs and benefits of setting up a quality management system

1. Costs…

  Common implementation costs that companies incur can be broken down into direct and indirect costs.

  The direct costs include, inter alia, the following:
  • hiring consultants or external trainers, if required;
  • sending personnel for external training;
  • acquiring relevant national and international standards of the ISO 9000 family and other related books and publications; and
  • acquiring additional equipment, instruments and other resources as identified by the company.

  The indirect costs include, inter alia, the following:
  • time spent by the management and other staff in developing the system;
  • reorganization of the processes, including improvements in the house-keeping, if required;
  • external calibration charges for equipment to ensure national and/or international measurement traceability;
  • organizing in-house training;
  • time spent by internal auditors for periodic internal audits;
  • corrective actions, including revision of manuals and procedures, if required; and
  • expenditure on word-processing, stationery and other consumables required for the preparation of manuals and documenting procedures, etc.

  Some factors can help to lower the above costs. They include:
  • having people in the company already conversant with QMS requirements;
  • having documented system-related activities such as work instructions, quality plans, procedures, etc. already in place;
  • using consultants only for specific activities like gap analysis, training of auditors, pre-assessment audits, etc., and having in-house staff oversee the remaining activities.

  On the other hand, there are factors that can mean higher implementation costs for the company. For example, if your company carries out activities at different locations, or if your company is involved in product design and development, this may increase costs.
In addition to the cost of implementing a QMS, if you wish to obtain third-party certification, you will have to pay a certification fee to the certification body selected for the purpose. It is advisable to obtain quotations of the fee involved from two or three accredited certification bodies before deciding on a particular certification body. The fee depends upon the size of your organization, the number of locations, the number of employees, etc. To take an example: in India, the fee charged by accredited certification bodies varies from USD 3000 (for a company with about 100 employees) to USD 5000 (for companies of about 400 employees). For smaller companies with up to 40 employees, the fee would be approximately USD 2000. All these estimated fees cover a certification period of three years, which includes five surveillance audits by the certification body. Bear in mind that you will need to add the cost of travel, boarding and lodging of the auditors to the basic fee.

2. …and benefits of obtaining ISO 9000 certification

Implementing a quality management system brings internal benefits to most organizations, as well as opening up opportunities vis-à-vis the outside world.

*Internal benefits* to the company include:
- improved customer focus and process orientation within the company;
- improved management commitment and decision-making;
- better working conditions for employees;
- increased motivation of employees;
- reduced cost of internal failures (lower rates of rework, rejection, etc.) and external failures (fewer customer returns, replacements, etc.); and last but not least,
- continual improvement of the quality management system.

The following *external benefits* are generated:
- customers are more confident that they will receive products conforming to their requirements, which in turn results in higher customer satisfaction;
- an improved image of the company;
- more aggressive publicity, as customers can be informed of the benefits of their doing business with a company that manages the quality of its outputs;
- more confidence that the company’s products meet relevant regulatory requirements;
- better objective evidence to defend product liability charges if such are brought by customers.

VI. **Implementing a quality management system**

An ISO 9000:2000 quality management system can be implemented by following the steps detailed as follows:
1. Evaluate the organization’s need/goals for implementing a QMS

Need may arise from repeated customer complaints; frequent warranty returns; delayed deliveries; high inventories; frequent production hold-ups; and high level of rework or rejection of products or services.

At this stage, identify the goals which you would like to achieve through a QMS, such as customer satisfaction, increased market share, improved communications and morale in the organization, greater efficiency and profitability, etc.

Another objective in implementing a QMS may be a demonstration of compliance through third party certification, which may be requested by an important client or required for enlisting as a supplier to large companies, e.g., original equipment manufacturers (OEMs).

2. Obtain information about the ISO 9000 family


Supporting information such as quality management principles, frequently asked questions (FAQs), guidance on clause 1.2 (application) of ISO 9001:2000, guidance on documentation requirements of ISO 9001:2000 and other brochures are available free of charge on the ISO web site at http://www.iso.org

3. Appoint a consultant, if necessary

If, within the organization, you do not have adequate competence to develop a QMS, you may appoint a consultant. Before doing so, it is good to check his/her background; knowledge about the product realization processes of your organization; and experience in helping other organizations to achieve their stated goals, including certification.

Carry out a cost-benefit analysis of hiring a consultant and agree the scope of his/her work in writing. It is also possible to appoint a consultant only for the training of key staff; the latter can then carry out further training and development of the system.

4. Awareness and training

Raise awareness about QMS requirements amongst all personnel performing activities that affect quality. Plan for and provide specific training on how to develop Quality Manuals; on procedures; on QMS planning; on how to identify and implement improvement processes; and on how to audit compliance with the QMS, etc.

The Institute of Quality Assurance (IQA), the American Society for Quality (ASQ) and the International Auditor and Training Certification Association (IATCA) can provide lists of training organizations.

5. Gap analysis

Evaluate gaps between your existing quality management system and the QMS requirements of ISO 9001. Prepare how to bridge these gaps, including by planning for any additional resources required. Gap analysis may be carried out through self-assessment or by the external consultant.
6. **Product realization processes**
   Review clause 7 of ISO 9001:2000 relating to “Product realization” to determine how the requirements apply or do not apply to your company’s QMS. The processes covered by this clause include:
   - Customer-related processes
   - Design and development
   - Purchasing
   - Production and service provision
   - Control of measuring and monitoring devices

   Note that if your company is not responsible for preparing the design of your product, you can exclude the requirement for “design and development” from your QMS and explain the reasons for doing so in your Quality Manual.

7. **Staffing**
   Decide on the responsibilities of the persons who will be involved in developing and documenting the QMS, including the appointment of a management representative who will oversee the implementation of the QMS. Establishing a project Steering Committee may also prove useful to oversee progress and provide resources wherever required.

8. **Planning a time frame**
   Prepare a complete plan to close the gaps identified in Step 5 to develop the QMS processes. In the plan, include activities to be performed, resources required, responsibilities and an estimated completion time for each activity. Clauses 4.1 and 7.1 of ISO 9001:2000 provide information that should be used when developing the plan. The total time required for each phase (planning, documentation, implementation and evaluation) depends on the extent of the gaps in your existing QMS.

9. **Draft a Quality Manual**
   In your Quality Manual:
   - Include how the QMS applies to the products, processes, locations and departments of the organization;
   - Exclude any requirement with justification for doing so as decided in step 6 above;
   - Refer to or include documented procedures for QMS;
   - Describe the interaction between the processes of the QMS, e.g., the interaction between product realization processes and other management, measurement and improvement processes; and
   - Draft the quality policy and quality objectives for the organization.

   The staff concerned in the organization should review the Quality Manual and the documented procedures so that their comments and suggestions can be taken into account before the Quality Manual and procedures are approved for issue and use. The effective date of implementation should also be decided.

10. **Carry out internal audits**
    During the phase of implementation of some three to six months after the documentation has been written, the trained auditors should carry out one or two
internal audits covering all activities for the QMS, and concerned management should take corrective action on the audit findings without delay. Wherever required, revise the manuals, procedures and objectives. After each internal audit, the top management should review the effectiveness of the system and provide necessary resources for corrective actions and improvements.

11. **Apply for certification**
   On satisfactory completion of Step 10, and if your company decides to obtain third party certification, you can make an application for certification to an accredited certification body. The certification audit process is explained section VII.

12. **Conduct periodic evaluations**
   After certification, the organization should periodically conduct internal audits to review the effectiveness of the QMS and see how it can be “continually improved”. The organization should evaluate periodically if the purpose and goals (see Step 1) for which the QMS was developed are being achieved, including its continual improvement.

**VII. Certification**

The process of becoming certified to ISO 9001, and how to maintain this status once you have achieved it, are given in the steps below:

1. **How to select a certification body**
   Organizations that desire to obtain a certificate need to submit an application to the certification body of their choice. The issues to consider when selecting a certification body include:
   - whether the nature of accreditation of the certification body is acceptable in the market to which the organization wants to export;
   - the market image of the certification body;
   - quotations for the certification and audit fees, etc.
   It is advisable that you select a certification body which is accredited. Accreditation is “a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks,” as per ISO/IEC Guide 2:1996. Thus an accredited certification body has been given formal recognition of its competence to carry out ISO 9000 certification/registration.

2. **Preparing for assessment**
   Under ISO 9001:2000, the first requirement is to define the organization’s processes that affect quality, so that the first step is that the auditor from the certification body meets with the organization's management to gain an understanding of its processes. Normally speaking, then, the certification audit process starts with a review of the organization’s Quality Manual and procedures by the certification body’s auditor, to ensure that the Manual covers the requirements of the standard. This is known as an “adequacy audit” or “document review audit”.

14
The auditor conveys any gaps (nonconformities) found in the documents to the organization for necessary actions and re-submission of the documents, if required. The certification body also examines, where relevant, the justification included in the Quality Manual for not including certain product realization processes (e.g., if a company does not design a product, it can exclude the requirements of Clause 7.3 of ISO 9001, but this would need to be explained in the Manual). Such exclusions should be acceptable to the certification body.

3. Auditing

After satisfactory completion of the document review audit, the auditors undertake the second part of the audit process at the organization’s location at a mutually agreed time and date(s) – certification audits are not surprise visits. The audit at location begins with an “opening meeting”. During this meeting, the auditors explain to the management how the audit will be conducted, and when and how the findings will be conveyed to the management.

The auditors collect evidence of conformity/nonconformity through observation of activities, examination of procedures/records, observations of conditions of housekeeping, through interviews with the concerned managers/personnel of the organization, etc., on a sampling basis. The information gathered through interviews is verified/tested by the auditors by acquiring the same information from other sources, such as physical observations/measurements performed on the product and their related records. The auditors visit and verify compliance with the QMS in all the departments and functions within the scope of the QMS.

4. Nonconformities

The evidence collected by the auditors is compared with the audit criteria (company’s policies and objectives, manuals, procedures, instructions, contracts, regulations etc.) and audit findings including nonconformities, if any, are clarified and reported to the management at the end of the site audit in a formal meeting with the management called “closing meeting”. The nonconformities (NCs) are graded by the auditors as “major” or “minor”. “Observations” are also noted.

A “major” NC indicates that:
- the company has failed to implement any one part of or the full QMS; or
- any specific department of the company has failed to implement the QMS as applicable to the department; or
- a number of “minor” nonconformities in the same QMS requirements are found.

A “minor” NC means an isolated incident of a failure to comply with a defined process or QMS requirement.

An “observation” indicates that if the situation as found during the audit is not addressed it may lead to an “NC” in future.

Where a major nonconformity is found, the recommendation for certification is deferred until corrective action on the same is verified through a follow-up audit.

After obtaining the organization’s timetable for corrective action, recommendations for certification are decided by the Lead Auditor (the leader of the audit team), and these recommendations are conveyed to the organization in the closing meeting itself.
5. Award of the ISO 9000 certificate

Based upon the recommendations of the Lead Auditor and after independent review of these recommendations by the certification body, the latter issues a certificate to the organization. The certificate is issued for the specific scope of the business and the products or services for which the organization has implemented a QMS.

6. Surveillance audits

The certificate is initially awarded for a period of three years. During this time, periodic surveillance audits (once or twice a year) are carried out by the certification body on mutually agreed dates. An audit plan for three years indicating the scope of audit in each surveillance audit is transmitted to the organization in advance by the certification body. These audits are planned in such a manner that all aspects of the QMS are audited over a period of three years. A re-certification audit is carried out after three years using steps 2 to 5 above.

During the period of certification, the certification body may examine records relating to the quality complaints made by customers either directly to the organization, or to the certification body, to check if the organization is taking appropriate action(s) to eliminate the cause of such complaints.

Any misleading use of the logo of the certification body and/or the accreditation body or incorrect references to the certification, if any, made by the organization are also examined by the certification body.
ANNEX

A. List of selected websites where information about ISO 9000 can be obtained

- http://www.iso.org
- http://www.bsi.org.uk/iso-tc176-sc2
- http://4abetterbusiness.com/services.htm
- http://www.iqa.org
- http://www.iatca.org
- http://www.asq.org
- http://praxiom.com
- http://www.iaf.nu

B. List of selected documents on ISO 9000

1. Documents downloadable free from the Internet
   - **ISO 9000 – Selection and use** (2001), available from http://www.iso.org/iso/en/isonline.frontpage Explains what the ISO 9000 standards are and how they are used; and provides guidelines on how to implement a quality management system.
of ISO 9001:2000, a list of records to be maintained for demonstrating implementation of quality management system.

- **Publicizing your ISO 9000 or ISO 14000 certification,**
  Also obtainable from National Standards Bodies in countries which are members of ISO. Provides guidelines to help businesses and other organizations which have achieved ISO 9000 or ISO 14000 certification avoid making false or misleading claims in advertisements and other types of announcements.

- **Guidance on ISO 9001:2000 clause 1.2 ‘Application’** (October 2000),
  Document number: (ISO/TC 176/SC2/N524) Provides guidelines for defining scope of quality management system, justification for exclusions, outsourcing processes etc., and gives examples of exclusion and outsourcing.

- **ISO 9000 Systems Conversion (1994 to 2000),** available from [http://4abetterbusiness.com/services.htm](http://4abetterbusiness.com/services.htm)
  Explains how to convert your 1994-based system to a year-2000-based system, including simplification of system administration, training and preparation for ongoing audits, and incorporation of process-based management systems.

2. **Books**

- **ISO Directory of ISO 9000 and ISO 14000 accreditation and certification bodies,** (2001), ISBN 92-67-10329-6, CHF 44, International Organization for Standardization (ISO), 1, rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland, Tel +41 22 749 0111, Fax +41 22 749 0947, E-mail: sales@iso.ch Internet: [http://www.iso.org](http://www.iso.org) Also obtainable from National Standards Bodies in countries which are members of ISO. Lists accreditation bodies (where one exists), then certification bodies by country (in alphabetical order).

- **Transition to ISO 9000:2000,** (2000), ISBN 1-903417-06-6, D.Hoyle and J.Thompson, GBP 22.50, Butterworth-Heinemann editions, Linacre House, Jordan Hill, Oxford OX2 8DP, United Kingdom, Tel: +44 1865 888180, Fax: +44 1865 314 572, E-mail: bhuk.orders@repp.co.uk Internet: [http://www.bh.com](http://www.bh.com)
  Guide with two primary objectives: to provide an analysis of the differences between the 2000 and 1994 versions; and to describe the implications of the differences for organizations.

- **The ISO 9000 Answer Book,** second edition (2000), Rob Kantner, USD 65, John Wiley and Sons Inc, 605 Third Avenue, New York, NY 10158-0012, USA, Tel:+1 212 850 6000, Fax:+1 212 850 6008, E-mail: info@wiley.com Internet: [http://www.wiley.com](http://www.wiley.com)
  Offers clear answers to over 100 commonly asked questions regarding the content and implementation of the standard.
• **ISO 9001:2000 for Small Business** (2000), Ray Tricker, GBP 19.99, Butterworth-Heinemann, Linacre House, Jordan Hill, Oxford OX2 8DP, United Kingdom, Tel:+44 1865 888 180, Fax: +44 1865 314 572, E-mail: bhuk.orders@repp.co.uk  Internet: http://www.bh.com  Fully revised and updated, this book explains the new requirements of ISO 9001:2000 and helps businesses draw up a quality plan that will enable them to meet the challenges of the market place.

• **ISO 9001:2000 Internal Audit Program**, USD 135, Praxiom Research Group Limited, Praxiom Research Group Limited, 3814 - 41 Avenue, Edmonton, Alberta T6L 5M4, Canada, Tel: +1 414 272 8575, Fax: +1 414 272 1734, E-mail: info@praxiom.com  Internet: http://praxiom.com  Describes step-by-step how to plan an internal audit program.

• **The Quality Audit for ISO 9001:2000**, (2000), David Wealleans GBP 49.50, Gower Publishing Customer service, Book Point Limited, 130 Milton Park, Abingdon, Oxon OX14 4SB, UK, Tel +44 1 235 82 77 30, Fax +44 1 235 40 0454, E-mail: orders@bookpoint.co.uk  Internet: http://www.gowerpub.com  Covers all aspects of auditing, including certification assessment, supplier investigation and internal audits.

• **ISO 9000:2000 New Requirements**, (2001), Jack Kanholm, USD 39, American Society for Quality (ASQ), PO Box 3005, Milwaukee, WI 53201 - 3005, USA, Tel +1 414 272 8575, Fax +1 414 272 1734, E-mail: asq@asq.org  Internet: http://www.asq.org  Explains every requirement of ISO 9001:2000 standard with regard to interpretation, and provides a list of specific actions that need to be taken to achieve conformance.

• **ISO/IEC Guide 62, General requirements for bodies operating assessment and certification/registration of quality systems**, (1996), CHF 62, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland, Tel: +41 22 749 0111, Fax +41 22 733 34 30, E-mail: sales@iso.ch  Internet: http://www.iso.org

• **ISO 9000-Survey 99**, (1999), Book and CD-ROM, USD 99.95, QSU & Plexus Corp., QSU, 3975 University Drive, Suite 230, Fairfax, VA 22030, USA, Tel +1 703 359 8462, Fax +1 703 359 8462, Internet: http://www.qsuonline.com  An analytical tool to assess the costs, benefits and savings of ISO 9000 registration.


• **Implementing ISO 9000:2000**, by Dr Matt Seaver, GBP 55, ISBN 0 566 08373 6, Gower Publishing, 130 Milton Park, Abingdon, Oxon OX14 4SB, UK, Tel. + 44 1252 331 551, Fax + 44 1252 317 446, E-mail,
ISO 9001:2000 Explained, By Charles A. Cianfrani, Joseph J Tsiakals, and John E. (Jack) West. The American Society for Quality (ASQ), 600 North Plankinton Avenue, Milwaukee, WI 53203, USA, or P.O. Box 3005, Milwaukee, WI 53201-3005, USA, Tel. + 1 414-272-8575 (outside the U.S. and Canada), 800-248-1946 in North America, Fax + 1 414-272-1734, E-mail: cs@asq.org, Internet://www.asq.org. A step by step guide to the clauses in ISO 9001:2000, with advice on what auditors will be looking for.


3. CD-ROM

ISO 9000:2000 Documentation: Quality Manual and Operational Procedures, (2000), Jack Kanholm, USD 390, American Society for Quality (ASQ), PO Box 3066, Milwaukee, WI 53201 - 3066, USA, Tel +1 414 272 8575, Fax +1 414 272 1734, E-mail: asq.asq@org Internet: http://qualitypress.asq.org or http://www.asq.org The package provides a model of a quality system that is simple, natural, and free from excessive paperwork, and also defines the baseline system that satisfies the ISO 9000 certification requirements.
The International Trade Centre (ITC) is the technical cooperation agency of the United Nations Conference on Trade and Development (UNCTAD) and the World Trade Organization (WTO) for operational, enterprise-oriented aspects of trade development.

ITC supports developing and transition economies, and particularly their business sectors, in their efforts to realize their full potential for developing exports and improving import operations.

ITC works in six areas:

- Product and market development
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- International purchasing and supply management
- Needs assessment, programme design for trade promotion