

ISO 9000 Standards, *A Baseline for Excellence*

Companies, like Duracell and Foxboro, that move rapidly today and get registered will find they have a significant edge.

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As the European Community (EC) lurches toward its January 1993 unification deadline, it is requiring each member country to adopt a single national quality standard, ISO 9000, as a baseline for excellence. In 1987 the European Committee for Standardization (ECS) adopted the ISO 9000 standards, renaming them EN29000 standards.

A truly international organization, ISO (The International Organization for Standardization) is made up of representatives from the standards boards of 91 countries, including the United States.

The ECS objective? The patchwork of each country's multiple technical standards hindered the free flow of goods. Sometimes the intent was to protect the national industry from foreign competition. But requiring each country to consolidate its standards into one national standard would still cause companies wishing to do business in the EC to negotiate 12 sets of standards. The ECS acknowledged a need for a common standard for quality in order to facilitate the flow of goods between the 12 member countries.

John Kirchenstein, a University of Tennessee quality consultant, points out this has

happened when mandatory standards related to health, safety, and environmental issues are not satisfied. These standards are in the process of being written for a variety of products. Some of the products for which they have already been written are toys, some pressure vessels, gas appliances, electro-medical devices, and construction products. When toys not meeting these standards were admitted by British Customs, the Local Trading Standards Officers were able to ban distribution.

American companies planning to do business in the EC and those already involved need to understand these standards and the certification process.

Even companies not exporting to the EC will be affected by the ISO 9000 standards if they supply a company that does. AT&T uses ISO 9000 as a tool to evaluate suppliers. The reason stated in the AT&T Quality Manager's Handbook: International customers require conformance to this standard.

Why Pursue Registration?

There are several reasons for a company to become ISO-registered:

- By the end of 1992 the EC will represent a

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Dick Anderson, The Foxboro Company

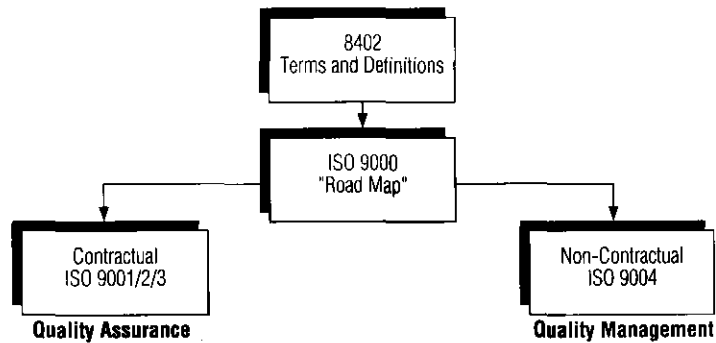


Figure 1.

unified market of 350 million people. Potential customers are likely to select suppliers from a registry of companies whose quality level is acceptable for contractual requirements. Failure to obtain registration will result in losing business to companies that are registered.

- European countries are lining up to register. Already more than 10,000 British companies have been registered as meeting ISO 9000 requirements.
- Supplying customers doing business in the EC will be easier. One of the requirements of ISO 9000 is to ensure purchased product conforms to specifications. This is to be done through assessments of the supplier.
- Government organizations, notably the Department of Defense (DoD) are considering replacing MIL-Q-9858A with ISO 9000 plus supplements. Over 50 countries have adopted ISO 9000 standards as national standards and purchasers within those countries are requiring registration.
- Once the certification process is completed, the registering agency has to perform periodic evaluations. The advantage is that the company will have far fewer audits from individual customers and if there is an audit it would be more focused.
- Although ISO-registration does not protect a manufacturer from lawsuits, not being registered in any industry where that practice has been adopted may prejudice the case if a lawsuit is brought against a manufacturer.

The Status of ISO 9000

The standards were constructed as a generic basic set of requirements for any quality assurance system. They are intended to apply to any industry in any of the 91 countries represented on the ISO, but they do not standardize quality systems implemented by businesses.

Presently, the standards include:

- ISO-9000 Quality management and quality assurance

standards guidelines for selection and use.

- 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 and installation.
- ISO-9003 Inspection and test.
- ISO-9004 Quality Management and quality system elements guidelines.

In addition there is:

- ISO-8402 Quality terminology and definitions.

The ISO 9000-series is intended to be used both in contractual and non-contractual situations. Figure 1 provides an overview of the different elements.

ISO 9004 gives guidance to all organizations for establishing a broad-based quality management program. It can be viewed as a short textbook and is considered non-contractual.

ISO 9001/2/3 are intended for external quality assurance purposes in contractual situations between two parties. They reflect the interests of the buyer. While these standards could be adopted as described, frequently they will need to be tailored for specific contractual situations.

ISO-9000 provides guidance on such tailoring. In addition, some industries are developing their own supplements. For example, the Chemical Industry Association provides guidelines for its industry.

Figure 2 shows the relationship between the four elements 9001 through 9004. The table shows that management responsibility is covered in section four of ISO 9004. A company certified to ISO 9001 would meet the most stringent requirements. But to get ISO 9002 certification the requirements would be less demanding. And, for ISO 9003 certification the requirements would be further relaxed.

Regulated Products

Before these standards can be universally respected, a uniform set of certification bodies must be formed in each country. The Global Approach to Certification and Testing (adopted in December 1989) established several objectives for fostering confidence in the safety of products and in manufacturers, testing laboratories, and certification bodies. One of the main elements is a modular system of testing and certifying products to assess their

Comparing the ISO Standards

conformity to a standard. The system of modules ranges from a manufacturer's declaration of conformity, through the operation of (independently) approved quality systems, to independent testing and certification.

For regulated products, the required method of demonstrating conformity is defined in the applicable directive. Each member state must allow any products so designated (usually by the "CE" mark) to be marketed as being in conformance with the requirements of the directive. The same rules apply regardless of the product's origin.

So, when French customs officials began to stop every shipment of toys for inspection and asked exporters to provide translated documents, the EC Commission took the side of the exporters. The Commission told the French they were in violation of directives. If the French had not complied, formal complaint procedures would have been initiated under Article 169 of the Treaty of Rome.

In conformance with the principles of the GATT Agreement on Technical Barriers to Trade, non-EC products have the same access to the certification systems laid down in EC Directives as EC products.

The Registration Process

First the company will want to compare its existing quality system to the standards, which are available through the American National Standards Institute and through the American Society for Quality Control (ASQC). After documenting the existing system and correcting any deficiencies, the next step is to contact a certification registrar. This body checks the existing quality system against the appropriate ISO 9000 standard. In about three months it delivers a quality system supplement report showing how the standard maps to the existing quality system.

A few European nations have already established third-party registration schemes and government-sponsored accreditation councils. The leader in these initiatives has been Great Britain. There the Department of Trade and Industry has established a National Accreditation Council for Certification Bodies (NACCB). This body has authorized 30 accreditation groups to certify companies as meeting standards. The smaller groups certify companies in specific industries such as electrical equipment. Groups such as Lloyd's Register Quality Assurance Ltd. handle a broader range of companies.

Non-Contract	Topic	Contractual		
ISO 9004 Clause		ISO 9001 Clause	ISO 9002 Clause	ISO 9003 Clause
4	Management responsibility	4.1	4.1*	4.1**
5	Quality system principles	4.2	4.2	4.2*
5.4	Auditing the quality system (internal)	4.17	4.16*	—
6	Economics — quality related costs	—	—	—
7	Quality in marketing (contract review)	4.3	4.3	—
8	Quality in spec. and design (design control)	4.4	—	—
9	Quality in procurement (purchasing)	4.6	4.5	—
10	Quality in production (process control)	4.9	4.8	—
11	Control of production	4.9	4.8	—
11.2	Material control and traceability	4.8	4.7	4.4*
11.7	Control of verification status (inspection and test)	4.12	4.11	4.7*
12	Product verification (inspect and test)	4.10	4.9	4.5*
13	Control of measuring and test equipment	4.11	4.10	4.6*
14	Nonconformity (control of nonconformity)	4.13	4.12	4.8*
15	Corrective action	4.14	4.13	—
16	Handling and post-production functions	4.15	4.14	4.9*
16.2	After-sales servicing	4.19	—	—
17	Quality documentation and records	4.5	4.4	4.3*
17.3	Quality records	4.16	4.15	4.10*
18	Personnel (training)	4.18	4.17*	4.11*
19	Product safety and liability	—	—	—
20	Use of statistical methods	4.20	4.18	4.12*
—	Purchaser supplied product	4.7	4.6	—

* Less demanding than ISO 9001

** Less demanding than ISO 9002

Figure 2.

Several U.S. companies are now able to certify companies. Some companies, such as ETL Testing Laboratories, Intertek Services, and Underwriters Laboratory have agreements with other accreditation groups.

ETL and Intertek have an agreement with the Lloyds Register Quality Assurance Ltd. to provide registration services. Underwriters has an agreement with the British Standard Institution. Four organizations have been recently authorized by the Registered Accreditation Board of the ASQC — ABS Quality Evaluators, AT&T Quality Registrar, Quality Systems Registrars, and BBQI.

Several European certification groups have located in the United States. A comprehensive list of quality system registrars is available through the Registration Accreditation Board of the ASQC (phone: 414/272-8575).

An assessment team performs an in-depth examination, documenting their findings as Non-Compliance Notes. This examination typically involves a two- to four-day site visit. Some registrars show two categories

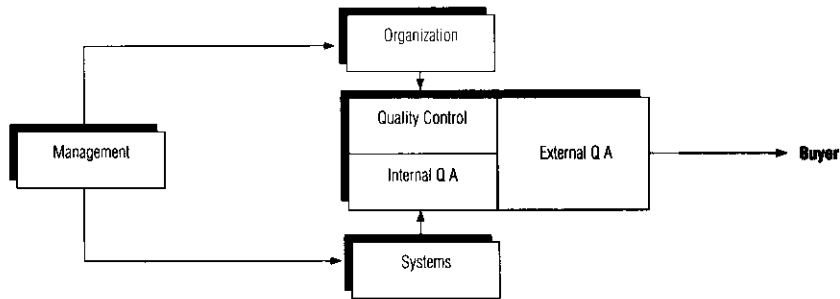


Figure 3.

of non-compliance: "hold point" deficiencies which must be fixed before a certificate can be issued, and ongoing system improvements which will not delay the issuance of a certificate.

Preparation for registration takes about 16 months. Following registration, system reviews occur twice a year, with some registrars reassessing every three years.

The registration process certifies the company as having a satisfactory quality program. This does not mean the company can place the CE mark on all its products. As described earlier, there are several advantages in affixing the CE mark to a regulated product when marketing it in the European Community.

Two U. S. Companies' Registration Experiences — Duracell and Foxboro

Both companies recently received ISO 9001 registration, Duracell Inc. at its Worldwide Technology Center (DWTC) and The Foxboro Company.

Duracell

Duracell Inc.'s New Products and Technology Division developed a quality management system to comply with ISO 9001. Other Duracell divisions are now working on similar quality systems to meet ISO requirements.

To Carl Davis, DWTC Management Representative for Quality, being project leader on the ISO 9001 team has been extremely rewarding. ISO is the foundation for DWTC's quality management system.

The DWTC effort started in early 1990 with senior management's decision to implement a corporate quality initiative called "Duracell Xcells." Registering DWTC to ISO 9001 was one part of the Xcells program. ISO registration was championed by senior management, including vice-president Dr. H.F. Gibbard. A European consulting organization experienced in ISO 9000 certification assisted.

A quality team formed of three project leaders — Frank Ciliberti and Ed Sczepanski from the Standards, Performance, and Quality Department in Bethel, CT, and Carl Davis from DWTC in Needham, MA — worked with the consultant and with employees. Due to the magnitude of the project, a top-down commitment was essential.

The team was aware that it had to document quality procedures in order to meet ISO 9000 standards. At the

same time, they were concerned that written procedures could create red tape which might alienate some employees and stifle creativity.

The DWTC solution was to create three levels of documentation. Level I is the New Products and Technology Division's Quality Policy Manual, addressing each of the items considered in ISO 9001 (see Figure 2).

Level II, Quality Assurance Procedures for DWTC, provided significantly more detail. Level II formed the bridge between Level I and Level III documents.

The Level III documents controlled methods, specifications, and drawings. Documentation at this level was specific to each department and in several instances was formally written for the first time.

The three levels of documentation were issued on a preliminary basis. Employee training and internal audits were conducted on a weekly basis by the quality team. During the internal audits the auditors checked to verify whether employees were complying with established procedures.

DWTC strategy was to specifically address four major concerns:

1. Employee commitment

The team and the consultant repeatedly stressed they were as sensitive about red tape as the research scientists and design engineers. They emphasized their intent to document procedures to assure ISO 9001 certification and their commitment to customer needs and to not exceed reasonable limits. However, it took several months for employees to understand this and to actively take part in the development of the new quality system.

2. Documentation control

The Quality Policy Manual (Level I) and the Quality Assurance Procedures (Level II), were initially written in hard-copy form and distributed to all department managers. However, revision control is an essential requirement of ISO 9001, and it became clear that maintaining photocopies throughout the facility would be difficult.

The quality team, with help from the Computer Services Department, significantly reduced hard-copies by distributing them electronically to all computers in the facility. Now, DWTC only needs to control revisions to the computer database.

3. Design control

Specifications, drawings, and methods are critical to the design process. Project leaders and team members were frequently audited to verify the revision currency of product drawings, specifications, and test methods. Today, project teams routinely maintain accurate information and provide traceability to critical documents during the entire design and development process.

4. Instrument calibration

To support Duracell's worldwide operations, DWTC has

hundreds of test and evaluation instruments, all of which were inventoried. Nearly two-thirds were identified as critical and entered into a calibration database. A schedule for recalibration had to be constructed and a process instituted to notify the department manager.

In March of 1991, the team notified Underwriters Lab (UL) they were ready for a Registration Audit. The consultants completed a pre-assessment audit in June. In July, a team of three people from UL conducted a three-day audit. Twenty-one relatively minor action requests required corrective action. Following the resolution of these action requests DWTC received its ISO 9001 registration in September 1991 from UL. DWTC also received dual registration from BSI in December.

Meanwhile, internal audits are conducted monthly by the quality team. UL and BSI will conduct routine surveillance audits every six months.

The Foxboro Company

The Foxboro Company started its push towards certification in January, 1990. An ISO 9000 Steering Committee was formed consisting of senior managers from several functions including manufacturing and marketing. At an operational level a Manufacturing Quality Council was formed under the direction of the corporate director of quality assurance. Concurrently, the senior quality engineer, Richard Anderson, took on the job of rewriting the corporate quality manual to align it with the ISO 9001 standards. The revised manual was distributed to each factory on a floppy.

Next a presentation was made to each of the divisions describing the importance of certification and requiring each to create a manual of procedures. The manuals had to be written by the manufacturing people, not just by the division's quality engineer. Typically, the plant manager and the product line manager would also be involved in the rewrite. Once a plant felt ready, Corporate Quality Assurance would conduct an intense audit followed by informal audits to ensure changes were made to manuals to fit the ISO standards.

Finally, in October of 1990, the company felt it was ready for certification and contacted DnV. The DnV auditors arrived with a checklist of 400-500 items and performed the toughest audit the company had since dealing with the audit by the Nuclear Procurement Issue Committee. The team spent three weeks at the company from mid-February through the first week of March, interviewing people in sales, R&D, service, order entry, marketing, and personnel in addition to manufacturing. Their aim was to see if 100 percent of the procedures were in place, with at least 75 percent implemented.

The auditors targeted these areas for checks:

1. Implementation of procedures

Implementation of procedures was checked by talking directly to the people working in each function. The audi-

tors made sure the procedures were in the area where the work was being performed. They confirmed that operators were collecting all of the statistics required by procedures.

2. Special processes

The auditors classified processes such as welding and brazing as special processes, all of which were examined in detail. For example, in welding they looked for a flow chart of the process, written documentation that included the qualifications of the operator, the type of machine, and the type of welding rod.

3. Documentation

They checked all functional areas for documentation. They checked the marketing plan. They asked how marketing provided input to design and then looked for documentation of these procedures. They checked the design function for documentation. They would pick a job on the factory floor and go back to development to see if the package with it was current.

During this same period, The Foxboro Company was implementing statistical process control (SPC) and a formal Quality Improvement Process (QIP). This involved 115 teams and 900 people; each team having quality indicators. The DnV auditors used what they observed in SPC and QIP to fulfill the requirements of element 20 of ISO 9000 — statistical techniques.

4. Training

The auditors checked the documentation to establish the required qualifications a person needed for each task. In individual interviews they would check if the person's qualifications matched. They also checked plans for past and future training.

Foxboro Results

Foxboro passed the audit. Each plant had at least 95 percent of the procedures implemented and 100 percent in place. But there still were findings. As the DnV team left each plant they performed an exit interview. One deficiency related to document control.

All people receiving the document had to be listed on the control listing. These people could not circulate copies of the documents to people not on the list. Also, they were responsible for keeping the document and could not throw it out.

The company did obtain certification in April, 1991 — 16 months after it had started. A follow-up audit took place in July to review the open findings; the first six-month audit took place in September.

At the follow-up audit, DnV told the company they would be examining eight specific elements. The auditors spent a week reviewing these at each plant. The company passed the audit. The next audit on another eight elements took place in March, 1992.

Meanwhile, Shanghai Foxboro Company Ltd. in China

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also decided to seek ISO certification. They were able to transfer several of the procedures from the American plants. With help from the Corporate Quality group in America and the European quality manager for The Foxboro Company, they achieved certification in December, 1991.

According to Dick Anderson, Foxboro's senior corporate quality assurance engineer, certification has been a help with the multitude of certification forms — "Some customers let us skip the audit because we are ISO certified. We hope someday to have a list of those certified companies — Foxboro might be able to skip their audit. We could cut down on everybody's work."

Mr. Anderson is frequently asked how difficult the process was. He replies that "anyone with a 9858A Milspec quality system, or 10CFR50 Appendix B should have very little trouble with ISO 9000 — they're almost there." Foxboro did it with the resources in place; the people doing the job wrote the procedures.

Will ISO 9000 Guidelines Change?

During the next decade we will see revisions of the existing standards and the development of new ones. Several committees are charged with creating new specifications and standardizing the certification activities in each country.

In 1990, an ad hoc task force of TC 176 suggested a new framework of "Generic Product Categories:"

- **Hardware:** Products consisting of manufactured pieces and parts, or assemblies thereof;
- **Software:** Products, such as computer software, consisting of written, or otherwise recordable information, concepts, transactions, or procedures.
- **Processed Materials:** Products (final or intermediate) consisting of solids, liquids, gases, or combinations thereof, including particulate materials, ingots, filaments, or sheet structures. (Processed materials typically are delivered [packaged] in containers such as drums, bags, tanks, cans, pipelines, or rolls.)
- **Services:** Intangible products which may be the entire or principal offering, or incorporated features of the offering, relating to activities such as planning, selling, directing, delivering, improving, evaluating, training, operating, or servicing for tangible product.

The task force's "Vision 2000" was formulated as follows:

- A single QM standard, an updated ISO 9004 for all four categories.
- A single QA standard, an updated ISO 9001 for all four categories.

- A high degree of commonality of architecture and concepts in the updated ISO 9001 and ISO 9004.
- No need for industry-specific standards.

A single Community mark, CE-mark, will be adopted for all future Community legislation. The CE-mark will not indicate that a particular procedure has been followed. However, when a third party is involved in one of the modules of the production phase of a conformity assessment procedure, it should affix its stamp/mark/seal next to the CE-mark.

Other groups — CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) — have been charged with determining the basis for regulating and harmonizing certification, accrediting, and testing activities. They developed an extensive series of standards termed EN 45000. The implementation of these standards within the 18 EC and EFTA countries will be the backbone of a system of mutual recognition of ISO certification:

- EN 45001 (the operation of testing laboratories)
- EN 45002 (the assessment of testing laboratories)
- EN 45003 (laboratory accreditation bodies)
- EN 45011 (certification bodies operating product certification)
- EN 45012 (certification bodies operating quality system certification)
- EN 45013 (certification bodies operating certification of personnel)
- EN 45014 (suppliers' declaration of conformity).

Conclusion

Becoming ISO-registered does not imply the company has a world-class quality system in place. *Editor's note: In Europe, being ISO registered means you have a license to drive, but it doesn't mean the bearer is a good driver!*

In order to realize the full benefits of lower costs and productivity improvements, the quality system would have to be developed beyond the requirements laid down by ISO 9000. There is a danger that companies might view getting certified as a destination when it is only a signpost on the road. These standards merely serve to document the status quo. With continuous improvement being a necessity for survival it is imperative that man-

agement continue to evolve the quality system.

The use of ISO 9000 standards and third party certification of products is accelerating in Europe. France, Germany, and the Netherlands have followed Great Britain and organized accreditation councils for certification groups. Non-European countries such as China are also adopting these standards. The momentum will cause the United States to accept the standards. As this happens, it is highly likely the certification bureaucracy will grow and there will be a lack of qualified assessors. This could mean the time required to obtain certification will extend to longer than two years. Companies that move rapidly today and get certified will find they have a significant competitive edge.

¹ Boehling, W.H. "Europe 1992: Its Effect on International Standards," *Quality Progress*, June, 1990.

² AT&T Quality Steering Committee, *Quality Manager's Handbook*, AT&T Customer Information Center, Indianapolis, IN, 1990.

³ Kendrick, J.J. "Certifying Quality Management Systems", *Quality*, August, 1990.

⁴ Klock, J.J., "How to Manage 3500 (or Fewer) Suppliers," *Quality Progress*, June, 1990.

⁵ Ferguson, K.H. "International Quality Standards May Affect Industry's Efforts in Europe," *Pulp & Paper*, March, 1991.

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