
Title: Introduction to ISO 9000

Course:
Year: 1993
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Report No: P93009

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We examine the evolution and relationship of the European Community and standards organizations as they have developed. Subsequently, the reasons for obtaining ISO 9000 certification and the ISO guidelines are examined.

# Introduction to ISO 9000

EMP-P9309

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## ABSTRACT

On January 1, 1993, the European Community became a single market by mandate. Whether this unification works or not is of great interest to the rest of the world. The Community believes that common standards are essential in realizing their goals of freedom of movement of people, goods, and capital within a single marketplace. The European Commission chose ISO 9000 to play a key role in achieving this. ISO 9000 has been adopted by most of Europe. In fact, these standards have been adopted internationally, as ISO 9000 is quickly becoming a requirement for doing business in Europe.

This paper examines the evolution and relationships of the European Community and standards organizations as they pertain to the development of ISO 9000. Subsequently, the reasons for obtaining ISO 9000 certification and the ISO guidelines are examined. Finally, key points for achieving ISO 9000 certification are presented as a ten-step implementation plan.

# INTRODUCTION

After World War II, Europe needed to rebuild its industry and economy. To facilitate this, all countries were concerned with developing product, quality, and regulatory standards. Unfortunately, these efforts were not unified and each country proceeded to develop its own sets of standards. Until recently, European producers considered their individual, professional, industrial, or national standards more than adequate [14].

When the European Community (EC) was created, its executive body, the European Commission, chose as one of its tasks, the harmonizing of European standards. The International Organization for Standardization (ISO) has been instrumental in this effort. The task has been difficult since over the past 30 years, only a few hundred standards have been harmonized out of the tens of thousands that exist [12]. Of these, only the ISO 9000 series defines the minimum requirements that a company must meet to assure a quality product to their customers.

The publication of the ISO 9000 series in 1987, together with the accompanying terminology standard, ISO 8402, has brought harmonization on an international scale and has supported the growing impact of quality as a factor in international trade [15]. In the United States, these standards have been released through the American National Standards Institute (ANSI) as the Q90 series with the accompanying A3 terminology standard [1],[2],[3],[4],[5],[6].

# STANDARDS ORGANIZATIONS

Today's products must conform to many regulations and standards. These conditions have been derived from the actions of both government regulatory agencies and private standards organizations. Usually, the technically detailed standards are created by private organizations. However, these voluntary standards often become mandatory as governments adopt and enforce them.

## UNITED STATES

### Government Regulation

Government power in the United States is divided among the executive branch, the judicial branch, and the legislative branch. Congress, the legislative branch, creates the laws governing the country. However, Congress' power is limited as defined by the Constitution. The Constitution's Commerce clause authorizes Congress to "regulate commerce with the foreign nations and among the several states" [18]. Congress establishes agencies as the means to handle the detailed implementation of congressional statutes.

In order to safeguard any actions taken by these appointed agencies, Congress created the Administrative Procedure Act (APA) which limits how Federal agencies make and enforce their rules

and regulations. The APA requires that all rules issued by agencies be subject to a notice and comment procedure. Notice of proposed rules must be published in the Federal Register and must state the terms of the proposed regulations and the authority allowing the agency to propose them. At least 30 days must pass before the rules become effective, and the agency must respond to written comments concerning the proposed rules. In addition to this right to comment, individuals have the right to petition agencies to initiate new rules or amend existing ones [21].

When initiating technical standards, Federal agencies can adopt existing private standards or write their own. However, the Office of Management Bureau (OMB) Circular No. A-119 urges Federal agencies to work with private standards organizations and incorporate privately developed standards in their rules. These adopted standards are still subject to the notice and comment procedure [21].

**Private Standards Organization**

ANSI

The primary standards organization in the United States' private sector is the American National Standards Institute (ANSI). ANSI functions as the United States National Committee to the International Electrotechnical Commission (IEC) and to the International Organization for Standardization (ISO). ANSI does not write standards itself, but acts only as a "national

clearinghouse" [21]. ANSI works with groups such as the Institute of Electrical and Electronic Engineers (IEEE), Underwriters Laboratory (UL), and the American Society for Quality Control (ASQC) to write standards. ANSI reviews these for technical accuracy and adherence to due process and, if approved, it becomes an American National Standard. To date, ANSI has issued about 10,000 standards [21].

The guiding principle for ANSI is standardization by consensus. Consensus implies "much more than the concept of a simple majority, but not necessarily unanimity." ANSI enforces "due process" by utilizing a process described in "The Procedures for Development and Coordination of American National Standards". Basically, this sets a standard of fairness that states "everyone with a direct or material interest has a right to express a viewpoint and, if dissatisfied, to appeal." Due process also requires balanced representation and that all have the opportunity to speak "without dominance by any single interest."

A proposed standard is sent to the Board of Standards Review (BSR) which publishes a notice of the proposed standard in the ANSI publication "Standards Action." The public has the opportunity to review and comment from 30 to 60 days. If any comments come up, a "concerted effort to resolve all objections must be made." Once adopted, standards are reviewed every five years [21].

ASQC

Founded in 1946, the original purpose of the American Society for Quality Control (ASQC) was to improve the quality of defense materials. Today, the ASQC is a worldwide leader in the development, promotion, and application of quality and quality related technologies for the quality profession. Its goals are to create a greater awareness of the need for quality, to promote research and the development of standards, and to provide educational opportunities to ensure product and service excellence through improved quality [31].

By working with the ANSI/RAB accreditation program, the ASQC is actively pursuing acceptance as the ISO 9000 accreditation body in the United States [29].

RAB

In November, 1989, the Registrar Accreditation Board (RAB) was established as an affiliate of the American Society for Quality Control (ASQC) to develop a program to evaluate the quality of services offered by registrars. Registrars are licensed private parties who perform ISO 9000 quality system audits. The RAB issued its first approval in March 1991, and several more firms have been approved since then [25]. In December, 1991, the RAB signed an agreement with ANSI to jointly administer this accreditation program [29].

## EUROPEAN COMMUNITY

### Government Regulations

The European Community (EC) is not a sovereign organization, but a group of twelve countries bound together by Common Market treaties. The goals of this organization include eliminating restrictions to free movement of goods, services, people, and capital within their Common Marketplace. Of primary concern to the EC is the removal of technical standards which act as trade barriers.

The EC's lawmaking process begins with the European Commission. This is comprised of appointees who ideally report only to the Community as a whole and not to any individual member state, including their own. The Commission's proposals must pass through two controlling bodies, the European Parliament and the Council of Ministers. While the Parliament is popularly elected, the Council consists of appointees from the member states. Parliament's power is limited, whereas the Council retains the ultimate legislative authority.

The results of this law making process are either Directives or Regulations. Regulations concern mainly agriculture and are effectively binding on all EC members. Directives do not create new laws. However, they do instruct member states to amend their national codes within a assigned time period. Originally, the Council of Ministers had to agree unanimously in order for a rule

to become a directive. However, with the passage of the Single European Act, directives could be passed by a weighted majority [21].

**Private Standards Organization**

IEC

Formed in 1906, the International Electrotechnical Commission (IEC) is the largest and perhaps most influential of all private sector standards organizations. Its membership currently represents 80% of the world's population [21].

Countries participate in the IEC through their national committee. A national committee is usually sponsored by a prominent standards organization in each country. Each national committee gets one vote on the IEC standards. ANSI serves as the United States' national committee.

The detailed work of the IEC is done through Technical Committees (TC). The Technical Committees typically delegate functions to sub-committees and working groups. After reaching agreement within a Technical Committee, a draft of the agreement is sent to all the national committees. The IEC currently has more than 80 Technical Committees. The sister organization of IEC is the International Organization for Standardization (ISO). Whereas, the IEC focuses on the electrical and electronic fields, ISO focuses its standards activities on non-electrical subjects.

CEN/CENELEC

The European Committee for Electrotechnical Standardization (CENELEC) has become a pervasive and effective force in standardizing requirements in Western Europe. CENELEC goals are similar to the IEC's. Also similar to IEC and ISO is the separation of responsibilities between CENELEC and its sister organization, European Committee for Standardization (CEN). CEN operates in the non-electrotechnical fields while CENELEC covers the electrical and electronic fields. CENELEC's documents come in the form of European Standards (EN) or Harmonization Documents (HD). Typically, these documents closely follow IEC standards [21].

EOTC

The European Organization for Testing and Certification (EOTC) was created in 1990 through a joint agreement of the European Community (EC), European Free Trade Association (EFTA), and CEN/CENELEC. Its main purpose is to support the development of European-wide certification systems and mutual recognition agreements in areas where the EC does not regulate by directive, such as voluntary standards. Quality systems registration, if not covered by an EC directive, is managed by the European Committee for Quality System Assessment and Certification (EQS). The EQS works to: avoid multiple assessments/certifications, enable mutual recognition, and develop second party confidence [32].

ISO

Founded in 1946, the International Organization for Standardization (ISO) is a global federation of national bodies that currently has over 91 members. Each member represents a separate country [26]. The organization's scope includes standardization in all fields except electrical and electronic standards. These fields are the responsibility of the IEC. Together, ISO and IEC form the world's largest private international system for voluntary industrial and technical standards [26].

The results of ISO technical work are published as International Standards. These ISO standards cover a wide range of disciplines. For example, ISO 7121 covers "Flanged Steel Ball Valves", ISO 5667 covers "Water Quality-Sampling", and ISO 10011 covers "Guidelines for Auditing Quality Systems." A common misconception is that the "ISO" in the title of the ISO standards represents the initials of the organization. However, according to ISO officials, the organization's short name was borrowed from the Greek word "isos", meaning "equal". Its selection was based on the conceptual relationships of "equal", "uniform", and "standard" [22].

ISO work is decentralized, being carried out by 172 Technical Committees (TC) and 653 sub-committees which are organized and supported by technical secretariats in 33 countries. The Central

Secretariat in Geneva, Switzerland assists in coordinating ISO operations, administers voting and approval procedures, and publishes the International Standards [26].

ISO 9000 DEVELOPMENT

In 1987, ISO published a series of five international standards, (ISO 9000, 9001, 9002, 9003, 9004) developed by ISO Technical Committee (TC) 176 on quality systems. These standards were derived from several predecessor standards.

In 1959, the U.S. Department of Defense (DOD) established a quality management program identified as MIL-Q-9858. Four years later, the program received its only revision and became MIL-Q-9858A. NATO adopted the provisions of this program in 1968 and published it as Allied Quality Assurance Publication 1 (AQAP-1). The Ministry of Defense in United Kingdom adopted the provisions of AQAP-1, in 1970, as part of their Management Program Defense Standard, DEF/STAN 05-8 [30].

Adopting the requirements of the stated MIL, AQAP, and DEF/STAN standards, the British Standards Institution (BSI) developed the first commercial Quality Management System standard in 1979. This became known as BS 5750. ISO adopted most of the BS 5750 standard in 1987 to develop the ISO 9000 guidelines. Later that year both documents were harmonized to make them equivalent documents [30]. Also, in 1987, ASQC and ANSI established and

published the Q90 series which is essentially identical to the ISO 9000 series. This year, ANSI will rename the Q90 series to Q9000. In Europe, the ISO 9000 series has been adopted by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELAC) as the European Norm (EN) 29000 series [20].

ISO 9000 CERTIFICATION

Certification for regulated product sectors can only be issued by a "notified" body. This is a third party agency within an EC member nation which has been notified by the government of that nation that they are qualified and authorized to conduct assessments against the requirements of the directive for which they were notified [33].

For non-regulated products, certification of compliance to ISO 9000 guidelines is done through an independent third party. Under this scheme, a company contracts to be audited by an accredited registrar. If the company's quality systems, documentation, and operations are found to meet the requirements of the applicable ISO 9000 standard, the registrar grants certification and lists the company in its directory of companies with certified quality systems [15].

Registrars are authorized through Accreditation Bodies such as the United Kingdom's National Accreditation Council for

Certification Bodies (NACCB). These accreditation bodies operate under CEN/CENELEC's European Committee for Quality System Assessment and Certification (EQS). Consequently, the accreditation bodies set the procedures, for assessment, certification and registration according to CEN/CENELEC's EN 45012, "General Criteria for Certification Bodies Operating Quality Systems Certification." This accreditation/certification scheme provides a traceable process from the assessment of the company to the accreditation body of the respective member states [17].

A key element in the accreditation process is that the certification body must use only certified assessors (auditors). The Institute of Quality Assurance in the United Kingdom is a governing and controlling body of the assessor training and certification process. Recently, ISO 10011, which outlines assessor certification, was accepted as the qualification criteria for auditors. One of the requirements for certification and registration of a company's quality management system is that only certified lead assessors can lead the audit team and perform the assessment [17].

# EUROPEAN ECONOMIC COMMUNITY

Unification of the European Community began in 1949, with the establishment of the North Atlantic Treaty Organization (NATO) shortly after World War II. A common European market place was first defined by the creation of the European Coal and Steel Community (ECSC) in 1951. In 1957, Belgium, France, Germany, Italy, Luxembourg, and the Netherlands signed the Treaty of Rome. The treaty's intent was to create an integrated marketplace that would be free of restrictions on the movement of goods, services, people, and capital. This treaty became the basis for the European Community (EC) which was officially established in 1958, by the original members of the treaty [36].

The next countries to join the EC were Ireland, the United Kingdom, and Denmark, in 1973. Both the United Kingdom and Denmark had previously been members of the European Free Trade Association (EFTA), along with Norway, Sweden, Switzerland, Austria, Finland, Iceland, and Liechtenstein. Greece joined the EC in 1981, and finally Spain and Portugal joined in 1986. Table 1 summarizes these two associations and their members [36].

The development of the EC's White Paper on Completion of the Internal Market in 1985 was a significant event in the promotion of a single market. Many barriers had to be removed for the EC to achieve its goals of a unified, free marketplace. The White

Paper described the actions necessary to accomplish this and declared December 31, 1992 as the targeted date of completion. Over 279 directives were created as a means to realize these goals. To date, the EC Council of Ministers has adopted about 220 of these [30].

The Single Europe Act was initiated in 1987. This upheld the original intent of the Treaty of Rome and further defined the European marketplace as one without internal borders. Additionally, this act changed the basis for approval of legislation from a unanimous vote to that of a weighted majority. The EC legislative process was significantly accelerated as a result [36].

A further development in the unification of Europe came when the European Free Trade Association, EFTA, aligned itself economically with the EC. Although past treaties existed, EFTA formally agreed to a economically unified marketplace in October, 1992 [19]. The EC and EFTA will join to form the European Economic Area (EEA). This agreement is expected to remove the last of the trade barriers between European trading partners and takes effect as early as August 1, 1993, for some countries and as late as January 1, 1994 for the remaining countries [27].

Together, the EC and the EFTA countries represent a marketplace that consists of 350 million citizens. This is the single largest marketplace in the world and compares with the combined markets of Japan (120 million) and the United States (250 million) [13].

**EC and EFTA MEMBERS**

| EUROPEAN FREE TRADE ASSOCIATION COUNTRIES | EUROPEAN ECONOMIC COMMUNITY COUNTRIES |
|---|---|
| Norway, Sweden, Switzerland, Austria, Finland, Iceland, Liechtenstein | Belgium, France, Germany, Italy, the Netherlands, Luxembourg, Ireland, the United Kingdom, Denmark, Greece, Spain, Portugal |

**TABLE 1**

# WHY IMPLEMENT ISO 9000 GUIDELINES?

Customer demand for better quality products and services has escalated greatly since World War II. This demand has contributed to the establishment of standards dedicated strictly to quality in many countries. While national standards may assure that compliant companies have initiated a quality program, it does not solve the problems of verification of compliance and comparison of requirements between different countries' standards. These type of issues contributed to the development of the ISO 9000 international standards [11].

The EC has divided all products into two categories: regulated and non-regulated. The requirements for regulated products are described by EC directives. These products, which affect health, safety, or the environment, represent 10 to 15 percent of all products manufactured and sold in the EC. However, they also represent half the total dollars of all products imported from the United States. Whereas, regulated products require certification, there are no legal requirements for non-regulated products. However, according to Robert Caine, president of the ASQC, market pressure and customer demand are making quality system registration the "price of admission for doing business in Europe" [29].

In response to this demand, most European companies are certifying their quality systems to ISO 9000. The United Kingdom has led other countries with over 10,000 firms being ISO 9000 certified [13]. The ISO 9000 series has also been adopted by many other nations and regional bodies and is rapidly supplanting national and industry-based standards as companies worldwide prepare to sell to the European Community [9]. Yet, some Asian countries, such as Japan, originally did not readily adopt ISO 9000 certification [11]. But recently, Japan has accelerated its acceptance of ISO 9000 [23].

Growing worldwide acceptance of ISO 9000, as shown in Figure 1 [24], demonstrates that quality systems are becoming increasingly important [7].

Businesses primarily implement ISO 9000 guidelines for the following reasons [10],[12],[13]:

* Selling in the European Community marketplace
* Gaining competitive advantage
* Quality improvement
* Management policy

The resulting benefits [7],[17] of certification include:

* Worldwide recognition by potential customers as a viable supplier

* Technical trade barriers become obsolete and company gains access to European Community marketplace

* Company gains a quality management system to use for continuous product and organization improvement

* Competitive advantage gained through quality assurance

* Cost-reduction due to proactive quality management

* Confidence created between customer and supplier

* Third party auditing protects confidential technology and promotes objectivity and consistency

* Supplier approvals facilitated

## 52 COUNTRIES ADOPTING ISO STANDARDS AS NATIONAL STANDARDS

KEY:

ISO 9000-1-2-3-4: Algeria, Argentina, Australia, Austria, Barbados, Belgium, Brazil, Canada, Chile, China, Columbia, Cuba, Cyprus, Czechoslovakia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Pakistan, Phillipines, Poland,● Portugal, Romania, Singapore, South Africa, Spain, Sweden, Switzerland, Tanzania, Thailand, Trinidad/Tobago, Tunisia, Turkey, United Kingdom, USA, Venezuela, Yugoslavia, Zimbabwe, The European Community

ISO 9001-2-3: Jamaica, Malaysia

ISO 9001-2: Russia (former USSR)

● Standard Translated and Published; Not Adopted as National Standard

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FIGURE 1

# WHAT IS ISO 9000?

Whether organizations sell products or services, customer expectations are usually incorporated into a set of specifications. However, these specifications are not guarantees for the consistency of a product's quality. This need for consistent quality has resulted in a series of standards, ISO 9000. The standards are basically a set of Quality Management System (QMS) practices and guidelines. However, the ISO 9000 system is not a unique "system" in itself. Implementing ISO 9000 forces a company to record its management systems in such a way that certain specific actions and procedures are not overlooked. However, the series is not intended to standardize quality systems implemented by these companies [16].

The ISO 9000 series must be looked at as a series of minimum quality system requirements. It can be thought of as the lowest common denominator of quality system requirements meant for all industry and service groups [7]. These standards focus on establishing and maintaining controls to assure that customer requirements are continually met. The five standards in the series are described in Table 2.

## ISO 9000 STANDARDS

| ISO NAME | CEN NAME | ANSI NAME | STANDARD TITLE | DESCRIPTION AND APPLICATION EXAMPLE |
|---|---|---|---|---|
| ISO 9000 | EN 29000 | Q90-1987 | Quality Management and Quality Assurance Standards - Guidelines for Selection and Use. | Guide for appropriate selection of standards 9001-9003. Applies to all companies. |
| ISO 9001 | EN 29001 | Q91-1987 | Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing. | Applies to companies that design and supply product, such as, engineering, and construction companies. |
| ISO 9002 | EN 29002 | Q92-1987 | Quality Systems - Model for Quality Assurance in Production and Installation. | Applies to companies that use processes to deliver a product, such as, manufacturers and primary contractors. |
| ISO 9003 | EN 29003 | Q93-1987 | Quality Systems - Model for Quality Assurance in Final Inspection and Test | Applies to companies that assure product conformance through inspection and test, such as, distributors or value-added contractors. |
| ISO 9004 | EN 29004 | Q94-1987 | Quality Management and Quality System Elements - Guidelines | Guide for the application of the elements used in developing and implementing Quality Management Systems. Applies to all companies. |

**TABLE 2**

# ELEMENTS OF ISO 9000

In order to implement ISO 9000 guidelines, a company needs to observe each of the elements described in the applicable standard. Each of these elements needs to be established, documented, and maintained as a minimum requirement for compliance, for example, if a company chooses to be certified to ISO 9001, a careful implementation of the elements [2] summarized in Table 3 would be necessary.

# ISO 9001 SUMMARY

| SECTION | DESCRIPTION |
|---|---|
| 4.1 Management Responsibility | Requires that quality policy be defined, documented, and communicated throughout the organization, responsibilities be defined, resources available for verification and that a management representative ensures these requirements are met. |
| 4.2 Quality System | Requires a quality system that meets the criteria of this ISO standard be established, documented, and maintained as a means of ensuring product conformance. |
| 4.3 Contract Review | Requires review of contracts to ensure defined requirements and capability to meet requirements. |
| 4.4 Design Control | Requires procedures for design/development planning, activities assignments, interfaces, input/output definition, verification, and controlling design changes. |
| 4.5 Document Control | Requires establishing and maintaining procedures for controlling documentation through approval, issue, change, and modification. |
| 4.6 Purchasing | Requires that purchased product conform to specified requirements ensured through subcontractor verification. |
| 4.7 Customer Supplied Product | Requires procedures for verification, storage, and maintenance of customer supplied product. |
| 4.8 Product Identification and Traceability | Requires procedures for identifying product during all stages of production, delivery, and installation. |
| 4.9 Process Control | Requires procedures to ensure control of production and installation processes, includes documentation and monitoring. |
| 4.10 Inspection and Testing | Requires procedures for inspection/testing at receiving, in-process and final stations, includes disposition of material. |
| 4.11 Inspection, Test, Measuring Equipment | Requires procedure for selection, control, maintenance, and calibration of all test and measuring equipment. |
| 4.12 Inspection and Test Status | Requires marking of product throughout production to show conformance or nonconformance to tests and inspectors. |
| 4.13 Nonconforming Product | Requires control of nonconforming product to ensure against inadvertent use; identify, segregate, and evaluate. |
| 4.14 Corrective Action | Requires procedures for investigating cause of nonconformance, includes actions taken to rectify and prevent future problems. |
| 4.15 Handling, Storage, Packaging, Delivery | Requires procedures for handling, storage, packaging, and delivery of product. |
| 4.16 Quality Records | Requires procedures for identification, collection, indexing, filing, and storage of quality records. |
| 4.17 Internal Quality Audits | Requires a system of internal audits to verify that quality activities comply with requirements. |
| 4.18 Training | Requires procedures to identify needs and provide training. |
| 4.19 Servicing | Requires procedures for servicing product. |
| 4.20 Statistical Techniques | Requires procedures identifying use of statistics in plant. |

**TABLE 3**

# ACHIEVING ISO 9000 CERTIFICATION

ISO 9000 compliance comes from having a quality management system that is guideline compatible and adequate for a company's business. ISO 9000 does not dictate what the management system should be, but only identifies the elements that the system needs to address. The system must be adequate in that it covers all items that affect the quality of the company's product or service. Many companies have some level of quality management system in place, however, it may not meet the ISO 9000 criteria. As a guide for implementation, ten basic steps for achieving ISO 9000 certification follows. These steps are basically a compilation derived from presentations by Sequent Computer Systems [37] and Archive Technology [36].

## 10 STEPS OF IMPLEMENTATION

1 UNDERSTAND REASONS FOR IMPLEMENTATION

This critical step has the company examine its objectives and needs for ISO certification. Questions to ask include:

* Does your company make regulated products for sale in the European Community?
* Does your company make non-regulated products for sale to the EC or other companies that sell to the EC?
* Does your company sell primarily to one or several EC nations?
* Who are your company's direct competitors?

* Does a key customer or majority of customers require ISO certification of you?
* What alternatives do your customers have to your products?
* What is the current state of your company's quality systems?
* What ISO guideline, 9001, 9002, or 9003, applies?
* Should the entire company be certified or only a particular product, factory site, or process?

Answering these questions will clarify the reasons for implementation, help determine which ISO guideline is appropriate, and help define the course for achieving certification.

## 2 GAIN TOP MANAGEMENT COMMITMENT

Installing an ISO compliant quality system is often a major task for a company. Policies, procedures, and possibly the entire focus of the business may change. Resources will be needed to effect these changes. Only if top management understands what ISO 9000 is and the need for it, can they make the commitment necessary for successful implementation.

## 3 ESTABLISH CROSS-FUNCTIONAL TEAM

Select a program manager and create a team with representatives from each department. Train this team to understand the ISO guidelines and requirements. Identify the major milestones and tasks necessary for implementation and prepare an implementation

plan. Identify the necessary resources to achieve the plan's goals. Assign specific tasks to team, committees or individuals to support the plan. Put metrics in place for monitoring progress of the plan. Correct or modify the plan as indicated by the level of progress.

## 4 QUALITY MANUAL

Creating the Quality Manual is a significant step as it sets the basic company policy for the quality management system. The team can work on this or the task can be assigned to a committee. However, the Quality Manual must address all the elements of the appropriate ISO guideline and any other activities that could affect the quality of the product or service. The manual needs to be reviewed and accepted by both the team and top management.

## 5 COMPLETE INTERNAL ASSESSMENT

An Internal Audit Committee should be created to develop an internal audit plan. The plan determines whether ISO guidelines are being met and that the Quality Manual policies are being followed. Members of the committee will probably need training for conducting a proper audit. Each department of the company needs to be audited in order to establish a baseline for the department and the company as a whole.

## 6 SELECT REGISTRAR

A Registrar Selection Committee needs to develop a process and criteria for the selecting a third party registrar. Selection criteria might include [37]:

* Credibility
  - References provide positive feedback
  - Acceptable to our customer(s)
  - Familiar with our industry
* Availability
  - Must be able to meet our schedule for assessment and certification
* Cost
  - Competitive pricing practices relative to other registrars
  - Willingness to negotiate registration and re-registration fees
* Accreditation
  - Must be accredited by appropriate accreditation body
* Flexibility
  - Willingness to adjust/grow scope of registration to match the company's ability over time
  - Willingness to adjust follow up audits frequency over time, that is, reduce number of future audits after company's capability is demonstrated

## 7 DEVELOP POLICIES, PROCEDURES, AND WORK INSTRUCTIONS

The relationship of ISO compliant documentation can be viewed as a four-tiered pyramid, see Figure 2 [35]. The Quality Manual is

at the top. Its purpose is to set the overall site objectives on quality. Site philosophy and policies are stated at this level. These policies are set for each major department or function in the company. Policies drive the need for procedures. Procedures address specific areas or processes within a company. They set the basic strategy for maintaining quality. Work instructions flow directly from the procedures. These are detailed directions for doing specific tasks.

*The Documentation Hierarchy*

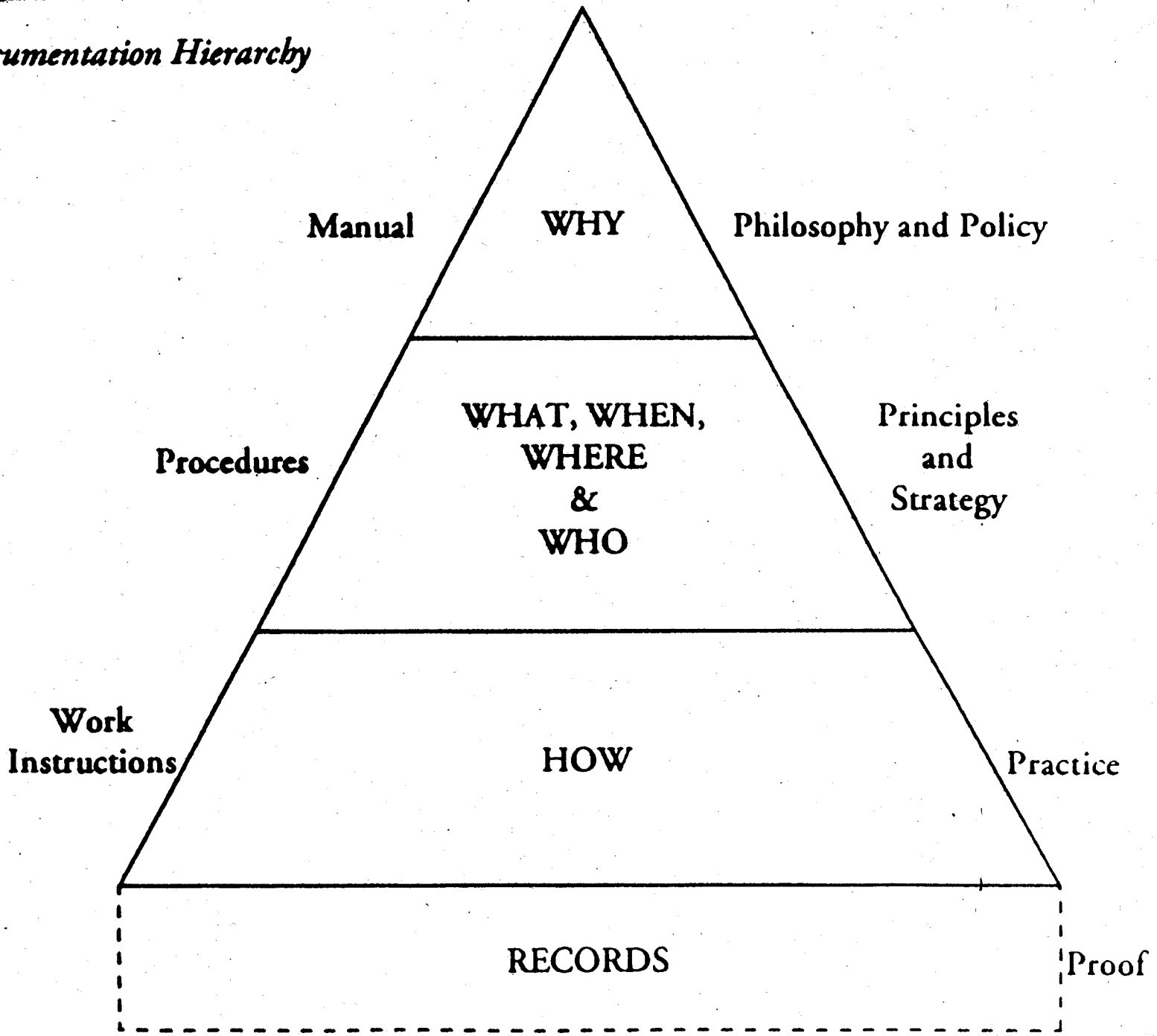


FIGURE 2

Finally, quality records are the results of specific tasks or actions. These are the supporting documents that prove compliance to the policies, procedures, and work instructions.

The creation of all of these documents is often the largest task for a company. Of critical importance is a documentation system that controls the issuance of documents and any changes to them. Also critical is the training of those who will be develop this documentation. Without this, there is little assurance that the documentation will be compliant.

## 8 PRE-ASSESSMENT AND CORRECTIVE ACTION

As noted in step 5, an Internal Audit Committee was formed and trained in order to establish a compliance baseline for the company. The ongoing purpose of this committee is to audit each department in the company for compliance to their policies and procedures. The deficiencies are noted and each department takes the necessary corrective action. This should evolve into a continuous cycle of audit (measure) and corrective action (improvement). Finally, when the committee thinks the company is ready, a formal pre-assessment audit should be performed by a lead auditor. Again, deficiencies are noted and corrective action taken.

9 CERTIFICATION REVIEW

After correcting all deficiencies found by the pre-assessment audit, a company should be ready for the real thing. A copy of the quality manual should be sent to the registrar as soon as a registrar is chosen and the manual is ready. The registrar will review the manual and if there are no issues, the auditors will come to audit the company. This audit will typically be more extensive than the internal ones. Typically, the auditors will find non-compliances. However, the company may not fail, if the basic quality system is intact and operational. In this case, the deficiencies are written up and the necessary corrective action needs to take place just as in the pre-assessment audits. Once these conditions are met, the company will receive a notice of certification from the registrar and will be registered in the certifying agency's directory.

10 PERIODIC AUDITS AND RE-REGISTRATION

Once certified, systems are reviewed at semi-annual intervals through follow-up audits. Complete reassessment is performed every three years. This audit will typically be similar to the original certifying audit.

## COSTS

Costs for certification and registration begin in the $10,000 to $30,000 range. However, internal costs can run much higher depending on the current level of the company's quality system. The total preparation and registration process usually takes from six to twenty-four months and 70% of the systems fail on the first attempt [34].

# DISCUSSION

Quality circles, Just-In-Time, Total Quality Management and other quality initiatives (see Appendix 1 for explanations and comparisons) have all become popular in the United States over the last 15 to 20 years. However, the implementation of these ideas has so often been unsuccessful, that many companies have developed a jaded opinion regarding new quality philosophies and programs. Isn't ISO 9000 just one more buzz word for quality improvement? Isn't ISO 9000 just the current "flavor of the month" offered by the quality profession?

From my research and experience, the answer to this question is a resounding "NO". ISO 9000 is unique in its approach to quality improvement in that it presents generic guidelines that can be used in any business. It is not a philosophy, but a systematic tool that is compatible with almost any business or quality philosophy. ISO 9000 identifies the items that a company needs to address without demanding any particular method of implementation or loyalty to a singular philosophy.

ISO 9000 is not just the latest quality craze, but the result of almost 50 years of international effort. Further, the European Economic Community requires ISO 9000 compliance for regulated products and worldwide acceptance of ISO 9000 is promoting certification in the non-regulated product sectors. Therefore,

ISO 9000 compliance is becoming a basic requirement for doing business around the world.

The "10 Steps of Implementation" presented in this paper can be used as a guide in achieving ISO 9000 compliance. While all the steps are necessary, steps 1, 2, and 6 are of critical importance.

Self examination will lead a company to understand whether or not ISO certification is essential to its business. Step 1 presents questions that should help a company identify its certification needs. The type of business and its customers will determine whether ISO 9001, 9002, or 9003 is chosen as the certification guideline. Some companies, however, have chosen and achieved certification at a lower level (9003 or 9002) when probably a higher level guideline (9002 or 9001) applied. This practice may place companies at risk, based on a recent NACCB memo. In October, 1992, the NACCB stated that "it is established NACCB policy that where design is involved, certificates of compliance to ISO 9002 should not be issued. The standard in that case is ISO 9001." The memo also emphasized that the British Ministry of Defence will reject certificates to ISO 9002 where it considers that the supplier is undertaking a form of design activity [8]. It is easy to appreciate the importance of understanding the company's business and certification requirements before making any commitments to pursue registration.

Should they register through a U.S. certification body and risk the chance of their certification not being recognized by European nations? Or, should they use a European registrar and if so, which registrar should they choose?

The ASQC is currently working with the ANSI/RAB accreditation program to become the ISO 9000 accreditation body in the U.S., Currently, the RAB has accredited several U.S. organizations, such as AT&T Quality Registrars, ABS Quality Evaluations, and Quality Systems Registrars [25]. Other groups such as, the Department of Defense unit responsible for purchasing common electronic components are also considering becoming ISO 9000 registrars [28]. However, U.S. companies may be at risk using these registrars until ASQC is recognized by Europe.

Another alternative is to use U.S. registrars that are accredited by European agencies such as the Netherlands' Dutch Council for Certification (RvC) or the National Council for Accreditation of Certifying Bodies (NACCB) in the U.K. These include registrars such as, Intertek (RvC), ABS Quality Evaluations (jointly accredited with RAB and RvC), and Perry Johnson Registrars (NACCB).

The last current alternative, and possibly the best is to choose a popularly accepted registrar in Europe, such as the British Standards Institution (BSI) in the U.K. This choice may be based

on the country that the company sells the most to or it may depend on what the company's customer recommends or requires. Choosing an appropriate European registrar should minimize the risks in having the company's certification recognized and accepted. However it is chosen, the selected registrar should be the best overall fit for the company's needs.

If a company completes these three steps carefully, it will guide the way for a successful implementation of ISO 9000.

# CONCLUSION

Through international effort, ISO 9000 guidelines have developed into a unique tool for implementing quality management systems in companies. Although the primary reason for certification is to do business in Europe, these guidelines are being accepted and adopted worldwide. Even though there is currently much civil unrest in parts of Eastern Europe, Western Europe is strongly moving towards marketplace unification. This further emphasizes the need for certification.

Businesses in the United States must closely examine their need to become certified. However, those that choose certification are at a disadvantage, compared to European countries, due to the lack of a mutually recognized accreditation body in the U.S. Registrars in the U.S., who have been accredited by the ASQC, may not be viable until the ASQC is recognized as the U.S. accreditation body. Therefore, U.S. companies should consider using European registrars or become jointly certified under both a European registrar and a U.S. registrar.

# FUTURE WORK

Topics for future consideration could include:

* Detailed examination of the methods and techniques for creating ISO compliant documentation.

* Investigation of the problems encountered and solutions found while implementing ISO guidelines for design control.

* Analysis of applying ISO guidelines to software development with comparison to and detailed explanation of the British TICKET certification program.

# APPENDIX I

## QUALITY INITIATIVES

Over the last twenty years, U.S. business has seen their market share erode as foreign companies with higher quality goods take over. What should U.S. business do? Obviously, U.S. companies need to implement quality improvement programs. But which program or philosophy should they choose? Is any one better than any other? Are they really all the same? Is the only difference the names and terms? Following is a brief examination of several popular approaches to quality improvement with discussion on how they compare to ISO 9000.

### Quality Circles

A quality circle typically consists of a group of employees gathered for a problem discussion. These groups meet periodically and exist as long as there are problems or opportunities for improvement. Quality circles often utilizes cause and effect analysis for productivity improvements. The "fish bone" diagram typically used in this analysis includes the system variables of Materials, Machinery, Methods, and Manpower. Quality circles are used considerably more in Japan than in the U.S., and where implemented, Japanese workers participate more

than U.S. workers [38]. Generally, quality circles can be a useful quality improvement tool.

However, ISO 9000 is more than a quality improvement tool. It a systematic approach to quality systems management. Quality circles work better in Japan partly because of they are culturally dependent [38]. ISO 9000 implementation appears to be culturally independent since it is being accepted and adopted worldwide.

Just-In-Time

Originally, Just-In-Time (JIT) was thought to be only a purchasing practice such that material would be delivered just in time. Later, JIT was thought to include manufacturing such that the product would be built just in time. Today, JIT can be viewed as a multifaceted process of continuous improvement comprised of Just-In-Time scheduling and manufacturing, Total Quality Control (TQC) of process and product, total elimination of waste and total people involvement through employee empowerment and team building. JIT emphasizes quality and cost control through continuous improvement strategies [39].

JIT achieves quality by pursuing improvement strategies for purchasing, process, product, and people. ISO 9000 addresses these same elements as well as others necessary for managing quality systems.

TQM

Total Quality Management is a customer oriented philosophy. Businesses usually employ TQM in order to focus on what is important to the customer. Ultimately, focusing on the customer's needs pays off in terms of competitive position and market share. TQM achieves quality through continuous process improvement and teamwork [40].

ISO 9000 guidelines easily fit into the TQM framework, but they cannot take the place of it. ISO 9000 presents a systematic approach to documenting quality processes and quality performance measurement. But, ISO 9000 does not directly deal with the TQM issues of leadership, strategic planning, benchmarking, and empowerment. ISO 9004, however, addresses common TQM elements such as development of quality policy and quality objectives [41].

Summary

There are many other quality initiatives that could be examined and compared to ISO 9000. Although, each may have some unique methods or ideas, typically they address materials, process, and people. ISO 9000 guidelines are unique in that they present basic quality system elements that can be used in almost any quality improvement strategy.

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