

ISO 9000, A ROAD TO TOTAL QUALITY MANAGEMENT (TQM)

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ISO 9000, A Road To Total Quality Management (TQM)

My name is Tadeusz K. Pilinski. I am an owner of a firm named QUATECH devoted to the Quality Management consulting services. We specialize in developing Quality Management Systems based on internationally recognized standards, i.e. ISO 9000, API, ASME and AAR.

I was thinking for a quite long time how to present the subject of Total Quality Management and the ISO 9000 series standards. I do realize that the audience represents quite a variety. I did not want to bore you with a lot of philosophical concepts, technical data, and requirements of the standards. Knowing that some of you may already know a lot about the subject, we decided to approach the presentation in two parts; first one - general introduction, and the second one - a panel discussion.

The objective of my presentation is to familiarize listeners with interpretations of the term Total Quality Management (TQM). To give the audience a general overview of the TQM philosophy and approaches to its implementation. Introduce listeners to the ISO 9000 series of standards. And to show how implementation of a Quality System based on the ISO 9000 series of standards could pave the road toward achieving Total Quality Management.

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Objectives.	
<ul style="list-style-type: none">• Familiarize listeners with interpretations of the term "Total Quality Management"• Introduce listeners to the ISO 9000 series of standards• Show how implementation of a Quality System based on the ISO 9000 series of standards could pave the road toward achieving TQM	
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The practice of management is as old as organization. Clay tablets dating back to 3000 B.C. recorded business transaction and laws in ancient Sumeria. Management historians place the start of the formal study of management in the early 1800s. For example, Robert Owen studied management in 1800s and Andrew Ure in 1835. Frederic W. Taylor is often referred to as the father of scientific management. He worked at Midvale Steel in Philadelphia, Pennsylvania, from 1878 to 1890.

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Quality management history.	
<ul style="list-style-type: none">• 3000 B.C. clay tablets recorded business transactions and laws in ancient Sumeria• 200-300 A.D. beginning of the Roman Catholic Church – an example of a management system that is still prosperous today• 1800s described as the first formal studies of management; Robert Owen, Andrew Ure - studies of management• 1911 Frederick Taylor published Principles of Scientific Management• 1900s Henri Fayol developed the 14 Principles of Management	
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In 1911 Taylor published Principles of Scientific Management. In the early 1900s Henri Fayol developed the 14 Principles of Management, which he felt could be used to plan, organize, command, coordinate, and control.

From 1920 to 1940, human relations theory was the prevailing management style. Elton, for example, felt that management should show more concern for their employees. Then Hawthorne made a significant discovery. His experiments conducted in the plant environment showed that productivity of workers was not related to physical conditions of work, but to how people were treated and how they felt about their work, their supervisors, and their coworkers.

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Quality management history (continued).	
<ul style="list-style-type: none">• 1920-1940 Elton felt that management should show more concern for their employees; Hawthorne showed that productivity of workers was not related to physical conditions of work, but to how people were treated• 1950s W. Edwards Deming honored by Japanese for work in the quality management area. He professed quantitative methods, techniques, and tools to analyze the problems involving operations.• 1961 Vallin Feigenbaum wrote Total Quality Control• Philip Crosby, Joseph M. Juran, Thomas J. Peters, Robert H. Waterman, Kaoru Ishikawa, Genichi Taguchi	
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For fifty years quality as a theme of management strategy and practice influenced the administrative structure of the industrial world. W. Edwards Deming, a name synonymous with quality management, has been honored and successfully emulated by the Japanese. Armand Vallin Feigenbaum, who devoted his career to the General Electric Company, wrote in 1961 the widely accepted Total Quality Control. Philip B. Crosby and Joseph M. Juran have made valuable contributions to the world of management. So did Thomas J. Peters and Robert H. Waterman. And the Japanese have made their contributions, just to name Kaoru Ishikawa and Genichi Taguchi.

I think it is prudent to identify the subject of our conversations by defining it. We are going to talk about Total Quality Management, popularly called TQM, and the ISO 9000 series of standards.

It is interesting to mention that Dr. Deming, one of the most famous people in the field of quality, never wanted to use the term TQM. He used to say that he did not know what that term meant. It is my opinion that Dr. Deming has a problem with a proper definition of the word "total" in the environment of the supplier - purchaser relationship. He preferred to speak of "company-wide quality control" or CWQC.

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There are many definitions of TQM in use. For our presentation, let's use James P. Corrigan's definition, where he describes TQM as "a management philosophy that builds a customer-driven environment in which the supplier is dedicated to total customer satisfaction with continuous improvement in the effectiveness and efficiency of its organization and its processes".

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Definitions.	
<u>Total Quality Management</u>	
"A management philosophy that builds a customer-driven environment in which the supplier is dedicated to total customer satisfaction with continuous improvement in the effectiveness and efficiency of its organization and its processes."	
- James P. Corrigan	
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A little different definition of TQM is described by the ISO 8402, where Total Quality Management is defined as "approach of an organization, centered on quality, based on the participation of all its members and aiming at long term success through customer satisfaction, and benefits to the members of the organization and to society".

To talk about TQM, its very important to define the term "**quality**". As one may expect, there are several definitions pertinent to this term. The standard ISO 8402 describes quality as "the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs".

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Definitions.	
<u>Quality</u>	
"The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs."	
- ISO 8402	
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Quality system is described by the ISO 8402 as "the organizational structure, responsibilities, procedures, processes, and resources needed to implement quality management".

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Definitions.	
<u>Quality System</u>	
"The organizational structure, responsibilities, procedures, processes, and resources needed to implement quality management."	
- ISO 8402	
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Quality management is defined by the ISO 8402 as "all activities of the overall management function that determine the quality policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement, within the quality system".

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Definitions.	
<u>Quality Management</u>	
" All activities of the overall management function that determine the quality policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement, within the quality system."	
- ISO 8402	
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Quality assurance is "all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality".

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Definitions.	
<u>Quality Assurance</u>	
"All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality."	
- ISO 8402	
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Quality control is "the operational techniques and activities that are used to fulfill requirements for quality".

To simplify the above terminology with common words, quality could be understood as representation of success. If success = customer satisfaction, then quality = degree of success. Quality system = a philosophy and organizational structure to achieve success. Quality management = implementation of the quality system, including planning. Quality assurance = procedures defined to assure the success (or quality). Quality control = actual collection of the data which measure the degree of success (quality of work, service, manufacturing, processing, etc.).

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Definitions.	
<u>Quality Control</u>	
" The operational techniques and activities that are used to fulfill requirements for quality."	
- ISO 8402	
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In order to complete our glossary of terms, we need to consider the word "total". Webster's Dictionary defines the term as "complete in all its parts".

It is virtually impossible to define "all" the factors that are functions of quality of a given entity. That is why Dr. Deming did not want to use the term TQM, which couldn't reflect the real life situation.

Whether you like the term TQM or not, it has made its way into the business landscape as philosophy devoted to total customer satisfaction through continuous improvement. All members of the organization must be driven to have a mind-set that is focused on satisfying customers' needs and expectations. This would lead to concentration on value-added activities directed at total customer satisfaction.

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Definitions.	
<u>Value-Added Activities</u>	
"Those activities that transform an input into a customer-usable output. The customer can be internal or external to the organization." The output must be of greater value than that of the input.	
- ISO 8402	
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To build a customer mind-set in employees, management must provide a support system. The business must have an effective quality system in place, continual

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education and training system, tailored recognition and reward system, accessible information system, and feedback system. If the TQM system is built without an underlying quality system, it will ultimately fail.

A successful TQM management system incorporates these principles into its quality policy. TQM requires continual care and upkeep to remain viable. Therefore, each TQM function continuously improves the effectiveness and efficiency of its processes, based on customer needs and expectations.

As was said before, any business has to have an effective quality system in place, without which there is no talking about TQM. Quality systems could be based on different philosophies or models. One of the most popular models these days is the ISO 9000 series of standards.

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Feasibility of TQM.	
Any business has to have an effective quality system in place, without which there is no talking about TQM.	
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The ISO 9001, ISO 9002, and ISO 9003 contain criteria that measure the effectiveness of different quality systems designed to meet customers' requirements.

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Overview of ISO 900 series of standards.	
<ul style="list-style-type: none">• ISO 9000 Quality Management and Quality Assurance standards• ISO 9001 Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation, and Servicing• ISO 9002 Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing• ISO 9003 Quality Systems - Model for Quality Assurance in Final Inspection and Test• ISO 9004 Quality Management and Quality System Elements - Guidelines	
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The quality system becomes a baseline from which to start quality improvement activities. Using an ISO 9000 standard for this assessment would provide excellent criteria and a structured approach to periodic evaluations of the quality system. A

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successful TQM effort will continuously force change in the quality system and this could become a critical long-term success factor.

ISO is the International Organization for Standardization, headquartered in Geneva, Switzerland, with over 90 member countries. Its purpose is to develop and promote standards worldwide. ISO work is done through over 180 Technical Committees (TC's). ISO/TC176, Quality Management and Quality Assurance Technical Committee, is responsible for quality standards. The US representative to ISO is the American National Standards Institute (ANSI). Poland is represented in ISO by Polski Komitet Normalizacyjny (PKN).

ISO 9000 is a series of five generic, baseline quality standards or models for quality assurance systems intended for broad application to a wide range of non-specific industries and products. These standards define the basics of how to establish, document, and maintain an effective quality system. The ISO 9000 series consists of both "models", which define specific minimum requirements for external suppliers, and "guidelines" for development of internal quality programs. The ISO 9000 series is based on the national standards of several ISO member countries, including Great Britain, France, Germany, Netherlands, Canada, and USA.

The rapid increase in interest in the ISO 9000 comes about for a variety of reasons:

- The realization that ISO 9000 registration will be an increasingly important factor in doing business in the European Community - either as a desirable marketing/competitive consideration or as a necessity.
- Recognition that the European Community represents the largest market of potential customers among industrialized nations in the world, and the largest US trading partner, with a population more than a third larger than the US and GNP almost as large as the US.
- The European Free Trade Association (EFTA) is seeking to join a united Europe. The EC and the EFTA, together with the Eastern Bloc countries, represents a potential market of 5000 million people.

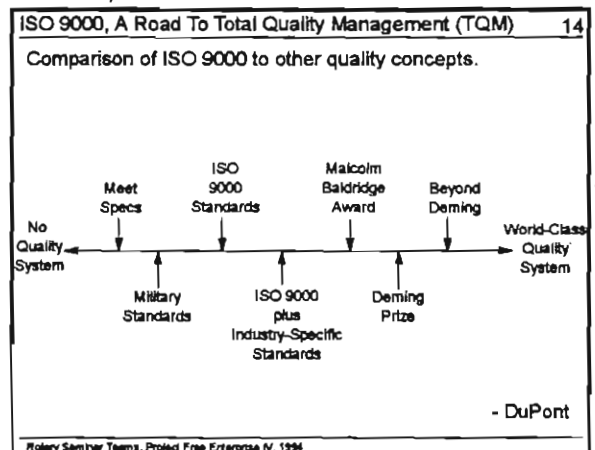
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Interest in ISO 9000 increases.	
• ISO 9000 registration - Important factor in doing business in the European Community	
• U.S. Department of Defense (DoD) and the Food and Drug Administration (FDA) would accept from their suppliers Quality Systems based on ISO 9000; also the Federal Aviation Administration (FAA), the National Aeronautical and Space Administration (NASA) and NATO are considering ISO 9000	
• Asian and Pacific nations adopted ISO 9000	
• Over 60 nations around the world have adopted ISO 9000 as their national standards	
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- Both the US Department of Defense (DoD) and the Food and Drug Administration (FDA) have announced their intention to change their current quality system requirements to comply with ISO 9000. The Federal Aviation Administration (FAA) and the National Aeronautics and Space Administration (NASA) are considering ISO 9000. NATO has announced its intention to adopt ISO 9000.
- Several multinational companies have stated that ISO 9000 registration by their suppliers will be required. Even without a requirement, registration is viewed as a definite competitive advantage.
- ISO 9000 registration represents one method of demonstrating control system conformance on some EC Regulated Products, and for UK food processing companies.
- Adoption of ISO 9000 by Asian and Pacific nations, in addition to all the above factors, completes the picture of ISO 9000 as truly an important world-wide standard that, as a minimum, must be given serious consideration.
- The growing amount of press coverage, articles, and advertisements for training and registration services has greatly increased the public awareness of ISO 9000.

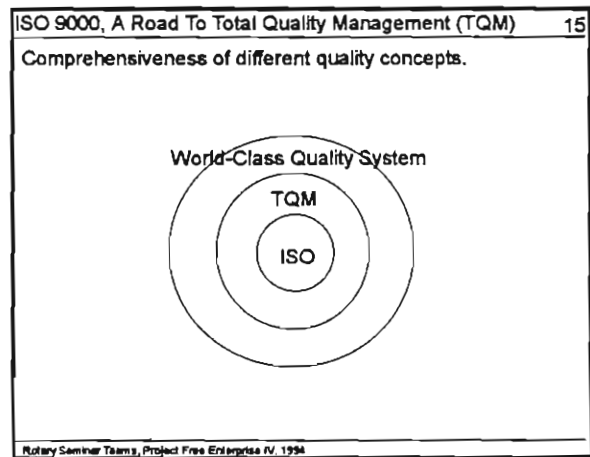
Over 50 nations around the world have adopted ISO 9000 as their national standards.

There are many different quality programs, standards, and awards in existence. There is no precise way to compare them. We could try to show their extent of coverage and stringency, ranging from no quality system to a world class quality system.



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Or better yet, the extent of a quality system could be shown on a circular graph, presenting the least developed system in the center, and each higher hierarchy quality system being represented by the bigger circle which includes the lower system in itself.



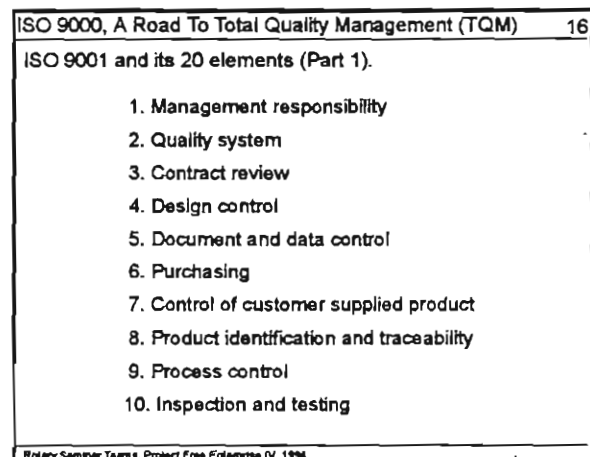
Of course, many individual companies have their own quality standards. The ISO 9000 series of quality standards should be viewed as a baseline for a quality system, or foundation for TQM, but not as a final quality system goal.

The Malcolm Baldrige National Quality Award is the most prestigious award in the USA. It consists of seven categories:

1. Leadership
2. Information and analysis
3. Strategic quality planning
4. Human resource development and management
5. Management of process quality
6. Quality and operational results
7. Customer focus and satisfaction

The ISO 9001 standard has 20 requirements.

1. Management responsibility
2. Quality system
3. Contract review
4. Design control
5. Document and data control
6. Purchasing
7. Control of customer supplied product
8. Product identification and traceability
9. Process control
10. Inspection and testing



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11. Control of inspection, measuring and test equipment
12. Inspection and test status
13. Control of nonconforming product
14. Corrective and preventative action
15. Handling, storage, packaging, reservation and delivery
16. Control of quality records
17. Internal quality audits
18. Training
19. Servicing
20. Statistical techniques

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ISO 9001 and its 20 elements (Part 2).	
11. Control of inspection, measuring and test equipment	
12. Inspection and test status	
13. Control of nonconforming product	
14. Corrective and preventative action	
15. Handling, storage, packaging, preservation and delivery	
16. Control of quality records	
17. Internal quality audits	
18. Training	
19. Servicing	
20. Statistical techniques	

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Of course, the purpose of the two documents, the Malcolm Baldrige Award's seven categories and 20 system requirements of the ISO 9001, are very different. Baldrige is a customer and results oriented award, with emphasis on the total system, feedback, and results, where the ISO 9001 focuses more narrowly on the quality system and documentation. However, many people refer to the ISO 9000 series of standards as an important element of the Baldrige criteria, or of a TQM system. The formal measurement of the entire TQM activity is performed by the Union of Japanese Scientists and Engineers (JUSE). A JUSE subcommittee, responsible for the Deming Prize awards, conducts a complete examination of an organization's implementation of TQM.

Deming Prize examiners measure the following areas:

1. Policy
2. Organizational design
3. Education/training
4. Information
5. Analysis
6. Standardization
7. Control
8. Quality assurance
9. Effectiveness
10. Future plans

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The ISO 9000 series of standards consists of five standards: ISO 9000, ISO 9001, ISO 9002, ISO 9003, and ISO 9004.

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ISO 9000 series of standards.	
<ul style="list-style-type: none">• ISO 9000• ISO 9001• ISO 9002• ISO 9003• ISO 9004	
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The ISO 9000, "Quality Management and Quality Assurance Standards - Guidelines for Selection and Use", explains fundamental quality concepts; defines key terms; and provides guidance on selecting, using the ISO 9001, ISO 9002, and ISO 9003.

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ISO 9000 Series consists of 5 standards	
<u>ISO 9000</u>	
The ISO 9000, "Quality Management and Quality Assurance Standards - Guidelines for Selection and Use," explains fundamental quality concepts; defines key terms; and provides guidance on selecting, using the ISO 9001, ISO 9002, and ISO 9003.	
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The ISO 9001, "Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing", is the most comprehensive standard in the series. The ISO 9001 covers elements listed in ISO 9002 and ISO 9003. In addition it addresses design capabilities.

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ISO 9000 Series consists of 5 standards	
<u>ISO 9001</u>	
The ISO 9001, "Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing," is the most comprehensive standard in the series. The ISO 9001 covers elements listed in ISO 9002 and ISO 9003. In addition, it addresses design capabilities.	
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The ISO 9002, "Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing". It is more extensive and more sophisticated than ISO 9003.

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ISO 9000 Series consists of 5 standards	
<u>ISO 9002</u>	
The ISO 9002, "Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing." It is more extensive and more sophisticated than ISO 9003.	
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The ISO 9003, "Quality Systems - Model for Quality Assurance in Final Inspection and Test", is the least comprehensive standard.

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ISO 9000 Series consists of 5 standards	
<u>ISO 9003</u>	
The ISO 9003, "Quality Systems - Model for Quality Assurance in Final Inspection and Test," is the least comprehensive standard.	
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The ISO 9004, "Quality Management and Quality System Elements - Guidelines", provides guidance for a supplier to use in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. ISO 9004 examines each of the quality system elements in greater detail and can be used for the preparation for development of a quality system based on one of the above three ISO standards.

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ISO 9000 Series consists of 5 standards	
<u>ISO 9004</u>	
The ISO 9004, "Quality Management and Quality System Elements - Guidelines," provides guidance for a supplier to use in developing and implementing a quality system and in determining the extent to which each quality system element is applicable.	
ISO 9004 examines each of the quality system elements in greater detail and can be used for the preparation for development of a quality system based on one of the above three ISO standards.	
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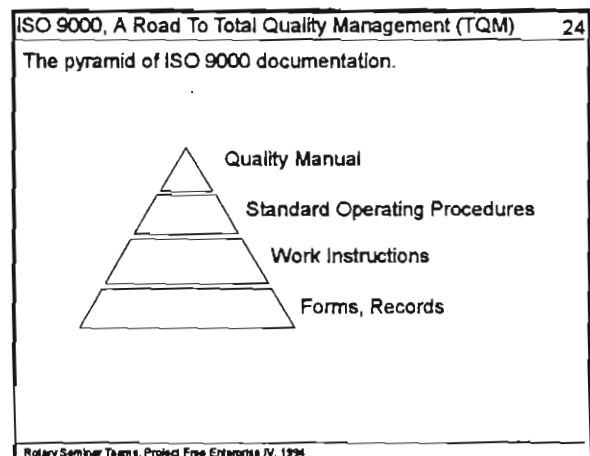
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It is very important to remember that the ISO 9000 series standards only define the requirements of a prevention-driven quality assurance system. If the system is adhered to, the supplier will always produce and deliver a predictable product or service.

The ISO 9000 standards are system standards, not product standards. All of the standard elements must be documented, the documentation must cover all the requirements, and the company must do what it has documented. Adequacy of the system and the producer's adherence to it is measured by auditing against the standard.

Documentation for the ISO 9000-based quality system is built on the principle of a four-tier approach.

The top of the system is taken by a Quality Program Manual, followed by Standard Operating Procedures, then Work Instruction, and at the lower level Quality Records. The Quality manual is the most important because supplier's procedures and instructions are derived from it. The manual is a management document in which the quality policy and objectives to which the supplier is committed are documented. All of the 20, mentioned before, elements of the ISO 9001 must be addresses in the manual.



From the Quality Manual, Procedures are developed for each system element. These procedures are interdepartmental. Ideally, they should be developed under the leadership of the organization responsible for the element and agreed to by all department and interrelated departments since the scope of the procedures is organization-wide.

The procedures lead to the next tier of documentation, called Instructions, which are departmental, step-by-step directions at the task level.

And finally, lowest level of the documentation "pyramid" is taken by the Records. They document the results of the activities required by the Instructions, Standard Operating Procedures, and Quality Manual.

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The ISO 9000 series standards are applicable virtually to any type of business; manufacturing, processing or service. As we mentioned before, the standards provide the model of a quality system which has to be adapted to a particular environment.

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The application of ISO 9000.	
<ul style="list-style-type: none">• The ISO 9000 series standards are applicable virtually to any type of business: manufacturing, processing, or service• The standards provide the model of a quality system which has to be adapted to a particular environment	
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Each company must weight the expected benefits of registration against the effort (time and money) of becoming registered. A list of primary advantages associated with the ISO 9000 registration is shown below:

- Improved entry to EC and other international markets
- Fewer, more directed audits
- Independent assessment of your quality management system
- Can lead to increased productivity and quality
- Competitive edge over non-registered competitors
- Recognizable logo on sales and advertising materials
- National/international recognition through listing in a Registry

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The benefits of ISO 9000 registration.	
<ul style="list-style-type: none">• Improved entry to EC and other international markets• Fewer, more directed audits• Independent assessment of your quality management system• Can lead to increased productivity and quality• Competitive edge over non-registered competitors• Recognizable logo on sales and advertising materials• National/international recognition through listing in a Registry	
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In general, registration is considered on the basis of commercial, regulatory, and technical reasons.

In spite of some limitations, it must be pointed out that the ISO 9000 is the benchmark standard that has been adopted world-wide, and which is gaining acceptance and use in more and more areas and companies.

When a company decides to become registered, the company must select an appropriate registrar. Unless the company has only one customer and that customer specifies the registrar to be used, this could be a difficult question. The decision on the

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registrar depends on the following considerations that must be reviewed from the given company's particular viewpoint:

- The registrar must have accreditation that will be accepted by a customer or regulator;
- Has registrar been accredited by the Registrar Accreditation Board (RAB)?
- The registrar's certificate must be recognized in all of the different countries in which a company expects to do business;
- The registrar has experience and references in your product and process area;
- Registrar's agreement (Memo of Understanding) with other registrars, to expand coverage of certificate;
- How long has registrar been in business; how many companies have they registered?
- How long is their waiting list to get audited?
- Are their fees compatible?
- What conditions does registrar have on use of its symbol or logo?
- What type of registry list is published, and how often?
- What is recourse if registrar goes out of business or loses its accreditation?
- What are registrar's post-registration requirements (confirmation audits and re-registration)?

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Selection of the registrar.	
• The registrar must have accreditation that will be accepted by a customer or regulator	
• The registrar's certificate must be recognized in all of the different countries in which a company expects to do business	
• The registrar has experience and references in your product and process area	
• What conditions does registrar have on use of its symbol or logo?	
• What type of registry list is published, and how often?	
• What are the registrar's post-registration requirements (confirmation audits and re-registration)?	

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All pertinent items above, and others that may be of concern, need to be explored and discussed with potential registrars before signing up with one registrar.

With this, let me finish my introduction to the TQM and ISO 9000 series of standards. Should you have any questions relevant to the presented topics, I will be more than happy to answer. We have allowed about one hour time for the Q and A. Should there be questions that will be deemed very specific, I will address them on individual basis.

Thank you very much for your attention.
Now, do we have any questions?

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Conclusion.
Questions and Answers
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