THE QUALITY MANAGEMENT SYSTEMS

FOR

THE SMALL AND MEDIUM ENTERPRISES

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INTRODUCTION

This training set is designed to provide a general overview of the Quality Management and its significance for the SMEs. It is assumed that the readers are not yet familiar with all the practical aspects of the system, including its implementation and its connections with the European Directives and the Community Acquis. The present monograph is not an exhaustive and detailed presentation of the Quality Management topics; ponderous treatises and manuals are available in all the bookshops, in all the languages. This is only a working instrument, to help users in the approach with the main principles and functioning.

The Quality Management is usually studied jointly with Standardisation, Normalization and Certification, because of their strict connections. Due to the importance of these disciplines, for the present BSP2 Project, UEAPME decided to examine these subjects separately, giving the due space to all the specific topics. However, to give a comprehensive view and a better understanding of all the quality management problems, this training set will recall some basic concepts of Standardisation and Certification, most strictly connected with the Quality Management Systems (QMS).

The presentation of a subject like the Quality Management, addressed to the craft and small enterprises, requires a very special approach; many SMEs still have a great reluctance towards these topics, wrongly reputed as practices destined to the large enterprises. Really the SMEs still meet big problems in approaching the implementation of a quality management system, mainly due to:
- Lack of specialized expertise;
- Involved costs, still high for the craft and small companies;
- Underestimation, by the craft and small enterprises, of the impact of the standardisation and certification.

Nevertheless, a growing number of SMEs have started to use a properly set up quality system; in any case they need a strong support and education to close this gap of expertise.

Most large industries have the ISO 9001:2000 quality systems in place and many are reaching now the 9004 level of quality excellence. New initiatives of ISO TC176 are growing the gap between the large and small enterprises, by giving prizes for Quality Excellence: Deming Prize, Malcolm Baldrige Award, etc. The craft and small enterprises, with their national or sectoral organisations and NORMAPME (the European Office of Crafts and SMEs for standardization), can act to reduce the gap in quality systems by setting up such systems in-house and by using appropriate and effective training seminars as well as professional assistance services.

The large companies avail of their internal competences and resources to define, implement and manage their quality systems. For crafts and SMEs, organised collectively, this expertise should be made available by their national and sectoral associations, supported by the technical competence of NORMAPME.

Quality Management Systems and Total Quality Management are used increasingly as instruments of competitiveness; therefore SMEs need to take advantage of this, specially because it is also a way of complying to product standards.
Although most of them are aware that quality is more and more a choice factor for consumers, it appears that a lot of SMEs consider that setting those systems is too costly in time and money.

A primary objective should be to encourage the use of these systems within the SMEs, in order to give them more opportunity when they compete with large groups in the same market, by using a type of management as efficient and applying similar standards.

For instance, e-commerce abolished the distinction between small firms and large companies, and the choice of the consumer is made according to the trust he has on the quality of the product and service.

In this case as in many others, a declaration of conformity with a QMS (which also means conformity to standards) may be of some advantage.

Appropriate training presentations for SMEs of the QMS and TQM can explain exactly what they are, the benefits that SMEs can get out of them, how it can be a broader way to apply standards, and how they can be applicable in SMEs.

These presentations should be dedicated to the SME managers and the staff of the SME organisations, to assist them in becoming experts in this sector and in disseminating their knowledge to the SMEs.

NORMAPME, whose mission is to defend the interests of the European SMEs within the standardization system, can provide an effective support and assistance to the national and sectoral SME organisations in the supply of these training services.
QUALITY AND ACQUIS COMMUNAUTAIRE

GENERAL

One of the main concerns of the international institutions (governments and nongovernmental organisations) has always been the elimination of technical barriers to trade.

The World Trade Organisation (WTO) is based upon the multilateral General Agreement on Tariffs and Trade (GATT), established in 1947. GATT promoted in 1979, in the area of the Conformity Assessment, an Agreement on Technical Barriers to Trade, pushing on the diffusion of the international standards. This agreement has been a market access instrument, using a variety of measures to prevent and eliminate the technical barriers to trade, caused by technical regulations, voluntary standards and conformity assessment procedures.

Realization of the fundamental economic freedoms has been one of the most pressing objective of the European Union; it involves realization of the free movement of goods, capitals and employees and of the free provision of services but in observance of health, consumer and environmental protection and occupational health and safety.

The free movement of goods has been a main concern of the European Commission not only with regard to the Single Market, but also beyond its borders, in the international movement of goods with other major trade partners (USA, Japan, Australia, etc.).

All these themes have been strongly emphasized by the European Commission, and the Acquis Communautaire includes most of them.

As all the readers know, the Acquis Communautaire is the common platform of rights and obligations, binding all the member states of Europe. All the candidate countries, to access to European Union, are requested to accept this Acquis; therefore they are now modifying all their corresponding laws, to comply with their legislation to the Acquis Communautaire.

A basic condition for a properly functioning European Single Market is the elimination of barriers to trade. The free movement of goods within the European Union can be impaired by differences in the national regulations and testing, certification and inspection procedures.

Confidence in the technical competence, capability, impartiality and integrity of the bodies performing the conformity assessment is of great importance for the Single Market and also for the relations between EU and third countries.

The ongoing development of international standards and their consistent application is therefore of great importance. However it must be ensured that the standards do not contravene the requirements resulting for example from the EU Single Market Directives.

The European standards (EN) are voted by national standard bodies. Harmonized standards are published in the European Official Journal (ECOJ) and refer to European Directives.

The implementation of a recognized Quality Management System is very useful for a complete integration with the European standards and to comply to the requirements of the European Directives.

In addition to the above considerations, the European Directive 85/374 puts the legal responsibility of defects on the producer, when the product leaves the plant. All this can translate in risks and cost disadvantages for craft and small enterprises.
This directive implies the use of a good quality management system, preferably compliant with ISO 9001, installed whatever the size of the company may be; a QMS can provide an effective protection against the legal liability.

In 2001, a Business Support Programme (BSP 1) project was addressed by UEAPME to the national and sectoral organisations of the SMEs of all the CEEC candidate countries, in order to deepen and clarify the main aspects of some key themes of the Acquis Communeautaire, most interesting for crafts and small enterprises. Some themes of the BSP1 project have anticipated the topics of the technical seminars of this SME-FIT Project:

- Free movement of goods and services in the Internal Market.
- European environmental policies.
- Consumers and health protection.
- Research and technology instruments.
- European standardisation, normalisation and quality management.
- Promotion of best practices on technology, quality and benchmarking.

The corresponding Training Tools, translated in all the languages of the CEEC candidate countries, are still available on the UEAPME’s web site: [www.weapme.com](http://www.weapme.com); then look at Projects, Business Support, Training Tools.

The importance of the quality systems can be appreciated only understanding the basic concepts of the disciplines most strictly connected: standardisation, normalisation, conformity assessment, certification.

Therefore we would strongly recommend a close examination of the two exhaustive monographs prepared by NORMAPME, for the present BSP2 project, on the above mentioned subjects.

Elimination of barriers to trade in Europe

It is opportune to mention the steps followed by the EU and the means adopted for the elimination of the barriers to trade:

- Articles 30-36 Treaty of Rome (1957),
- Article 100 (94) Treaty of Rome
- Directives 83/189/EEC and 98/34
- New Approach: policy aiming at technical harmonisation and standards
- Article 100a (95) Treaty of Rome
- Case law of the European Court of Justice; “Cassis de Dijon” judgement (1979).

Quality Management and the European Directives

The implementation of the Quality Management Systems (QMS) is a voluntary and not compulsory decision.

It is however opportune to notice that many international and European laws and directives acknowledge the preventive value of the QMS for the community protection, and mention the use of ISO 9000 systems in the legislative documents.

We can give a couple of examples:

- For the products subject to compulsory CE Marking, the EU Directives recommend the notified bodies to verify the presence of a QMS, with a specific reference to ISO 9000.
- Some national laws for the public tenders ask, as evidence of the bidder’s qualifications, for the preliminary submission of a recognized certification, mandatory for all the prospective bidders.
The European approach does appreciate the benefits for the SMEs to be conformed to internationally recognized and respected Quality Management Systems.

The recent issue of the new standard of quality management system 9001:2000 has produced some specific involvements with the European Directives of the above mentioned “New Approach”; those regulating the CE Marking for the products freely moving inside the EU. These directives define the essential requirements for such products, as well as the required methods to give evidence of their conformity to these requirements. Among these methods, a specific mention is reserved to the implementation of a “Approved Quality Management System”, practically complying to one or more of the old 9001, 9002 and 9003:1994. To help a correlation between the requirements of the old standards and the new 9001:2000, a comparison table has been prepared, in order to individuate the items of the new standards, that can be listed in the exclusions.
For the 9002:1994, it was excluded the only point relevant to design and development.
For the 9003:1994, the exclusions covered, in addition to design and development, also the following points: product construction planning, procurement, production control activities, production processes validation, identification and traceability.

Terms & Definitions

For a better understanding of the topics of Quality Management, Standardisation and Certification some official terms have to be explained.
The definitions given here below are mostly taken from EN 45020 “General terms and their definitions concerning standardisation and related activities”.


ORIGIN AND EVOLUTION OF THE QUALITY MANAGEMENT

Origin of the Quality Management Systems

The roots of the quality management systems can be found in the military applications. At the beginning of the Second World War, the allied fleet was being sunk at a rapid rate. The Americans wanted to build new ships quickly; everything and everyone was brought in. Ships were manufactured in separate parts, in different places and put together in a shipyard. So everything had to fit and be delivered on time.

To ensure that the parts would fit together detailed technical specifications were necessary. The suppliers had to meet these specifications to be able to deliver products. Military staff checked whether the companies in fact met these requirements. Many parts had to be rejected. The final products only used approved parts.

This was in fact a first large-scale application of quality management. This method was also continued after the war.

Later on, within NATO, the attention shifted from the final inspection of products (against established specifications), to checking the capacity of the organisations to fulfil agreements made on products to be supplied. The quality assurance of these supplier organisations had to meet the requirements laid down in the NATO standards.

Following the example of the NATO standards, many countries developed national standards for quality management. However when trade increasingly crossed the national borders, this became problematic.

The development of internationally recognized QMS is essentially related to the “high technology” industrial sectors (space, aviation, nuclear, power and petrochemical plants, etc.) and their relevant standards (ASME, ANSI 45.2, Mil.Std.Q 9858, etc.), issued after the 2^ World War.

Obviously some internal quality systems were already existing in the good operating practices of many large enterprises, and their importance was connected with the dimensions of the company and of its organisation structure.

In the 70’s the Quality Assurance programmes had a strong development in the mentioned “high technology” sectors, in order to guarantee safety, reliability and investment’s protection. However, as some of us still remember, the manufacturing companies gave different meanings and contents to the words “quality assurance”, conforming to the different customers.

Until the 80’s the principle of division of the functions (functions operating the controls vs. functions subject to the controls) has been a big problem, mainly for the SMEs, due to the consequent personnel costs and to the difficulties in the system application.

Only the ISO 9000 have introduced the concepts of “diffused” quality and joined/collective responsibilities for the quality problems.

For the quality systems, ISO 9000 have been a fundamental instrument of unification, able to knock down both geographical and cultural barriers; they forced a convergence process from the different national standards towards a single common standard as well as they extended and generalized the same concepts to very different sectors.

This has been achieved graduating the application of the 20 clauses of the standards, in conformity with the different needs:

ISO 9003 were only for inspection and testing of the final products;
ISO 9002 were only for production and installation processes;
ISO 9001 included the design and development of the products.

The ISO 9000 were developed as international standards, following the example of the national standards. The first ISO 9000 Standards were published in 1987. The recent issue of ISO 9000:2000 Vision represents a positive evolution of the quality standards, since it emphasizes the managerial contents; the quality system becomes an instrument for the management of the company (it can include environment, safety, ethic, etc.).

On the opposite site, for the crafts and small enterprises, the simple organisation allows a quick allocation of responsibilities and competences; there is a clear alternation of the production and control activities, the necessary dosing of the resources, proportionally to the workload, is in front of everybody; risks and rewards are unequivocally connected. Only when the dimensions of the organisation structure pass over the personal control of all the problems, we feel the need of a “system”, with allotment of limited and specializing tasks, but with the consequent difficulties of co-ordination and communication among the people (both single persons or groups) involved in the execution of the work.

Evolution of the Quality Concept and Methods

The question is: how is it possible to make quality within enterprises and organisations?
The answer to this question includes over fifty years of evolution.

- Until the ‘20s quality was essentially “inspection”; the know-how of inspection was the know-how of quality. A better quality was a better and extensive inspection activity.
- In the ‘30s the statistic methods were applied to the technical processes. Controlling few pieces in a proper way, it was possible to collect more information, rather than controlling all the pieces. Quality therefore was the correct application of statistic methods to production.
- In the ‘50s quality moved to the design/engineering control and to the reliability techniques. Quality was mainly the “conformity degree”.
- The ‘60s and ‘70s are fundamental years for quality; quality involves the complete organisation structure of the enterprises, also in order to individuate the responsibilities (nuclear, space petrochemical projects) of the single departments. It was cheaper to control the quality of an organisation than of the single products. The Quality Assurance was born!
- At the end of ‘70s, quality becomes “customer satisfaction”.
- The main concept at the beginning of the ‘80s is: competitiveness is a higher quality at a lower cost. The objective is a faster improvement of the organisation processes. This approach to quality leads to the Total Quality Management.

The main, substantial changes occurred in this long evolution are:
- from quality control (final inspections) to quality planning;
- from quality as absence of defects to quality as higher customer’s satisfaction;
- from quality as achievement of the fixed requirements to quality as continuous improvement or even method to accelerate the improvement.
- from quality as task of few specialists to quality as task of every person: value for enterprises, organisations, persons.
The main aspects connected with this transformation are:
- from a sectoral aspect to a general aspect,
- from a specialized vision to a global vision,
- from a tendency “past oriented” (inspection of goods already produced) to a tendency “future oriented” (future objectives, continuous improvement).
- from “production oriented” to “market oriented”;
- from a bureaucratic approach to a functional approach;
- from quality as a cost to quality as an investment.

ISO has been able to regulate and organise all the matter with an intersectoral strategy.

FOUNDERS OF MODERN QUALITY MANAGEMENT

We would here recall some of the pioneers of the quality management, to show how their theories, revolutionary fifty years ago, are still relevant and therefore re-discovered for the development of the modern Quality Management Systems and Total Quality Management.

The American W.E. Deming can be considered one of the main founders of the modern quality management. In the ‘20s he applied statistics to quality control in mass manufacturing. From this he learned that quality control is based on variance control.
The significant managerial content of the Deming’s theories was summarized in his famous “14 Points” and detailed in his important books.

A contemporary of Deming was J.M. Juran; he devised, in his famous Handbook, a key definition of quality: quality is fitness to use. The client is then of central importance in quality management. Juran was of opinion that the prime responsibility for quality management lays with the senior management of an organisation.
It has to ensure that quality planning, quality control and quality improvement take shape.

Deming and Juran were sent to Japan in 1950, in the frame of the USA initiatives for the industrial reconstruction of this country, after the Second World War.
Japan gave a great attention to their methods and their courses were extremely successful.
Japan did not invent anything different from the theories published in the American literature, they only followed the theoretic concepts only marginally applied by the American enterprises.
Japanese products were known for their poor quality. By the systematic utilization of the quality management, the Japanese industry was able to increase the quality of their products so much that in many case they were better than American and European products.
This Japanese performance stimulated a great interest in quality management in the West.

In the ‘80s the Americans re-discovered Deming and Juran; then their theories have been very significant for the quality development of the USA car industry.

A.V. Feigenbaum can be considered the father of the Total Quality Control, he first coined this name at the end of the ’50s. He introduced into General Electric a system for the “quality costs” as an evaluation principle of the quality systems. He first dedicated to the quality of the organisation activities (engineering, sales, management, etc.) the same attention given to the products.

P.B. Crosby emphasized, in the ‘70s, that quality is an investment and not a cost, as well as how the quality starts from the persons. He underlined that the “client” is every person receiving our work (i.e. who is downstream to our production activity).
GENERAL CONCEPTS

What is Quality?

The concept of quality has been subject to several developments during the last 50 years. Quality is a dynamic concept, passing from the products to the organizations. For many years the most used definitions for quality of a product have been the following:
- Quality is suitability to a service
- Quality is compliance with the specifications

The new definition, proposed by ISO 9000:2000, is:
Quality is the degree to which the needs and the expectations are met; therefore quality represents all the features and properties, of a product or of a service, which are required by the client.

The important point is that a product gives that what a customer expects.

What means Quality Management?

Quality Management is a complex of co-ordinated activities to lead and control an organisation, as far as quality is concerned. To lead and control an organisation, as regards quality, means to define: quality policy, quality objectives, quality planning, resources allocation, quality control, quality assurance and quality improvement, organisation and implementation of all the quality control activities for any product/process/service internal and external to the company, as well as the periodical review of the results compared with the objectives.

Therefore Quality Management means what the organisation does to ensure that its products conform to the customer’s requirements.
It is the complex of measures to ensure that the needs of the client are met.

What means Management System?

A system is a whole of parts connected and interdependent. To manage a system means to master the links and interrelations; therefore we cannot cut off its single components because each of them can affect the result and viceversa the whole affects the single components of a system. Therefore a Management System is a complex of activities to establish policy and objectives and to achieve such objectives.

How a Quality System works

- It is a voluntary (not compulsory), professionally organised and documented quality audit applied to all the stages of the company processes: procurement, production, sales, etc.
- It records the quality assessment at these stages and prescribes preventive and corrective actions for immediate implementation and for future production.
- It fixes the parameters of the product, by defining the customer’s needs and translating them into process and product parameters, which are then continuously controlled and recorded.
- It fixes the quality parameters, by defined and usually standard-based test methods.
- It involves all the personnel of the enterprise, who must understand the quality system, fully apply it and must be involved in the continuous improvement of quality.
- It eliminates non-conform products at each stage of the process, so that the final product is 100% under control and within the limits of quality as defined.

Why SMEs should implement a QMS

Primarily it is the customers of a company who lay down requirements for the quality of the product or service supplied. It is therefore necessary, for many companies, to have a certified quality system to maintain their place in the market.
The quality system ensures in particular that the quality level for products and services, requested by the client, is reached and maintained.

In many cases, the government also attached values to the quality requirements that a product meets. It lays down requirements for products in the field of safety, health and environment. Products that meet these essential requirements can be given a CE mark.
In some cases the CE marking is only awarded if the company manufactures the product with a quality system, meanly set up on the basis of ISO 9001.

However, the achievement of a QMS (like ISO 9000) certification should be beneficial not only to customers but to the company’s organisation itself: in this way the QMS is a management tool and not a goal itself.
Therefore the achievement of the QMS certification should be a moment of growing up for the enterprise. This is a good opportunity to monitor, control, analyse and improve the production processes. Activities need to be controlled!
It means to proceed examining the processes relevant to the core business of the company and to discuss the main current activities and practices of each department.

SMEs can afford QMS and TQM; low-cost solutions are possible if the necessary expertise is made available to SMEs, organised collectively within their national and sectoral associations.

The benefits of implementing QMS are:
- Technical
- Commercial
- Financial
- Legal: Conformity & Liability
- Image

Briefly the reasons why SMEs should implement QMS are:
- It might be costly, but there are ways to avoid it, working together
- More efficient management system of the company
- Better quality products and no cost for return of defect products
- Legal protection. Obey European Directives
- More market shares
- Image benefit
- Strategic tool leading to sustainable development.
Reasons and Benefits of a QMS

Most new users obtain measurable benefits early in the process of deploying the standard requirements in their operations. These initial benefits are generally due to improvements in their organisation and internal communication. The benefits must be strengthened through effective internal auditing and management review of system performance.

Like all systems, it either improves or becomes less effective. It does not remain static for long. Quality cannot be tested and audited at the end of the product, but is realized with the product; quality regards all the stages of the product’s life, therefore quality is a problem of everybody.

The decision of implementing, managing and maintaining a QMS has been taken or is near to be taken by many hundred thousands of organisations. The reasons of this decision, certainly involving some external costs, sometimes do not include the virtuous willingness of a good enterprise’s management, but only a specific need: a competitive positioning on the market or a compliance with the customer requirements. Many organisations adopted a quality system not to improve their production effectiveness but only to have the certification stamp. Therefore the mainspring of the QMS success is the market.

However the “virtuous” decision for a QMS could be based also on reasons of different type, more strategic and of higher content. Let us examine some of them:

1) Respect of the contractual obligations
   The suppliers have to satisfy the customer expectations. A QMS forces all the organisations to the achievement of this objective also obliging, at contract’s negotiation stage, a clarification of all the points, not sufficiently or suitably specified.

2) Product responsibility
   Since 1985, an EU Directive is punishing the CEO of the enterprises producing damages, with their defective products. A QMS is a strong preventive instrument: it is working since the product’s design and development, then during its production and also during its utilization (through the post-sales activities). It is important to note that, in the unlucky event of an accident, the evidence of an installed QMS is a valid extenuation towards the consequent responsibilities and allows to limit the damages, with effective warning campaigns; moreover it helps to individuate external responsibilities, to be implicated for compensation acts.

3) Profitability
   The implementation of a QMS has to be considered as an investment and not a cost! The costs coming from the non-quality are definitively higher than the costs relevant to the implementation of a QMS. Low quality can add more than 10% to the project costs.

4) Image and competition
   A certified QMS provides a better reputation, at least until the certifications are not a generalized appointment. This is important mainly if your Certification Body is in the confidence of the consumers and their organisations.
5) Know-how protection
The QMS Documentation covering (in addition to the organization aspects) also the technical processes and the systematic collection of data, allows the internal transfer and dissemination of the company’s know-how, in a consistent and objective way, independently of the turnover of the personnel, as well as the training of the new employees. Consolidation of company’s know-how provides also its better evaluation in case of corporate operations (merging, take-over, incorporation, etc.).

6) Certification of the system and of the product/service
The implementation of a QMS, complying to an international standard, can grant a certification of conformity internationally recognised and respected. A certified QMS facilitates the certification (voluntary or compulsory) of the product, since it improves the confidence of the Certification Body. This means a reduced number of tests and control of the system, and consequently reduced cost and expenditures for the enterprise.

7) Measuring and improvement
The implementation of a QMS forces the enterprises to a frequent review of their organisation and resources allocation, to satisfy their clients. It is recommendable to measure the internal efficiency and effectiveness of your system, in order to improve your objectives, by a comparison both internal and mainly with your competitors.

8) Successful enterprise and social benefits
The implementation of a QMS increases the success expectations of an enterprise and of its products. A successful enterprise generates resources that can be re-invested. Therefore a QMS increases the survival chances of an enterprise, assuring a working continuity for its labour forces.

We would mention here below the results of some recent surveys about the real benefits, registered after the implementation of a QMS.
- more than 80% of the interviewed top managers noticed a better management control and a higher satisfaction of the customers and stakeholders;
- more than 60% noticed a better competitiveness, improved production efficiency and a substantial reduction of rejected/wasted articles;
- more than 50% noticed a better marketing efficiency, production cost’s reduction, increase of the market share;
- more than 25% noticed an increase of the export volume.

QMS Requirements
The basic requirements for an effective QMS are:
- to determine needs and expectations of customers and stakeholders;
- to establish the policy and the objectives for the quality of the organisation;
- to determine and provide the resources necessary for the quality objectives;
- to establish methods for measuring efficiency and effectiveness of each process;
- to carry out the actions to measure the efficiency and effectiveness of each process;
- to establish the means to prevent the non-conformities and to eliminate their causes;
- to establish and apply a process to improve the existing QMS.
QMS and SMEs

An evident advantage of the SMEs, when compared with big companies, is that often the SME is a family-related company with a Director on the top (who is the owner of the company), with relatives and friends, working together for the company’s success. They are all directly motivated in the prosperity of the business, satisfying and attracting their clients.

The management of such a business is often very informal. The “system” is that the Director (owner), like a Patriarch/Matriarch, gives oral indications: who does what and how.

The others follow those indications under his/her constant guidance, checking and controlling the quality of the product/service.

A Director of a small company has usually a broad experience in the business and is appreciated by the personnel for his/her skilfulness, understanding and wisdom.

Such a Director takes care of employees like loved family members, no wonder: they have devotion and motivation for “their” company.

In general, such organisations have an established way or system of doing business successfully.

If the customer satisfaction is a value to the enterprise and delivery times and costs are convenient to clients, then the system established in a small business is quite effective; however, it is informal and rarely documented.

Small business need only a small amount of documentation: mostly of financial nature like bills, receipts, orders, contracts, etc.

Beyond the private business practices, governments and public sector organisations do have established ways of operating.

Therefore the legal framework of a country or a region is the basis for such systems and is in general well documented; unfortunately the application and effectiveness is difficult to assess.

International QMS standards (like ISO 9001:2000 Requirements) identify those features that can help a private or public business to consistently meet its customer’s satisfaction.

Quality systems are about evaluating how and why things are done, writing down how things are done and recording the results to show they were done properly.

The writing down represents the documentation task, and this can often be new and hard for SMEs.

The QMS requirements are complementary to requirements for products.

Users and customers are looking for confidence, that can be provided by a business having a quality management system; they will happily remain loyal, constant partners.

Although different organisations require different processes, within one sector or sub-sector there will be strong similarities. For instance, textile production plants, in a country, will have many common features both in the processes and in their basic documentation.

Consequently their QMS will have a considerable proportion of identical elements.

Experience shows that SMEs in the same sector (like suppliers of auto parts, electric and electronic supply chains, small shoe production factories) may have almost identical basic procedures and QMS.

Well known global chains went very far in standardisation of their processes (this is one of the main reasons of their success), and they indeed do have and apply identical QMS as well.

An example could be the franchiser chain of fast food restaurants all over the world.

The new ISO 9001:2000 specify Requirements for a quality management system that can be used for internal applications by organisations, both for certification or for contractual purpose.

It focuses on the effectiveness of the QMS, in meeting customer requirements and customer satisfaction.
It specifies requirements for a QMS where the organisation (company, SME, etc):
- needs to demonstrate its ability to consistently provide product/service that meets customer and applicable regulatory requirements;
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

All requirements of ISO 9000 are generic and are intended to be applicable to all organisations, regardless of type, size and product/service provided.
The ISO 9001 type of standards are applicable to all size of enterprises but the large company really adapted the system first. They have applied that QMS first over the past 10-15 years and have invested large sums of money to get that fully implemented.
It is true that the quality assurance/management were invented for big companies having mass production. However, with refining them throughout the years, they have been made apt for SMEs as well. The small enterprises are eager to follow suit, although the QMS are now widely applied and the advantages well proven. But the cost in money and time does not make it easy to apply it.

However the cost of not being ISO 9001 certified becomes very high for the SMEs, because:
- They risk loosing the large customers,
- It stop them from export business as the recall of defective products is prohibitive in cost.
- Using ISO 9001 QMS usually leads to cost saving.
- Last but not the least, the European Directive 85/374 puts the legal responsibility of defects on the producer, when the product leaves the plant. This directive implies the use of ISO 9001 QMS.

All this translates in risks and cost disadvantages for the Craft and Small Enterprises. Hence the need to get a good quality management system, compliant with ISO 9001, installed whatever the size of the company may be.

Customers are looking for the confidence that can be given by a business having QMS.
While this expectation can be one reason for a SME to have a QMS, there may be others, which include:
- Improvement of performance, co-ordination and productivity;
- Greater focus on business objectives and customers’ expectations;
- Continuous improvement of the quality of the products/services, to achieve customer’s satisfaction;
- Management confidence that the intended/planned quality improvement of the products/services is being achieved;
- Evidence to clients and new potential customers of the organisation’s (SME’s) capabilities and performance.
- Opening up new market opportunities while keeping satisfied existing customers;
- Certification/Registration.
- Opportunity for the SMEs to compete on the same basis as larger organisations.

At this point we would think of the situation of big companies versus small companies. Big companies have the disadvantage of the bureaucracy, slow reactions, red tapes; partly created by them, forcing on themselves excessive rules and prescribing unnecessary documentation.

We can give an example of a small soap factory, with an 80% level of export. To comply with relevant FDA requirements, this business introduced a QMS, following the ISO 9001 requirements, in four months. This because they would have to stop their exports if actions were not taken within six months after an audit.
To implement the QMS, one of the managers was appointed as Quality Manager by the top management; a Quality Board (Committee) was created and the documentation generated within three months. The internal audits were carried out during the following months to ensure the effective implementation and maintenance of the system.

In this particular case, a certification by a third party was not relevant and the business could rely on the quality audits performed internally.

In conclusion, at SMES - contrary to big organizations/companies – in most cases there is a transparent ownership; thus, it is always evident: who is the boss, who has in hand the resources, who can decide on immediate purchase of something needed to satisfy the clients.

At big companies, decisions need to do their elaborated course. This may require sometimes so much time that the actions upon it come too late, resulting in loss of customers.

The most important benefit of the QMS, like ISO 9001, for the SMEs is that they give them the best tool to make the necessary overhauling of the company to win the competition with the big ones.

Outsourcing

Outsourcing is becoming one of the main operating practices of the organisations; its value currently exceeds the 50% of the turnover.

The quality of the purchased products can therefore remarkably affect the quality of the final product as well as the company’s productivity: the cost to remove a defect, at final stage, is estimated 3-10 times higher than in its early stages.

Outsourcing is an idiom indicating the sub-supply; therefore it is definitively a procurement activity, regulated by the requirements indicated for the purchasing.

Regarding the responsibilities, it is widely confirmed that the QMS of the organisation must cover this process, at least for controlling procedures.

This interpretation is strictly connected with the possibility given to the enterprise to include in its QMS (and mention in the certificate) all the outsourced processes, under its own responsibility.

The relationships with the sub-suppliers are changing quite fast. From several forms of co-operation (co-makership, key supplier, nominated sub-supplier, etc), an enterprise can arrive to share the risks (co-risk) through joint-ventures, partnerships, consortia or other forms of co-operation.

Recommendations for SMEs

Quality should be made a Top Priority. Business plans should begin with the quality goals and quality planning. Companies are used to have financial goals, sales goals, goals for new products development. Quality goals, if existed at all, were somewhere down in the lower levels of the organisation or not a priority at all.

Now it has been reinforced that real, (preferably measurable) quality goals need to be at the top of the business plan.

Quality planning needs to include a deployment process, which identifies what must be done in order to meet quality goals and who is responsible for performing the tasks and who ensures that they are given the resources and training, to enable them to do these deeds.

The chief executive (CEO) must not only participate to the deployment process – since it involves providing resources and he/she is the only company’s officer who can do that – there is also need for his/her personal review of progress.
A further efficient methodology, followed in this regard, is the Internal Quality Audit. Management and financial audits in general were a best practice, well before Quality Management Systems were introduced. While external quality audits (specifically third party audits) are necessary to obtain a Certification by an Accredited Certification Body, the internal audits are important to determine whether the established QMS conforms to the planned arrangements and requirements, fixed by the enterprise, as well as is correctly and effectively implemented and maintained.

Basic Actions

Some basic actions, to be performed by a SME, for development and implementation of an effective QMS can be summarized as follows:
- Appointment of the company’s Quality Team, composed by a Quality Manager and a Quality Committee.
  The members of the Quality Committee are employees (not necessarily managers), representative of the most important company’s departments.
  All the members of the quality staff are internal officers of the company, because they need a deep knowledge of the working procedures inside their departments.
  They can care and develop the Quality activities as part-time of their assigned job. Therefore the company should not need any additional personnel for the Quality activities.
  A detailed job description must be provided for the Quality Manager (splitting his activities before, during and after certification); similarly the tasks and duties for each member of the Quality Committee have to be fixed.
  The quality staff shall be successful only if the company’s top management will give them a constant and effective support.
- Preparation of the internal quality documents of the company (Quality Manual, Operating Procedures, Working Instructions, etc.).
  These documents are prepared by the members of the quality committee, under the supervision of the Quality Manager, and with the assistance (if necessary) of the relevant departmental managers.
- Definition of the practical objectives and detailed schedule of the expected results, with dates for each activity.
- Prospective introduction of an Incentive Programme, for the company’s personnel, strictly connected with measurable results and objectives.
  Such incentive programme should defeat the expected resistance also of many departmental managers, usually reluctant to any working modifications.
- Any review of the company’s organisation structure should comply with the indications of ISO 9000.
STANDARDISATION

To clarify the Quality Management System standards, it is opportune to recall some general concepts on the European Voluntary Standardisation System and its significance for SMEs. The definitions given in this training tool, to explain the official terms of the specific topics, are taken from EN 45020, “General terms and their definitions concerning standardisation and related activities”.

What is a standard?

A standard is a document, agreed by consensus and approved by a recognized Standard Body. This document provides – for common and repeated use- rules, guidelines or characteristics for products, activities or their results. It aims at the achievement of the optimum degree of order in a market. It is based on consolidated results of science, technology and experience. It aims at the promotion of optimum community benefits. When products meet our expectations, we are usually unaware of the role played by standards in raising levels of quality, safety, reliability, efficiency and interchangeability, as well as in providing such benefits at an economical cost.

Standards are documented, voluntary agreements which establish important criteria for products, services and processes. Standards therefore help to make sure that products and services are fit for their purpose and comparable and compatible.

Consensus can be defined as a “general agreement”, characterised by the absence of sustained opposition, to substantial issues, by any important part to the concerned interests and by a process that involves seeking to take into account the view of all parties concerned, and to reconcile any conflicting argument. Consensus need not imply unanimity.

Application of the standards is voluntary!

Types of Standards

The standards can be of various types:
- basic standards, terminology standards, testing standards, product standards, process standards, service standards, interface standards, standards on data to be provided.
The European standards are progressively replacing the national standards.

They are made by a process called standardisation, with the participation of all the interested parties.

The type of standard more interesting for craft and SMEs are:
- Product & service standards
- Quality Management System (QMS) standards
- Environment standards

The European standards are progressively replacing the national standards.

Principles of Standardisation

Consensus, openness (involvement of all the stakeholders), transparency, quality of results, coherence.
Benefits of Standardisation

The benefit of standardisation lies essentially in the integration of market requirements and reduction of costs. The saving potential through standardisation is generally divided into the following divisions:
- Lowering of transaction costs;
- Achieving economies of scale;
- Reduction of external effects (environmental impact).

The benefits of standardisation for the various stakeholders are:
- Simplification of the growing variety of products and procedures in human life;
- Variety control and efficient use of materials, energy and human resources;
- Compatibility and interchangeability communication;
- Safety, health and protection of life and environment;
- Reduction of the degree of market uncertainty;
- Protection of consumers and community interest;
- Fitness to purpose;
- Elimination of the trade barriers.

Standards and SMEs

Often the SMEs consider standards as a burden, made by large groups for large groups, and think that they are not involved. A KAN questionnaire, answered by German SMEs, revealed widely spread points of view across Europe. SMEs would advise that standards should:
- Be comprehensible and clearly arranged;
- Contain clear requirements;
- Contain instructions for implementing the standards and concrete technical solutions (instead of general concepts);
- Repeat excerpts from other standards instead of merely refer to them.

By applying standards, organisations can ensure that their products and services are consistent, compatible, safe and effective.

SME managers rely more on experience than on believes with no proof; however many examples where the application of standards have had extremely positive effects on the business are available. These cases are in various sectors: industry, electricity, food, dentistry, etc.

Interest within SMEs depends also on the activity: more an SME is interested in export activities, more the standard issues will be important.

SMEs and QMS Standards

Whatever the advantages of using standards are, SMEs use firstly standards to satisfy their Quality Management System demands, when they do have one. Quality Management Systems are somehow a “bulk of standards” made to achieve product and service quality; and more and more it is becoming now “management quality”, which means involving more and more factors.

We have already mentioned the advantages for the SMEs in using quality management systems; they are important and numerous and can be summarized as such:
- it might be costly but there are ways to reduce these costs by working together
- more efficient company’s management system
- better quality products; no cost for return of defective products
- legal protection; they obey the European directives
- increase of the market shares
- image benefit
- strategic tool leading to sustainable development.

Corporate Social Responsibility is a new important part in the most recent quality systems. This part of the standard can lead to tangible benefits for SMEs; the first is the improvement of loyalty of the customer, the second is the improvement of relations with the general community/public authorities.

European & International Standardisation: Actors and their Roles

**European Commission**
Institution of the European Union regulating also the European standardisation. It is in charge of writing Directives under the New Approach and gives mandates to CEN, CENELEC and ETSI to write standards.

**European Standardisation Bodies**
- CEN: European multisectoral standardisation organisation active in all the fields except the electrotechnical and telecommunication field. The national standard organisations of candidate countries are already affiliated to CEN.
- CENELEC: European organisation responsible for standardisation in the electrotechnical area.
- ETSI: European organisation active in the standards for telecommunication field.

These European standard organisations are responsible for drafting and publishing the European Standards (EN), governing Accreditation Bodies and Conformity Assessment Bodies.

**International Standardisation Bodies**
- ISO: International multisectoral standardisation organisation active in all the fields except the electrotechnical and telecommunication field; ISO is a network of the national standards institutes of 147 countries.
- IEC: International organisation responsible for standardisation in the electrotechnical area.
- ITU: International organisation active in the standards for telecommunication field.

**National Standardisation Organisations**
They write national standards and implement European and some their national legislation. DIN, BS and UNI are the most active.

**Private Standardisation Organisations**
Some standards can be developed on private basis, within forum or groups of interest. In 90’s standards elaborated by private forums grew in importance. The automobile standard QS 9000 is one of the most famous.

**Links between European and International Standard Bodies**
The co-operation with the respective international partners is essential for the European standardisation system.
“Vienna Agreement” regulates co-operation between CEN and ISO.
“Dresden Agreement” regulates the co-operation between CENELEC and IEC.
EU Standardisation and Certification Policy

1970/1985 – *Old Approach* policy to combat the technical barriers to trade
1983-03 - Directive 83/189 on technical regulation
1985-05 – *New Approach* to technical harmonisation and to standardisation.
1989-12 – *Global Approach* to conformity assessment, certification and testing.

To balance the free movement of goods within the Internal Market with the requirement to ensure a “high level of protection concerning health, safety, environmental protection and consumer protection.

1990-12 – *Modular Approach* to conformity assessment procedures and technical harmonisation directives
1992-06 – Council Resolutions on the role of standardisation in the European economy
1993-07 – Council Decision on “modules” and rules for affixing and use of CE marking

**Old Approach versus New Approach**

<table>
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<th>OLD Approach</th>
<th>NEW Approach</th>
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<td>- Directive is very technical and detailed</td>
<td>-Directive contains only the “essential requirements”.</td>
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<td>- Time-consuming elaboration</td>
<td>- Only reference to standards</td>
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The *New Approach* policy has introduced the following fundamental principles:
- Directives limited to the harmonisation of the *essential minimum requirements*, which must be fulfilled by the products at distribution, in order to assure the free movement of goods.
- *Reference to standards* : harmonised standards define the technical specifications for products, which comply with the essential requirements.
- *Conformity Assessment policy* : products conforming (manufactured in accordance) with harmonised standards are presumed to conform with the essential requirements, set forth in the relevant directive.
- *Application of the standards remains voluntary (and not compulsory)*.

NORMAPME can provide a complete list of all the New Approach Directives, for any specific material and sector.

Standardisation also provides one basis for conformity assessment procedures, which are intended to allow products to gain access to the market, under the best possible conditions from the point of view both of producers and consumers alike.

Harmonised standards provide detailed specifications in terms of objectives, with regard to the practical fulfilment of essential requirements.
Harmonised standards are under all circumstances of *voluntary application*. 
CERTIFICATION

Before deepening the topics of the quality management, it is opportune to explain also some basic concepts, giving the official definitions about certification, conformity assessment and the related activities.

The definitions given in this training tool, to explain the official terms of the specific topics, are taken from EN 45020, “General terms and their definitions concerning standardisation and related activities”.

General Concepts

**Certification (of conformity)**
Is a procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.
Certification aims at proving – through a certificate, a marking or a label – the conformity to a referential system of products, services, organisations and persons.
Certification can be described as a conformity proof. The product and services conformity can be with standards or with the essential requirements of an European Directive.
The certification may be imposed by regulation (regulatory certification) or can be chosen by the manufacturers themselves, mostly for commercial reasons (voluntary certification).

**Conformity with standards is a voluntary based action**!
At moment, the ISO 9000 Certification, for enterprises and organisations, is certainly one of the most popular.
Manufacturers can use their ISO 9000-based quality system to implement certain conformity assessment procedures (“modules”) foreseen in the Community legislation, since ISO 9000 achieve the objectives of the directives.

It is sometimes claimed that ISO 9000 is mandatory in order to fulfil the requirements of the New Approach directives. This is absolutely not true!!
Any other type of quality system can be used to fulfil the requirements of the legislation; however, in this case, the manufacturer does not benefit from a presumption of conformity.

*ISO 9000 quality systems are not obligatory, but they help as they give presumption of conformity.*

The foreword to the European version of ISO 9001:2000 includes a table of correspondence between the requirements of the standard and those of the different “modules” (conformity assessment procedures).

**Conformity Assessment**
is the systematic examination to determine the extent to which a product, process or service fulfils specified requirements.

**Conformity Assessment Body**
is a Body performing conformity assessment activities; it is “engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled”.
The conformity assessment body is resident in the country of the party executing the agreement.
**Accreditation**

is the determination, by an impartial third party, that a Body satisfies the defined requirements and is competent to perform defined *conformity assessment activities*. It is the procedure by which an Authoritative Body gives formal recognition that an organisation or person is competent to carry out specific tasks. Accreditation is a licence to certify; in general, Accreditation Bodies are authorized by public authorities.

The European Co-operation for Accreditation (EA), is a “club” of national accreditation bodies, for a mutual recognition of the accreditation bodies.

If an Authoritative Body gives formal recognition that a Body (or person) is competent to carry out certification, inspection and testing tasks, then this body is referred as *accredited* for these tasks.

**Accreditation bodies**

are the third parties conducting accreditation; they act on behalf of the designating authorities. They may be responsible for ascertaining the technical competence of the Conformity Assessment Bodies.

**Certification Bodies** are the bodies that conduct certifications of conformity; **Inspection Bodies** are the bodies that perform inspection tasks; **Testing laboratories** are the laboratories that perform test;

**Testing** is the carrying out of technical operations, in order to determine characteristics of a product, process or service according to specified procedures.

**Inspection** is the evaluation for conformity by measuring, observing, testing or gauging the relevant characteristics of the product, process or service.

**Certification system** is a system, with its own rules of procedure and management, for carrying out certification of conformity (includes rules for testing and inspection). It may be operated on a national, regional or international level.

**Certification scheme** is a certification system related to specified products, processes or services to which the same standards and the same procedure apply.

**Certificate of conformity** is a document indicating that a product, process or service is in conformity with a specific standard or other normative document. The conformity is assessed according to several types of referential systems : standards, specifications or technical rules, a schedule of conditions, norms, level of competences, etc. The two basic forms of conformity assessment are:
- Conformity assessment of products, services, processes, systems and persons
- Conformity assessment of bodies

**Mark of conformity** is a protected mark, applied under the rules of a certification system, indicating that the relevant product, process or service is in conformity with a specific standard or other normative document. The marking does not necessarily mean that the product is reliable or functioning. The marking is applied by the manufacturer himself and generally under his own responsibility. On the increasingly competitive market, the voluntary quality markings may have a strong influence on the customer’s choice.
**CE Marking** is the only way of marking compliance with Community Regulations. It gives physical form to the meeting, by a product, with the obligations resting upon manufacturers; namely compliance with:
- essential requirements regarding safety, public health, environment;
- the intended compliance assessment procedures;
- specific obligations relating to the CE Marking (specific use of a product, etc.)

**Manufacturer Responsibilities**
The manufacturer is responsible for:
- designing and manufacturing the product in accordance with the *essential requirements* laid down by the directives;
- carrying out *conformity assessment*, in accordance with the procedures laid down by the directives.

The manufacturer is obliged to understand both the design and the construction of the product, to be able to take the responsibility for the product being in compliance with all the provisions of the relevant New approach directives.
This applies both to situations where the manufacturer designs, manufactures, packs and labels the product himself, and to situations where some of all of these operations are carried out by a subcontractor.

**Products imported from third countries**
- A manufacturer established in a third country is responsible in the same way as a manufacturer established in a Member State, for designing and manufacturing a product in accordance with all the applicable directives, as well as for carrying out the requested conformity assessment procedure, when the product is intended to be placed or put into service on the Community Market.
- Where the manufacturer is not established in the Community, the importer or person responsible for placing the product on the Community market may become responsible to some extent.
- Customs authorities shall, in case of products imported from third countries, suspend the release of goods.

**Problems faced by SMEs for Certification**
If conformity is valuable, the certification is a quite complex issue as:
- It can be voluntary or compulsory (need identification) can be hard to make;
- The quality of the certification bodies are different;
- The certification value for money is not easy to determine.

A large percentage of SMEs would like to be better informed on the standards they have to be conformed with.

The quality of a Certification Body is a big issue, mainly due to the fact it is a commercial activity! For instance, in 2003, some certification bodies have been issuing a large percentage of ISO 9000:1994 certificates, although this standard will not be valid anymore after December 2003. SMEs managers are not always aware of the standard changes and can be an easy prey for undelicate certification companies.
Selection and appointment of a reliable and professional Certification Body must be done on the base of their qualifications and references.
Therefore, before proceeding to contact the local Certification Bodies, we strongly recommend to apply to ISO ([www.iso.ch](http://www.iso.ch)), to have indications and recommendations.
Most certification issued are related to the Quality Management Systems; the advantages to be conformed to these types of systems have been extensively clarified hereinafter.

But as it might be hard and expensive to implement, and often means trusting consultants they are not able to check out for their work quality, the SME managers often do not identify clearly the benefits, here mentioned, for their company.

A fundamental task of the SME national and sectoral Associations is a co-ordinated support and assistance to their members for the solution of these problems !!
FREQUENT QUESTIONS ABOUT ISO

What is ISO?

ISO (International Organisation for Standardisation) is a worldwide federation of National Standards Bodies, on the basis of one member for each country.
It is a network of the National Standard Institutes of 147 countries, with a Central Secretariat in Geneva (Switzerland), that co-ordinates the system.

The object of ISO is to promote the development of standardisation and related activities in the world, in order to facilitate international exchange of goods and services and to develop the co-operation in the spheres of scientific, technological and economic activity.
The results of the ISO technical work are published as International Standards.

Origin of ISO

ISO was created in 1947 as an international organisation “to facilitate the international co-ordination and unification of industrial standards”.
In the early 1970s ISO began to publish International Standards, but only in 1980s its standards acquired their own validity in the market place and ISO was asked to prepare the first standards on particular topics, moving away from its original mission of harmonizing national standards.

Global markets needed international standards, and the future of ISO was therefore assured, favoured by two major events:
1) The decision of the European Commission to create the Single European Market (SEM) on the basis of a Community-wide legislation, supported by voluntary consensus standards, developed by the European Standard Bodies.
The New Approach Directives in Europe resulted in a very significant expansion of standardisation activities of CEN (European Committee for Standardisation) and ISO.
2) The Vienna Agreement, for technical co-operation between CEN and ISO, emphasized that the Single European Market (SEM) needed to be integrated into the Global Market, given the volume of trade to and from Europe.

A final consequence has been a much increased rate of adoption of the ISO standards, as national standards, not only within the European Union but also in other countries around the world.
Around 40% of all the European standards are direct adoptions of ISO standards.

What is ISO 9000?

The ISO 9000 is a family of standards, representing an international consensus on good management practices, with the aim of ensuring that the organisation can time and time again deliver the product or services that meet the client’s quality requirements.

These good practices have been distilled into a set of standardized requirements for a quality management system, regardless of what your organisation does, its size, or whether it is in the private or public sector.
Why should my Organisation implement ISO 9000?

To keep customers - and to keep them satisfied – your product (or services) needs to meet their requirements.

ISO 9000 provides a tested framework for taking a systematic approach to managing your business processes (your organisation’s activities) so that they consistently turn out product conforming to the customer's expectations.

That means consistently happy customers!

ISO 9000:2000 is used if you are seeking to establish a management system that provides confidence in the conformance of your product to established or specified requirements.

How do ISO 9000 Standards work?

The requirements for a quality system have been standardised, although most of us think our business is unique.

ISO 9000 lays down what requirements your quality system must meet, but not dictate how they should be met in your organisation – which leaves great scope and flexibility for implementation in different business sectors and business cultures.

So the ISO family includes standards that give organisations guidance and requirements on what constitutes an effective quality management system.

The family also includes models against which this system can be audited, to give the organisation and its clients assurance that the system is operating effectively.

Lastly, the family includes a standard on terminology, and other standards which can be described as “supporting tools”, that give guidance on specific aspects, such as auditing quality systems.

Which are the ISO 9000 Quality Models?

If you have heard of ISO 9000, then it is probably through ISO 9001, ISO 9002 or ISO 9003, the three quality assurance models against which the organisations could be certified.

In 1987 ISO published the first edition standards of the ISO 9000 series for the quality management, then revised in 1994:

- ISO 9001, ISO 9002 and ISO 9003 are three standards for quality assurance, with requirements that can serve as a basis for certification;
- ISO 9004 are the standards giving guidelines on the elements of quality management and a quality system;
- ISO 9000, a guide for applying these standards.

The difference among ISO 9001, 2 and 3 is this:

- ISO 9001 sets out the requirements for an organisation whose business processes range all the way from design and development to production, installation and servicing; therefore it is the QMS model for companies providing also the design of the supplied products and services.
- ISO 9002 is the appropriate standard for an organisation which does not carry out design and development, but only production, installation and servicing. It does not include the design control requirements of ISO 9001 – otherwise its requirements are identical.
ISO 9003 is the appropriate standard for an organisation whose business processes do not include **design control**, **process control**, **purchasing** or **servicing**, and which basically uses **inspection and testing** to ensure that final products and services meet specified requirements. Therefore this is the QMS model for companies whose activities are limited to trading and/or distribution of products and services, hence interested only to their final inspection and testing.

So, organisations have chosen that their **quality system** be certified against ISO 9001, ISO 9002 or ISO 9003 according to the business processes covered by the quality system. This without any difference of quality ranking between the three standards.

The consecutive editions of the ISO 9000 series of standards (1987, 1994, 2000) have been revised to incorporate proposed extensions and improvements, making them apt for SMEs as well. Some of most important improvements are: growing importance of involvement and dedication of senior managers, employee participation and continuous improvement of the processes.

**From ISO 9000:1994 to ISO 9000:2000**

ISO 9000:1994 and 2000 have been coexisting from 15 December 2000 to 15 December 2003. Many companies have not yet upgraded their ISO 9000:1994 into an ISO 9001:2000 because most of them are not aware they will **not** be accredited ISO after the 15/12/2003. Certification Bodies have still been delivering ISO 9000:1994 during 2003 !!

In the year 2002 almost 50% of the delivered ISO 9000 certifications were year 1994 !! Everybody will want to be certified ISO 9000:2000 early December 2003 !

Selection and appointment of a reliable and professional Certification Body must be done on the base of their qualifications and references. Therefore, before proceeding to contact the local Certification Bodies, we strongly recommend to apply to ISO ([www.iso.ch](http://www.iso.ch)), to have indications and recommendations.

Two of the most important **objectives** in the revision of the ISO 9000 series of standards have been:

- To develop a simplified set of standards that will be equally applicable to small as well as medium and large organisations;
- For the amount and detail of documentation required, to be more relevant to the desired results of the organisation’s process activities.

The main **purposes** of this revision have been:

- To reflect modern management approaches
- To improve organisational practices
- To adopt necessary structural changes

The main **changes** occurred with this revision are relevant to:

- **Structure**
- **Process approach**
- **Top management role**
- **Continual improvement**
- **Application**
- **Customer satisfaction**
- **Resources**
- **Terminology**
- **Documentation**
The key point of the ISO 9000:2000 family of standards is that it has completed the development process from the Quality Assurance to the Quality Management.

The ISO 9000:1994 were based on the fundamental difference between Quality Assurance and Quality Management, defined as follows:

**Quality Assurance** is the complex of activities executed according to a quality system, in order to provide the necessary confidence that an organisation will meet the quality requirements. To be effective, a quality assurance needs a continuous evaluation of all the factors affecting the design and the specifications, as well as a proper control and audit on the production and equipment. Confidence means to *provide evidence* through a support documentation.

**Quality Management** is the complex of activities of company management, fixing the quality policy, the objectives and the responsibilities; putting them into practice (in the frame of the quality system) through the quality planning, the quality control, the quality assurance and the quality improvement.

The ISO:2000 family of standards merged the two concepts: the final subject so became only the Quality Management System.

What is ISO 9000 : 2000 ?

ISO Technical Committee is responsible for reviewing its standards every 5 years, in order to determine their continued relevance.
ISO 9000:1994 contained more than 20 standards and documents.
ISO 9000:2000 family consists of four primary standards supported by a considerably reduced number of supporting documents.


The 4 primary standards of the ISO 9000:2000 family are :

**ISO 19011** : Guidelines for auditing quality and/or environmental management systems.
IMPLEMENTING YOUR QUALITY MANAGEMENT SYSTEM

We would now define the several steps to implement a QMS.

**Identify the goals you want to achieve**

Typical goals may be:
- Be more efficient and profitable;
- Produce products and services that consistently meet the customer requirements;
- Achieve customer satisfaction;
- Increase market share;
- Maintain market share;
- Improve communications and morale in the organisation;
- Reduce cost and liabilities
- Increase confidence in the production system.

**Identify the objectives of interested parties**

The main objective is to satisfy the expectations of the interested parties (stakeholders), such as:
- Customers and end users: requiring products able to satisfy their needs;
- Suppliers: requiring stable and realistic relationships;
- Employees: requiring working methods able to give gratifications;
- Shareholders: requiring profits remunerative and consistent with their investments;
- Society: the community asks the enterprises for working procedures lawful, ethical and respectful to the environment.

**Obtain information about the QMS**

Marketing oriented product and services organisations need to achieve standards of quality, internationally recognised and respected. ISO 9001:2000 is recommendable if you are seeking to establish a management system that provides confidence in the performance of your product to established or specified requirements. It is now the only standard, in the ISO family, against whose requirements your quality system can be certified by an external agency.

The standard recognizes that the word “product” applies to services, processed material, hardware and software, required by your customer.


**Apply the ISO 9000 family of standards in your management system**

Use the new ISO 9001:2000 as basis for the certification.

The validity of the old ISO 9001, 9002, and 9003:1994 expires on 15 December 2003!!

**Obtain guidance on specific topics within the QMS**

For your guidance, the ISO topic-specific standards are:
- ISO 10006 for project management,
- ISO 10007 for configuration management,
- ISO 10012 for measurement systems,
- ISO 10013 for quality documentation,
- ISO/TR 10014 for managing the economics of quality,
- ISO 10015 for training,
- ISO 19011 for auditing.
Establish your current status, determine the gaps between your management system and the requirements of ISO 9001:2000
You may use one or more of the following:
- Self assessment,
- Assessment by an external organisation.

Determine the processes that are needed to supply products/services to your customers
In the new standard ISO 9001:2000 there are five Sections, specifying the activities to be considered when you implement your system.
Review the Section (Clause) 7. “Product Realisation”, to determine which requirements are applicable to the activities you use to supply your products, and excluding those not applicable to your operations. These include:
- Customer related processes;
- Design and/or development;
- Purchasing;
- Production and service operations;
- Control of measuring and monitoring devices.

Develop a plan to close the gaps and carry out your plan
Identify the actions needed to close your gaps, allocate resources to perform these actions, assign responsibilities and establish a schedule to complete the needed actions.
The paragraphs 4.1 and 7.1 of ISO 9001:2000 provide the information you need to consider when developing the plan.
Proceed to implement the identified actions and track progress to your schedule.

Undergo periodic internal assessment
Use ISO 19011 for guidance in internal auditing, auditor qualification and managing audit programmes.

Undergo independent audit
Engage a reliable Accredited Registration/Certification Body, to perform an audit and to certify that your QMS complies with the requirements of ISO 9001:2000.
A list of local qualified and reliable Certification Bodies can be requested to ISO (www.iso.ch).

Continue to improve your business
Review the effectiveness and suitability of your QMS.
ISO 9004:2000 provides a methodology for improvement.
ISO 9004:2000 is used to extend the benefits obtained from ISO 9001:2000 to all parties that are interested in or affected by your business operations.
The interested parties include the stakeholders: your employees, owners, suppliers and society in general.
PRESENTATION OF ISO 9000 : 2000

General

ISO 9000 is rapidly becoming the most important quality standard. Thousands of companies in over 120 countries have already adopted it, and many more are in process of doing so. Why?
Because it controls quality. It helps to save money. Customers expect it. Competitors use it.
ISO 9000 applies to all types of organisations. It doesn’t matter what size they are or what they do.
It can help both product and service oriented organisations to achieve standards of quality that are recognized and respected throughout the world.

The 4 primary standards of the ISO 9000:2000 family are:
ISO 19011 : Guidelines for auditing quality and/or environmental management systems.

The new ISO 9000:2000

The term ISO 9000 refers to a set of quality management standards.
ISO 9000 currently includes three main quality standards:
All of these are process standards and not product standards!

They help organisations to produce products/services well.
They don’t help to decide if a single product/service is well done or not, but they assure the market that an organisation is able to produce products/services along the requirements.
ISO’s purpose is to facilitate the international trade, by providing a single set of standards that people everywhere would recognize and respect.
ISO 9000:2000 apply to all kinds of organisations in all kinds of areas.

How does ISO 9000:2000 work?

Here’s how it works.
You decide that you need to develop a quality management system that meets the new ISO 9000 Standards.
You choose to follow this path because:
- you feel the need to control or improve the quality of your products and services, in order to reduce the costs associated with the poor quality,
- or to become more competitive,
- or you choose this path simply because your customers expect you do so,
- or because a governmental body has made it mandatory.
Then you develop a quality management system that meets the Requirements specified by ISO 9001:2000 (ISO 9002 and ISO 9003 have been dropped).

Your management system must meet ISO’s requirements and not ISO’s guidelines; therefore you are not obliged to consult the ISO 9000 and ISO 9004 guidelines.

You may ignore ISO’s guidelines unless you need additional clarification or you wish to develop a quality system that goes beyond the ISO 9001:2000 requirements.

How to develop such a system?

You start with a Gap Analysis; an ISO 9001:2000 Gap Analysis will tell you exactly what you need to do to meet the new ISO 9001 QMS. It will help you to identify the gaps that exist between the new ISO 9001 Standard and your organisation’s processes. Once you know precisely where the Gaps are, you can take steps to fill your gaps. By doing so, you will not only comply with the new ISO 9001 Standard, but you will also improve the overall performance of your organisation’s processes.

Once your quality system has been fully developed and implemented, you carry out an Internal Audit to ensure that all the departments of your organisation have met every single ISO 9001:2000 requirement.

When you are ready, you ask an external Registrar to audit the effectiveness of your QMS. If your external auditors like what they see, they will certify that your QMS has met ISO’s requirements. They will then issue an official certificate to you and they will record your achievement in their registry. You can then announce to the world that the quality of your products and services is managed, controlled and assured by a registered ISO 9001 QMS!

However you are not obliged to be registered! ISO does not require a formal certification (registration). You can be in compliance without being registered by an accredited auditor. But your customers are more likely to believe that you have an effective QMS if an independent external auditor says so.

ISO 9000:2000 Basic Principles

The new ISO 9000:2000 standards are based on 8 quality management principles. ISO chose these principles because they can be used to improve organisational performance and achieve success. But how can you make sure that your organisation applies these principles?

The answer is to implement a QMS that meets the new ISO 9001:2000 standard. If you do so, your organisation will automatically apply these principles. This because they permeate the new standard and will therefore be built into any quality system that is based on this standard.

The 8 Quality Management Principles

**Principle 1 - Focus on your customers**

Organisations rely and depend on their customers and therefore should:
- understand current and future customer needs.
- meet customer requirements.
- Strive to exceed customer expectations.
Key benefits:
- Increased revenue and market share, obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organisation resources, to enhance customer satisfaction.
- Improved customer loyalty, leading to repeat business.

Principle 2 – Provide Leadership
Organisations rely on leaders; therefore leaders must:
- Establish a unity of purpose and set the direction the organisation should take.
- Create and maintain an internal environment that encourages and involves people to achieve the organisation’s objectives.

Key benefits:
- People will understand and be motivated towards the organisation’s goals and objectives.
- Activities are evaluated, aligned and implemented in an unified way.
- Miscommunication between levels of an organisation will be minimized.

Principle 3 – Involve People
Organisations rely on people.
People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation’s benefit. Therefore the organisations must:
- encourage the involvement of people at all levels;
- help people to develop and use their abilities.

Key benefits:
- Motivated, committed and involved people within the organisation;
- Innovation and creativity in furthering the organisation’s objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

Principle 4 – Use a process approach
Organisations are more efficient and effective, in achieving a desired result, when they use a process approach. Therefore:
- Organisations must use a process approach to manage activities and related resources.

Key benefits:
- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organisation’s resources to enhance customer satisfaction.
- Improved customer loyalty, leading to repeat business.

Principle 5 – Take a systems approach
Organisations are more efficient and effective, in achieving their objectives, when they use a systems approach to management. Organisations therefore must:
- identify and understand the interrelated processes and treat them as a system
- use a systems approach to manage their interrelated processes.

Key benefits:
- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to consistency, effectiveness and efficiency of the organisation.
**Principle 6 – Encourage continual improvement**

Organisations are more efficient and effective when they have the objective to continually improve their performance. Therefore:

- Organisations must make a permanent commitment to continually improve their overall performance.

**Key benefits:**

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

**Principle 7 – Get the facts before you decide**

Organisations perform better when their decisions are based on the facts: factual approach to decision making. Therefore:

- Organisations must base decisions on the analysis of factual information and data.

**Key benefits:**

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

**Principle 8 – Work with your suppliers**

Organisations depend on their suppliers; an organisation and its suppliers are interdependent and a mutually interested to enhance the ability of both to create value. Therefore:

- Organisations must maintain a mutually beneficial relationship with their suppliers.

**Key benefits:**

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

The Standard ISO 9001:2000

It consists of an introduction and the following eight Sections (Clauses), forming the structure of the standard:

1. Scope
2. Normative references
3. Terms and definitions
4. Quality Management System requirements
5. Management responsibility
6. Resources management
7. Product and/or service realisation
8. Measurement, analysis and improvement

The basis of the documented quality management system is formed by the Clauses from 4 to 8. These five Clauses/Sections specify the activities that need to be considered when you implement your system.

You will describe the activities you use to supply your products, and may exclude the parts of the Section 7, Product Realization, that are not applicable to your operations.

The only acceptable, justified exclusions must be limited to the requirements of this Section 7.
What about the requirements of the other four Clauses/Sections: 4-Quality Management System Requirements, 5-Management Responsibility, 6-Resources Management, and 8-Measurement, Analysis and Improvement?

They apply to all the organisations and you will demonstrate how you apply them to your organisation in your Quality Manual and other documentation.

It is not the intent of ISO:9001:2000 to imply uniformity in structure of quality management systems or uniformity of documentation. Furthermore, the QMS requirements specified in ISO 9001 are complementary to requirements for products.

Together, these five Sections of ISO 9001:2000 define what you should do consistently to provide products that meet customer and applicable statutory or regulatory requirements. In addition, you will seek to enhance customer's satisfaction by improving your quality management system.

When you adopt ISO 9001:2000, you must strive for the satisfaction of your customers and the continual improvement of your quality management system.

Continual improvement is a process of increasing the effectiveness of your organisation to fulfil your quality policy and quality objectives.

ISO 9001:2000 requires that you plan and manage the processes necessary for the continual improvement of your quality management System.

The Standard ISO 9004:2000

This standard is used to extend the benefits obtained from ISO 9001 to all the parties that are interested in or affected by your business operations.

Interested parties include your employees, owners, suppliers and society in general.


ISO 9004 provides information that will be helpful in going beyond ISO 9001, to improve the efficiency of your operation.

It is recommended that you obtain data from various sources, both internal and external, to assess the appropriateness of your quality system goals.

This information can also be used to improve the performance of your processes.

ISO 9001 and ISO 9004:2000 are harmonized in structure and terminology to assist you to move smoothly from one to the other. Both standards apply a process approach.

Some organisations may expand their management systems by extending the ISO 9001 structure to include the requirements of ISO 14001:1996, Environmental management systems.

Process Organisation

All the standards of the ISO 9000:2000 family apply a “process approach”, according to the above mentioned Principle 4.

Processes are recognized as consisting of one or more linked activities that require resources and must be managed to achieve predetermined output.

The output of one process may directly form the input of the next process; the final product is often the result of a network or system of processes.
The standard is configuring the enterprise as a *system of processes*, strictly interrelated among them; in this way the output of a process (information, products, services, etc) is the input of the subsequent, interrelated processes.

This “*process approach*” model is realized by:
- a *main* process, finalized to the realization of the product/service to supply to the customer:
  - Product and/or service realization;
- an additional group of processes, finalized to *support* and enhance the main process:
  - Management responsibility, Resource management, Measurement, analysis and improvement.

**Main process**

“*Product/service realization*(Clause 7) is the only process taken in consideration by the standard as *main process*. It is inclusive of all the primary activities for the product and service realization, in connection with: its own market, its own organisation structure, the company objectives.

This main process is then divided in the following important sub-processes:

1. **Planning of product realization**;
2. **Customer-related processes**: determination and review of requirements related to the product (that meets customer’s expectations);
3. **Design and development**;
4. **Purchasing**;
5. **Production and service provision**;
6. **Control of monitoring and measuring devices**.

**Support processes**

The ISO 9001 quality management system requires the following *support* activities/processes with their relevant sub-processes:

1. **Management responsibility** (Clause 5):
   - Management commitment: support quality;
   - Customer focus: satisfy your customers;
   - Quality policy: establish a quality policy;
   - Planning: carry out quality planning (formulating your quality objectives and planning your quality management system);
   - Responsibility, Authority and Communication: control your quality system (defining responsibilities and authorities, appointing management representative, supporting internal communications);
   - Management Review: perform management reviews (reviewing your QMS, examining management review inputs, generating management review outputs).

2. **Resources (human resources, facilities, work environment) management** (Clause 6):
   - Provision of Resources: provide quality resources;
   - Human Resources: provide quality personnel (using competent personnel and supporting competence);
   - Infrastructure: provide quality infrastructures (identify, provide and maintain);
   - Work Environment: provide quality environment.

3. **Measurement, analysis and improvement** (Clause 8):
   - General: define the crucial information you need and perform remedial processes;
8.2 - Monitoring and Measurement: monitor and measure quality (monitor and measure: customer satisfaction, quality processes, product characteristics; plan and perform regular internal audits);
8.3 - Control of Nonconforming Products;
8.4 - Analysis of Data: analyse quality information;
8.5 - Improvement: make quality improvements (improving your QMS, correcting actual nonconformities, preventing potential nonconformities).

This new structure of the standard is harking back to the methodology known as the Deming circle, summarized with the acronym PDCA (Plan-Do-Check-Act). PDCA means:

- **Plan**: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organisation’s policies.
- **Do**: implement the process.
- **Check**: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
- **Act**: take actions to continually improve process performance and focusing on the quality of product/service.

This Circle means different processes for different organisations; however, within one sector there will be strong similarities.

**Quality Management System Requirements**

A special attention should be given to the QMS Requirements, indicated in the Clause/section 4 of the standard ISO 9001:2000; they are divided in the following two parts.

### 4.1 General Requirements: to establish your quality system

- Identify the processes needed for your QMS, and the activities affecting the quality of the product. For example, certain accounting activities (such as payroll) may not be part of the scope of a quality system (unless accounting is a core part of the business).
- Determine the sequence and interaction of these processes.
- Determine criteria and methods needed to ensure the effective operation and control of these processes. Activities need to be controlled.
  
  *The QMS should be beneficial to customers and organisation itself.* In this way it is a management tool, and not a goal in itself!
- Use resources and information as key factors in controlling activities. A QMS should reflect all the changes occurred inside the organisation.
- Monitor, measure and analyse these processes. Improvement is only possible if you know where to improve.
- Improve the QMS. This is an important additional requirement of ISO 9001:2000. This means that it should not only be a tool for control of processes, but also for continuous improvement.

### 4.2 Document Requirements: to document your quality system

- Develop quality system documents (quality policy, quality objectives, a quality manual, operating procedures, planning documents and quality records);
- Prepare quality system documents,
- Control quality system documents,
- Maintain quality system records.
Technical Documentation

A special emphasis must be given to the Document Requirements, covered by the Clause 4.2 of the ISO 9001:2000, documentation represents an important and critic topic for a craft or small enterprises.

All systems require a level of traceability and so written documentation. This could be simple lists to tick off. Such documentation helps to keep record of the past and allows to improve the future production (Continuous Improvement process).
This traceability is also needed to show compliance with the New Approach Directives and for CE Marking. It can also protect against legal liability (Directive 85/374/CEE).
It is thus a help and not only a burden to the enterprises, whatever the size, provided its level of detail is properly adapted to the size and the complication of enterprise.

ISO 9001:2000 requires that certain aspects of the quality management system are documented. Specifically, this includes a quality policy, quality objectives, a quality manual, procedures, planning documents and quality records.
The quality management system should be an effective, user friendly balance of procedures, work instructions and forms, which will assist personnel in their day-to-day work.
People must have the information they need to do the job.
Documentation should not mean bureaucracy and excessive paperwork or lack of flexibility.

Type of documentation
According to ISO 9001, the quality management system documentation of an enterprise includes:
1) documented statements of a quality policy and quality objectives;
2) a quality manual;
3) documented procedures required by the international standard;
4) documents needed by the organisation to ensure the effective planning, operation and control of its processes;
5) records required by this international standard.

The heavy documentation requested by the old QMS has been one of the biggest concerns of the SMEs, also as regards the previous editions of ISO 9000.
The new ISO 9001:2000 has taken in due consideration this criticism and has given a new approach, in order to meet the requirements both of the QMS and the organisations.

Therefore it is now better distinguishing two types of documentation:
1) Compulsory documentation, expressly requested by the QMS, including the documents above mentioned, 1) through 5).
2) Auxiliary (optional) documentation, necessary for planning, realizing and controlling the organization’s processes. It lies with the organization to decide the extension, contents and form of this documentation, adapting it to the internal specific needs.

We heard many declarations about the substantial reduction of the required documentation in the ISO 2000 versus ISO 1994, because of the present requirement of only 6 documented procedures, instead of about 20 as in the past issue.
This thesis is absolutely debatable! The volume of necessary documentation is determined by the needs of the single organisations.
The reduced number of documented procedures (6 instead of 20) does not affect substantially the extent of work to be performed by the enterprise’s quality staff.
For most SMEs the heaviest task is the development of the *internal operating procedures* relevant to the key activities of the main departments (production, marketing & sales, purchasing, finance & administration, etc.).

**Procedures**

Procedures describe what is being done in an organisation, identifying responsibilities and authorities. They can help to make things clear for personnel, and they can also to create *consistency* in work. A quality management system is not a set of procedures, describing every minute detail of an organisation’s operation. The effectiveness of the procedures depends on how they are applied to an organisation. In other words, they should be tailored to each organisation. Over-documentation can easily result in unnecessary bureaucracy and inflexibility. Larger organisations, with more complicated activities, should have more detailed procedures, but in all cases the procedures should still be as practical as possible.

ISO 9001:2000 does not in all cases require *documented* procedures. In some cases there is no need to document the existing practices. However, there must still be a procedure in place: a consistent way of performing the work involved.

Note: the minimum documented procedures required by ISO 9001:2000 (9001:1994 were requiring about 20 basic documented procedures) are the following.

1) Control of Documents
2) Corrective Action
3) Preventive Action
4) Control of Records
5) Internal Audit
6) Control of Nonconforming Product

**Quality Manual**

The organization shall establish and maintain a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusions (limited to the only section 7);

b) the documented procedures established for the quality management system, or referenced to them;

c) a description of the sequence and interaction between the processes of the quality management system.

The quality manual is the “road map” of the quality management system. It should give readers an overview of how the quality management system operates. The quality manual must state the scope of the quality management system. This can be communicated in a single sentence stating exactly what the organisation does. For example, “Design and manufacture of steel storage tanks”.

The quality manual must include or reference the 6 documented procedures required by ISO 9001:2000, as well as any other documented procedures (hopefully) utilized in the quality management system.

ISO 9001:2000 requires that the quality manual contain a description of the sequence and interactions between the processes of the quality management system.
This description must clearly indicate how the activities of the organisation interact. This can be done effectively in a flow chart; however, any other format is acceptable as long as it describes the interaction between all processes of the quality management system (i.e. purchasing, design, inspection, construction, etc.).

Eventual exclusions to the standard must be stated in the manual. Exclusions must be limited to the requirements of the clause 7 (Product and/or service realization) only, and not affect the organisation’s ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

**Control of Documents**
Documents required by the quality management system need to be controlled. The intent of this element is to ensure that people use the correct versions of the correct documents. The use of incorrect or obsolete documents can result in mistakes and, ultimately, in nonconforming product and/or service.

New or revised documents should be approved prior to issue. Signature or any form of approval is acceptable, as long as the relevant procedure indicates what constitutes the evidence that documents are approved.

In order to control the use of documents, ISO 9001:2000 requires a method for identifying the current revision status of documents.

A documented procedure shall be established to define the controls needed to:
- approve documents for adequacy prior to issue;
- review and update as necessary and re-approve documents;
- ensure that changes and current revision status of documents are identified;
- ensure that relevant versions of applicable documents are available at point of use;
- ensure that documents remain legible and readily identifiable;
- ensure that documents of external origin are identified and their distribution controlled;
- prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

**Control of Records**
Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records remain legible, readily identifiable and retrievable.

A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

There is a difference between *documents* and *records*. Essentially, *documents* are used to describe or control how things are to be done and are capable of being revised to reflect changing circumstances. *Records* are generated as a result of some activity and are statements of facts existing at the time.

For example: a form used for ordering products or services from vendors (Purchase Order) is a document. A completed purchase order, stating what has been ordered from the vendor, is a record. Other example of records are:
- inspection records;
- quotations;
- customer orders;
- audit reports;
- minutes of design review meetings;
- completed non-conformance reports.
**Recommendations**

We have emphasized how the implementation of the QMS must be beneficial not only to customers, but to the organisation itself.

To promote the growing up of the enterprise, it is essential, during the implementation of the QMS, to monitor, control and analyse the production and managerial processes.

Therefore, for a SME, it is strongly recommendable to start drawing up the documentation with the description (examination is subsequent) of the main activities and processes relevant to the core business of the company. This means to individuate the main current activities and practices of the key company’s departments.

Then the Q-Manager, with the essential support of the relevant departmental member of the Q-Committee, should describe - in writing - the current operating procedures for each of the individuated key activities, and subsequently draw up this document, in compliance with the ISO forms.

To clarify the important work mentioned here, we would give an example: individuating some typical key activities in the usual departments of a manufacturing company, in order to define the relevant operating procedures.

1) Marketing & Sales
   1a - Submission of offers to the customers.
   1b – Cost estimation and sale prices evaluation

2) Procurement
   2a – Selection of qualified suppliers
   2b – Placement of order to suppliers
   2c – Registration of suppliers’ performances
   2d – Inspection and testing of the purchased components

3) Engineering & Maintenance
   3a – Maintenance programme for the production machinery
   3b – Maintenance and control of the electric plants

4) Production
   4a – Packing and delivery of the finished goods to clients
   4b – Manufacturing process: production flow-chart, definition and control of the process parameters for the different production steps, definition and control of the main critical factors.

5) Finance & Administration
   5a – Payment of the invoices to suppliers
   5b – Issue of invoices to clients
   5c – Payment of wages
   5d – Payment of the travelling expenses

As far as the above indicated six basic documented procedures are concerned, the enterprise’s Quality staff can easily recover some fac-simile from other companies, to be adapted to their organisation.
Course of Quality in the Organizations

To understand the main, present quality problems, we should overcome two conflicting approaches:
1) Quality as conformity versus quality as improvement.
2) Quality of the product versus quality of the organization process.

In these last years, we have noticed two clear and distinct passages:
1) From “Product Quality” to the “Quality Management Systems”.
2) From the “Quality Assurance” to the “Quality Management Systems” to the “Total Quality Management”.

As already mentioned, ISO 9000:2000 realized the passage from the Quality Assurance to the Quality Management System.
The passage from the Quality Management System to the Total Quality Management (TQM) is currently realized by a very restricted number of enterprises, due to its difficulties and risks.

The three quality models (ISO 9001, ISO 9004 and TQM linked to the prizes) follow three different concepts:
1) ISO 9001:2000 can be defined a “contractual” model, necessary to have a QMS conforming to the minimum essential requirements – of conformity and effectiveness – requested by the System.
2) ISO 9004:2000, consistent and complementary with ISO 9001, has the scope to improve the organization’s performance, in order to satisfy all the interested parties (stakeholders). Therefore, unlike ISO 9001, ISO 9004 includes the comparison with the competitors and the development of the human resources; it is interested in the development of the company and not only to the customer’s satisfaction. The priority emphasis is on the improvement.
3) The third logic of TQM is addressed to Excellence, to the top performances and measures the distance from the top; therefore, this model includes the measurement of the results more stringently than ISO 9001 and 9004.
   It requires some other features like Leadership, strategies, innovation and organization learning.

A main criticism addressed to the old approach of “regulated quality” was its static nature, and the consequent flattening to the minimum level of threshold, as well as the low integration capacity with other quality standards.
The recent issue of ISO 2000 has modified the old approach, becoming a dynamic (evolutionary) system; the continual improvement is a concept embracing the similar requirements of other management systems (Environment ISO 14000, Safety Ohas 18000, Social responsibility Sa 8000, etc.).

All these systems are based on the above mentioned PDCA Deming Circle, on the Management responsibility, the improvement plans, the measurement of the process effectiveness, the organization and awareness of trained, conscious and competent personnel, the transparency and communication with the stakeholders.
The concepts of dynamic system and continual improvement are changing the organizations management, opening the time of the “rating” for the enterprises: the possibility of self-evaluation and to be evaluated, according to a mark scale, able to clarify your own position among similar organizations.
This does not mean to enter into a competition to gain a prize, but to acquire a full self-consciousness of our own capabilities, both in terms of absolute value and compared with other competitors.

From this first measurement it is possible to proceed towards the Excellence, investing in human and material resources, individuating where an intervention can result more effective, and then measuring the effects of such an intervention.

The knowledge of our own trend and the comparison with the competitors, in accordance with appropriate benchmarks, can trigger a competitive process with consequent, conscious management choices.

In this process, communication remains essential: both internally to motivate your own personnel and externally with all the stakeholders.

A different approach is now definitely consolidated also about costs: we moved from the “cost of quality” to “cost of non-quality” or “cost of low quality” and therefore to the concept of return of the investment for quality.

Quality is considered as “prevention” and prevention rewards!

The document ISO/Tr 10014 is addressed to the Economy of quality (not only the costs); it considers both the internal aspects (costs) and external (customer satisfaction and customer loyalty).
BENCHMARKING

During the examination of the route of quality, we have already mentioned the practices of evaluation and comparison of the internal processes effectiveness with appropriate benchmarks, in order to improve our performances. We think opportune therefore to give only some basic concepts about the Benchmarking as instrument of quality improvement. For a further close examination of this subject you can find comprehensive manuals in all the languages.

The discipline of Benchmarking has a fundamental importance for the development of the Quality Management and of the Total Quality Management, both as instrument for the continual improvement and as management technique able to define the strategic positioning of our organisation. The benchmarking concept was originally developed for the industrial enterprises. Afterwards other organisations, such as hospitals or universities, discovered the advantages of benchmarking to improve their processes and systems.

What is the Benchmarking

Benchmarking can be defined as a continuous, systematic process for comparing performances of organizations, functions or processes against the best in the world, aiming not only to match those performance levels, but to exceed them. In other words, benchmarking is a tool for improving performance by learning from best practices and understanding the processes by which they are achieved.

An accepted definition of benchmarking is the following: Benchmarking is a systematic and continuous process of measurement; it measures the processes of an enterprise and compare them with those of the world leader enterprises, in order to get information and data, useful for our performance improvement.

Benchmarking provides the opportunity to involve the whole organization in the improvement of the company’s processes. It is a pragmatic approach directed to acquire from other organizations new information about some operating processes, to be then applied to our organization. Benchmarking allows to analyse and improve key business processes, eliminate waste, improve performance, profitability and market share. Benchmarking’s strength is that it allows management decisions based on facts, not only on intuition. Modern benchmarking tools allow visual representation of results. A company can now see its score place, in relation to a national, sectoral or European comparison of enterprises.

It is crazy to expect improved results if you continue to make things in the same way! Key words in benchmarking are: comparison, learning, transfer and improvement. Benchmarking is a process with the objective of improvement by learning from others. We would however recall the fundamental Deming’s recommendation: Adapt, do not adopt!

Benchmarking is therefore a quality instrument to improve company’s processes and competitiveness, adapting or adopting the best practices of the leading enterprises. Benchmarking is more than just a comparison of figures, more than the specification of target values; it is an activity of anticipating and learning rather than checking results of calculations.
Therefore benchmarking is related not only to the figures, it is applicable to the manufacturing processes, to procurement or administrative procedures and thus it goes definitively beyond the tasks of the controllers.

Results of Benchmarking

We emphasized how benchmarking is a management tool for supporting management strategies. Main target is the improvement of competitiveness through identification and adaptation of best practice at process, organisation and management level.

A benchmarking procedure involves four main steps:
1) Understanding the company processes in details.
2) Analysis of the processes of other companies
3) Comparison of the own performance with that of the others.
4) Implementation of the measures necessary to close the performance gap.

The results of the benchmarking are of two types:
a) Benchmark : it measures the excellence of the process performance to be taken as model.
b) Enabler : it identifies the practices, which have been able to produce the excellent performance. These enablers are the key of the performance improvement for the enterprise carrying out the benchmarking; they are the real objective of a benchmarking study.

Benchmarking could be defined a quality science. The basis of the benchmarking success are the acquisition and the correct application of the quality practices, combined with a continuous deepening and close examination of the acquired knowledge. Therefore benchmarking is management practice allowing a continual acquisition of new information: it is a systematic and continuous measurement process.

Principles of Benchmarking

The main principles of benchmarking are:
1) Reciprocity
Benchmarking is a practice based on the mutual relationships, on sharing and exchange of information. In such a situation both the parties become winning.
In a benchmarking alliance, each partner wants guarantees about the intentions of the other party. When looking for a benchmarking partner, an enterprise must be aware that the operation success will be jeopardized if your potential partner has the doubt that he has nothing to gain. Mistrust produces a flop of the project.
2) Analogy
The model of a benchmarking project must be a partner with similar characteristics and problems. Analogy for a comparison can be of different type: industrial sector, turnover, personnel, geographic position, or a combination of such factors.
3) Exchange
Benchmarking is always a “do ut des”. It is essential that all the partners are sure to receive a compensation of their investments, in terms of time for study. Be clear about the type of information that you do not want to share.
3) Secrecy
All the data must be treated as absolutely confidential, not to be disclosed to other parties without a previous approval of the partner.
Development of a Benchmarking Project

The development of a benchmarking project can be distinguished in two stages: Diagnostic benchmarking and Process benchmarking.

**Diagnostic benchmarking**
It answers to the question: *WHAT* result does my benchmarking partner (or the best-in-class) achieve?
This is a first approach, providing a simple introduction to benchmarking. It gives structured and cost-effective feedback, requiring only a minimum of resources. It enables companies to:
- improve their performances, by identifying critical competencies, strengths and weaknesses;
- then to learn the best practices to achieve the necessary improvements.

In this phase of short duration analysis, the company explores the performance of different functions of the business; a questionnaire asks a manager to rate against a set of business criteria. In a second stage, the totality of the business is examined, to identify key areas for improvement.

This stage examines all the areas of the business, looking at systems and processes and providing qualitative and quantitative information, based on trends and ratios.

**Process benchmarking**
It answers to the question: *HOW* does my benchmarking partner (or the best-in-class) achieve the results?
After a first diagnosis, Process Benchmarking (conducted by a project team) helps a company to find innovative solutions, providing the means to transfer them into the business.
It can promote a learning culture in which knowledge is shared.
The first step specify the process (or interconnected processes) to be studied.
Afterwards a benchmarking partner (with a superior performance in this process) is identified.
In this way it is possible to evaluate the performance gap and to understand its causes. On this basis the improvement plan can be implemented.

Diagnostic and Process benchmarking are not completely independent, their effects and connections often efface the border.

**Benchmarking and SMEs**

Benchmarking is a management process, to promote the continuous improvement of the enterprises, developed at beginning of the 70’s, after the success achieved by Xerox and other big organisations. However, after the recent, big development of the information technologies and the specialized data banks, these instruments have been extended also to the SMEs.

Of course the SMEs can meet several difficulties, when approaching the benchmarking methods, due to:
- Length of projects (about 9-12 months);
- Considerable costs involved vs. the limited financial possibilities of the SMEs;
- Personnel to be involved for the whole duration of the project vs. the limited staff capacities of the SMEs;
- Costly and long search of the partner;
- Lack of benchmarking know-how.
In addition to such difficulties, SMEs can meet some additional general problems such as:
- mental barriers,
- lack of trust to transfer own data,
- lack of management support,
- high competitive pressure,
- availability of data

A mental barrier can be the sharing of specific company data with potential competitors, if benchmarking partner is active in the same industry.
Also in case of cross-industry benchmarking (i.e. not with a direct competitor), the entrepreneur has to overcome a barrier, we could define “traditional”.
Another major problem met by the SMEs in the implementation of this important management tool is the recruitment of a benchmarking partner, willing to share their know-how with another similar company.
This problem can be solved only joining a network and its databank, to share data and information.

In spite of all these difficulties, benchmarking is a management tool very suitable for SMEs, since they have the potential to improve the performance of their processes.
The processes in SMEs are more transparent than in large enterprises; their structures are clearer and less complicated; therefore SMEs are more flexible and adaptable than large organizations.
This facilitates a fast introduction of best practices.
Of course a SME can start the examination of its performances, promoting the benchmarking process also for a single key company department, where more problems and weaknesses have been registered. This approach, step by step, can help to save time and money.

To achieve a better acceptance by normally reluctant managers and staff officers, benchmarking should be implemented for designing the future more than for analysing or solving past problems. Benchmarking is not a final process, but an effective trigger of a comprehensive process of change. Another major recommendation, in the preparation of a benchmarking project, is the exhaustive information to all employees about the project, its organization and aims, from the outset.

The European organizations give a big importance to the role of benchmarking, to increase the competitiveness of the SMEs, and its capacity to transform information into knowledge. Therefore they are trying to create the favourable conditions where the economic actors can profit from opportunities arising from the current rapid changes.
Benchmarking can play an important role, providing the tools for identifying and learning the world wide best practices; this can accelerate the rate of response to the mentioned changes of the market conditions.

The SMEs Organizations are called to play an important role, to support their members to solve the major problems connected with in this implementation; several projects have already been launched to create a network (and relevant database) of Benchmarking Centres for the SMEs, located in each European countries and connected to a head centre through a web site.
These projects allow to compare the participant enterprises on over 80 performance indicators. The primary objective of these projects is to compare the performances of thousands SMEs and to monitor, every year, the occurred changes in the performance of each enterprise.
NORMAPME can provide an effective support to the SMEs Associations, in the selection of reliable benchmarking centres in Europe.
TOTAL QUALITY MANAGEMENT (TQM)

We would introduce now some of the main concepts of the Total Quality Management, already mentioned in this Training Tool, in order to clarify its logic sequence and its connections with the Quality Management System.

We can start from the two main passages of the quality’s route:
- From the Product Quality to the Quality Management System.
- From Q-Assurance to Q-Management to Total Quality Management (TQM).

We have examined the changes introduced by ISO 9000:2000, which has concluded the passage from the Q-Assurance to Q-Management, already started with the 9000:1994.
We have clarified that ISO 9004:2000 is a guideline for the performance improvement; it takes into consideration all the interested parties (stakeholders) and drives definitively towards the TQM.
The different logics, inspiring the three basic models ISO 9001, ISO 9004 and TQM, have been summarized as follows:
- ISO 9001 is a contractual Quality Management System, looking at the conformity to the essential requirements specified by the system.
- ISO 9004, consistent and complementary with ISO 9001, is looking at the improvement of the organisation’s performances, in the interest of all the stakeholders.
- TQM is aimed at excellence, at top performances, and measures the distance from the best ones.

As already mentioned, the finale passage to TQM is more difficult than the previous ones and the differences among different organisations become more considerable. Therefore the passage from the Quality Management to TQM is operated by a limited number of enterprises.

The main objective of the TQM is the satisfaction of the customer and all the stakeholders.
This objective is achieved by the maximum rationalisation of all internal resources, reached with a continual improvement of efficiency and effectiveness of the organisation and its processes.
The activities of quality control and quality assurance are not neglected; however they are included in a wider approach, as management tools.
A great emphasis is given to the capacity of satisfying the customers, overcoming the competitors’ performances in order to acquire new market shares.

We can say that TQM is more “management quality” than “quality management”!
Its peculiarities are:
- Involves all stakeholders,
- Is a process system,
- Seeks for continuous improvement,
- Considers quality with a global point of view.

Origin of TQM

Before the 80’s, the Japanese industry had carried out a successful offensive on the international markets, based on the quality of the products and their lower cost, consequent to the quality of their processes.
The first reaction came from the American industry, which tried to understand the roots of the Japanese competitive advantage through many analysis and visits to Japan of managers and entrepreneurs. They appreciated the importance of the Prize for quality, Deming Application Prize (DAP), established in Japan in 1951, to reward the enterprises able to reach a top quality level.

In 1987, an USA Public Law established the Malcolm Baldrige National Quality Award (MBNQA), in order to try to improve both productivity and competitiveness of the American enterprises. The winners were obliged to share and disseminate the best practices, through which they had arrived to excellence. The basic strategy of the prize awards was:

- to create "national champions", models for the roles;
- to stimulate a spirit of emulation;
- to disseminate the TQM culture.

Please note that in the same year (1987) ISO 9000 published their model of “external” Quality Assurance, finalized to the conformity’s audit and control.
The concepts introduced by Malcolm Baldrige, for the evaluation of the results, were effectiveness, customer satisfaction and continual improvement of the capacity to acquire and keep the customers. It is evident that the MBNQA represented a significant improvement, if compared with the old and static quality approach of ISO, left only in 1994 and concluded only with ISO Vision 2000.

Europe followed the American example in 1988; 14 leading European enterprises established the European Foundation for the Quality Management (EFQM), to promote the competitiveness through the TQM. The result was the establishment of the European Quality Award (EQA). In 1998 EFQM issued the improved version of their Model for Excellence, becoming a “measurement standard” for the evaluation of the excellence level.

An important consequence of the MBNQA was the growing up of the “self-assessment”. Only a restricted number of enterprises was participating to the Prize Award; however a large number of companies used the Malcolm Baldrige model for a self evaluation, to understand their position when compared with excellence. The concept of self-assessment can be defined as follows: a comprehensive evaluation of the organisation, performed by the organisation itself, for own internal purposes.

TQM Principles

The two different approaches to the quality can be identified as follows:
- Quality Management Systems: represented mainly by the ISO 9000 family of standards.
- Total Quality Management: represented by Excellence Prizes, like the Deming Prize and the Malcolm Baldrige Award.

The principles for excellence, according to the Malcolm Baldrige assessment, cover seven key areas, with different scores:
1) Leadership 12,5%
2) Strategic planning 8,5%
3) Customer and market focus 8,5%
4) Information and its analysis 8,5%
5) Human resources focus 8,5%
6) Process management 8,5%
7) Business results 45%
Organisations must submit details showing their achievements and improvements in the above key areas.

For a comprehensive understanding of the TQM, it is opportune to list the 14 Deming points:

1) Keep the course of your mission constantly improving the products and the services.
2) Adopt the new philosophy of management and lead the change of a firm hand.
3) Do in a manner that the product quality asks for only a minimum of controls. Integrate quality from the design.
4) Give up the low price purchase rule. Rather seek to reduce the total cost. Reduce to a minimum the number of suppliers per article, by establishing with them long-term relations of honesty and confidence.
5) Constantly improve all processes of planning, production and service, which will involve a reduction of costs.
6) Institute a continuing education for all the personnel of the company.
7) Institute a modern form of authority (leadership), having for goal to facilitate the work of the men and machines.
8) Make fear disappear, so that everyone can contribute to the success of the company.
9) Reverse the barriers between services. The team work will avoid problems which can appear during the development and the product use.
10) Remove exhortations, slogans and objectives which require from the employees to reach the “zero defect” and to increase the productivity.
11) Remove quotas of production, the method known as “management by objectives” (DPO) and any form of management by figures.
12) Remove obstacles which prevent the employees, the engineers and the executives from being proud of their work.
13) Institute a vigorous program of education and personal improvement.
14) Make work all forces of the company to achieve the transformation.

Implementation of the TQM

The basic precondition for the TQM’s implementation is the Top management involvement.

The 8 major stages for such a implementation are:
- Auditing the existing situation
- Ranking priorities
- Programming TQM
- Developing TQM
- Planning & executing first period actions
- Evaluating performance and feedback on the first period actions
- Improvement and eventual re-focusing
- Generalizing

The reasons for the implementation of TQM can be summarized as follows:
- Logical achievement of a worldwide evolution
- Diversity of application systems according to the organisation type
- TQM aims are to integrate subsystems
Two goals of TQM are:
- Correction: abolishing the negative impacts of independent subsystem organisations.
- Improvement: management systems should be improved to achieve continual improvement of the organisation.

The difficulties connected with the implementation of the TQM in the SMEs require a strong support of the national and sectoral associations; therefore these organisations should organise an internal sector able to give an effective service in this field to their members, with the assistance of external experts.
New initiatives of ISO/TC 176 aim to grow the gap between the large and small enterprises, awarding prizes for Quality excellence: Deming, Baldrige prize, etc.

NORMAPME can counter this trend and aims, with the support of CEN and the Commission, to promote an own level of Excellence for the SMEs. However the SMEs and their Associations, with the support of NORMAPME, must act to reduce the gap in Quality Systems by setting up such systems in-house, by using training seminars, and improving the assistance services provided to their members.