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ПРОФЕССИОНАЛЬНЫЙ АНГЛИЙСКИЙ ЯЗЫК
Часть 4. Система и стандарты ISO

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Part 4. The ISO system and ISO standards

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Lesson 4-1. Overview of the ISO system.

1. Why standards matter? What if standards did not exist?

If there were no standards, we would soon notice. Standards make an enormous contribution to most aspects of our lives - although very often, that contribution is invisible. It is when there is an absence of standards that their importance is brought home. For example, as purchasers or users of products, we soon notice when they turn out to be of poor quality, do not fit, are incompatible with equipment we already have, are unreliable or dangerous. When products meet our expectations, we tend to take this for granted. 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.

ISO (International Organization for Standardization) is the world's largest developer of standards. Although ISO's principal activity is the development of technical standards, ISO standards also have important economic and social repercussions. ISO standards make a positive difference, not just to engineers and manufacturers for whom they solve basic problems in production and distribution, but to society as a whole.

The International Standards which ISO develops are very useful. They are useful to industrial and business organizations of all types, to governments and other regulatory bodies, to trade officials, to conformity assessment professionals, to suppliers and customers of products and services in both public and private sectors, and, ultimately, to people in general in their roles as consumers and end users.

ISO standards contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer. They provide governments with a technical base for health, safety and environmental legislation. They aid in transferring technology to developing countries. ISO standards also serve to safeguard consumers, and users in general, of products and services - as well as to make their lives simpler.

When things go well - for example, when systems, machinery and devices work well and safely - then it is because they conform to standards. And the organization responsible for many thousands of the standards which benefit society worldwide is ISO.

The ISO Strategic Plan 2005-2010 outlines the global vision of the Organization in 2010, together with the seven strategic objectives set out to meet the expectations of the ISO members and stakeholders.

2. Who ISO is?

ISO is a network of the national standards institutes of 156 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organization: its members are not, as is the case in the United Nations system, delegations of national governments. Nevertheless, ISO occupies a special position between the public and private sectors. This is because, on the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by



their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.

Therefore, ISO is able to act as a bridging organization in which a consensus can be reached on solutions that meet both the requirements of business and the broader needs of society, such as the needs of stakeholder groups like consumers and users.

3. What ISO's name means?

Because "International Organization for Standardization" would have different abbreviations in different languages ("IOS" in English, "OIN" in French for *Organisation internationale de normalisation*), it was decided at the outset to use a word derived from the Greek isos, meaning "equal". Therefore, whatever the country, whatever the language, the short form of the organization's name is always ISO.

4. How it all started?

International standardization began in the electrotechnical field: the International Electrotechnical Commission (IEC) was established in 1906. Pioneering work in other fields was carried out by the International Federation of the National Standardizing Associations (ISA), which was set up in 1926. The emphasis within ISA was laid heavily on mechanical engineering. ISA's activities came to an end in 1942. In 1946, delegates from 25 countries met in London and decided to create a new international organization, of which the object would be "to facilitate the international coordination and unification of industrial standards". The new organization, ISO, officially began operations on 23 February 1947.

5. What “international standardization” means?

When the large majority of products or services in a particular business or industry sector conform to International Standards, a state of industry-wide standardization can be said to exist. This is achieved through consensus agreements between national delegations representing all the economic stakeholders concerned - suppliers, users, government regulators and other interest groups, such as consumers. They agree on specifications and criteria to be applied consistently in the classification of materials, in the manufacture and supply of products, in testing and analysis, in terminology and in the provision of services. In this way, International Standards provide a reference framework, or a common technological language, between suppliers and their customers - which facilitates trade and the transfer of technology.

6. How ISO standards benefit society?

For businesses, the widespread adoption of International Standards means that suppliers can base the development of their products and services on specifications that have wide acceptance in their sectors. This, in turn, means that businesses using International Standards are increasingly free to compete on many more markets around the world.



For customers, the worldwide compatibility of technology which is achieved when products and services are based on International Standards brings them an increasingly wide choice of offers, and they also benefit from the effects of competition among suppliers.

For governments, International Standards provide the technological and scientific bases underpinning health, safety and environmental legislation.

For trade officials negotiating the emergence of regional and global markets, International Standards create "a level playing field" for all competitors on those markets. The existence of divergent national or regional standards can create technical barriers to trade, even when there is political agreement to do away with restrictive import quotas and the like. International Standards are the technical means by which political trade agreements can be put into practice.

For developing countries, International Standards that represent an international consensus on the state of the art constitute an important source of technological know-how. By defining the characteristics that products and services will be expected to meet on export markets, International Standards give developing countries a basis for making the right decisions when investing their scarce resources and thus avoid squandering them.

For consumers, conformity of products and services to International Standards provides assurance about their quality, safety and reliability.

For everyone, International Standards can contribute to the quality of life in general by ensuring that the transport, machinery and tools we use are safe.

For the planet we inhabit, International Standards on air, water and soil quality, and on emissions of gases and radiation, can contribute to efforts to preserve the environment.

7. The hallmarks of the ISO brand.

Equal footing. Every participating ISO member institute (full members) has the right to take part in the development of any standard which it judges to be important to its country's economy. No matter what the size or strength of that economy, each participating member in ISO has one vote. ISO's activities are thus carried out in a democratic framework where each country is on an equal footing to influence the direction of ISO's work at the strategic level, as well as the technical content of its individual standards.

Voluntary. ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce their implementation. A certain percentage of ISO standards - mainly those concerned with health, safety or the environment - has been adopted in some countries as part of their regulatory framework, or is referred to in legislation for which it serves as the technical basis. Such adoptions are sovereign decisions by the regulatory authorities or governments of the countries concerned; ISO itself does not regulate or legislate. However, although ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9000 quality management systems, or of dimensions of freight containers and bank cards.

Market-driven. ISO develops only those standards for which there is a market requirement. The work is carried out by experts from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use. These

experts may be joined by others with relevant knowledge, such as representatives of government agencies, consumer organizations, academia and testing laboratories.


Consensus. Although ISO standards are voluntary, the fact that they are developed in response to market demand, and are based on consensus among the interested parties, ensures widespread applicability of the standards. Consensus, like technology, evolves and ISO takes account both of evolving technology and of evolving interests by requiring a review of its standards at least every five years to decide whether they should be maintained, updated or withdrawn. In this way, ISO standards retain their position as the state of the art, as agreed by an international cross-section of experts in the field.

Worldwide. ISO standards are technical agreements which provide the framework for compatible technology worldwide. Developing technical consensus on this international scale is a major operation. In all, there are some 3 000 ISO technical groups (technical committees, subcommittees, working groups etc.) in which some 50 000 experts participate annually to develop ISO standards.

ISO and world trade. ISO - together with IEC (International Electrotechnical Commission) and ITU (International Telecommunication Union) - has built a strategic partnership with the WTO (World Trade Organization) with the common goal of promoting a free and fair global trading system. The political agreements reached within the framework of the WTO require underpinning by technical agreements. ISO, IEC and ITU, as the three principal organizations in international standardization, have the complementary scopes, the framework, the expertise and the experience to provide this technical support for the growth of the global market. The WTO's Agreement on Technical Barriers to Trade (TBT) includes the Code of Good Practice for the Preparation, Adoption and Application of Standards. The TBT Agreement recognizes the important contribution that International Standards and conformity assessment systems can make to improving efficiency of production and facilitating international trade. Therefore, where International Standards exist or their completion is imminent, the Code states that standardizing bodies should use them as a basis for standards they develop. The Code requires that standardizing bodies that have accepted its terms notify this fact to the ISO/IEC Information Centre located at the ISO Central Secretariat. Standardizing bodies having accepted the Code must publish their work programmes and also notify the existence of their work programmes to the ISO/IEC Information Centre. On behalf of the WTO, ISO periodically publishes a Directory of standardizing bodies that have accepted the WTO TBT Standards Code.

ISO and developing countries. ISO standards represent a reservoir of technology. Developing countries in particular, with their scarce resources, stand to gain from this wealth of knowledge. For them, ISO standards are an important means both of acquiring technological know-how that is backed by international consensus as the state of the art, and of raising their capability to export and compete on global markets. The whole spectrum of ISO's activities in favor of developing countries is encompassed in the *ISO Action Plan for developing countries 2005-2010*. ISO has a policy committee on developing country matters, DEVCO, with a membership of nearly 117 standards institutes from both industrialized and developing countries.

8. How to recognize an ISO standard?



An ISO standard can be anything from a four-page document to one several hundred pages' long and, in the future, will increasingly be available in electronic form. It carries the ISO logo and the designation, "International Standard". In most cases, it is published in A4 format - which is itself one of the ISO standard paper sizes.

Between 1947 and the present day, ISO published more than 15 000 International Standards. ISO's work program ranges from standards for traditional activities, such as agriculture and construction, through mechanical engineering, to medical devices, to the newest information technology developments, such as the digital coding of audio-visual signals for multimedia applications.

Standardization of screw threads helps to keep chairs, children's bicycles and aircraft together and solves the repair and maintenance problems caused by a lack of standardization that were once a major headache for manufacturers and product users. Standards establishing an international consensus on terminology make technology transfer easier and can represent an important stage in the advancement of new technologies.

Without the standardized dimensions of freight containers, international trade would be slower and more expensive. Without the standardization of telephone and banking cards, life would be more complicated. A lack of standardization may even affect the quality of life itself: for the disabled, for example, when they are barred access to consumer products, public transport and buildings because the dimensions of wheel-chairs and entrances are not standardized.

Standardized symbols provide danger warnings and information across linguistic frontiers. Consensus on grades of various materials give a common reference for suppliers and clients in business dealings.

Agreement on a sufficient number of variations of a product to meet most current applications allows economies of scale with cost benefits for both producers and consumers. An example is the standardization of paper sizes.

Standardization of performance or safety requirements of diverse equipment makes sure that users' needs are met while allowing individual manufacturers the freedom to design their own solution on how to meet those needs.

Standardized protocols allow computers from different vendors to "talk" to each other. Standardized documents speed up the transit of goods, or identify sensitive or dangerous cargoes that may be handled by people speaking different languages. Standardization of connections and interfaces of all types ensures the compatibility of equipment of diverse origins and the interoperability of different technologies.

Agreement on test methods allows meaningful comparisons of products, or plays an important part in controlling pollution - whether by noise, vibration or emissions. Safety standards for machinery protect people at work, at play, at sea... and at the dentist's.

Without the international agreement contained in ISO standards on quantities and units, shopping and trade would be haphazard, science would be - unscientific - and technological development would be handicapped.

More than half a million organizations in more 149 countries are implementing ISO 9000 which provides a framework for quality management throughout the processes of producing and delivering products and services for the customer.

ISO 14000 environmental management systems are helping organizations of all types to improve their environmental performance at the same time as making a positive impact on business results.

9. What makes ISO 9000 and ISO 14000 so special?

The ISO 9000 and ISO 14000 families are among ISO's most widely known standards ever. ISO 9000 has become an international reference for quality requirements in business to business dealings, and ISO 14000 looks set to achieve at least as much, if not more, in helping organizations to meet their environmental challenges.

The vast majority of ISO standards are highly specific to a particular product, material, or process. However, the standards that have earned the ISO 9000 and ISO 14000 families a worldwide reputation are known as "generic management system standards". "Generic" means that the same standards can be applied to any organization, large or small, whatever its product - including whether its "product" is actually a service - in any sector of activity, and whether it is a business enterprise, a public administration, or a government department. "Management system" refers to what the organization does to manage its processes, or activities. "Generic" also signifies that no matter what the organization is or does, if it wants to establish a quality management system or an environmental management system, then such a system has a number of essential features which are spelled out in the relevant standards of the ISO 9000 or ISO 14000 families.

ISO 9000 is concerned with "quality management". This means what the organization does to enhance customer satisfaction by meeting customer and applicable regulatory requirements and continually to improve its performance in this regard. ISO 14000 is primarily concerned with "environmental management". This means what the organization does to minimize harmful effects on the environment caused by its activities, and continually to improve its environmental performance.

10. What makes conformity assessment so important?

At its simplest, "conformity assessment" means checking that products, materials, services, systems or people measure up to the specifications of a relevant standard. Today, many products require testing for conformance with specifications or compliance with safety, or other regulations before they can be put on many markets. Even simpler products may require supporting technical documentation that includes test data. With so much trade taking place across borders, conformity assessment has become an important component of the world economy. Over the years, ISO has developed many of the standards against which products are assessed for conformity, as well as the standardized test methods that allow the meaningful comparison of test results so necessary for international trade. ISO itself does not carry out conformity assessment. However, in partnership with IEC (International Electrotechnical Commission), ISO develops ISO/IEC guides and standards to be used by organizations which carry out conformity assessment activities. The voluntary criteria contained in these guides and standards represent an international consensus on what constitutes best practice. Their use



contributes to the consistency and coherence of conformity assessment worldwide and so facilitates trade across borders.

11. Where to find information on standards?

ISO's entire portfolio of standards is listed in the ISO Catalogue which can be accessed online. The site also provides access to the World Standards Services Network (WSSN) which is a network of publicly accessible Web servers of standards organizations around the world. Through these Web site, WSSN provides information on international, regional and national standardization and related activities and services.

In fact, there are several hundred thousand standards and technical regulations in the world containing special requirements for a particular country or region. Finding information about these, or about related conformity assessment activities, can be a heavy task. ISONET, the ISO Information Network, can ease the problem. This is a worldwide network of national standards information centers which have cooperatively developed a system to provide rapid access to information about standards, technical regulations, and testing and conformity assessment activities in operation around the world. The World Trade Organization's Agreement on Technical Barriers to Trade (WTO/TBT) calls upon its signatory countries to establish a national enquiry point to answer questions on these same areas in relation to that country. In many countries, the ISONET and WTO enquiry points are one and the same.


12. Who can join ISO?

Membership of ISO is open to national standards institutes most representative of standardization in their country (one member in each country). Full members, known as "Member bodies", each have one vote, whatever the size or strength of the economy of the country concerned. In addition, ISO has two categories of membership for countries which do not yet have a fully developed national standards activity. They pay reduced membership fees. "Correspondent members" are entitled to participate in any policy or technical body as observers, with no voting rights. "Subscriber members" are institutes from countries with very small economies that nevertheless wish to maintain contact with international standardization.

Although individuals or enterprises are not eligible for membership, both have a range of opportunities for taking part in ISO's work, or in contributing to the development of standards through the ISO member in their country. Individuals may be selected by member institutes to serve on national delegations participating in ISO technical committees, or may provide their input during the process of developing a national consensus for presentation by the delegation. International organizations and associations, both non-governmental and representing industry sectors, can apply for liaison status to a technical committee. They do not vote, but can participate in the debates and the development of consensus.

13. How the ISO system is managed?

All strategic decisions are referred to the ISO members, who meet for an annual General Assembly. The proposals put to the members are developed by the ISO Council, drawn from the membership as a whole, which resembles the board of directors of a business organization. ISO



Council meets two times a year and its membership is rotated to ensure that it is representative of ISO's membership. Operations are managed by a Secretary-General, which is a permanent appointment. The Secretary-General reports to the ISO Council, the latter being chaired by the President who is a prominent figure in standardization or in business, elected for two years. The Secretary-General is based at ISO Central Secretariat in Geneva, Switzerland, with a compact staff which provides administrative and technical support to the ISO members, coordinates the decentralized standards' development program, and publishes the output.

14. How the ISO system is financed?

ISO's national members pay subscriptions that meet the operational cost of ISO's Central Secretariat. The subscription paid by each member is in proportion to the country's Gross National Income and trade figures. Another source of revenue is the sale of standards. However, the operations of ISO Central Secretariat represent only about one fifth of the cost of the system's operation. The main costs are borne by the member bodies which manage the specific standards' development projects and the business organizations which provide experts to participate in the technical work. These organizations are, in effect, subsidizing the technical work by paying the travel costs of the experts and allowing them time to work on their ISO assignments.


15. How ISO decides what standards to develop?

Working through the ISO system, it is the sectors which need the standards that are at the origin of their development. What happens is that the need for a standard is felt by an industry or business sector which communicates the requirement to one of ISO's national members. The latter then proposes the new work item to ISO as a whole. If accepted, the work item is assigned to an existing technical committee. Proposals may also be made to set up technical committees to cover new scopes of activity. In order to use resources most efficiently, ISO only launches the development of new standards for which there is clearly a market requirement.

The focus of the technical committees is necessarily specialized and specific. In addition, ISO has three general policy development committees and their job is to provide strategic guidance for the standards' development work on cross-sectoral aspects. They are: CASCO (conformity assessment); COPOLCO (consumer policy), and DEVCO (developing country matters). These committees help to ensure that the specific technical work is aligned with broader market and stakeholder group interests.

16. Who develops ISO standards?

ISO standards are developed by technical committees comprising experts from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations, environmentalists, academic circles and so on. The experts participate as national delegations, chosen by the ISO national member institute for the country concerned. These delegations are required to represent not just the views of the organizations in which their participating experts work, but of other stakeholders too. According to ISO rules, the member institute is expected to



take account of the views of the range of parties interested in the standard under development and to present a consolidated, national consensus position to the technical committee.

17. How ISO standards are developed?

The national delegations of experts of a technical committee meet to discuss, debate and argue until they reach consensus on a draft agreement. This is then circulated as a Draft International Standard (DIS) to ISO's membership as a whole for comment and balloting. Many members have public review procedures for making draft standards known and available to interested parties and to the general public. The ISO members then take account of any feedback they receive in formulating their position on the draft standard. If the voting is in favor, the document, with eventual modifications, is circulated to the ISO members as a Final Draft International Standard (FDIS). If that vote is positive, the document is then published as an International Standard.

Every working day of the year, an average of ten ISO meetings are taking place somewhere in the world. In between meetings, the experts continue the standards' development work by correspondence. Increasingly, their contacts are made by electronic means and some ISO technical bodies have already gone over entirely to electronic working, which speeds up the development of standards and reduces travel costs.


18. When speed is of the essence?

ISO standards are developed according to strict rules to ensure that they are transparent and fair. The reverse side of the coin is that it can take time to develop consensus among the interested parties and for the resulting agreement to go through the public review process in the ISO member countries. For some users of standards, particularly those working in fast-changing technology sectors, it may be more important to agree on a technical specification and publish it quickly, before going through the various checks and balances needed to win the status of a full International Standard. Therefore, to meet such needs, ISO has developed a new range of "deliverables", or different categories of specifications, allowing publication at an intermediate stage of development before full consensus: Publicly Available Specification (PAS), Technical Specification (TS), Technical Report (TR), International Workshop Agreement (IWA).

19. ISO's international partners.

ISO collaborates with its partners in international standardization, the IEC (International Electrotechnical Commission) and ITU (International Telecommunication Union). The three organizations, all based in Geneva, Switzerland have formed the World Standards Cooperation in order to better coordinate their activities, as well as the implementation of International Standards.

ISO is one of the few non-governmental organizations having an observer status in the World Trade Organization. Its contribution is increasingly solicited in relation to the elimination of technical barriers to trade.



ISO collaborates with the United Nations Organization and its specialized agencies and commissions, particularly those involved in the harmonization of regulations and public policies such as:

- CODEX Alimentarius for food safety measurement, management and traceability;
- UN ECE for the use of ISO Standards in relation to the safety of motor vehicles or the transportation of dangerous goods;
- WHO, the World Health Organization for health technologies;
- WMO, the World Maritime Organization, for securing maritime and intermodal transport;
- WTO-T, the World Tourism Organization, for the quality of services related to tourism;

or with those engaged in bringing assistance and support to developing countries such as UNCTAD, UNIDO or the International Trade Centre.

ISO's technical committees have formal liaison relations with some 580 international and regional organizations, which complement this impressive network and which, together with the network of its national members, is key for the global relevance, actual use and recognition of its Standards by the market forces and the general public.

Relations with international groups of stakeholders have also been reinforced. ISO is now an institutional member of the World Economic Forum, has increased its collaboration with NGOs representing societal or professional interests, such as Consumers International, the World Business Council on Sustainable Development or the international Federation of Standards Users (IFAN) and collaborates regularly with the major international organizations involved in metrology, quality and conformity assessment.

20. ISO's regional partners.

Many of ISO's members also belong to regional standardization organizations. This makes it easier for ISO to build bridges with regional standardization activities throughout the world. ISO has recognized regional standards organizations representing Africa, the Arab countries, the area covered by the Commonwealth of Independent States, Europe, Latin America, the Pacific area, and the South-East Asia nations. These recognitions are based on a commitment by the regional bodies to adopt ISO standards - whenever possible without change - as the national standards of their members and to initiate the development of divergent standards only if no appropriate ISO standards are available for direct adoption.

Words and expressions

International Organization for Standardization (ISO),

Economic stakeholders - suppliers, users, government regulators and other interest groups, such as consumers,

Compatibility of technology.

See also Appendix 2 ISO 9000 definitions in the end of the Course book 4.

Home assignment

Read the text and answer the questions:

1. Why do standards matter?
2. How ISO standards benefit society?
3. What makes ISO 9000 and ISO 14000 so special?
4. What makes conformity assessment so important?
5. Where to find information on standards?

Lesson 4-2. Introduction to ISO 9000.

1. What is ISO 9000?

In 1987, the Geneva-based International Organization for Standardization (ISO) published the ISO 9000 series international standards to serve as the basis for a quality management system. It is the descendant of British standard BS-5750. The American equivalent is Q9000.

ISO 9000, which couples a total quality management approach with documentation methodology to create an internal auditing system, is also the first-ever attempt to create an international quality assurance standard to cover all industries and the service sector.

ISO first published its quality standards in 1987, revised them in 1994, and then republished an updated version in 2000. These new standards are referred to as the "ISO 9000 2000 Standards".

The so-called ISO 9000 standard is actually comprised of a series of standards. The three new standards that were released on December 15, 2000 are:

- ISO 9000:2000 Quality Management Systems - Fundamentals and Vocabulary
- ISO 9001:2000 Quality Management Systems - Requirements
- ISO 9004:2000 Quality Management Systems - Guidance for Performance Improvement

ISO 9000:2000 describes underlying concepts and approaches for the new ISO 9000:2000 family, and provides definitions for the vocabulary. ISO 9000 is not a specification, however, it is named in ISO 9001 as a normative reference and thus can be used by auditors to support their interpretation of ISO 9001 requirements - in particular in reference to the vocabulary.

ISO 9001:2000 presents the actual *requirements* for the quality management system, while ISO 9000:2000 and ISO 9004:2000 present *guidelines*. The requirements define the criteria for the quality system. The role of this standard in the series has not changed, but its content and organization are completely revised.

ISO 9004:2000 describes a quality system that goes beyond the basic requirements specified in ISO 9001. It is intended as a guide for organizations that want to further expand and improve the quality system after implementing ISO 9001 (i.e., in the post-certification phases). ISO 9004 is not a requirement and should not be used by third-party auditors for registration audits.

ISO's purpose is to facilitate international trade by providing a single set of standards that people everywhere would recognize and respect. All of these are *process standards* (not product standards).

The ISO 9000:2000 Standards apply to all kinds of organizations in all kinds of areas. Some of these areas include manufacturing, processing, servicing, printing, forestry, electronics, steel, computing, legal services, financial services, accounting, trucking, banking, retailing, drilling, recycling, aerospace, construction, exploration, textiles, pharmaceuticals, oil and gas, pulp and paper, petrochemicals, publishing, shipping, energy, telecommunications, plastics, metals, research, health care, hospitality, utilities, pest control, aviation, machine tools, food processing, agriculture, government, education, recreation, fabrication, sanitation, software development, consumer products, transportation, design, instrumentation, tourism, communications, biotechnology, chemicals, engineering, farming, entertainment, horticulture, consulting, insurance, and so on.

ISO 9001:2000 has replaced the old ISO 9001:1994 standard. In addition, the old ISO 9002:1994 and ISO 9003:1994 quality standards have been discontinued. They are now obsolete. If you are now ISO 9001 certified, you are going to have to update your quality management system in order to meet the new ISO 9001:2000 requirements. And if you are now ISO 9002 or ISO 9003 certified, you are going to have to become ISO 9001:2000 certified.

ISO 9000 is sweeping the world. It is rapidly becoming the most important quality standard. Thousands of companies in over 100 countries have already adopted it, and many more are in the process of doing so. Why? Because it controls quality. It saves money. Customers expect it. And competitors use it.

ISO 9000 applies to all types of organizations. It does not matter what size they are or what they do. It can help both product and service oriented organizations achieve standards of quality that are recognized and respected throughout the world.

ISO is the *International Organization for Standardization*. It is located in Switzerland and was established in 1947 to develop common international standards in many areas. Its members come from over 120 national standards bodies.

2. How does ISO 9000 Work?

Here is how it works. You decide that you need to develop a **quality management system** that meets the new Quality Standard. That is your **mission**. You choose to follow this path because you feel the need to control or improve the quality of your products and services, to reduce the costs associated with poor quality, or to become more competitive. Or, you choose this path simply because your customers expect you to do so or because a governmental body has made it mandatory. You then develop a quality management system that meets the **requirements** specified by **ISO 9001:2000** (ISO 9002 and 9003 have been dropped).

In the course of doing so, you may also wish to consult the ISO 9000:2000 and ISO 9004:2000 **guidelines**. However, please remember that your quality management system must meet ISO's requirements, not its guidelines.

But how do you develop such a quality management system? There are at least two approaches. You can do either a Gap Analysis or follow a detailed **System Development Plan**. If you have already got a quality management system and you are happy with the way it operates, then we suggest that you use a Gap Analysis to upgrade to the new ISO 9001:2000 standard. A Gap Analysis will tell you exactly what you need to do to meet the ISO 9001:2000 Quality Management Standard. It will help you identify the gaps that exist between the new ISO Standard and your organization's processes. Once you know where the gaps are, you can take steps to fill your gaps. By following this incremental approach, you will not only comply with the new ISO 9001 Standard, but you will also improve the overall performance of your organization's processes.

However, if you do not have a quality management system or you are not happy with the one you have got, then we suggest that you use our ISO 9001 2000 Process Oriented Quality Management System Development Plan to develop your quality management

system. If you follow the detailed steps that make up our System Development Plan, you will end up with a quality management system that will meet your needs and ISO's requirements.

Once your quality management system has been fully developed and implemented, you carry out an Internal Audit to ensure that you've met every single ISO 9001:2000 requirement.

When you are ready, you ask a Registrar to audit the effectiveness of your quality management system. If your auditors like what they see, they will certify that your quality system 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 Quality Management System! However, you do not have to be registered. ISO does not require formal registration (certification). 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 quality management system if an independent external auditor says so.

3. Why is ISO 9000 Important?

ISO 9000 is important because of its **orientation**. While the content itself is useful and important, the content alone does not account for its widespread appeal.

ISO 9000 is important because of its **international orientation**. Currently, ISO 9000 is supported by national standards bodies from more than 120 countries. This makes it the logical choice for any organization that does business internationally or that serves customers who demand an international standard of quality.

ISO is also important because of its **systemic orientation**. We think this is crucial. Many people in this field wrongly emphasize motivational and attitudinal factors. The assumption is that quality can only be created if workers are motivated and have the right attitude. This is fine, but it doesn't go far enough. Unless you institutionalize the right attitude by supporting it with the right policies, procedures, records, technologies, resources, and structures, you will never achieve the standards of quality that other organizations seem to be able to achieve. Unless you establish a quality attitude by creating a quality system, you will never achieve a world-class standard of quality.

Simply put, if you want to have a quality attitude you must have a quality system. This is what ISO recognizes, and this is why ISO 9000 is important.

4. ISO 9000:2000 principles.

According to ISO, the new ISO 9000:2000 standards are based on eight quality management principles. ISO chose these principles because they can be used to improve organizational performance and achieve success. but how can you make sure that your organization applies these principles?

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

need to develop and implement an ISO 9001:2000 quality management system that applies the eight principles listed below.

1. **Focus on your customers.** Organizations rely on customers. Therefore:
 - Organizations must understand customer needs.
 - Organizations must meet customer requirements.
 - Organizations must exceed customer expectations.
2. **Provide leadership.** Organizations rely on leaders. Therefore:
 - Leaders must establish a unity of purpose and set the direction the organization should take.
 - Leaders must create an environment that encourages people to achieve the organization's objectives.
3. **Involve your people.** Organizations rely on people. Therefore:
 - Organizations must encourage the involvement of people at all levels.
 - Organizations must help people to develop and use their abilities.
4. **Use a process approach.** Organizations are more efficient and effective when they use a process approach. Therefore:
 - Organizations must use a process approach to manage activities and related resources.
5. **Take a system approach.** Organizations are more efficient and effective when they use a systems approach. Therefore:
 - Organizations must identify interrelated processes and treat them as a system.
 - Organizations must use a systems approach to manage their interrelated processes.
6. **Encourage continual improvement.** Organizations are more efficient and effective when they continually try to improve. Therefore:
 - Organizations must make a permanent commitment to continually improve their overall performance.
7. **Get the facts before you decide.** Organizations perform better when their decisions are based on facts. Therefore:
 - Organizations must base decisions on the analysis of factual information and data.
8. **Work with your suppliers.** Organizations depend on their suppliers to help them create value. Therefore:
 - Organizations must maintain a mutually beneficial relationship with their suppliers.

5. Comparing ISO 9000 and TQM

Although Total Quality Management (TQM) came on the scene first as a method for companies to improve profits and repeat business, complying to the ISO 9000 standards is the first thing a company should consider to improve the way it does business. Questions you may have are:

- Why should ISO 9000 be used first?
- What is the role of using TQM concepts?
- What are the benefits of using the two together?

This lesson will try to answer those questions. There is a mini-quiz at the end of the lesson.

Using ISO 9000 first. ISO 9000 consists of a set of international standards for running a business in an effective manner. These standards require a business to document their plans, specifications, procedures, activities, and such.

Like planning household finances. Using ISO 9000 is analogous to planning your household finances and keeping your records straight for paying your bills and taxes. Keeping your records straight, as recommended in the ISO 9000 standards, is the first step in effectively running a business.

Organizes business. Getting your house in order is the very first thing a company should do in order to run effectively. You must make sure you know where your money and goods are going. You need records for paying your bills and taxes. You need your employees to do consistent work. A business that follows the ISO 9000 standards will usually eliminate wasteful and careless practices that can drain their profits.

Verify following standards. By becoming registered in ISO 9000, a company is verifying that it is fulfilling the general requirements for operating a business in an effective manner. It is also possible for a company to simply comply to the standards, as a business strategy, without formally becoming certified.

TQM enhances good company. On the other hand, TQM is a way of running a business that concentrates on satisfying the customer. Its use will result in repeat and continued business. TQM should usually be started after a business properly documents its activities, as per ISO 9000. Besides satisfying the customer TQM also is concerned with empowering the workers. This will ensure that their skills are effectively used and that they feel they have a stake in the success of the organization.

A final aspect of TQM is the use of statistics to determine the correct areas to make changes and improvements.

Companies use both to their benefit. Companies that have effectively implemented ISO 9000 standards and TQM concepts have dramatically improved their profits and customer retention.

Can be misused. Unfortunately, both of these methods have been misinterpreted and misused by many companies. Some companies have simply paid lip-service to ISO 9000 and schemed to find ways to get around the requirements and to fool the auditors. They see ISO 9000 as an intrusion to the way they prefer to do business, instead of a good method to reduce costs in the long run.

Many companies have used TQM as an excuse to downsize and pressure their workers to produce more for less money. Downsizing was later taken over by the re-engineering movement. Customer satisfaction became more of a buzz-word than a practice.

Proves beneficial. In general, companies that have honestly employed ISO 9000 and/or TQM have been proven to be better run, have fewer problems, have less waste, get more repeat business, and have increased profits. Of course, having a well-run company is not the only thing that results in success. A good product line, effective marketing, and being able to beat out the competition are very important factors. But by employing first ISO 9000 and then TQM methods, a company can get a leg up on its competition.

In conclusion. ISO 9000 standards are concerned with effectively documents the way you run your business, in order to improve your profit margin. TQM concerns customer satisfaction and worker effectiveness, in order to increase business and cut costs. A business should first

follow ISO 9000 standards and then implement TQM practices to improve their profits and customer retention.

6. Reasons a company becomes certified in ISO 9000

ISO 9000 certification or registration can be an expensive process. A company must consider the reasons and promised benefits for going through this process. If a company decides to seek certification, they should consider making sure their suppliers are certified or at least compliant to the ISO 9000 standards. Questions you may have concerning becoming certified are:

- What are some major reasons companies become certified?
- What about our suppliers?
- What is the best reason to follow ISO 9000?

This lesson explains the logical reasons for seeking ISO 9000 certification. The information should help you in guiding your own company's decisions.

- **The major reasons.** In the early 1990s, companies seem to be jumping on the certification bandwagon without seriously considering the rationale for doing so. Often they did so because competitors or "everybody else" is getting registered. Today companies seriously look at the reasons and benefits for becoming registered. The major reasons that company leadership or management decides to seek ISO 9000 certification are to gain continued or increased business and to maintain effective operations.
- **Improved business.** A company can maintain a relationship with customers, as well as get increased business through complying to the ISO 900 standards or becoming certified. This comes from satisfying customer demands, the desire for European business, and to advertise.
- **Customer demands.** The first and most common motivation is when a company's prime customer demands such certification of its suppliers. Companies want to make sure they get parts that fulfill their specifications and that they get what they are paying for. For example, the big three automotive companies require all their suppliers to be certified in QS 9000, the industry equivalent to ISO 9000.
- **European business.** Another reason to become registered in ISO 9000 is that the company feels it will have better access to European markets. Many European companies have agreed only to deal with ISO 9000 registered suppliers to assure quality parts and services. This seemed to be a big factor in the 1990s, but its importance and impact has greatly diminished.
- **Advertising.** Finally, some companies want to become certified, so they can advertise that fact and give the impression of being better than their competitors. You have seen ads with a logo stating the company is certified at some ISO 9000 level. It apparently gives those companies a leg up on competitors not registered. Again, this seemed more important in the 1990s, but you don't see that many companies using ISO 9000 certification as an advertising tool.
- **Improved operations.** By conforming to the ISO 9000 standards, a company can greatly improve their efficiency of operations, provided care is taken not to become too rigid, document too much, or to not apply the standards to completely fit your business.

- **Demand suppliers be certified.** Besides becoming certified in ISO 9000, a company would also want their suppliers to be ISO 9000 registered to make sure those suppliers are run effectively and will be able to deliver goods consistently and reliably. Another reason to have suppliers certified is because the company's customer demands that even the subcontractors follow ISO 9000. This is the case in the automotive industry, mentioned above.

Don't miss the most important reason. These are all valid reasons, but many companies miss out on the most important reason to follow the ISO 9000 standards: **ISO 9000 is supposed to make sure your business is run in an orderly manner that will assure continued success.** One would think that a goal such as being run effectively and able to deliver goods consistently and reliably would also be desirable for a company's own operation. Surprisingly, many companies do not consider that as a goal.

In conclusion. The reasons to become certified in ISO 9000 are that you are required to by your customer, to be able to do business in Europe, to be able to advertise your certification, and to improve your company's operations.

Words and expressions

See the ISO 9000 definitions in the Appendix 2 in the end of the Course book 4.

Home assignment

Read the text and use this mini-quiz to check your understanding.

1. Why should you use ISO 9000 first?

- It helps to organize your business and record-keeping
- It is less expensive than TQM for a beginning business
- Because TQM is obsolete.

2. Why is customer satisfaction important?

- It cuts down time customers spend in the showroom
- It results in repeat and new business
- It is clever advertising.

3. Why would a company misuse ISO 9000 or TQM?

- It is more profitable to cut corners than to jump through hoops
- Anything that gives a profit is acceptable
- Their philosophy of business does not consider long-term results.

If you got all three correct, you are on your way to becoming a champion in using ISO 9000. If you had problems, you had better look over the material again.

Lesson 4-3. ISO 9000 Documents

There are four tiers of documentation recommended for satisfying ISO 9000 requirements. These documents are: the Quality Policy Manual, Procedures, Work Instructions, and Records. Questions you may have include:

- Who needs to know about these documents?
- What are the characteristics of each?
- How do they relate to ISO 9000 compliance?

This lesson will explain these four types of documentation. There is a mini-quiz at the end of the lesson.

Who needs to know? A number of people within a company should be familiar with these documents and their requirements:

- **Upper management.** Since ISO 9000 starts with upper management, they should be aware of what types of documentation is needed to assist in keeping their business well-organized.
- **Head of Quality.** The Head of Quality in a company is often in charge of controlling these documents and specifying the requirements for them, so obviously that person needs to be familiar with what they are about.
- **Technical writers.** The technical writers or others who are assigned to write these documents and manuals need to be fully aware of their significance.
- **Workers.** Finally, the workers who may use the documents as guides, or who may have to fill in records, must know about the ideas behind these ISO 9000 documents, as well as the significance of them to the company and their jobs.

The four tiers of ISO 9000 documentation are the Quality Policy Manual, Procedures, Work Instructions, and Records.

Quality Policy Manual. The Quality Policy Manual (also simply called Quality Manual) is a top-level document that states the company philosophy toward providing quality product and work. It states what you plan to do. Since it states the company philosophy and outlines how the business is to be run, it should be written in direct coordination with top management. Companies that do not have direct involvement of their executive officers in the drafting of the Quality Policy Manual are doomed to failure - least in the proper implementation of ISO 9000.

The Quality Policy Manual usually includes the policy toward each of the ISO 9000 requirements. This goes beyond simply re-stating the requirement. Instead it needs a mission and vision from management. A useful approach toward the Quality Policy Manual is to add the rationale for each policy in the manual. In other words, you should include the reason for a given policy in order to show how it will benefit the company, its operations, and its profits.

Procedures. A Procedure Manual should state how you plan to implement the policies stated in the Quality Policy Manual. It also states who is responsible for each ISO 9000 section. Procedures often involve several departments or work areas within a company. They often outline the work flow between departments, suppliers, and the customer.

Work Instructions. Work Instructions involve the details of how an individual or group is to perform a specific task or job. This is very important to maintain uniformity, as well as to ensure that the job can still be done if a key employee is unavailable.

Records. Record keeping is certainly important to track design, costs, work, and product. The records should be value-added. Some poorly-run companies are careless in keeping records, while others keep unnecessary records.

If a company is well organized, it is less likely to be involved in foolish mistakes or to have dysfunctional areas within the company. Thus there is a great need for some standards of organization. By following the ISO 9000 standards, along with having a good company policy toward quality, procedures that tell what will be done and who will do it, work instructions to assure consistency of operations, and solid record-keeping, a company can enhance its chances for success.

Continual Improvement

In ISO 9000:2000 continual improvement is not a discreet process or element of the quality system, but rather a way of managing the system. The standard requires that opportunities and priorities for improvement of the quality system be identified by comparing the actual quality performance to objectives defined in the quality policy and quality objectives. The actual quality performance is determined by analyzing customer satisfaction information, product and process conformance data, supplier performance data, internal audit results, and other data and information relevant to quality performance. Management reviews are responsible for analyzing this information against the quality policy and objectives, and for determining where improvements are needed. Corrective and preventive actions and special management programs are the means for implementing improvements. In this model there are no new elements or activities. All necessary quality system elements and processes are already required elsewhere in the standard. Continual improvement is just a way to use the system to facilitate improvement.

Following five new requirements relate to continual improvement:

- Clause 5.3 requires the quality policy to include commitment to continual improvement of the effectiveness of the quality system.
- Clause 5.4.1 requires that measurable quality objectives be established to support the commitment to continual improvement.
- Clause 5.6.3 requires management reviews to be concluded with actions related to improvement of the quality system and products, and to assign resources for their implementation.
- Clause 8.4 requires collecting and analyzing quality performance data for identifying where improvements can be made.
- Clause 8.5.1 requires organizations to continually improve the effectiveness of the quality system through the use of quality policy and objectives, quality performance data, corrective and preventive actions, and management reviews.

These clauses clarify how the cycle of continual improvement is intended to work. General policies (Clause 5.3) create a framework for more specific objectives (Clause 5.4.1) that are supported by planned activities and resources (Clause 5.6.3). The organization collects and

analyzes data to determine the effectiveness of the implemented activities (Clause 8.4). The quality policy, objectives and data on quality performance are input into the management review (Clause 8.5.1), which then outputs changes to the policy, adjustments to objectives, and actions to improve the system. It's imperative to understand these clauses as elements of such a continual cycle and to create appropriate interfaces and linkages.

Implementation of these requirements will include:

- Revision of the quality policy to include commitments to meeting requirements and to continual improvement
- Establishment of quality objectives consistent with the quality policy and the commitment to continual improvement
- Establishment of plans to achieve quality objectives
- Establishment of a system for collecting and analyzing quality performance data
- Revision of the existing management review procedure to address new requirements concerning the scope and output of the review

Words and expressions

Quality Policy Manual,

Procedures,

Procedure Manual,

Work Instructions,

Records,

Head of Quality,

See also Appendix 2 ISO 9000 definitions in the end of the Course book 4.

Home assignment

Use the mini-quiz to check your understanding.

1. Why should upper management be directly involved in writing the Quality Policy Manual?

- To give them something to do
- They have greater writing skills
- To state the company business philosophy.

2. Which is one thing to include in Procedures?

- Hourly wage of workers
- Who is responsible
- Philosophy of doing business.

3. What could happen if a company didn't bother with these documents?

- They could save a lot of money
- Workers may go on strike
- Business could go into disarray.

If you got all three correct, you are on your way to becoming a champion in using ISO 9000.
If you had problems, you had better look over the material again.

Lesson 4-4. Quality Manual

1. Introduction.

This first step in building a Quality Management System is the creation of a "Quality Manual". This is a separate and distinct step from developing quality procedures. The purpose is to state in a concise and brief format, the policies and objectives of the company required to achieve a desired level of quality for the organization or division.

More than likely the input for the Quality Manual will come from your customers. It is the customer that drives the Quality Process. Their requirements, needs, and future desires are the basis for implementing an ISO 9000 quality system in the first place.

At a minimum, the Quality Manual is required to address each one of the paragraphs of the applicable ISO Series that the company plans to become registered against. ISO 9001:2000 is the focus of this manual. But, you may need to expand the scope to include EMS 14001, QS-9000, AS-9000, or other industry specific quality requirements. Each area that is written should include, at a minimum, three parts: *Scope*, *Policy* and *Responsibilities*. The *Scope* portion should simply state the purpose of the covered area. The *Policy* portion should state the company policy regarding the applicable ISO clause. The *Responsibility* portion should state who, in generic titles or positions, is responsible for the policy.

ISO 9000 does not require a specific format for the Quality Manual. A sample manual is provided in this lesson for your use as a template to create your own Quality Manual. The Quality Manual Table of Contents is based on the ISO 9000 standard itself. This ensures that each required element is addressed and provides an excellent starting point for building your Quality System.

2. A sample Quality Manual table of contents.

A sample Quality Manual can have a structure like the following:

1. Purpose
2. Scope
- 2.1. Exclusions:
3. Relation to ISO 9001:2000
4. Our Company Quality Management System
- 4.1. General Requirements
- 4.2. Documentation requirements
- 4.2.1. General
- 4.2.2. Quality Manual
- 4.2.3. Control of Documents
- 4.2.4. Control of Records
- 4.2.5. Referenced Procedures:
5. Management Responsibility
- 5.1. Management Commitment
- 5.2. Customer Focus

- 5.3. Quality Policy
- 5.4. Planning
 - 5.4.1. Quality Objectives
 - 5.4.2. Quality Management System Planning
- 5.5. Responsibility, Authority, and Communication
 - 5.5.1. Responsibility and Authority
 - 5.5.2. Management Representative
 - 5.5.3. Internal communication
 - 5.5.4. Referenced Procedures:
- 5.6. Management Review
 - 5.6.1. General
 - 5.6.2. Review Input
 - 5.6.3. Review Output
 - 5.6.4. Referenced Procedures:
- 6. Resource Management
 - 6.1. Provision of Resources
 - 6.2. Human Resources
 - 6.2.1. General
 - 6.2.2. Competence, Awareness, and Training
 - 6.2.3. Referenced Procedures:
 - 6.3. Infrastructure
 - 6.4. Work Environment
- 7. Product Realization
 - 7.1. Planning of Product Realization
 - 7.2. Customer Related Processes
 - 7.2.1. Determination of Requirements Related to the Product
 - 7.2.2. Review of Requirements Related to the Product
 - 7.2.3. Customer Communication
 - 7.2.4. Referenced Procedures:
 - 7.3. Design and Development
 - 7.3.1. Design and Development Planning
 - 7.3.2. Design and Development Inputs
 - 7.3.3. Design and Development Output
 - 7.3.4. Design and Development Review
 - 7.3.5. Design and Development Verification
 - 7.3.6. Design Validation
 - 7.3.7. Design Changes
 - 7.3.8. Referenced Procedures:
 - 7.4. Purchasing
 - 7.4.1. Purchasing process
 - 7.4.2. Purchasing information
 - 7.4.3. Verification of purchased product
 - 7.4.4. Referenced Procedures:
 - 7.5. Production and Service Provision

- 7.5.1. Control of Production and Service Provision
- 7.5.2. Validation of Processes for Production and Service Provision
- 7.5.3. Identification and Traceability
- 7.5.4. Customer Property
- 7.5.5. Preservation of Product
- 7.5.6. Referenced Procedures:
- 7.6. Control of Monitoring and Measuring Devices
 - 7.6.1. Calibration Activities
 - 7.6.2. Referenced Procedures:
- 8. Measurement, Analysis, and Improvement
 - 8.1. General
 - 8.2. Monitoring and Measurement
 - 8.2.1. Customer Satisfaction
 - 8.2.2. Internal Audit
 - 8.2.3. Monitoring and Measurement of Processes
 - 8.2.4. Monitoring and Measurement of Product
 - 8.2.5. Referenced Procedures:
 - 8.3. Control of Nonconforming Product
 - 8.3.1. Nonconforming Product Actions
 - 8.3.2. Referenced Procedures:
 - 8.4. Analysis of Data
 - 8.4.1. Quality Management System Evaluation
 - 8.4.2. Referenced Procedures:
 - 8.5. Improvement
 - 8.5.1. Continual Improvement
 - 8.5.2. Corrective Action
 - 8.5.3. Preventive Action
 - 8.5.4. Referenced Procedures

3. Manual Preparation.

These advices on developing the prototype ISO 9000:2000 Policies and Procedures Manual are to assist organizations in preparing for ISO 9001:2000 certification, which can be custom tailored to fit one's individual company concerns and operations. The language style and usage is generally representative of practices in companies in the United States. In some cases, information may be used, which is not applicable to every business. When you edit and construct a policy it should be easy to read, to the point and convey a message that is clearly understood by both the employee and the management staff.

When you have completed your Quality Manual and Quality Procedures, have a team of managers review them and make appropriate comments. After corrections, you may want your company attorney to review the draft for compliance with federal state and local laws. The corrected and finished product is then ready for distribution. But remember, building a Quality Management System is not an event, it is a continuous process so revisions will be required from time to time.

4. Considerations in writing your manual.

It is now common practice to use pronouns that are applicable to either sex or to use his or her, or the more personal and direct, "you". Social changes influence policies on topics concerning smoking, physical fitness, etc.

Have your manual reviewed by an attorney to ensure that you are in compliance with all applicable federal, state, and local laws.

Define terms used in your manual. Definitions should be placed in each procedure as needed. (ISO Definitions are provided in the ISO 9000 Overview section.)

Use the appropriate style and format for your manual:

- Use a cover or title page.
- Include a table of contents.
- Put policy statements on a 8 1/2" x 11 " page and print only on one side to make revisions easier.
- Organize material by major headings for easy reference.
- Include an alphabetized index if your manual is lengthy.
- Avoid a detailed paragraph identification systems of numbers and letters as this will detract from its' readability and the message will be lost.
- Write in simple easy to understand statements to avoid confusion. Some companies include sample administrative forms with their procedures along with instructions for their completion. This product includes a forms section for use at your discretion in the tabbed section in the back of publication.

5. Revisions

Every organization is dynamic and in some state of change. This will lead to changes to policies from time to time. Revisions should be completed and sent to all personnel who hold a copy of the manual. The revision should have an effective date and of course should be distributed in advance of the effective date. When making a change to your manual be cognizant that the language might have an indirect impact on other policies. And finally, make sure that there is a clear record of revisions made and that all employees have current information in a timely manner. The Quality Manual as well as each procedure includes a revision section at the end. It is important to keep this revision section up-to-date. It will be the only way to ensure that distributed copies of your manual are current.

Words and expressions

See Appendix 2 ISO 9000 definitions in the end of the Course book 4.

Home assignment

Read the text. Choose any item from the sample Quality Manual and provide its content for some company or organization.

Lesson 4-5. Ten tips on writing for ISO 9000

Here are some practical and useful tips on writing the documents which we considered in Lessons 4-3 and 4-4.

Tip 1. While preparing to meet ISO 9000 standards, write an action plan listing every activity that must be accomplished along the way. Before starting to pursue ISO 9001, the quality manager at some company wrote an action plan of 267 steps - that was just for creating the quality manual. The plan listed every task, the people responsible for it and an estimated time to complete the task. The first task, "List all procedures that are associated with each clause," was estimated to take a week.

This type of global thinking is also exemplified by the quality manager at another company, who sent out a long memo to his staff about achieving certification for ISO 9002. The memo listed 16 steps toward achieving certification. The first four were:

- Obtain management commitment
- Appoint a management representative to lead the process.
- Form a steering committee or team that includes hourly people and has all areas represented.
- Educate the team about the ISO 9000 registration process.

Tip2. Write ISO 9000 procedures that are specific but do not handcuff your people in completing their work. If you were writing, for example, a procedure on how a report was to be bound, you might write: "Put all sheets in a 'Clear-Vue' see-through report cover and thread a black spine over the left side of the cover to bind the report." But what if you run out of "Clear-Vue" covers? Are others just as good? And what about those black spines? Would a green one make a big difference? Perhaps you could write: "Put all sheets in a see-through report cover and thread a spine over the left side of the cover to bind the report."

Tip 3. If any of those who must write ISO 9000 procedures are inexperienced writers, have them create flowcharts describing their tasks. While flowcharts are not a substitute for narrative in an ISO 9000 procedure, they can help procedure writers explain what they do. Many engineers think visually and it is easier for them to do a flowchart than to construct a paragraph or even a series of bullet points. Flowcharts should be easy to read and contain less than eight steps. Try to fashion a set of procedures based on the flowchart.

Streamline procedures by bulleting parallel items, especially those that start with verbs. Often, there is no need to put procedures in paragraph form. For example, instead of a paragraph filled with items separated by commas or semicolons, break out of the paragraph by putting in a colon after that announces a break from the prose; then put in a series of bullet points to line up the thoughts for the reader.

Tip 4. Keep your ISO 9000 quality policy manual to less than 40 pages. The quality policy manual is sometimes thought of as pointing to or referencing lower-level documents. The quality manual is not the place to go into detail about who does what or how things are done. It is a place to set policy.

The quality manual should contain no proprietary material. In fact, it should be written as if it were to be given to customers and, in some cases, competitors. If the manual has more than 40

pages, it's probably going into more depth than necessary or is redundant. At that point, the manual will start to resemble a list of procedures or work instructions.

Tip 5. Model your quality manual after the ISO 9000 standards. The topic order in the ISO 9000 standard should guide you in organizing your quality policy manual. Even if you have a manual partially written, it is best to start again, mirroring the topics and order of the particular ISO 9000 standard for which your company is trying to become certified. By making the manual's topics the same as the standard's, you help potential auditors follow your thoughts and make sure you have covered the required topics.

Tip 6. Make quality manuals easily auditable and maintainable. Making a quality manual auditable means making it easy to read, easy to reference and easy to reread. By reflecting the ISO 9000 standards, the manual becomes easier to audit quickly.

Other format issues to consider include wide margins (a lot of white space makes reading easy on the eyes); consistent spacing (helps highlight what is important); consistent numbering (shows readers which topics are subsets of others); large, serif typefaces (helps readability, save italics for emphasis only); correct capitalization; and title blocks that include the company name, document name, revision or signature line, page number and document number.

Title blocks help you maintain your manual by making it easy to see where revised pages fit and by telling you the last time a document was revised.

Tip 7. Keep documentation concise.

Do not throw in the kitchen sink. Like every other type of writing, documentation is selective and should contain the minimum amount necessary to convey the idea. Avoid redundancies like, "All quality systems, current and new, used . . ." Knock out "current and new." Here is another redundancy: "The sales division will completely document all the processes that affect the customer-supplier relationship between Acme and its customers." Leave out "customer-supplier."

Avoid wordy expressions (e.g., "on an annual basis") and the obvious (e.g., "all staff reporting directly or indirectly will support this policy.") Avoid clichés and puffery such as, "Quality is the basis of our corporate culture" or "We will produce perfect products and services every time, on time."

Tip 8. Make documentation self-explanatory and authoritative. Ralph Waldo Emerson once said you should write not just so that you will be understood but so that you cannot be misunderstood. To do this, you must delete any hedging. Get rid of words like "basically," "perhaps," "under certain circumstances" and "in most cases."

Here is a vague and weak purpose statement: "To assign the responsibilities and authorities of the various departments within the company." Here is the sharper, more authoritative version: "To assure individual department compliance with quality management system guidelines for managing responsibilities."

Tip 9. Use hierarchical, easy-to-follow numbering systems for sections and subsections. Stay consistent:

1.0 PURPOSE

2.0 SCOPE

3.0 DEFINITIONS

4.0 The headings are all capital. Subtopics are indented and line up underneath the headings:

- 3.0 DEFINITIONS

- 3.1 Document - The original media that conveys information or proof of an activity, task or procedure.
- 3.2 Standard Operating Procedure
- 3.3 Process Sheet.

Tip 10. When trying to explain your tasks to a layperson, ask yourself, "How would I explain this to a very bright child?" When talking to children, you automatically know to boil down difficult-to-grasp concepts. The same idea should apply when circulating documents to people who are not versed in your technical field. Do not expect that they "know it." They may not. They often need help from you in forming a mental image of the product or process you are trying to describe. Avoid vague phrases such as, "To ensure that the requirements between ACME Co. and its customers are effectively communicated . . ." Which requirements? Contractual? Procedures? Do not make the reader guess. "Use the correct word and not," as Mark Twain once said, "its second cousin."

Words and expressions

See the ISO 9000 definitions in Appendix 2 in the end of the Course book.

Home assignment

Read the text. Give your understanding of how to write for ISO 9000.

Lesson 4-6. ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2000

In conjunction with the publication of the International Standards ISO 9001:2000 and ISO 9004:2000, ISO/TC 176/SC 2 has published a number of guidance modules:

- N524 – Guidance on ISO 9001:2000 Sub-clause 1.2 'Application'
- N525 – Guidance on the Documentation requirements of ISO 9001:2000
- N526 – Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000
- N544 – Guidance on the Concept and Use of the Process Approach for management systems
- N630 – Guidance on 'Outsourced Processes'

Together these are being made available as the ISO/TC 176/SC 2 'ISO 9000 Introduction and Support Package'.

The modules, and further information on the year 2000 ISO 9000 standards, may be downloaded from web sites: www.iso.org and www.iso.org/tc176/sc2

1. Introduction

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

- a) to develop a simplified set of standards that will be equally applicable to small as well as medium and large organizations, and
- b) for the amount and detail of documentation required to be more relevant to the desired results of the organization's process activities.

ISO 9001:2000 *Quality management systems – Requirements* has achieved these objectives, and the purpose of this additional guidance is to explain the intent of the new standard with specific regard to documentation.

ISO 9001:2000 has significantly reduced the documentation requirements and is much less prescriptive than the 1994 version of the standard. It allows an organization more flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to develop the minimum amount of documentation needed in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS.

It is stressed that ISO 9001 requires (and always *has* required) a “*Documented quality management system*”, and not a “*system of documents*”.

2. What is a “document”? - Definitions and references

The following are some of the main objectives of an organization's documentation, independent of whether or not it has implemented a formal QMS:

- a) Communication of information as a tool for information transmission and communication.
- The type and extent of the documentation will depend on the nature of the organization's

products and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.

- b) Evidence of conformity - provision of evidence that what was planned, has actually been done.
- c) Knowledge sharing in order to disseminate and preserve the organization's experiences. A typical example would be a technical specification, which can be used as a base for design and development of a new product.

A list of commonly used terms relating to documentation is presented in Annex A in the end of this lesson (taken from ISO 9000:2000). It must be stressed that, according to ISO 9001:2000 clause 4.2 *Documentation requirements* documents may be in any form or type of medium, and the definition of "document" in ISO 9000:2000 clause 3.7.2 gives the following examples:

- paper
- magnetic
- electronic or optical computer disc
- photograph
- master sample.

Users are also referred to ISO/TR 10013 *Guidelines for quality management systems documentation* for further guidance.

3 ISO 9001:2000 Documentation Requirements

ISO 9001:2000 clause 4.1 *General requirements* requires an organization to "establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard".

Clause 4.2.1 *General* explains that the quality management system documentation *shall* include:

- a) documented statements of a quality policy and quality objectives;
- b) a quality manual;
- c) documented procedures required by this International Standard;
- d) documents needed *by the organization* to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard.

The notes after Clause 4.2 make it clear that where the standard specifically requires a "documented procedure", the procedure has to be established, documented, implemented and maintained. It also emphasizes that the extent of the QMS documentation may differ from one organization to another due to:

- the size of organization and type of activities;
- the complexity of processes and their interactions, and
- the competence of personnel.

All the documents that form part of the QMS have to be controlled in accordance with clause 4.2.3 of ISO 9001:2000, or, for the particular case of records, according to clause 4.2.4.

4 Guidance on Clause 4.2 of ISO 9001:2000

The following comments are intended to assist users of ISO 9001:2000 in understanding the intent of the general documentation required of the International Standard.

4.1. Documented statements of a quality policy and objectives:

- Requirements for the quality policy are defined in clause 5.3 of ISO 9001:2000. The documented quality policy has to be controlled according to the requirements of clause 4.2.3. Some organizations may be revising their quality policy for the first time, in order to meet ISO 9001:2000 requirements, and will need to pay particular attention to clause 4.2.3 (c), (d) and (g).
- Requirements for the quality objectives are defined in clause 5.4.1 of ISO 9001:2000. These documented quality objectives are also subject to the document control requirements of clause 4.2.3.

4.2. Quality Manual

Clause 4.2.2 of ISO 9001:2000 specifies the minimum content for a quality manual. The format and structure of the manual is a decision for each organization, and will depend on the organization's size, culture and complexity. Some organizations may choose to use the quality manual for other purposes besides that of simply documenting the QMS

A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard.

Large, multi-national organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

The quality manual is a document that has to be controlled in accordance with the requirements of clause 4.2.3.

4.3. Documented procedures.

ISO 9001:2000 specifically requires the organization to have "documented procedures" for the following six activities:

- 4.2.3. Control of documents
- 4.2.4. Control of records
- 8.2.2. Internal audit
- 8.3. Control of nonconforming products
- 8.5.2. Corrective action
- 8.5.3. Preventive action

These documented procedures have to be controlled in accordance with the requirements of clause 4.2.3.

Some organizations may find it convenient to combine the procedure for several activities into a single documented procedure (for example, corrective action and preventive action). Others may choose to document a given activity by using more than one documented procedure (for example, Internal audits). Both are acceptable.

Some organizations (particularly larger organizations, or those with more complex processes) may require additional documented procedures (particularly those relating to product realization processes) in order to implement an effective QMS.

Other organizations may require additional procedures, but the size and/or culture of the organization could enable these to be effectively implemented without *necessarily* being documented. However, in order to demonstrate compliance with ISO 9001:2000, the organization has to be able to provide objective evidence (not necessarily documented) that its QMS has been effectively implemented.

4.4. Documents needed *by the organization* to ensure the effective planning, operation and control of its processes:

- In order for an organization to demonstrate the effective implementation of its QMS, it may be necessary to develop documents other than documented procedures. However, the only documents specifically mentioned in ISO 9001:2000 are:
 - Quality policy (clause 4.2.1.a)
 - Quality objectives (clause 4.2.1.a)
 - Quality manual (clause 4.2.1.b)

There are several requirements of ISO 9001:2000 where an organization *could* add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples may include:

- Process maps, process flow charts and/or process descriptions
- Organization charts
- Specifications
- Work and/or test instructions
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans

All such documents have to be controlled in accordance with the requirements of clause 4.2.3 and/or 4.2.4, as applicable.

Records. Examples of records specifically required by ISO 9001:2000 are presented in Annex B. Organizations are free to develop other records that may be needed to demonstrate conformity of their processes, products and quality management system. Requirements for the control of records are different from those for other documents, and all records have to be controlled according to those of clause 4.2.4 of ISO 9001:2000.

5 Organizations preparing to implement a QMS

For organizations that are in the process of implementing a QMS, and wish to meet the requirements of ISO 9001:2000, the following comments may be useful.

For organizations that are in the process of implementing or have yet to implement a QMS, the new ISO 9001:2000 emphasizes a process approach. This includes:

- Identifying the processes necessary for the effective implementation of the quality management system
- understanding the interactions between these processes.
- *Documenting* the processes to the extent necessary to assure their effective operation and control. (It may be appropriate to document the processes using process maps. It is emphasized, however, that documented process maps are *not* a requirement of ISO 9001:2000.).

These processes include the management, resource, product realization and measurement processes that are relevant to the effective operation of the QMS.

Analysis of the processes should be the driving force for defining the amount of documentation needed for the quality management system, taking into account the requirements of ISO 9001:2000. It should *not* be the documentation that drives the processes.

6 Organizations wishing to adapt an existing QMS

For organizations that currently have a QMS meeting the requirements of ISO 9001:1994 or ISO 9002:1994, the following comments are intended to assist in understanding the changes to documentation that may be required or facilitated by the transition to ISO 9001:2000:

- An organization with an existing QMS should not need to rewrite all of its documentation in order to meet the requirements of ISO 9001:2000. This is particularly true if an organization has structured its QMS based on the way it effectively operates, using a process approach. In this case, the existing documentation may be adequate and can be simply referenced in the revised quality manual.
- An organization that has not used a process approach in the past will need to pay particular attention to the definition of its processes, their sequence and interaction.
- Because ISO 9001:2000 is less prescriptive than the 1994 versions of the standard, an organization may be able to carry out some simplification and/or consolidation of existing documents, in order to simplify its QMS.

7 Demonstrating conformity with ISO 9001:2000

Organizations wishing to demonstrate conformity with the requirements of ISO 9001:2000, for the purposes of certification/registration, contractual, or other reasons, it is important to remember the need to provide evidence of the effective implementation of the QMS.

- Organizations may be able to demonstrate conformity without the need for extensive documentation.
- In order to claim conformity with ISO 9001:2000, the organization has to be able to provide objective evidence of the *effectiveness* of its processes and its quality management system. Clause 3.8.1 of ISO 9000:2000 defines “objective evidence” as “*data supporting the existence or verity of something*” and notes that “*objective evidence may be obtained through observation, measurement, test, or other means.*”
- Objective evidence does not necessarily depend on the existence of documented procedures, records or other documents, except where specifically mentioned in ISO 9001:2000. In some cases, (for example, in clause 7.1(d) *Planning of product realization*,

and clause 8.2.4 *Monitoring and measurement of product*), it is up to the organization to determine what records are necessary in order to provide this objective evidence.

- Where the organization has no specific internal procedure for a particular activity, and this is not required by the standard, (for example, clause 5.6 *Management Review*), it is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2000. In these situations, both internal and external audits may use the text of ISO 9001:2000 for conformity assessment purposes.

Home assignment

Read the text. Give your understanding of what is needed to be done by organizations preparing to implement a QMS.

Annex A. Terms and Definitions relating to Documents

The following terms and definitions are taken from ISO 9000:2000:

Term	ISO 9000:2000 Clause	Definition
Document	3.7.2.	Information and its supporting medium
Procedure	3.4.5.	Specified way to carry out an activity or a process (Note: Procedures can be documented or not)
Quality Manual	3.7.4.	Document specifying the quality management system of an organization
Quality Plan	3.7.5.	Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract
Record	3.7.6.	Document stating results achieved or providing evidence of activities performed
Specification	3.7.3.	Document stating requirements

Annex B. Records required by ISO 9001:2000

Clause	Record required
5.6.1	Management reviews
6.2.2 (e)	Education, training, skills and experience
7.1 (d)	Evidence that the realization processes and resulting product fulfil requirements
7.2.2	Results of the review of requirements related to the product and actions arising from the review
7.3.2	Design and development inputs relating to product requirements
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations
7.5.2 (d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use
7.6 (a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results and follow-up actions
8.2.4	Indication of the person(s) authorizing release of product.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2	Results of corrective action
8.5.3	Results of preventive action

Lesson 4-7. ISO 9001:2000 Translated into Plain English

ISO 9001 applies to all types of organizations. It doesn't matter what size they are or what they do. It can help both product and service oriented organizations achieve standards of quality that are recognized and respected throughout the world. ISO 9001:2000 has replaced the old ISO 9001:1994 standard. In addition, the old ISO 9002:1994 and ISO 9003:1994 quality standards have been discontinued. They are now obsolete! If you are now ISO 9001:1994 certified, you are going to have to update your quality management system in order to meet the new ISO 9001:2000 requirements. And if you are now ISO 9002 or ISO 9003 certified, you are going to have to become ISO 9001:2000 certified!

Please note that ISO presents requirements in sections 4 to 8 of ISO 9001:2000. Therefore, the following material begins with section 4. Sections 1 to 3 cover a variety of introductory and legalistic topics.

The text of this lesson gives a picture of what is needed to be done to meet the requirements of the ISO 9001:2000 Standard in an informal way or what we called “plain English”. It will serve a basis for discussions at classes.

1. ISO 9001: 4. Systemic Requirements

4.1 Establish your quality system:

- Develop your quality management system.
- Identify the processes that make up your quality system.
- Describe your quality management processes.

Improve your quality management system:

- Monitor process performance.
- Improve process performance.

4.2 Document your quality system

4.2.1 Develop quality system documents:

- Develop documents to implement your quality system.
- Develop documents that reflect what your organization does.

4.2.2 Prepare quality system manual:

- Document your procedures.
- Describe how your processes interact.
- Define the scope of your quality system.

4.2.3 Control quality system documents:

- Approve documents before you distribute them.
- Provide the correct version of documents at points of use.
- Review and re-approve documents whenever you update them.
- Specify the current revision status of your documents.
- Monitor documents that come from external sources.
- Prevent the accidental use of obsolete documents.
- Preserve the usability of your quality documents.

4.2.4 Maintain quality system records:

- Use your records to prove that requirements have been met.
- Develop a procedure to control your records.
- Ensure that your records are useable.

2. ISO 9001: 5. Management Requirements

5.1 Support quality

Promote the importance of quality:

- Promote the need to meet customer requirements.
- Promote the need to meet regulatory requirements.
- Promote the need to meet statutory requirements.

Develop a quality management system:

- Support the development of a quality system.
- Formulate your organization's quality policy.
- Set your organization's quality objectives.
- Provide quality resources.

Implement your quality management system:

- Provide resources to implement your quality system.
- Encourage personnel to meet quality system requirements.

Improve your quality management system:

- Perform quality management reviews.
- Provide resources to improve the quality system.

5.2 Satisfy your customers

Identify customer requirements

- Expect your organization to identify customer requirements.

Meet your customers' requirements

- Expect your organization to meet customer requirements.

Enhance customer satisfaction

- Expect your organization to enhance customer satisfaction.

5.3 Establish a quality policy

Define your organization's quality policy

- Ensure that it serves your organization's purpose.
- Ensure that it emphasizes the need to meet requirements.
- Ensure that it facilitates the development of quality objectives.
- Ensure that it makes a commitment to continuous improvement.

Manage your organization's quality policy

- Communicate your policy to your organization.
- Review your policy to ensure that it is still suitable.

5.4 Carry out quality planning

5.4.1 Formulate your quality objectives

- Ensure that objectives are set for functional areas.
- Ensure that objectives are set at organizational levels.

- Ensure that objectives facilitate product realization.
- Ensure that objectives support the quality policy.
- Ensure that objectives are measurable.

5.4.2 Plan your quality management system

- Plan the development of your quality management system.
- Plan the implementation of your quality management system.
- Plan the improvement of your quality management system.
- Plan the modification of your quality management system.

5.5 Control your quality system

5.5.1 Define responsibilities and authorities

- Clarify responsibilities and authorities.
- Communicate responsibilities and authorities.

5.5.2 Appoint management representative

- Oversee your quality management system.
- Report on the status of your quality management system.
- Report on the status of your quality management system.
- Support the improvement of your quality management system.

5.5.3 Support internal communications

- Ensure that internal communication processes are established.
- Ensure that communication occurs throughout the organization.

5.6 Perform management reviews

5.6.1 Review quality management system

- Evaluate the performance of your quality system.
- Evaluate whether your quality system should be improved.

5.6.2 Examine management review inputs

- Examine audit results.
- Examine product conformity data.
- Examine opportunities to improve.
- Examine feedback from customers.
- Examine process performance information.
- Examine corrective and preventive actions.
- Examine changes that might affect your system.
- Examine previous quality management reviews.

5.6.3 Generate management review outputs

- Generate actions to improve your quality system.
- Generate actions to improve your products.
- Generate actions to address resource needs.

3. ISO 9001:2000. 6 Resource Requirements

6.1 Provide quality resources

6.1.1 Identify quality resource requirements

- Identify resources needed to support the quality system.
- Identify resources needed to improve customer satisfaction.

6.2.2 Provide quality system resources

- Provide resources needed to support the quality system.
- Provide resources needed to improve customer satisfaction.

6.2 Provide quality personnel

6.2.1 Use competent personnel

- Ensure that your personnel have the right experience.
- Ensure that your personnel have the right education.
- Ensure that your personnel have the right training.
- Ensure that your personnel have the right skills.

6.2.2 Support competence

- Define acceptable levels of competence
- Identify training and awareness needs
- Deliver training and awareness programs
- Evaluate effectiveness of training and awareness
- Maintain a record of competence.

6.3 Provide quality infrastructure

6.3.1 Identify infrastructure needs

- Identify building needs
- Identify workspace needs
- Identify hardware needs
- Identify software needs
- Identify utility needs
- Identify equipment needs
- Identify support service needs.

6.3.2 Provide needed infrastructure

- Provide needed buildings
- Provide needed workspaces
- Provide needed hardware
- Provide needed software
- Provide needed utilities
- Provide needed equipment
- Provide needed support services

6.3.3. Maintain your infrastructure

- Maintain your buildings.
- Maintain your workspaces.
- Maintain your hardware.
- Maintain your software.
- Maintain your utilities.
- Maintain your equipment.
- Maintain your support services.

6.4. Provide quality environment

Identify needed work environment

- Identify factors needed to ensure products meet requirements.

Manage needed work environment

- Manage factors needed to ensure products meet requirements.

4. ISO 9001: 7 Realization Requirements

7.1. Control realization planning

Plan product realization processes

- Define product quality objectives and requirements
- Identify product realization needs and requirements

Develop product realization processes

- Develop product realization documents.
- Develop product realization record keeping systems
- Develop methods to control quality during product realization

7.2. Control customer processes

7.2.1 Identify customers' product requirements

- Identify the requirements that customers want you to meet.
- Identify the requirements that are dictated by the product's use.
- Identify the requirements that are imposed by external agencies
- Identify the requirements that your organization wishes to meet

7.2.2 Review customers' product requirements

- Review requirements before you accept orders from customers
- Maintain a record of your product requirement reviews
- Control changes in product requirements

7.2.3 Communicate with your customers

- Develop a process to control communications with customers
- Implement your customer communications process

7.3 Control product development

7.3.1 Plan design and development

- Define your product design and development stages.
- Clarify design and development responsibilities and authorities
- Manage interactions between design and development groups
- Update your design and development plans as changes occur

7.3.2 Define design and development inputs

- Specify product design and development inputs
- Record product design and development input definitions.
- Review product design and development input definitions

7.3.3 Generate design and development outputs

- Create product design and development outputs
- Approve design and development outputs prior to release
- Use design and development outputs to control product quality

7.3.4 Carry out design and development reviews

- Perform product design and development reviews.
- Record product design and development reviews

7.3.5 Perform design and development verifications

- Carry out product design and development verifications
- Record product design and development verifications

7.3.6 Conduct design and development validations

- Perform product design and development validations
- Record product design and development validations

7.3.7 Manage design and development changes

- Identify changes in product design and development
- Record changes in product design and development
- Review changes in product design and development
- Verify changes in product design and development
- Validate changes in product design and development.
- Approve changes before they are implemented

7.4 Control purchasing function

7.4.1 Control purchasing process

- Ensure that purchased products meet requirements.
- Ensure that suppliers meet requirements

7.4.2 Document product purchases

- Describe the products being purchased
- Specify the requirements that must be met.

7.4.3 Verify purchased products

- Verify purchased products at your own premises
- Verify purchased products at suppliers' premises (when required).

7.5 Control operational activities

7.5.1 Control production and service provision

- Control production and service processes
- Control production and service information
- Control production and service instructions
- Control production and service equipment
- Control production and service measurements
- Control production and service activities

7.5.2 Validate production and service provision

- Prove that special processes can produce planned outputs
- Prove that process personnel can produce planned results
- Prove that process equipment can produce planned results

7.5.3 Identify and track your products

- Establish the identity of your products (when appropriate).
- Maintain the identity of your products (when appropriate
- Identify the status of your products (when appropriate).

- Record the identity of your products (when required).

7.5.4 Protect property supplied by customers

- Identify property supplied to you by your customers
- Verify property supplied to you by your customers
- Safeguard property supplied to you by your customers

7.5.5 Preserve your products and components

- Preserve products and components during internal processing
- Preserve products and components during final delivery

7.6 Control monitoring devices

Identify monitoring and measuring needs

- Identify the monitoring and measuring that should be done

Select monitoring and measuring devices

- Select devices that meet your monitoring and measuring needs

Calibrate monitoring and measuring devices

- Perform calibrations
- Record calibrations

Protect monitoring and measuring devices

- Protect your devices from unauthorized adjustment
- Protect your devices from damage or deterioration

Validate monitoring and measuring software

- Validate monitoring and measuring software before you use it
- Revalidate monitoring and measuring software when necessary

Use monitoring and measuring devices

- Use devices to ensure that your products meet requirements

5. ISO 9001: 8 Remedial Requirements

8.1 Perform remedial processes

Plan remedial processes

- Plan how remedial processes will be used to assure conformity
- Plan how remedial processes will be used to improve the system

Implement remedial processes

- Use remedial processes to demonstrate conformance.
- Use remedial processes to improve quality management system

8.2 Monitor and measure quality

8.2.1 Monitor and measure customer satisfaction

- Identify ways to monitor and measure customer satisfaction
- Monitor and measure customer satisfaction
- Use customer satisfaction information

8.2.2 Plan and perform regular internal audits

- Set up an internal audit program
- Develop an internal audit procedure
- Plan your internal audit projects

- Perform regular internal audits
- Solve problems discovered during audits
- Verify that problems have been solved

8.2.3 Monitor and measure quality processes

- Use suitable methods to monitor and measure your processes
- Take action when your processes fail to achieve planned results

8.2.4 Monitor and measure product characteristics

- Verify that product characteristics are being met.
- Keep a record of product monitoring and measuring activities

8.3 Control nonconforming products

Develop a procedure to control nonconforming products

- Define how nonconforming products should be identified
- Define how nonconforming products should be handled

Identify and control your nonconforming products

- Eliminate or correct product nonconformities
- Prevent the delivery or use of nonconforming products
- Avoid the inappropriate use of nonconforming products

Re-verify nonconforming products that were corrected

- Prove that corrected products now meet requirements

Control nonconforming products after delivery or use

- Control events when you deliver or use nonconforming products

Maintain records of nonconforming products

- Describe your product nonconformities
- Describe the actions taken to deal with nonconformities.

8.4 Analyze quality information

Define quality management information needs

- Define the information you need to evaluate your quality system
- Define the information you need to improve your quality system

Collect quality management system data

- Monitor and measure the suitability of your quality system
- Monitor and measure the effectiveness of your quality system

Provide quality management information

- Provide information about your customers
- Provide information about your suppliers
- Provide information about your products
- Provide information about your processes

8.5 Make quality improvements

8.5.1 Improve quality management system

- Use your audits to generate improvements
- Use your quality data to generate improvements
- Use your quality policy to generate improvements
- Use your quality objectives to generate improvements

- Use your management reviews to generate improvements.
- Use your corrective actions to generate improvements
- Use your preventive actions to generate improvements

8.5.2 Correct actual nonconformities

- Review your nonconformities
- Figure out what causes your nonconformities.
- Evaluate whether you need to take corrective action.
- Develop corrective actions to prevent recurrence
- Take corrective actions when they are necessary
- Record the results that your corrective actions achieve
- Examine the effectiveness of your corrective actions

8.5.3 Prevent potential nonconformities

- Detect potential nonconformities.
- Identify the causes of potential nonconformities
- Study the effects of potential nonconformities
- Evaluate whether you need to take preventive action.
- Develop preventive actions to eliminate causes
- Take preventive actions when they are necessary
- Record the results that your preventive actions achieve
- Examine the effectiveness of your preventive actions.

Lesson 4-8. Quality management principles

1. Introduction

In this lesson we will introduce the eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based. These principles can be used by senior management as a framework to guide their organizations towards improved performance. The principles are derived from the collective experience and knowledge of the international experts who participate in ISO Technical Committee ISO/TC 176, Quality management and quality assurance, which is responsible for developing and maintaining the ISO 9000 standards.

The eight quality management principles are defined in ISO 9000:2000, *Quality management systems. Fundamentals and vocabulary*, and in ISO 9004:2000, *Quality management systems. Guidelines for performance improvements*. The text of this lesson gives the standardized descriptions of the principles as they appear in ISO 9000:2000 and ISO 9004:2000. In addition, it provides examples of the benefits derived from their use and of actions that managers typically take in applying the principles to improve their organizations' performance. So, the list of the principles looks as follows:

- Principle 1: Customer focus
- Principle 2: Leadership
- Principle 3: Involvement of people
- Principle 4: Process approach
- Principle 5: System approach to management
- Principle 6: Continual improvement
- Principle 7: Factual approach to decision making
- Principle 8: Mutually beneficial supplier relationships.

2. Principle 1 Customer focus

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

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.

- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

3. Principle 2 Leadership

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

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

Applying the principle of leadership typically leads to:

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

4. Principle 3 Involvement of people

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

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

Applying the principle of involvement of people typically leads to:

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

5.Principle 4 Process approach

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

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

Applying the principle of process approach typically leads to:

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

6. Principle 5 System approach to management

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

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

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

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

7. Principle 6 Continual improvement

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

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

- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

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

8. Principle 7 Factual approach to decision making

Effective decisions are based on the analysis of data and information. Key benefits:

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

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

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

9. Principle 8 Mutually beneficial supplier relationships

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

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

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

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.
- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers.

10. The next step:

This document provides a general perspective on the quality management principles underlying the ISO 9000:2000 series. It gives an overview of these principles and shows how, collectively, they can form a basis for performance improvement and organizational excellence.

There are many different ways of applying these quality management principles. The nature of the organization and the specific challenges it faces will determine how to implement them. Many organizations will find it beneficial to set up quality management systems based on these principles.

The requirements of quality management systems and supporting guidelines are given in the ISO 9000 - Selection and use. Further information on the ISO 9000 standards is available from ISO's national member institutes or from the ISO Central Secretariat ISO 9000 enquiry service.

Lesson 4-9. ISO 9000 Procedure Writing Information

1. Procedures: general requirements.

First of all, let us give a definition of a procedure. For purposes of the ISO 9001 implementation, a procedure can be defined as a documented process for quality activities that are interdepartmental. The intents of the procedures are to be used as a reference where they will provide guidance and consistency when employees perform quality related tasks.

Responsibilities for procedures can be divided as follows:

- Each department must be responsible for writing their procedures.
- Managers of departments have approval of all procedures under their areas of responsibility.

The following requirements are usually applied to procedures:

- Procedures must be under some form of document control. They must be numbered, signed and dated. Some technology of the procedure revision must be stated.
- Procedures should reference inner-related procedures and quality system documentation created from following the procedure.
- Quality Records as required by the ISO 9001 standard that are generated by a procedure or work instruction must be listed in a Quality Records Procedure. This is not always required by all registrar's, however, is required by many and is appreciated.

What should procedures specify? Procedures should specify the following issues:

- What should be done?
- Who will do it?
- When will it be done and in what sequence?
- How will it be done?
- What equipment, tools or materials will be used?
- What forms or other documents will be used?
- An appendix for all forms used in the procedure should be added to the description of the procedure.
- A flow chart for the procedure is also a convenient form of presentation. Of course, it works only where applicable - the flow chart can describe the procedure if it is understandable.
- Signed, dated authorizations under revision control with controlled distributions.

Other important and useful considerations and issues to be incorporated in procedures are:

- Definitions.
- Referencing standards.
- Safety or danger warnings related to the procedure.
- Documentation.
- Quality Records.

And now, the Bottom Line for procedure writing: ***For ISO or QS 9001 compliance, the bottom line is to write what you do, then do what you have written.***

2. Tips on procedures.

Here are some practical tips on procedures writing are the following:

Tip 1: The more general the procedure, the more flexible, however, the more specific the guidance, for those responsible for carrying out job duties, the easier the system is to maintain.

Tip 2: There must be at least one procedure for each element for the standard, dependant upon complexity of the element. Writing separate procedures for manageable activities will be less confusing than one grand activity.

- Note: At this time all the elements are to be covered, however, as a company changes, it changes how it does, hence, the number of procedures may change.

Tip 3: A reference can be put into the procedures referencing other procedures if you are documenting the elements other than by the ISO Standard numbering scheme.

Tip 4: Try to keep the procedures from being too specific. Assign who (by job title) does a task and when does it happen.

- Note: Specific instructions on how to do tasks are work instructions.

Tip 5: When assigning responsibility, the use of assignee, designee or successor following the title of the person responsible in the process will keep the process flexible and provide an option should the responsible person be unavailable at any specific time.

Tip 6: Keep the use of symbols minimized.

Tip 7: There must be consistency in action.

Tip 8: Use of a flow chart is not required, however, is highly recommended. For additional information on flow charts, please see the Appendix 1 to this lesson.

- Note: The reason flowcharting is recommended is that an auditor may chose to flow chart the procedure to check it out. He/she may make an error to the flow because of the complexity of the procedure which may not readily be found. This could be a problem if he/she determines there is a noncompliance and the error can not be found.

3. Work instructions vs. procedures.

Work instructions are another way of saying "procedure". Work instructions are not as general as procedures and are very task specific. They should tell how to do or use something (i.e. How to solder, how to assemble a Widget.).

A work instruction (for purposes of quality system implementation) is defined as a documented process for quality activities that are intra-departmental. The intent of the work instructions are to be used as a reference where they will provide guidance and consistency when employees perform specific quality related tasks within a department.

Responsibilities for work instructions should be divided as follows:

- Each department must be responsible for writing their procedures.
- Managers/Supervisors for the departments have approval of all work instructions under their areas of responsibility.

Now, let us consider the requirements usually applied to work instructions. Procedures and work instructions must be under some form of document control by the generating department (numbered, revision procedure stated, signed and dated, distribution maintained). Work Instructions should reference related procedures and quality system documentation created from

following the procedure. Quality Records required by the ISO 9001 standard that are generated by a procedure or work instruction must be listed in a Quality Records Procedure.

Note 1: Quality Records are typically referenced in Quality System Procedures, but may be generated as a part of a work instruction. A separate Quality Records section is not required for work instructions provided general instruction exist within the Quality System Procedures that reference the record.

Note 2: The Quality Records Element requires that records be listed. It is recommended to list them under the appropriate ISO element within the Quality Records Procedure, list the proper name of the record, location where stored, person responsible for maintaining the record, by title and the retention period for the document.

Work instructions should specify the following issues:

- What should be done?
- Who will do it?
- When will it be done and in what sequence?
- How will it be done?
- What equipment or materials will be used?
- What forms or other documents will be used?
- An appendix for all forms used in the procedure.
- A flow chart for the procedure (where applicable - the flow chart can be the procedure if it is understandable)
- Signed, dated authorizations under revision control with controlled distributions.

Other considerations to incorporate in work instructions are:

- Definitions,
- Referencing standards,
- Safety or danger warnings related to the procedure
- Documentation
- Quality Records

Appendix 1. QUALITY ASSURANCE MANUAL (a sample)

1. INTRODUCTION

The ELTECH Networking Systems and Services, Ltd. was formed in 1984 to satisfy customer requirements for data networking products. This business has developed well and is expanding successfully.

Additional capabilities have been added to the organization to include technical assistance and support, installation, maintenance of products and systems, and design of systems.

The company is now engaged in including design, engineering, stocking and distribution, installation, commissioning and maintenance of equipment and systems.

This Quality System relates to the full range of company activities.

2. POLICY and OBJECTIVES

The ELTECH Networking Systems and Services' quality policy is to achieve sustained, profitable growth by providing services which consistently satisfy the needs and expectations of its customers.

This level of quality is achieved through adoption of a system of procedures that reflect the competence of the Company to existing customers, potential customers, and independent auditing authorities.

Achievement of this policy involves all staff, who are individually responsible for the quality of their work, resulting in a continually improving working environment for all. This policy is provided and explained to each employee by the Managing Director or Quality Manager.

To achieve and maintain the required level of assurance the Managing Director retains responsibility for the Quality System with routine operation controlled by the Quality Manager.

The objectives of the Quality Assurance System are:

a) To maintain an effective Quality Assurance System complying with International Standard ISO9001 (Quality Systems).

b) To achieve and maintain a level of quality which enhances the Company's reputation with customers.

c) To ensure compliance with relevant statutory and safety requirements.

d) To endeavor, at all times, to maximize customer satisfaction with the services provided by the ELTECH Networking Systems and Services.

I. Sidorov - Managing Director

October 1995

3. DEFINITIONS

The terms and descriptions used in this Manual are generally defined within ISO9001 - Quality Systems. Additional definitions apply for items not covered by the documents: (Site Any location, other than the Company's established premises, where work is undertaken as part of a formal contract).

4. QUALITY SYSTEM

The Quality Assurance System applies to all activities of the Company, and has been developed in accordance with ISO9001. The Quality Assurance System is fully documented and structured in levels:

Level 1: Quality Manual.

This document details the corporate quality policy and structure of the Company and references appropriate Operating Procedures.

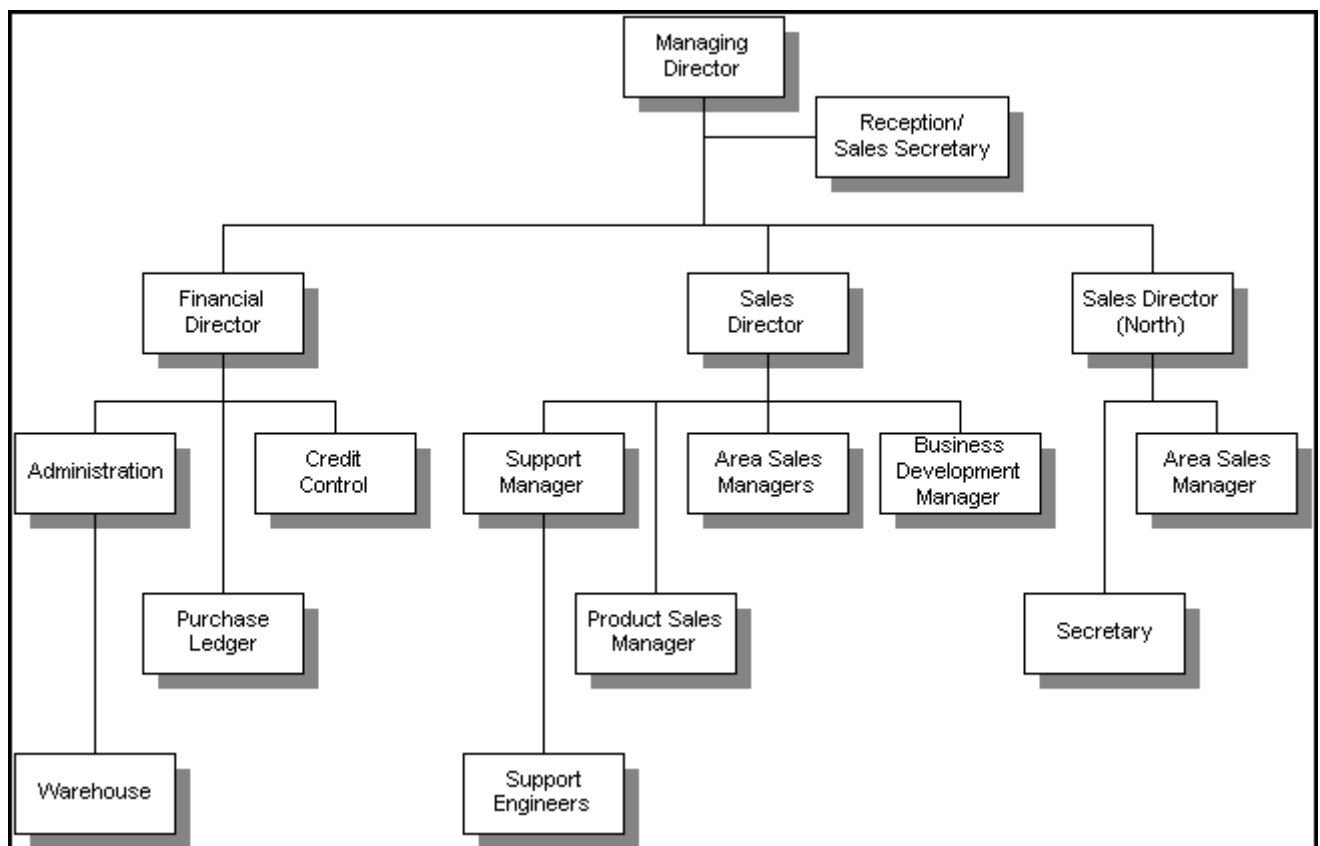
Level 2: Operating Procedures.

These documents describe the actual process, and controls applied, to all activities concerned with the attainment of a quality assured contracting service.

A list of Operating Procedures is given in the Index Section of this Quality Assurance Manual.

As the Company operates a standard type and range of services, customer satisfaction and quality are achieved by operation in accordance with the documented quality system. Specific customer requirements are identified and documented during the contract review process, allowing these requirements to be communicated and achieved, ensuring satisfaction of all customer declared needs.

5. ORGANIZATION



6. AUTHORITY & RESPONSIBILITIES

6.1 Authority

6.1.1 All staff members are allocated with authority to perform their allocated responsibilities. The following provides a summary of the principal responsibilities of each job role, and these are clarified in greater detail within the Operating Procedures.

6.1.2 All staff members share the authority and responsibility of identifying noncompliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

6.1.3 The Managing Director continually reviews the company's resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

6.2 Responsibilities

6.2.1 Managing Director:

- Approval of the Quality Assurance System,
- Management Review,
- Design Control,
- Supplier Selection & Purchasing,
- Contract Management & Control,
- Training.

6.2.2 Quality Manager (ISO9001 Management Representative):

- Internal Audit,
- Resolution of Quality Assurance System Discrepancies,
- Control & Maintenance of the Quality Assurance System,
- Documentation & Change Control (Quality System Documents).

6.2.3 Sales Director:

- Management & Co-ordination of Sales and Support FunctionsContract Review,
- Sales Order Processing,
- Design Control,
- Estimating,
- Project Management,
- Control of Contract Documentation,
- Planning & organization,
- Supplier Selection & Purchasing,
- Definition of Installation, Inspection, Test & Maintenance Requirements,
- Training.

6.2.4 Sales Managers:

- Quotations,
- Contract Review and Order Processing.

6.2.5 Support Manager:

- Planning and Co-ordination,
- Control of Production and Measuring Equipment,
- Maintenance of Support Stores,

- Processing of Sales Orders,
 - Purchasing.
- 6.2.6 Support Engineers:
- Planning & Performance of Installation, Technical Assistance,
 - Repairs, Testing and Maintenance Activities,
 - Control of Equipment and Materials Allocated.
- 6.2.7 Financial Director:
- Control of Finance, Accounts and Warehouse Operations,
 - Training,
 - Supplier Selection and Purchasing.
- 6.2.8 Warehouse:
- Control of Stock,
 - Replenishment Recommendation,
 - Protection and Preservation of Stock,
 - Receiving Inspection,
 - Packaging and Despatch.
- 6.2.9 Business Development Manager:
- Sales,
 - Estimating,
 - New Product Identification & Evaluation,
 - System Design.
- 6.2.10 Administration Order Processing Clerk:
- Sales Database Administration,
 - Checking of Sales Orders,
 - Allocation of Order Reference Numbers.

7. COMPLIANCE WITH ISO9001

This Quality System is structured with policy statements relating to each area of activity being within the relevant Operating Procedure. However, the following items of ISO9001 are not addressed within the operating procedures as they are not applicable to this Company: Statistical Techniques.

8. MANAGEMENT REVIEW AND INTERNAL AUDIT

Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

a) To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customers needs and expectations, and functioning in accordance with the established Operating Procedures.

b) To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.

c) To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.

d) To review any complaints received, identify the cause and recommend corrective action if required.

e) To review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.

f) To review the reports of nonconforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Program is compiled at least a year in advance however, should particular needs be identified, the frequency of audit may be increased at the discretion of the Quality Manager.

Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited within that Company. Nonconformance observed is brought to the attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification.

9. CONTRACT REVIEW

The Company offers both standard products and specialist services to meet each customer's needs. Standard products are displayed in a catalogue for customer selection. Specialist service requirements differ from one customer to another (and from one contract to another), therefore each tends to be quoted for the specific contract.

Once a proposal is accepted by the customer, or an order is placed, it is recorded and reviewed to establish that the requirements of the order are adequately defined and documented, any differences from the proposal are resolved, and the Company is capable of fully satisfying the customers requirements.

In addition to the original order/ contract specification the customer may also request addition/ variation work to be undertaken by the Company. In these circumstances the work content is documented and agreed with the customer prior to execution to ensure that no ambiguity exists.

The Company operates on a computerized order processing system to ensure rapid fulfillment of customer orders.

10. DESIGN CONTROL

All Design activities are strictly controlled to ensure that the design output information complies with customer/ contract requirements, and all design input data.

Design activities are planned and normally executed by specialists and are subject to regular management, review and verification by the Sales Director, and where relevant, agreement with the Customer.

The design input and output items are documented, and where ambiguity exists, will be clarified and documented. All items of design documentation and notes are recorded in a design project file. Design output documentation is produced and reviewed to ensure that it:

- meets the design input,
 - references the design input or appropriate criteria,
- and identifies all of the characteristics which are critical to the safe and effective operation of the system(s).

Design output is reviewed and approved by the Sales Director, and is also provided to the Customer for approval prior to use. Validation of the design is achieved during commissioning of the system to confirm compliance to the customer's requirements.

The designer is required to specify any inspections or tests which may verify the design, by practical means, at the earliest possible stage of development.

All changes to the design criteria, input or output are subject to strict review and documentation control procedures.

11. DOCUMENTATION & CHANGE CONTROL

All documentation utilized within the Company related to the management system itself, or to the execution of individual customer contracts is controlled to ensure that it is issued to the appropriate personnel, under the correct level of authority, is revised and reissued as necessary, and all obsolete versions are removed from the point of use.

Such documentation typically includes:

- Specifications, Customer Orders, Plans/ Drawings,
- Quality Assurance Manual/ Operating Procedures,
- National/ International Standards and Codes of Practice.

The Quality Assurance Manual, Procedures and Quality Plans are maintained by the Quality Manager who ensures that the appropriate items, at the correct revision levels, are issued to all who need them within the Company.

National/ International Standards, Codes of Practice are maintained by the Support Engineers who ensure that appropriate documents are available within the Company, and are issued at the correct revision levels. External suppliers of documentation are contacted regularly to ascertain that the documents held remain current.

The distribution of standard documents is controlled and recorded on Distribution Lists, which also show the current issue status. The Distribution Lists are reviewed and updated as changes occur.

All changes to documents are reviewed and approved by the person responsible for the original issue and, where appropriate, the nature of the change is indicated on the document. Master copies of the revised documents are retained as records of the changes and renewed as necessary to ensure clarity.

Each contract has a File which contains all relevant information. Information is also held on the company's computer system for ease of access and manipulation.

12. PURCHASING

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due consideration to the quality, statutory obligations, timescale and cost. A list of approved suppliers and sub-contractors is maintained which is compiled on the following criteria:-

- a) Previous performance in supplying to similar specifications and requirements.
- b) Stocking of high volume standard items conforming to a relevant British Standard, or supplied with a statement of conformity.
- c) Compliance with an approved third party product/ quality registration scheme.
- d) Recommendation by other similar purchasers or manufacturers of equipment.
- e) A trial order and evaluation of performance.

All supplies and sub-contracts are subject to an authorized Purchase Order providing full clarification of the type and extent of supply.

Should a supplier, not appearing on the Approved Suppliers List be proposed, they will be analyzed by capability and subject to acceptance on the authority of a Director.

13. CUSTOMER SUPPLIED ITEMS

Goods received from customers (i.e. free issue items or equipment being serviced) are always visually inspected at the receipt stage, with any un-declared non-conformance being immediately reported to the customer.

14. PROCESS CONTROL

All productive work is planned and undertaken in accordance with the company's procedures, and any specific documents agreed for individual contracts (e.g. contract specifications).

Work instructions are provided by the agreed contract specification and any documents referenced therein, alternatively work is performed in accordance with nationally accepted codes of practice (e.g. BS6701).

15. RECEIVING INSPECTION

All stores areas are maintained as secure as practical. All items received by the Company are identified and verified in accordance with the requirements of the Delivery Note and Purchase Order, and are inspected for correct identity, quantity and any signs of damage.

All goods received are documented and, in the event of non-conformance, the items are placed in a reject area or labelled to ensure identification. The extent of the non-conformance is noted and subject to disposition review by nominated personnel.

16. INSPECTION AND TESTING

Inspection and testing is carried out on completion of installation and maintenance activities, with results being documented. Should items not be acceptable against the agreed

contract criteria they will either be repaired, replaced or identified for a subsequent evaluation and decision. All repaired items are subject to a re-inspection to ensure acceptability.

On completion of installation and maintenance works, the customer is also invited to check the work performed to ensure full acceptability.

17. PRODUCTION & MEASURING EQUIPMENT

Production and measuring equipment held is maintained in good condition, and capable of safe and effective operation within a specified tolerance of accuracy. Test and measuring equipment is regularly inspected or calibrated to ensure that it is capable of accurate operation, by comparison with external sources traceable back to National Standards.

Electrostatic protection equipment is utilized when handling sensitive components, and this equipment is regularly checked to ensure that it remains fully functional.

18. INDICATION OF INSPECTION STATUS

As goods are inspected, the status is defined by location in stores, with all non-conforming items being placed in a reject area or marked as reject for review. The status of work in progress is established by markings or associated documentation recording the inspections undertaken and their acceptability.

19. NON-CONFORMING ITEMS, PREVENTIVE & CORRECTIVE ACTION

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification by nominated personnel. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All employees are encouraged to suggest improvements in methods, materials, suppliers, and sub-contractors. The Company has established procedures for review of all activities in order to identify and evaluate all possible improvements in methods/ materials and its procedures.

20. HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

The identification of materials/ equipment, where it is not obvious, is confirmed by the presence of a manufacturers/ suppliers part number or description label, or other marking for each item. The identification of the item may be on the packaging or on the item itself, and this identification remains in place for as long as possible, provided it does not hamper effective use of the item. Materials and consumables are not identified by the company where they are obvious to a trained/ experienced employee, however, should a risk of misinterpretation exist between two or more types of material these will be marked in a suitable manner to ensure that no ambiguity exists.

All items with serial numbers are recorded individually.

Materials and goods received, whether the property of the company or others, will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer, or disposed of to a third party. The objective is to prevent deterioration and damage whilst in storage, or in the process of transportation, installation, commissioning or maintenance.

21. RECORDS

Storage facilities are allocated which ensure that all stored records are identifiable and retrievable, and the storage areas are free from damp and other agents which could cause premature deterioration.

Where records are maintained on computer magnetic media, and these are subject to "back-up" at regular intervals, with the "back-up" information being stored in a protected location to ensure security from loss/ damage of active data.

All records are retained for a minimum of 2 years.

22. TRAINING

The policy of the company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The company generally procures and recruits employees capable of meeting the technical, skill, experience and educational requirements of the company's activities.

All staff and senior employees are responsible for recommending the training needs of others, and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks. Once training needs are identified these are provided under the responsibility of the Directors.

Full records are maintained of all training undertaken by employees.

23. SERVICING

Service and maintenance contracts are offered to all customers, and these activities are controlled in the same manner as Process Control.

Appendix 2. ISO 9000 Definitions

Conformity	<i>Conformity</i> is all about meeting requirements. ISO 9001 2000 lists many quality system requirements. If your organization meets these requirements, you can say that it <i>conforms</i> to these requirements.
Continual improvement	<i>Continual improvement</i> is a set of activities that an organization routinely carries out in order to enhance its ability to meet requirements. <i>Continual improvement</i> can be achieved by carrying out internal audits, performing management reviews, analyzing data, and implementing corrective and preventive actions.
Contract review	<i>Contract review</i> is a set of activities that an organization carries out in order to make sure that customer orders and contracts specify all the requirements that must be met, and in order to establish that the organization can actually meet these requirements.
Corrective actions	<i>Corrective actions</i> are steps that are taken to remove the causes of an existing nonconformity or to make quality improvements. Corrective actions address actual problems. In general, the corrective action process can be thought of as a problem solving process.
Customer	A <i>customer</i> is anyone who receives products or services from a supplier. A customer can be either external or internal to the supplier organization.
Customer satisfaction	<i>Customer satisfaction</i> is a perception. It is also a question of degree. It can vary from <i>high satisfaction</i> to <i>low satisfaction</i> . If customers believe that you have met their requirements, they experience <i>high satisfaction</i> . If they believe that you've not met their requirements, they experience <i>low satisfaction</i> .
Design	A <i>design review</i> is a set of activities whose purpose is to evaluate how well a potential product (a design) meets all quality requirements. During the course of this review, problems must be identified and solutions must be developed.
Design validation	<i>Design validation</i> is a process whose purpose is to examine products and to use objective evidence to confirm that these products meet user needs.
Design verification	<i>Design verification</i> is a process whose purpose is to examine design outputs and to use objective evidence to confirm that outputs meet input requirements.
Document	The term <i>document</i> refers to information and the medium that is used to bring it into existence. A document can be digital or physical. ISO identifies five types of documents: specifications, quality manuals, quality plans, records, and procedure documents.
Entity	An <i>entity</i> could be a product, process, person, activity, machine, service, system, department, company, institution, or organization. An <i>entity</i> could be a product, process, person, activity, machine, service, system, department, company, institution, or organization.
Infrastructure	The term <i>infrastructure</i> includes buildings, workspaces, equipment, hardware, software, utilities, and support services such as transportation and communication.
Internal quality audit	<i>Internal audits</i> are carried out by your personnel. Internal quality audits examine the elements of a quality management system in order to evaluate how well these elements comply with quality system requirements.

Management review	The purpose of a <i>management review</i> is to evaluate the overall performance of an organization's quality management system and to identify improvement opportunities. These <i>reviews</i> are carried out by the organization's top managers and are done on a regular basis.
Nonconforming products	When one or more characteristics of a product fail to meet specified requirements, it is referred to as a <i>nonconforming product</i> . When a product deviates from quality requirements, it fails to conform.
Nonconformity	ISO 9001 2000 lists quality management system requirements. When your organization deviates from these requirements, a <i>nonconformity</i> occurs. When a product, process, procedure, system, or structure deviates from ISO requirements, a formal <i>nonconformity</i> exists.
Organization	An <i>organization</i> is a company, corporation, firm, or institution that has its own functions and administration. It can be either incorporated or unincorporated, privately or publicly owned.
Organizational structure	The <i>structure</i> of an organization is the pattern of responsibilities, authorities, and relationships that control how people perform their functions and govern how they interact with one another.
Preventive actions	<i>Preventive actions</i> are steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process.
Procedures	Quality <i>procedures</i> control processes or activities. A well defined procedure controls a logically distinct process or activity, including the associated inputs and outputs. Such a procedure defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work. While quality procedures may be documented or undocumented, ISO usually expects them to be documented.
Process	<p>In general, a <i>process</i> uses resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out. Processes can be administrative, industrial, agricultural, governmental, chemical, mechanical, electrical, and so on. An ISO 9001 Quality Management System is made up of the following processes:</p> <ul style="list-style-type: none"> • Purchasing process. • Production process. • Product design process. • Product protection process. • Service provision process. • Document control process. • Record keeping process. • Internal audit process. • Planning process. • Training process. • Monitoring process. • Measurement process. • Market research process. • Regulatory research process.

	<ul style="list-style-type: none">• Continual improvement process.• Internal Communications process.• Customer Communications process.• Customer needs assessment process.• Nonconformance management process.
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Process approach	The <i>process approach</i> is a management strategy. When managers use a <i>process approach</i> , it means that they control the <i>processes</i> that make up their Quality Management Systems, the interaction between these <i>processes</i> , and the inputs and outputs that glue these <i>processes</i> together. It means that they manage by focusing on <i>processes</i> .
Product	A <i>product</i> is an output that results from a process. Products can be tangible or intangible, a thing or an idea, hardware or software, information or knowledge, a process or procedure, a service or function, or a concept or creation. Please note that when ISO uses the term <i>product</i> they also mean <i>service</i> .
Product inspection	<i>Product inspection</i> is an activity that compares product characteristics with product requirements in order to establish conformity. More precisely, product inspection is an activity that compares one or more characteristics of a product with specified requirements in order to determine if the product meets these requirements.
Product nonconformity	When one or more characteristics of a product fail to meet specified requirements, they are referred to as <i>product nonconformities</i> .
Product realization	A product starts out as an idea. The idea is <i>realized</i> or actualized by following a set of <i>product realization processes</i> . So <i>product realization</i> refers to all the processes that are used to bring products into being.
Quality	A <i>quality</i> is a <i>characteristic</i> that a product or service must have. For example, products must be reliable, useable, and repairable. These are some of the characteristics that a good quality product must have. Similarly, service should be courteous, efficient, and effective. These are some of the characteristics that a good quality service must have. In short, a <i>quality</i> is a <i>desirable characteristic</i> . However, not all qualities are equal. Some are more important than others. The most important qualities are the ones that customers want. These are the qualities that products and services must have. So providing quality products and services is all about meeting customer requirements. It's all about meeting the needs and expectations of customers. So a <i>quality product or service</i> is one that meets the needs and expectations of customers.
Quality assurance	<i>Quality assurance</i> (Q.A.) is defined as a set of activities whose purpose is to demonstrate that an entity meets all quality requirements. Q.A. activities are carried out in order to inspire the confidence of both customers and managers, confidence that all quality requirements are being met.
Quality audits	<i>Quality audits</i> examine the elements of a quality management system in order to evaluate how well these elements comply with quality system requirements.
Quality control	<i>Quality control</i> is defined as a set of activities or techniques whose purpose is to ensure that all quality requirements are being met. In order to achieve this purpose, processes are monitored and performance problems are solved.
Quality improvement	<i>Quality improvement</i> refers to anything that enhances an organization's ability to meet quality requirements.
Quality management	<i>Quality management</i> includes all the activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement.
Quality manual	A <i>quality manual</i> documents an organization's Quality Management

	System. It can be a paper manual or an electronic manual.
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Quality planning	<i>Quality planning</i> is defined as a set of activities whose purpose is to define quality system policies, objectives, and requirements, and to explain how these policies will be applied, how these objectives will be achieved, and how these requirements will be met. It is always future oriented.
Quality plan	A <i>quality plan</i> explains how you intend to apply your quality policies, achieve your quality objectives, and meet your quality system requirements.
Quality policy	A <i>quality policy</i> statement defines or describes an organization's commitment to quality.
Quality record	A <i>quality record</i> contains objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.
Quality requirement	A <i>quality requirement</i> is a characteristic that an entity must have. For example, a customer may require that a particular product (entity) achieve a specific dependability score (characteristic).
Quality surveillance	<i>Quality surveillance</i> is a set of activities whose purpose is to monitor an entity and review its records to prove that quality requirements are being met.
Quality management system	A <i>quality management system</i> is a web of interconnected processes. Each process uses resources to turn inputs into outputs. And all of these processes are interconnected by means of many input-output relationships. Every process generates at least one output, and this output becomes an input for another process. These input-output relationships glue all of these processes together - that's what makes it a <i>system</i> .
Quality system requirement	A <i>quality</i> is a characteristic. A <i>system</i> is a set of interrelated processes, and a <i>requirement</i> is an obligation. Therefore, a <i>quality system requirement</i> is a characteristic that a process must have.
Record	A <i>record</i> is a document that contains objective evidence which shows how well activities are being performed or what kind of results are being achieved. It always documents what has happened in the past.
Requirement	A <i>requirement</i> is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, and product requirements.
Resources	<i>Resources</i> include people, money, information, knowledge, skill, energy, facilities, machines, tools, equipment, technologies, and techniques.
Service	<i>Service</i> is a customer-oriented <i>result</i> . This result is produced when an organization performs activities that are oriented towards meeting customer needs and expectations.
Service delivery	<i>Service delivery</i> is a customer-oriented <i>activity</i> . Service delivery activities are carried out by organizations and are oriented towards meeting customer needs and expectations.
Special process	A <i>special process</i> is any production or service delivery process that generates outputs that cannot be measured, monitored, or verified until it is too late. It is often too late because deficiencies may not be obvious until after the resulting products have been used or services have been delivered. In order to prevent output deficiencies, these <i>special processes</i> must be validated in order to prove that they can

	generate planned results.
Standard	<p>A <i>standard</i> is a document. It is a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.</p> <p>ISO's <i>standards</i> are <i>agreements</i>. ISO refers to them as <i>agreements</i> because its members must agree on content and give formal approval before they are published.</p> <p>ISO standards are developed by technical committees. Members of these technical committees come from many countries. Therefore, ISO standards tend to have very broad support.</p>
Supplier	<p>A <i>supplier</i> is an organization that provides products or services to customers. Customers can be either internal or external to the supplier organization.</p>
Total quality management	<p><i>Total quality management</i> is defined as a management approach that tries to achieve and sustain long-term organizational success by encouraging employee feedback and participation, satisfying customer needs and expectations, respecting societal values and beliefs, and obeying governmental statutes and regulations.</p>
Work environment	<p>The term <i>work environment</i> refers to all the factors that influence work. In general, these include social, cultural, psychological, physical, and environmental conditions. The term <i>work environment</i> includes lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices as well as reward and recognition programs. All of these things influence how work is performed.</p>