SECTION 11
THE ISO 9000 FAMILY OF INTERNATIONAL STANDARDS

Donald W. Marquardt

OVERVIEW

Role in Facilitating International Trade. The ISO 9000 standards exist principally to facilitate international trade. In the pre-ISO 9000 era there were various national and multinational quality system standards. These were developed for military and nuclear power industry needs, and, to a lesser extent, for commercial and industrial use. These various standards had commonalities and historical linkages. However, they were not sufficiently consistent in terminology or content for widespread use in international trade.

The ISO 9000 standards have had great impact on international trade and quality systems implementation by organizations worldwide. These international standards have been adopted as national standards by over 100 countries and regional groups of countries. They are applied in a wide range of industry/economic sectors and government regulatory areas. The ISO 9000 standards deal with the management systems used by organizations to design, produce, deliver, and support their products. The standards apply to all generic product categories: hardware, software, processed materials, and services. Specific ISO 9000 family standards provide quality management guidance, or quality assurance requirements, or supporting technology for an organization's management system. The standards provide guidelines or requirements on *what* features are to be present in the management system of an organization but do not prescribe *how* the features are to be implemented. This nonprescriptive character gives the standards their wide applicability for various products and situations. The ISO 9000 family does not deal with any technical specifications for a product. The ISO 9000 standards for an organization's management system are complementary to any technical specifications, standards, or regulations applicable to the organization's products or to its operations.

The standards in the ISO 9000 family are produced and maintained by Technical Committee 176 of the International Organization for Standardization (ISO). The first meeting of ISO/TC176 was held in 1980. ISO 8402, the vocabulary standard, was first published in 1986. The initial ISO 9000 series was published in 1987, consisting of:

- The fundamental concepts and road map guideline standard ISO 9000
- Three alternative requirements standards for quality assurance (ISO 9001, ISO 9002, or ISO 9003)
- The quality management guideline standard ISO 9004

Since 1987, additional standards have been published. The ISO 9000 family now contains a variety of standards supplementary to the original series, some numbered in the ISO 10000 range. In particular, revisions of the basic ISO 9000 series, ISO 9000 through ISO 9004, were published in 1994. This section is written in relation to the 1994 revisions. Table 11.1 lists the standards published as of the beginning of 1996. Additional standards are under development.

ISO 9001, ISO 9002, and ISO 9003 have been adopted and implemented worldwide for quality assurance purposes in both two-party contractual situations and third-party certification/registration situations. ISO 9001 and ISO 9002 together have predominant market share in this segment. Their use continues to grow, as does the infrastructure of certification/registration bodies, accreditation bodies, course providers, consultants, and auditors trained and certified for auditing to these standards. Mutual recognition arrangements between and among nations continue to develop, with the likelihood of ISO-sponsored quality system accreditation recognition in the near future. The number of quality systems that have been certified/registered worldwide now exceeds 100,000 and continues to grow.

The periodic surveillance audits that are part of the third-party certification/registration arrangements worldwide provide continuing motivation for supplier organizations to maintain their quality systems in complete conformance and to improve the systems to continually meet their objectives for quality.

The market for quality management and quality assurance standards is itself growing, partly in response to trade agreements such as European Union (EU), General Agreement on Tariffs and Trade (GATT), and North American Free Trade Association (NAFTA). These agreements all are dependent upon standards that implement the reduction of nontariff trade barriers. The ISO 9000 family occupies a key role in the implementation of such agreements.

Certain industry/economic sectors are developing industry-wide quality system standards, based upon the verbatim adoption of ISO 9001, together with industry-wide supplemental requirements. The automotive industry, the medical devices industry, government regulatory agencies, and military procurement agencies are adopting this approach in many places worldwide.

External Driving Forces. The driving forces that have resulted in widespread implementation of the ISO 9000 standards can be summed up in one phrase: the globalization of business. Expressions such as the "post-industrial economy" and "the global village" reflect profound changes during recent decades. These changes include:

TABLE 11.1 The ISO 9000 Family of International Standards

ISO 8402	Quality Vocabulary (1994)
ISO 9000	Quality Management and Quality Assurance standards
	Part 1: Guidelines for Selection and Use (1994)
	Part 2: Generic Guidelines for the Application of ISO 9001, ISO 9002, and ISO 9003 (1993)
	Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply, and Maintenance of Software (1991, reissue 1993)
	Part 4: Application for Dependability Management (1993)
ISO 9001	Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing (1994)
ISO 9002	Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing (1994)
ISO 9003	Quality Systems—Model for Quality Assurance in Final Inspection and Test (1994)
ISO 9004	Quality Management and Quality System Elements
	Part 1: Guidelines (1994)
	Part 2: Guidelines for Services (1991, reissue 1993)
	Part 3: Guidelines for Processed Materials (1993)
	Part 4: Guidelines for Quality Improvement (1993)
ISO 10005	Quality Management—Guidelines for Quality Plans (1995)
ISO 10007	Guidelines for Configuration Management (1994)
ISO 10011	Guidelines for Auditing Quality Systems
	Part 1: Auditing (1990, reissue 1993)
	Part 2: Qualification Criteria for Quality Systems Auditors (1991, reissue 1993)
	Part 3: Management of Audit Programs (1991, reissue 1993)
ISO 10012	Quality Assurance Requirements for Measuring Equipment
	Part 1: Management of Measuring Equipment (1992)
ISO 10013	Guidelines for Developing Quality Manuals (1994)

Source: Marquardt, D. W., et al. (1991). "Vision 2000: The Strategy for the ISO 9000 Series Standards in the '90s," *Quality Progress,* May, pp. 25–31.

- New technology in virtually all industry/economic sectors
- Worldwide electronic communication networks
- Widespread worldwide travel
- Dramatic increase in world population
- Depletion of natural resource reserves

  Arable land, fishing grounds, fossil fuels
- More intensive use of land, water, energy, air

  Widespread environmental problems/concerns
- Downsizing of large companies and other organizations

  Flattened organizational structure

  Outsourcing of functions outside the core functions of the organization
- Number and complexity of language, culture, legal, and social frameworks encountered in the global economy

  Diversity a permanent key factor
- Developing countries becoming a larger proportion of the total global economy

  New kinds of competitors and new markets

These changes have led to increased economic competition, increased customer expectations for quality, and increased demands upon organizations to meet more stringent requirements for quality of their products.

The globalization of business is a reality even for many small- and medium-size companies. These smaller companies, as well as large companies, now find that some of their prime competitors are likely to be based in another country. Fewer and fewer businesses are able to survive by considering only the competition within the local community. This affects the strategic approach and the product planning of companies of all sizes.

Internal Response to the External Forces. Companies everywhere are dealing with the need to change. There is greater focus on human resources and organizational culture, on empowering and enabling people in their jobs. Dr. W. Edwards Deming often said that many workers do not know what their job is. ISO 9000 implementation involves establishing policy, setting objectives for quality, designing management systems, documenting procedures, and training for job skills. All of these are parts of clarifying what people's jobs are.

Companies are adopting the process perspective. This concept is emphasized in the 1994 revision of the ISO 9000 standards. In implementing the ISO 9000 standards, companies are using flowcharts and other devices to emphasize work-process diagnosis and to find opportunities for process simplification and improvement. Metrics are being used increasingly to characterize product quality and customer satisfaction more effectively.

Companies are implementing better product design and work-process design procedures, and improved production strategies. Benchmarking and competitive assessment are used increasingly. Enterprise models, electronic data exchange, and other information technology approaches are growing in scope and impact.

It may be asked: In this world of rapid change, how can a single family of standards, ISO 9000, apply to all industry/economic sectors, all products, and all sizes of organizations?

The "Separate and Complementary" Concept. The ISO 9000 standards are founded on the concept that the assurance of consistent product quality is best achieved by simultaneous application of two kinds of standards:

- Product Standards (technical specifications)
- Quality system (management system) Standards

I call this the "separate and complementary" concept because the two types of standards are separate from each other and they are complementary. The two types of standards are needed to provide confidence that products will meet consistently the requirements for quality.

Product standards provide the technical specifications that apply to the characteristics of the product and, often, the characteristics of the process by which the product is produced. Product standards are specific to the particular product: both its intended functionality and the end-use situations the product may encounter.

The management system is the domain of the ISO 9000 standards. It is by means of the distinction between product specifications and management system features that the ISO 9000 standards apply to all industry/economic sectors, all products, and all sizes of organizations.

The standards in the ISO 9000 family, both guidance and requirements, are written in terms of *what* features are to be present in the management system of an organization but do not prescribe *how* the features are to be implemented. The technology selected by an organization determines how the relevant features will be incorporated in its own management system. Likewise, an organization is free to determine its own management structure.

Comment. In regard to terminology, three terms are in current use, all of them having the same essential meaning. *Quality system* is the formal term currently defined internationally in ISO 8402, the ISO/TC176 vocabulary standard. *Management system* is the term frequently used in the daily language of business. *Quality management system* is the term coming into increasing use for discussing an organization's management system when the focus is upon the overall performance of the organization and its results in relation to the organization's objectives for quality. A benefit of the term "quality management system" is its effectiveness in emphasizing both:

- The commonalities in management system features
- The differences in the objectives for the results of an organization's management system, for various areas of application (e.g., quality management systems and environmental management systems)

Characteristics of ISO 9000 Standards. Some of the ISO 9000 family standards contain *requirements,* while others contain *guidelines.*

ISO 9001, ISO 9002, and ISO 9003 are *requirements* standards. They are quality system models to be used for quality assurance purposes for providing confidence in product quality. A requirements standard becomes binding upon a company or organization wherever:

- It is explicitly called up in a contract between the organization and its customer
- The organization seeks and earns third-party certification/registration

The text of a requirements standard is phrased in terms of the verb "shall," with the meaning that the stated requirements are mandatory.

ISO 9004 is an example of a *guideline* standard. Guideline standards are advisory documents. They are phrased in terms of the word "should," with the meaning that they are recommendations. The scope of ISO 9004 is broader than the scope of ISO 9001, because it covers not only quality system features necessary to provide customer confidence in product quality, but also quality system features for organizational effectiveness.

All of the ISO 9000 family standards are *generic,* in the sense that they apply to any product or any organization. All of the ISO 9000 family standards are *nonprescriptive* in the sense that they describe what management system functions shall or should be in place; but they do not prescribe how to carry out those functions.

The Clauses of ISO 9001 and Their Typical Structure. The ISO 9000 family is best known for ISO 9001, the most comprehensive of the quality assurance requirements standards. As indicated by their titles listed in Table 11.1, ISO 9002 is identical to ISO 9001 except that ISO 9002 does not contain requirements for the design function (clause 4.4). Between them, ISO 9001 and ISO 9002 account for the largest current market share of use of the ISO 9000 family documents. The third quality assurance requirements standard, ISO 9003, is much less comprehensive and is based on final product inspection only. Its current market share is very small, less than 2 percent in most parts of the world.

The clause titles of ISO 9001 are shown in Table 11.2. The actual quality management system requirements are spelled out in clause 4, specifically in subclauses 4.1 through 4.20. The scope of ISO 9001 is focused on management system features that directly affect product quality. This emphasis is consistent with the most fundamental purpose of ISO standards: to facilitate international trade.

To illustrate the structure, content, and style of ISO 9001, two brief subclauses are quoted below:

Quality systems, general (clause 4.2.1)

> The supplier shall establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

Document and data control, general (clause 4.5.1)

> The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard, including, to the extent applicable, documents of external origin such as standards and customer drawings.

TABLE 11.2 International Standard ISO 9001:1994(E)

Quality systems—Model for quality assurance in design, development, production, installation, and servicing

	Clause titles
1	Scope
2	Normative reference
3	Definitions
4	Quality system requirements
4.1	Management responsibility
4.2	Quality system
4.3	Contract review
4.4	Design control
4.5	Document and data control
4.6	Purchasing
4.7	Control of customer-supplied product
4.8	Product identification and traceability
4.9	Process control
4.10	Inspection and testing
4.11	Control of inspection, measuring, and test equipment
4.12	Inspection and test status
4.13	Control of nonconforming product
4.14	Corrective and preventive action
4.15	Handling, storage, packaging, preservation, and delivery
4.16	Control of quality records
4.17	Internal quality audits
4.18	Training
4.19	Servicing
4.20	Statistical techniques

Some key words and their meanings are

Supplier: The organization to which the standard is addressed; namely the organization that will supply the products to the customer organization

Establish: To institute permanently

Document: To record in readable form

Maintain: To keep up-to-date at all times

Documents: Examples are overall quality manual, quality system procedures, work instructions for specific jobs, etc. (as distinct from *records* of actions completed, measurements made, etc.)

As a result of these clauses not being prescriptive as to how the requirements are to be implemented, it is expected that there may be wide variations from one supplier to another. The appropriate method of implementation will depend upon such characteristics as the type of product, its complexity, regulatory requirements that must be satisfied for legal reasons, and size of supplier organization.

One important benefit of the nonprescriptive character of the ISO 9000 standards—in particular, ISO 9001—is across-the-board applicability to *all organizational structures.* The requirements of ISO 9001 are equally relevant whether the supplier organization is large or small; has one site or many; is downsized, bereft of middle management; is heavily networked and/or based on joint ventures; uses contract subsuppliers, part-time and/or temporary personnel; or has multinational legal and/or economic arrangements. The only organizational requirement is that the organization shall have "management with executive responsibility" and that the executive management "appoint a member of the

supplier's own management" to be the management representative with responsibility for the establishment, implementation, maintenance, and reporting on the performance of the quality system.

THE FACETS OF PRODUCT QUALITY

The guideline standard ISO 9000-1:1994 explains many concepts that are fundamental to the ISO 9000 family. Among these is the concept of the four facets of product quality:

1. Quality due to definition of needs for the product
   - Defining and updating the product to meet marketplace requirements and opportunities
2. Quality due to product design
   - Designing into the product the characteristics that enable it to meet marketplace requirements and opportunities:

     Features that influence intended functionality

     Features that influence the robustness of product performance under variable conditions of production and use
3. Quality due to conformance to product design
4. Quality due to product support throughout the product life cycle

Facets 1, 2, 3, and 4 encompass all stages of the product life cycle.

The publication of the ISO 9000 series in 1987 brought necessary harmonization on an international scale. As expected, the initial emphasis of ISO 9000 standards application was primarily on facet 3, eliminating nonconformities in product supplied to customers. But, to many people's surprise there was little use of ISO 9003. By the late 1980s suppliers were recognizing that the preventive approach of ISO 9001 and ISO 9002 was more effective than final-inspection alone as the means to achieve quality due to conformance to product design. In the years before the ISO 9000 standards were developed and put into commercial and industrial uses, the national predecessor counterparts of ISO 9003 had the predominant market share; they focused on a final-inspection-only approach to facet 3.

ISO 9002 implementation now has the largest market share of the three requirements standards. With the growing worldwide emphasis on quality, suppliers involved in international trade have continued to gain maturity of understanding about quality systems. Consequently, the market share of ISO 9001 has increased, reflecting the widening appreciation of facet 2 by customers and suppliers.

The 1994 revisions of the ISO 9000 standards include significant changes in many features of the requirements and guidelines for a quality management system. These changes tend to strengthen the quality contributions from all of facets 1, 2, 3, and 4. However, primary emphasis still remains on facet 3 and the first group of features under facet 2. The next revision is likely again to have some broadening of the emphasis, reflecting the continually changing needs of international trade.

THE COMMONALITIES AND DISTINCTIONS BETWEEN QUALITY MANAGEMENT AND QUALITY ASSURANCE

One of the most pressing needs in the early years of ISO/TC176 work was to harmonize internationally the meanings of terms such as "quality control" and "quality assurance." These two terms, in particular, were used with diametrically different meanings among various nations, and even within nations. In my role as convener of the working group that wrote the ISO 9000:1987 standard, I

proposed early in the 1980s that the term "quality management" be introduced into the ISO 9000 standards as the umbrella term for quality control and quality assurance. The term "quality management" was defined, included in ISO 8402, adopted internationally, and is now used worldwide. This, in turn, enabled agreement on harmonized definitions of the meanings of each of the terms "quality control" and "quality assurance."

However, discussions in TC176 during 1995 revealed that the essential commonalities and distinctions between quality management and quality assurance are still not universally understood. This may be a result of the expansion of ISO 9000 standards use to many more countries than participated in the early 1980s, or lack of widespread reference to ISO 8402, or deficiencies in the ISO 8402 definitions. Undoubtedly, all these reasons have contributed. In any event, the meanings of the terms "quality management" and "quality assurance" need careful articulation to achieve clarity. Table 11.3 describes the essence and is the same as the meanings intended in ISO 8402:1986 and ISO 8402:1994. The quality control aspects of the umbrella term "quality management" are focused on the word "achieving," but all bullet points in the left-hand column of Table 11.3 relate at least indirectly to quality control. The right-hand column of Table 11.3 shows that the quality assurance aspects of the umbrella term "quality management" have primary focus on the notions of *demonstrating and providing confidence* through objective evidence.

VISION 2000

"Vision 2000" refers to the report of the ISO/TC176 Ad Hoc Task Force (Marquardt et al. 1991). It outlines the strategy adopted by TC176 for the ISO 9000 standards in the 1990s. Several key concepts and strategies from that report are essential to any discussion of the ISO 9000 standards.

Generic Product Categories. The task force identified four generic product categories:

- Hardware
- Software
- Processed materials
- Services

Table 11.4, from Marquardt et al. (1991), provides descriptors of the four generic product categories. Several of these now have formal definitions in ISO 8402:1994. These categories encompass

TABLE 11.3 The Prime Focus of Quality Management and Quality Assurance

The Prime Focus of	
Quality management	Quality assurance
• *Achieving* results that satisfy the requirements for quality	• *Demonstrating* that the requirements for quality have been (and can be) achieved
• Motivated by stakeholders *internal* to the organization, especially the organization's management	• Motivated by stakeholders, especially customers, *external* to the organization
• Goal is to satisfy *all stakeholders*	• Goal is to satisfy all *customers*
• Effective, efficient, and continually improving, overall quality-related *performance* is the intended result	• *Confidence* in the organization's products is the intended result
• Scope covers all activities that affect the total quality-related *business results* of the organization	• Scope of demonstration covers activities that directly affect quality-related *process and product results*

TABLE 11.4 Generic Product Categories*

Generic product category	Kinds of product
Hardware	Products consisting of manufactured pieces, 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
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 a tangible product

*All generic product categories provide value to the customer only at the times and places the customer interfaces with and perceives benefits from the product. However, the value from a service often is provided primarily by activities at a particular time and place of interface with the customer.

†Processed materials typically are delivered (packaged) in containers such as drums, bags, tanks, cans, pipelines, or rolls

Source: Marquardt et al. (1991).

all the kinds of product that need explicit attention in quality management and quality assurance standardization. The initial 1987 standards were acknowledged to have inherited some of the hardware bias of the predecessor standards. To remedy this, supplemental standards for each of the other three generic product categories were developed and published (ISO 9000-3; ISO 9004-2; ISO 9004-3); see Table 11.1.

One of the principal strategies in Vision 2000 was stated as follows:

> We envision that, by the year 2000, there will be an intermingling, a growing together, of the terminology, concepts, and technology used in all four generic product categories. This vision implies that, by the year 2000, the need for separate documents for the four generic product categories will have diminished. Terminology and procedures for all generic product categories will be widely understood and used by practitioners, whatever industry/economic sector they might be operating in.
>
> Consequently, our Vision 2000 for TC176 is to develop a single quality management standard (an updated ISO 9004 that includes new topics as appropriate) and an external quality assurance requirements standard (an updated ISO 9001) tied together by a road map standard (an updated ISO 9000). There would be a high degree of commonality in the concepts and architecture of ISO 9004 and ISO 9001. The requirements in ISO 9001 would continue to be based upon a selection of the guidance elements in ISO 9004. Supplementary standards that provide expanded guidance could be provided by TC176 as needed.

This strategy continues to guide TC176 in its work on the next revisions.

Acceptance, Compatibility, and Flexibility. Vision 2000 proposed four goals that relate to maintaining the ISO 9000 standards so that they continually meet the needs of the marketplace. These goals are *universal acceptance,* being adopted and used worldwide; *current compatibility,* facilitating combined used without conflicting requirements; *forward compatibility,* with successive revisions being accepted by users; and *forward flexibility,* using architecture that allows new features to be incorporated readily.

TC176 continues to use these goals as guides, recognizing as in Vision 2000 that "Proposals that are beneficial to one of the goals might be detrimental to another goal. As in all standardization, compromises and paradoxes might be needed in specific situations."

Avoiding Proliferation. Vision 2000 recognized that the role of the ISO 9000 standards to facilitate international trade could be maintained only if the remarkable, rapid, worldwide success in replacing national standards with harmonized ISO 9000 international standards did not itself lead to new rounds of proliferation. The issue was stated as follows:

> If the ISO 9000 series were to become only the nucleus of a proliferation of localized standards derived from, but varying in content and architecture from, the ISO 9000 series, then there would be little worldwide standardization. The growth of many localized certification schemes would present further complications. Once again, there could be worldwide restraint of trade because of proliferation of standards and inconsistent requirements.

and

> Vision 2000 emphatically discourages the production of industry/economic-sector-specific generic quality standards supplemental to, or derived from, the ISO 9000 series. We believe such proliferation would constrain international trade and impede progress in quality achievements. A primary purpose of the widespread publication of this article is to prevent the proliferation of supplemental or derivative standards.
>
> It is, however, well understood that product-specific standards containing technical requirements for specific products or processes or describing specific product test methods are necessary and have to be developed within the industry/economic sector.

Proliferation has been virtually eliminated worldwide in terms of national standards because of the withdrawal of prior national standards and adoption of the ISO 9000 standards. Moreover, the fundamental role of the ISO 9000 standards in relation to other areas of international standardization has been incorporated into the ISO/IEC Directives, which govern the operations of all Technical Committees of ISO and IEC. (ISO and IEC together coordinate and publish international voluntary consensus standards for all sectors of the economy and all technical fields. IEC, the International Electrotechnical Commission, deals with standards in industries related to electrical and electronic engineering; ISO deals with all other areas of standardization.) Clause 6.6.4 of the ISO/IEC Directives, Part 2, reads:

> 6.6.4 When a technical committee or sub-committee wishes to incorporate quality systems requirements in a standard for a product, process, or service, the standards shall include a reference to the relevant quality systems standard (ISO 9001, ISO 9002 or ISO 9003). It shall not add to, delete, change or interpret the requirements in the quality systems standard.
>
> Any requests for additions, deletions, changes or interpretations shall be submitted to the secretariat of ISO/TC176/SC2: *Quality systems.*
>
> When the industry or sector terminology is sufficiently different, a document explaining the relationship between the quality assurance terminology and the sector terminology may be prepared.

This clause may be viewed as an operational definition of avoiding proliferation. It is being applied to good effect within ISO/IEC, and as a result a number of other ISO TCs have not prepared proposed new standards that would have represented unnecessary proliferation within specific industry/economic sectors. However, in one area of application, the ISO Technical Management Board has ruled that a new Technical Committee, TC207, on Environmental Management Systems should be set up. This is discussed further in this section (see Other Areas of Application), and should be viewed as one of the necessary "compromises and paradoxes" quoted above from Vision 2000.

BEYOND VISION 2000

Even before publication of the 1994 "Phase 1" revisions, TC176 and its subcommittees began explicit planning for the next revisions, which had been referred to in Vision 2000 as the Phase 2 revisions. In addition, TC176 appointed a Strategic Planning Advisory Group (SPAG). The SPAG study included a formal strategic planning effort examining the TC176 products, markets, benefits to users, beliefs about the value of such standardization, external trends, competitive factors, and unmet market needs. From these examinations emerged a number of strategic opportunities and, ultimately, strategic goals.

The essential concepts and strategies of Vision 2000 were reaffirmed. However, the study concluded that ISO 9004 should and could have more impact in guiding practitioners of quality management. To do so requires an expansion of scope and change of approach. During 1995 TC176 also reexamined, in various meetings and study groups, the developing plans for the next revisions of the ISO 9000 standards. At the Durban, South Africa, meeting in November 1995, work was completed on specifications for the revision of ISO 9000, ISO 9001, ISO 9004, and a proposed new document on quality management principles. The specifications were prepared for formal comment by the member bodies representing the various nations. Also TC176 achieved tentative consensus on the architecture and content of the ISO 9000 family for the year 2000. One of the guiding themes is to avoid unnecessary proliferation of standards within the ISO 9000 family itself, as well as external to TC176. The leaders of the delegations of the more than 40 countries represented at Durban spent several days on these issues, including the detailed texts of vision and mission statements and of key strategies for TC176 activities and products.

QUALITY SYSTEM CERTIFICATION/REGISTRATION

Origin of the Need. The earliest users of quality assurance requirements standards were large customer organizations such as electric power providers and military organizations. These customers often purchase complex products to specific functional design. In such situations the quality assurance requirements are called up in a two-party contract, where the providing organization (i.e., the supplier) is referred to as the "first party" and the customer organization is referred to as the "second party." Such quality assurance requirements typically include provisions for the providing organization to have internal audits sponsored by its management to verify that its quality system meets the contract requirements. These are first-party audits. Such contracts typically also include provisions to have external audits sponsored by the management of the customer organization to verify that the supplier organization's quality system meets the contract requirements. These are second-party audits. Within a contractual arrangement between two such parties, it is possible to tailor the requirements, as appropriate, and to maintain an ongoing dialogue between customer and supplier.

When such assurance arrangements become a widespread practice throughout the economy, the two-party, individual-contract approach becomes burdensome. There develops a situation where each organization in the supply chain is subject to periodic management system audits by many customers and is itself subjecting many of its subsuppliers to such audits. There is a lot of redundant effort throughout the supply chain because each organization is audited multiple times for essentially the same requirements. The conduct of audits becomes a significant cost element for both the auditor organizations and auditee organizations.

Certification/Registration-Level Activities. The development of quality system certification/registration is a means to reduce the redundant, non-value-adding effort of these multiple audits. A third-party organization, which is called a "certification body" in some countries, or a "registrar" in other countries (including the United States), conducts a formal audit of a supplier organization to assess conformance to the appropriate quality system standard, say, ISO 9001 or ISO 9002. When the supplier organization is judged to be in complete conformance, the third party issues a *certificate* to the supplying organization and *registers* the organization's quality system in a publicly available register. Thus, the terms "certification" and "registration" carry the same marketplace meaning because they are two successive steps signifying successful completion of the same process.

To maintain its registered status, the supplier organization must pass periodic surveillance audits by the registrar. Surveillance audits are often conducted semiannually. They may be less comprehensive than the full audit. If so, a full audit is performed every few years.

In the world today, there are hundreds of certification bodies/registrars. Most of them are private, for-profit companies. Their services are valued by the supplier organizations they register, and by the customer organizations of the supplier organizations, because the registration service adds value in the supply chain. It is critical that the registrars do their work competently and objectively and that

all registrars meet standard requirements for their business activities. They are, in fact, supplier organizations that provide a needed service product in the economy.

Accreditation-Level Activities. To assure competence and objectivity of the registrars, systems of registrar *accreditation* have been set up worldwide. Accreditation bodies audit the registrars for conformity to standard international guides for the operation of certification bodies. The quality system of the registrar comes under scrutiny by the accreditation body through audits that cover the registrar's documented quality management system, the qualifications and certification of auditors used by the registrar, the record keeping, and other features of the office operations. In addition, the accreditation body witnesses selected audits done by the registrar's auditors at a client supplier organization's facility.

Accreditation and Registration Flowchart, Including Related Activities. This process as it operates in the United States is depicted graphically in Figure 11.1. The three columns in the figure depict the three areas of activity of the Registrar Accreditation Board: accreditation of registrar companies, certification of individuals to be auditors, and accreditation of the training courses which are part of the requirements for an auditor to be certified. The relevant ISO/IEC international standards and guides that apply in each of these activities are shown in Figure 11.1. The ISO criteria documents for auditing quality systems are the ISO 10011 standard, Parts 1, 2, and 3. See Table 11.1. Part 2 of ISO 10011 deals specifically with auditor qualifications.

In the United States the registrar accreditation is carried out by the Registrar Accreditation Board (RAB) under a joint program with the American National Standards Institute (ANSI). This joint program is called the American National Accreditation Program for Registrars of Quality Systems. The auditor certification and training course accreditation portions of the entire scheme shown in Figure 11.1 also are carried out by RAB.

Materials governing accreditation procedures for the American National Accreditation Program for Registrars of Quality Systems are available from the Registrar Accreditation Board, P.O. Box 3005, Milwaukee, WI 53201-3005.

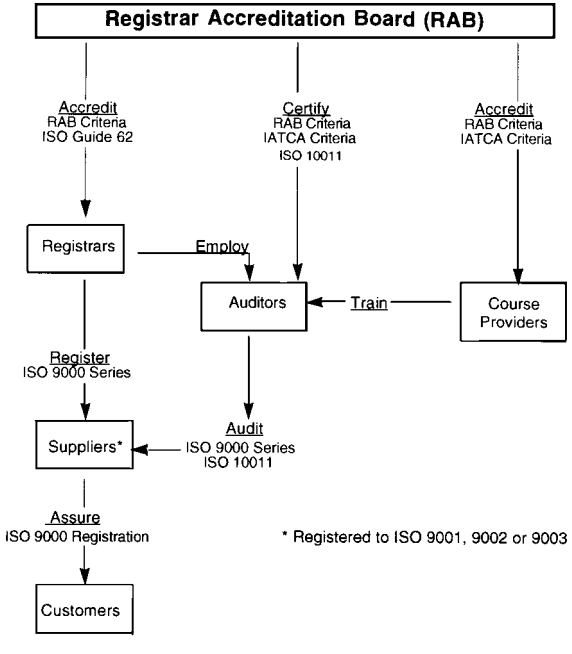

FIGURE 11.1 Accreditation and registration process.

Mutual International Acceptance. Various other countries have implemented these three areas of activity, too:

- Accreditation of certification bodies/registrars
- Certification of auditors
- Accreditation of auditor training courses

The systems in the Netherlands and in the United Kingdom have been in place longer than most. At this time, various bilateral mutual recognition agreements are in place between certain countries whereby, for example, the certification of an auditor in one country carries over into automatic recognition of that certification in another country. In other situations, a memorandum of understanding has been negotiated between, say, the accreditation bodies in two countries, whereby they enter into a cooperative mode of operation preliminary to entering into a formal mutual recognition agreement. Under a memorandum of understanding, the accreditation bodies may conduct jointly the audit of a registrar, and the auditors may jointly document the results of the audit. However, each of the accreditation bodies would make its own decision whether to grant or continue, as the case may be, the accreditation.

In principle, there should be no need for a supplier organization to obtain more than one certification/registration. A certificate from a registrar accredited anywhere in the world should, in principle, be accepted by customer organizations anywhere else in the world. In practice, it takes time to build infrastructure comparable to Figure 11.1 in any country. It takes additional time (measured in years) for that infrastructure to mature in its operation and for confidence to build in other countries. Of course, not all countries decide to set up their own infrastructure but may choose to have their supplier organizations who wish to become registered do so by employing the services of an accredited registrar from another country.

Indeed, many registrar companies have established operations internationally and provide services in many countries. Such registrars often seek accreditation in multiple countries because their customers (the supplier organizations) look for accreditation under a system with which they are familiar and have developed confidence.

At the present time, there are a multiplicity of arrangements involving single or multiple accreditations of registrars, single or multiple certifications of auditors, and single or multiple accreditations of training courses. The overall system is moving toward widespread mutual recognition, but the ultimate test of credibility is the marketplace willingness to accept a single certification and a single accreditation.

The ISO/IEC are themselves sponsoring development and implementation of a truly international system of mutual recognition for the accreditation of certification bodies/registrars. Called QSAR, it has been worked out in detail through international negotiations and is starting to be implemented. It is expected that the QSAR arrangement will accelerate the process of mutual recognition internationally.

The current status where registrars and course providers may have multiple accreditations, and auditors may have multiple certifications, may seem to have more redundancy than necessary. If we step back and compare the current situation to the alternative of widespread second-party auditing of supplier organizations' quality systems, it must be acknowledged that the present situation is better in the following ways:

- Much less redundancy of auditing
- Much improved consistency of auditing
- Potential for even less redundancy and further improved consistency through the use of international standards and guides as criteria and through mutual harmonization efforts driven by the marketplace.

Formal International Mutual Recognition. For the United States, there is one further complication. Almost alone among the countries of the world, the U.S. standards system is a private-sector activity. American National Standards Institute (ANSI), a private sector organization, is the coordinating body for standards in the United States. Under the ANSI umbrella many organizations

produce and maintain numbers of American National Standards. Most of these standards relate to product technical specifications. Among the largest U.S. producers of standards are organizations such as the American Society of Testing and Materials (ASTM), the American Society of Mechanical Engineers (ASME), and the Institute of Electrical and Electronics Engineers (IEEE), but there are many other organizations that produce American National Standards applicable to specific products or fields of activity. The ANSI system provides a consistent standards development process that is open, fair, and provides access to all parties that may be materially affected by a standard. The success of the U.S. system is attested to by the predominance of the U.S. economy internationally and the widespread adoption of U.S. standards for multinational or international use.

However, there are three levels of activities and infrastructure in relation to conformity assessment in international trade. Two of these levels have already been discussed: the certification/registration level and the accreditation level. The third level is the *recognition* level. At the recognition level, the national government of country A affirms to the government of country B that A's certification and accreditation infrastructure conforms to international standards and guides. In most countries of the world, where the standards system is run by a government or semigovernment agency and the accreditation activities are carried out by that agency, the recognition level is virtually automatic. In the United States, various government agencies may be called upon to provide the formal recognition.

For example, in dealing with the European Union (EU) on products that fall under one of the EU Directives that regulate products that have health, safety, and environmental risks, the EU insists upon dealing through designated government channels. The relevant U.S. government agency varies from one EU Directive to another. In many areas, the recognition responsibility will come under the recently authorized National Voluntary Conformity Assessment System Evaluation (NVCASE) program to be run by the Department of Commerce, through the National Institute of Standards and Technology. The NVCASE program had not come into operation at the time of this writing.

CONFORMITY ASSESSMENT AND INTERNATIONAL TRADE

The conformity assessment approach of the European Union typifies what is happening in many parts of the world. For a regulated product to be sold in any EU country, it must bear the "CE" mark. Under the Modular Approach of the EU, to qualify for use of the mark the supplier organization must produce evidence of conformity in four areas:

- Technical documentation of product design
- Type testing
- Product surveillance (by samples, or by each product)
- Quality assurance surveillance.

Depending on the directive, the EU will offer suppliers various routes (modules) to satisfy the requirements. These routes range from "Internal Control of Production," which focuses on the product surveillance aspects, to "Full Quality Assurance," which typically focuses on certification/registration to ISO 9001 and relies upon the ISO 9001 requirements for capability in product design. In most modules the manufacturer must submit product units, and/or product design technical information, and/or quality system information to a certification body that has been designated by the government as a "notified body." The notified body must, in some modules, also provide for product tests where required. Several modules involve certification to ISO 9001, ISO 9002, or ISO 9003.

The implementation of this modular approach to conformity assessment for regulated products by the European Union (then called the European Community) was the largest, single, early impetus to the rapid spread of certification/registration to ISO 9001 or ISO 9002 worldwide. For example, about half of the dollar volume of U.S. trade with Europe is in regulated products.

Nevertheless, the global trends in technology and in requirements for quality, and the cost savings of third-party versus widespread second-party auditing, as discussed previously in this section,

are powerful additional incentives and staying power for sustained international use and growth of third-party quality system certification/registration.

Moreover, for a supplier organization it is not effective to attempt to have two quality management systems, one for regulated products and another for nonregulated products. Consequently, there are multiple incentives for large numbers of supplier organizations, engaged directly or indirectly in international trade, to operate a quality management system that conforms to ISO 9001 or ISO 9002, as appropriate.

STANDARDIZATION PROBLEMS AND OPPORTUNITIES FOR THE ISO 9000 FAMILY

The rapid worldwide adoption and implementation of the ISO 9000 standards, and the rapid growth of the infrastructure of certification/registration bodies, accreditation bodies, course providers, consultants, auditors, trade magazines, books, and ISO 9000 journalists is virtually unprecedented in any field of standardization. This can appropriately be regarded as a remarkable success story for the ISO 9000 standards. Accompanying this success story are several problems and opportunities that need careful attention.

Problems and Opportunities. In all important endeavors, "problems" and "opportunities" abound. It is important to understand that these are two sides of the same coin. Every problem is a doorway to opportunities; and every opportunity carries problems with it. This universal truth certainly applies in relation to the ISO 9000 family. Coming to grips with these problem-opportunities deepens our understanding of the ISO 9000 standards themselves. These problem-opportunities will be with us for a long time because they come from fundamental economic issues that are always present in national and international trade. Some, or all, of them could be make-or-break issues for the success of ISO 9001, and with it the ISO 9000 family. As a preliminary to discussing a number of problem-opportunities, it is important to understand what is implied by the concept of standardization.

The Scope of Standardization. "Standardization" encompasses activities in two interrelated areas:

- The conception, planning, production, promotion, and selling of *standards*
- The conception, planning, establishment, control, promotion, and maintenance of standards *implementation*

In practice, the standardization problems and opportunities for the ISO 9000 family relate to *implementation* activities at least as much as to the *standards* themselves. The topics discussed in the following illustrate the predominance of problem-opportunities that arise from implementation activities.

The Concept of Continuous Improvement. The philosophy of using quality assurance standards has changed over the years. In the 1960s the virtually universal perspective of business managers was "If it ain't broke, don't fix it." In that philosophical environment of maintaining the status quo, the characteristics shown at the top of Table 11.5 prevailed in most of industry and commerce. Today, as illustrated by the minimal use of ISO 9003, the philosophy of 30 years ago is giving way to a philosophy of continuous improvement. Continuous improvement is increasingly necessary for economic survival in the global economy and is becoming a widely pursued goal. It is the only reliable route to sustaining marketplace advantage for both customer and supplier.

As shown at the bottom of Table 11.5, the focus of quality assurance standardization is now on prevention of nonconformities. This requires a "process" focus, which is reflected in the documentation and many other features.

TABLE 11.5 Philosophy of Using Quality Assurance Standards

30 years ago	
• Quality goal:	Maintain status quo.
• Business goal:	The best deal for this contract.
• Methods:	Final-inspection oriented; sort good product from bad. "Records" paperwork was featured.
• Customer/supplier relationship:	Adversarial.
Today	
• Quality goal:	Continuous improvement.
• Business goal:	Mutual marketplace advantage.
• Methods:	Prevention oriented; don't make bad product. "Process" documentation is featured.
• Customer/supplier relationship:	Partnership.

The Role of Continuous Improvement in ISO 9001. In the first years of use since 1987 an unfortunate mind-set has been adopted by many registrars/certifiers and their auditors. This mind-set can be called the "status quo mind-set." Reminiscent of the 1960s, it is characterized by the ditty:

> "Say what you do.
> Do what you say."

This simple ditty is correct as far as it goes, but is *far short of the requirements in the ISO 9000 standards set in 1987 and revised in 1994.* It focuses only on adherence to established procedures. For example, the status quo mind-set ignores the *linked requirements* to demonstrate continuing adequacy of the quality system:

- For business objectives
- For customer satisfaction

Intrinsic to the 1994 revision of ISO 9001 is a reshaped mind-set as summarized in Table 11.6. The reshaped mind-set is *a cycle of continuous improvement,* which can be depicted in terms of the classic plan-do-check-act management cycle. The P-D-C-A cycle is expected to be used explicitly in the next revisions of the ISO 9000 standards.

Comment. Various people, in both the United States and Japan (e.g., Shewhart, Deming, Mizuno), have been associated with the early evolution of the P-D-C-A management cycle. The history is traced by Kolesar (1994, pp. 14–16). In its form and application to depict the management cycle, "P-D-C-A plays a central role in Japanese thought" (Kolesar 1994, p. 16). In recent years, P-D-C-A has been widely accepted in the Western world as a simple but robust embodiment of management as an activity. The P-D-C-A management cycle is compatible, in particular, with the contemporary concept that all work is accomplished by a process (ISO 9000-1:1994, clause 4.6).

Continuous improvement is a necessary consequence of implementing ISO 9001 (and ISO 9002). There are two groupings of linked clauses in ISO 9001 that work together to ensure continuous improvement.

The linkages among the clauses are really quite clear in ISO 9001 if your mind-set does not block them out. The intention of the ISO 9000 standards has always been that the clauses are elements of an integrated quality system. In implementing any system, the interrelationships among the elements, that is, the linkages, are as important as the elements themselves.

The linkages among clauses in ISO 9001 can be recognized in three ways:

- Explicit cross references between linked clauses shown by parenthetic expressions "(see *z.zz*)" in the text of certain clauses
- Use of key words or phrases in clauses that have linked requirements, for example, "objectives" for quality in clauses 4.1.1 (Quality Policy) and 4.1.3 (Management Review)
- Content interrelationships which cause linkages among the activities required by two or more clauses, for example, clauses 4.1.1 (Quality Policy), 4.1.3 (Management Review), 4.14 (Corrective Action), and 4.17 (Internal Quality Audits).

The two groupings of linked clauses that work together to ensure continuous improvement are

1. *Continuous improvement via objectives for quality and ensuring the effectiveness of the quality system:* The 1994 revision of ISO 9001 expands and strengthens the requirements for executive management functions and links a number of clauses by requirements to define "objectives" for quality [clauses 4.1.1 (Quality Policy) and 4.1.3 (Management Review)] and to "ensure the effectiveness of the quality system" [clauses 4.1.3 (Management Review), 4.2.2 (Quality System), 4.16 (Quality Records), 4.17 (Internal Quality Audits)]. In today's competitive economy, the objectives for quality must continually be more stringent in order to maintain a healthy business position. More stringent objectives for quality translate inevitably into the need for an increasingly effective quality system.
2. *Continuous improvement via internal audits and management review:* The 1994 revision of ISO 9001 expands and strengthens the requirements of four clauses in the 1987 standard that link together for continuous improvement in the supplier organization. These are internal quality audits (clause 4.17), corrective and preventive action (clause 4.14), management representative (clause 4.1.2.3), and management review (clause 4.1.3). The interplay of activities required by these four clauses provides a mechanism to institutionalize the pursuit of continuous improvement.

It is instructive to display simultaneously the similarities of the three managing processes that have had great influence on the practice of quality management. These are the P-D-C-A cycle, the ISO 9001/ISO 9002 requirements, and the Juran Trilogy. These are summarized in Table 11.7. Viewed from this perspective, the similarities are striking.

If the ISO 9000 implementation community fails to embrace adequately the continuous improvement requirements in the standards, the competitiveness of the standards themselves will be seriously compromised in the global marketplace.

TABLE 11.6 The Reshaped Mind-Set

A cycle of continuous improvement (built into ISO 9001 by the linked requirements)

- *Plan* your objectives for quality and the processes to achieve them.
- *Do* the appropriate resource allocation, implementation, training, and documentation.
- *Check* to see if
  - You are implementing as planned
  - Your quality system is effective
  - You are meeting your objectives for quality
  - Your objectives for quality are relevant to the expectations and needs of customers
- *Act* to improve the system as needed.

TABLE 11.7 Similarities of Three Managing Processes

P-D-C-A cycle	ISO 9001/9002 requirements	Juran Trilogy
Plan	Say what you will do • "Plan, define, establish, document" • "Objectives for quality" • "Provide resources"	Planning • Determine needs • Establish product • Establish process • Develop process • Set goals
Do	Do what you say • "Implement, maintain" Record what you did • "Quality records"	Control (remove sporadic deficiencies) • Run process • Evaluate performance • Compare to goals • Act on differences
Check	Check results versus expectations • Management review • Internal audits • External audits	Improvement (remove chronic deficiencies) • Nominate projects • Establish teams • Use improvement process • Provide resources
Act	Act on any deficiencies • Quality system revision • Preventive action • Corrective action	

Source: Kolesar (1994).

The Role of Statistical Techniques. From the earliest days of the quality movement, statistical techniques have been recognized as having an important role. In fact, during the 1940s and 1950s, statistical techniques were viewed as the predominant aspect of quality control. During succeeding decades, the management system increasingly took center stage. In the 1987 version of ISO 9001, clause 4.20 on statistical techniques paid only lip service to its subject. The implementation of quality assurance standards worldwide has reinforced the deterioration of emphasis on statistical techniques to the point that important technical advances in statistical techniques for quality have been deprecated by many practitioners who have claimed that only the simplest, most primitive, and most ancient statistical techniques are needed, provided they are conscientiously implemented. Then they neglect to implement even those!

It is critical that this situation be remedied and that statistical techniques and management systems each be given an important place in quality.

Fortunately, the 1994 version of ISO 9001 contains explicit, meaningful requirements relating to statistical techniques (clause 4.20, Statistical Techniques), citing their relation to "process capability" and "product characteristics." Recalling the ISO 9001 mechanisms to link clauses, there is direct linkage between clause 4.20 and process control (clause 4.9, especially 4.9g), as well as indirect linkages to other clauses. These requirements, if conscientiously implemented, would guarantee that statistical techniques are enabled to have their important place in quality under the ISO 9001 umbrella.

Unfortunately, a large majority of personnel in the existing infrastructure of auditors, registrars, and accreditation bodies—and their supporting consultants, training course providers, etc.—have little knowledge or experience in statistical techniques. Consequently, despite the requirements in clause 4.20 of ISO 9001:1994, the clause still is receiving little emphasis.

Like all problems, this creates opportunities for entrepreneurial supplier companies, registrars, auditors, consultants, and course providers. I hope many will seize these opportunities (which really are obligations) in the near future. Moreover, this problem places responsibilities on accreditation bodies. They have the responsibility to ensure that the third-party registration system is implemented in conformance to the applicable international standards and guides. In particular, this includes ISO 9001 itself, and clause 4.20.

In the United States, the Registrar Accreditation Board (RAB) has taken some initiatives in this direction. The RAB has, among these initiatives, issued to all ANSI/RAB-accredited registrars a bulletin stating RAB's intention to monitor the operations of registrars with respect to the linked requirements and the implementation of clause 4.20. I have emphasized this issue in various national and international presentations and publications (e.g., Marquardt 1995, 1996a), encouraging the accreditation bodies and certification/registration bodies in other countries to take similar steps. There are opportunities for ISO/TC176, too. TC176 is cooperating with ISO/TC69 (Application of Statistical Methods) to provide guidance documentation on the use of statistical techniques when implementing the standards in the ISO 9000 family.

Interpretations of the Standards. In actual application ISO standards are published by ISO in English and French (and often in Russian), which are the official ISO languages. ISO requires that "the texts in the different official language versions shall be technically equivalent and structurally identical" (ISO/IEC Directives, Part 1, 1.5, 1989). Sometimes ISO itself publishes standards in languages other than the official languages; then "each is regarded as an original-language version" (ISO/IEC Directives, Part 1, F.3, 1995). "However, only the terms and definitions given in the official languages can be considered as ISO terms and definitions" (ISO/IEC Directives, Part 3, B2.2, 1989).

When a nation "adopts" an ISO standard, the standard is first *translated* by the national body into the national language, and processed through the official national procedures for adoption. In the United States, the translation issue is minimal, consisting, when deemed necessary, of replacement of British English (the ISO official English) with American English spellings or other stylistic editorial details. In the United States, the adoption process is under the American National Standards Institute procedures, which ensure the objectivity, fairness, and lack of bias that might favor any constituency; these are requirements for all American National Standards.

In situations where the national language is not one of the ISO official languages, ISO has, at present, no formal procedure for validating the accuracy of the national body translation. Translation from one language to another always presents challenges when great accuracy of meaning should be preserved. There are many ways in which the meaning may be changed by a translation. These changes can be a troublesome source of nontariff trade barriers in international trade.

The problem-opportunity relating to interpretations of the ISO 9000 standards goes beyond problems of translation into languages other than the official ISO languages. In the global economy many *situations of use* are encountered; the intended meaning of the standard is not always clear to those applying the standard in some situations of use. For such situations each member body of ISO is expected to set up interpretation procedures. There will, nevertheless, be cases where an official ISO interpretation is required. ISO has, at present, no formal procedure for developing and promulgating such official interpretations. ISO/TC176 has taken the initiative with ISO Central Secretariat to establish an official procedure; ultimately ISO/TC176 should be the point of the final interpretation of the ISO 9000 standards which it is responsible to prepare and maintain.

When the situation of use is a *two-party* contractual situation between the supplier organization and the customer organization, differences of interpretation should normally be revealed and mutually resolved at an early stage (e.g., during contract negotiation and contract review). Official international interpretations become more necessary in third-party certification/registration situations. In *third-party* situations negotiations between supplier and customer tend to focus on the technical specifications for the product, plus only those quality system requirements, if any, that go beyond the scope of the relevant ISO 9000 requirements standard.

Defining the Scope of Certification/Registration

Background. There is great variability in the documented definitions of scope of registration of suppliers' quality systems. This variability is observed from supplier to supplier for a given registrar, from registrar to registrar in a given nation, and from one nation to another. Greater consistency in defining and documenting this scope is an essential prerequisite for:

- Establishing marketplace credibility of quality system certification/registration to ISO 9001, ISO 9002, or ISO 9003
- Negotiating meaningful mutual recognition arrangements among nations

Beyond the benefits of marketplace credibility, there are important benefits to registrars if the ground rules for defining scope are consistent for all parties. This topic is an important problem-opportunity for the ISO 9000 standards.

To describe adequately the scope of certification/registration of a supplier's quality system, four questions must be asked:

- Which standard?
- Which geographic sites or operating units?
- Which products?
- Which portions of the supply chain?

The first three elements of scope are dealt with in ISO/IEC Guides in generic terms. The last (supply-chain boundaries) is not dealt with in the Guides but is equally important.

Certificates of registration are the original records from which other records (e.g., lists of registered quality systems) are derived. Examination of samples of certificates and registers shows that even the first three elements are not universally or uniformly documented today.

Selection of Standard. The procedure should provide confidence to the customer that the selection of the appropriate standard jointly by the supplier and the registrar has taken adequately into consideration the amount and nature of product design activity that is involved in the products produced by the supplier, as well as the nature of the production processes through which the supplier adds value to the product. In some cases ISO 9003 or ISO 9002 has been selected when it appears that a more comprehensive quality assurance model would be more appropriate. In some cases, the mismatch may not be readily apparent to the supplier's customer.

An example where clarity is important is distributor operations. Many are registered to ISO 9003 under the rationale that the distributor does not produce the (tangible) products themselves. However, a distributor's product is the service products of acquiring, stocking, preserving, order fulfilling, and delivery. Hence ISO 9002 is appropriate to cover the production of these services. Distributors who design their service products should be registered to ISO 9001.

Specification of Boundaries in Terms of Geographic Location or Operating Unit. The procedure should inform the customer whether the product the customer receives is processed within the registered quality system, even in situations where the supplier may have multiple sites or operating units dealing with the same product, not all of which may be registered. The lack of consistent procedures for scope description in regard to geographic locations or operating units included sets the stage for misrepresentation.

Specification of Boundaries in Terms of Product Processed. The procedure should inform the customer whether the product the customer receives is processed within the registered quality system, even in situations where the supplier may deal with multiple products at the same site or operating unit and not all of the products may be processed within the registered quality system. The lack of consistent procedures in regard to product processed sets the stage for misrepresentation.

Specification of Boundaries in Terms of Supply-Chain Criteria. The procedure should inform the customer regarding:

- The starting points of the supplier's registered operations (e.g., the raw materials, parts, components, services, and intermediate products that are provided by subsuppliers)
- The ending points of the supplier's registered operations (i.e., the remaining steps on the way to the ultimate consumer that are excluded from the supplier's registered operations)

- The nature of the value that has been added by the supplier's registered operations

Where the registered quality system represents only a fraction of the supplier's operations, or a fraction of the total value added in the product, this should be stated in registration documentation so that, as a consequence, customers may be aware of this fact.

The procedures should not invite suppliers who wish to be registered, but want to exclude portions of their operations from scrutiny by the registrar, to declare the excluded portions to be subcontractor operations. It does not matter whether the excluded portions are in another nation, elsewhere in the same nation, or simply another part of the same production site.

Procedures for this element of scope would apply also to support functions that are critical to product quality, such as a test laboratory, which may not be included in the supplier's quality system as registered to ISO 9001 or ISO 9002.

Guiding Principle. There are many registrars; each is registering many supplier quality systems. Each supplier is dealing with many customers. It is impractical to monitor adequately the operations of such a system solely by periodic audits conducted by an accreditation body. Consequently the guiding principle should be

> Primary reliance must be placed on the concept of "truth in labeling," by means of which every customer has routine, ready access to the information upon which to judge all four elements of scope of a supplier's registered quality system.

Alternate Routes to Certification/Registration. Organizations differ in regard to the status of their quality management efforts. Some are at an advanced state of maturity and effectiveness. Others have hardly begun. Most are at some intermediate state. The ISO 9000 standards have as their primary purpose the facilitation of international trade. They are, therefore, positioned to ensure a level of maturity and effectiveness that meets the needs for reducing nontariff trade barriers in international trade. This required level of maturity and effectiveness will change with the passage of time (compare the minimal use of ISO 9003 and the growth of use of ISO 9001).

At any point in time, there will be some organizations that have well-established, advanced quality management systems based on an approach that may go beyond the requirements of ISO 9001. For such organizations, the cost of registration/certification by the usual third-party route is perceived to be high compared to the incremental value added to their quality management system. This is, and will continue to be, a significant problem-opportunity.

In the United States a number of such companies that have major international presence, especially ones in the electronics and computer industry, have been working with organizations involved in the implementation of third-party certification/registration to devise an approach that would gain international acceptance. The approach would have to take cognizance of their existing quality management maturity and reduce the cost of certification/registration, while supporting their international trade by providing the assurance conferred by certification/registration.

Industry-Specific Adoptions and Extensions of ISO 9000 Standards

Industry-Specific Situations. In some sectors of the global economy there are industry-specific adoptions and extensions of the ISO 9000 standards. These situations are a classic example of a problem-opportunity. As problems, such adaptations and extensions strain the goal of nonproliferation. As opportunities, they have been found effective in a *very few industries* where there are special circumstances and where appropriate ground rules can be developed and implemented consistently. These special circumstances have been characterized by

1. Industries where the product impact on the health, safety, or environmental aspects is potentially severe; as a consequence most nations have regulatory requirements regarding the quality management system of a supplier
2. Industries that have had well-established, internationally deployed industry-specific or supplier-specific quality system requirements documents prior to publication of the ISO 9000 standards

Fortunately, in the very few instances so far, the operational nonproliferation criteria of the ISO/IEC Directives have been followed.

Medical Device Industry. Circumstance 1 relates to the medical device manufacturing industry. For example, in the United States, the Food and Drug Administration (FDA) developed and promulgated the Good Manufacturing Practice (GMP) regulations. The GMP operates under the legal imprimatur of the FDA regulations, which predate the ISO 9000 standards. The FDA regularly inspects medical device manufacturers for compliance with the GMP requirements. Many of these requirements are quality management system requirements that parallel the subsequently published ISO 9002:1987 requirements. Other GMP regulatory requirements relate more specifically to health, safety, or environmental aspects. Many other nations have similar regulatory requirements for such products.

In the United States, the FDA is in late stages of developing and promulgating revised GMPs that parallel closely the ISO 9001:1994 standard, plus specific regulatory requirements related to health, safety, or environment. The expansion of scope to include quality system requirements related to product design reflects the recognition of the importance of product design and the greater maturity of quality management practices in the medical device industry worldwide. Similar trends are taking place in other nations, many of which are adopting ISO 9001 verbatim for their equivalent of the GMP regulations.

In ISO, a new technical committee, ISO/TC210, has been formed specifically for medical device systems. TC210 has developed standards that provide supplements to ISO 9001 clauses. These supplements primarily reflect the health, safety, and environment aspects of medical devices and tend to parallel the regulatory requirements in various nations. These standards are in late stages of development and international approval at this time.

Automotive Industry. Circumstance 2 relates to the automotive industry. In the years preceding publication of the 1987 ISO 9000 standards, various original equipment manufacturers (OEMs) in the automotive industry had developed company-specific proprietary quality system requirements documents. These requirements were part of OEM contract arrangements for purchasing parts, materials, and subassemblies from the thousands of companies in their supply chain. The OEMs had large staffs of second-party auditors to verify that these OEM-specific requirements were being met.

Upon publication of ISO 9001:1994, the major U.S. OEMs began implementation of an industry-wide common standard, labeled QS-9000, that incorporates ISO 9001 verbatim plus industry-specific supplementary requirements. Some of the supplementary requirements are really prescriptive approaches to some of the generic ISO 9001 requirements; others are additional quality system requirements which have been agreed on by the major OEMs; a few are OEM-specific.

QS-9000 is being deployed by these OEMs in their worldwide operations. Part of this deployment involves separate registrations to QS-9000, through existing registrars who have been accredited specifically to the QS-9000 system. These QS-9000 registrars must use auditors who have had specific accredited training in those QS-9000 requirements which are more prescriptive than, or go beyond, ISO 9001 requirements. Accreditations are provided through specially designated accreditation bodies, including RAB in the United States.

The QS-9000 system, by removing the redundancy of multiple second-party audits to multiple requirements documents, is providing cost reductions for both the OEMs and the large number of organizations in their supply chain. Assuming that credibility is maintained by continuous improvement to meet marketplace needs and requirements, the goals of improved quality industry-wide and worldwide, together with reduced costs, can be attained.

Computer Software. The global economy has become permeated with electronic information technology (IT). The IT industry now plays a major role in shaping and driving the global economy. As in past major technological advances, the world seems fundamentally very different, and paradoxically, fundamentally the same. Computer software development occupies a central position in this paradox.

First, it should be noted that computer software development is not so much an industry as it is a *discipline.*

Second, many IT practitioners emphasize that computer software issues are complicated by the multiplicity of ways that computer software quality may be critical in a supplier organization's business. For example:

- The supplier's product may be complex software whose functional design requirements are specified by the customer.
- The supplier may actually write most of its software product, or may integrate off-the-shelf packaged software from subsuppliers.
- The supplier may incorporate computer software/firmware into its product, which may be primarily hardware and/or services.
- The supplier may develop and/or purchase from subsuppliers software that will be used in the supplier's own design and/or production processes of its product.

However, it is important to acknowledge that hardware, processed materials, and services often are involved in a supplier organization's business in these same multiple ways, too.

What, then, are the issues in applying ISO 9001 to computer software development? There is general consensus worldwide that:

- The generic quality management system activities and associated requirements in ISO 9001 are relevant to computer software, just as they are relevant in other generic product categories (hardware, other forms of software, processed materials, and services).
- There are some things that are *different* in applying ISO 9001 to computer software.

There is at this time no worldwide consensus as to *which* things, if any, are different enough to make a difference and what to do about any things that are different enough to make a difference.

ISO/TC176 developed and published ISO 9000-3:1991 as a means of dealing with this important, paradoxical issue. ISO 9000-3 provides guidelines for applying ISO 9001 to the development, supply, and maintenance of (computer) software. ISO 9000-3 has been useful and widely used. ISO 9000-3 offers guidance that goes beyond the requirements of ISO 9001, and it makes some assumptions about the life cycle model for software development, supply, and maintenance. In the United Kingdom a separate certification scheme (TickIT) for software development has been operated for several years, using the combination of ISO 9001 and ISO 9000-3. The scheme has received both praise and criticism from various constituencies worldwide. Those who praise the scheme claim that it

- Addresses an important need in the economy to provide assurance for customer organizations that the requirements for quality in software they purchase (as a separate product, or incorporated in a hardware product) will be satisfied
- Includes explicit provisions beyond those for conventional certification to ISO 9001 to assure competency of software auditors, their training, and audit program administration by the certification body
- Provides a separate certification scheme and logo to exhibit this status publicly

Those who criticize the scheme claim that it

- Is inflexible and attempts to prescribe a particular life cycle approach to computer software development which is out of tune with current best practices for developing many types of computer software
- Includes unrealistically stringent auditor qualifications in the technology aspects of software development, qualifications whose technical depth is not necessary for effective auditing of management systems for software development
- Is almost totally redundant with conventional third-party certification to ISO 9001, under which the certification body/registrar already is responsible for competency of auditors, and accreditation bodies verify the competency as part of accreditation procedures

- Adds substantial cost beyond conventional certification to ISO 9001 and provides little added value to the supply chain

In the United States a proposal to adopt a TickIT-like software scheme was presented to the ANSI/RAB accreditation program. The proposal was rejected, primarily on the basis that there was not consensus and support in the IT industry and the IT-user community.

At this writing:

- ISO/TC176 is revising ISO 9000-3 for the short term to bring it up-to-date with ISO 9001:1994 and to remedy some technical deficiencies.
- ISO/TC176 is planning the next revision of ISO 9001 with the long-term intention of incorporating ISO 9001 quality assurance requirements stated in a way that will meet the needs of all four generic product categories without supplementary application guideline standards such as ISO 9000-3.
- Various national and international groups, conferences, and organizations are discussing whether there is enough of a difference to warrant a special program, and if so, what such a program should look like.

The one thing that is currently clear is that no worldwide consensus exists.

Other Areas of Application. The special case of environmental management systems and their relation to quality management systems has been discussed earlier in this section. This situation, too, is a classic example of a problem-opportunity from the perspective of the ISO 9000 standards. Companies are likely to have to do business under both sets of requirements: the ISO 9000 standards from ISO/TC176 and the ISO 14000 standards from ISO/TC207. The opportunity for mutually beneficial consistency promises important benefits. These benefits relate to the operational effectiveness of having one consistent management approach in both areas of the business activities and can translate also into cost benefits of such a single approach. The ISO Technical Management Board has mandated that TC176 and TC207 achieve compatibility of their standards.

In the United States and other nations, the compatibility of the ISO 9000 standards and the ISO 14000 standards is one part of the standardization job. The implementation part requires that similar harmonization and compatibility be established in each nation in the infrastructure of accreditation bodies, certification/registration bodies, and auditor certification bodies, operating under internationally harmonized guidelines. At this writing the ISO 14000 infrastructure is in its infancy.

RELATION OF ISO 9000 STANDARDS TO NATIONAL QUALITY AWARDS AND TO TOTAL QUALITY MANAGEMENT (TQM)

Various nations and regional bodies have established quality awards. The most widely known of these are the Deming Award in Japan; the Malcolm Baldrige National Quality Award (MBNQA) in the United States; and the European Quality Award, a European regional award. These awards incorporate concepts and principles of Total Quality Management (TQM).

TQM means different things to different people. ISO 8402:1994 defines TQM as follows:

> …management 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 all members of the organization and to society.

For purposes of this section the criteria of the Baldrige Award or the Deming Award or the European Quality Award can be considered to be an operational definition of full-scale TQM implementation.

Questions often are asked about the relationships between the criteria upon which these awards are based and the content of the ISO 9000 standards. This discussion is in two parts: the relationship to ISO 9001 and the relationship to ISO 9004.

Overall, it is important to understand that the purpose of the ISO 9000 standards is to facilitate international trade. To achieve that purpose, the ISO 9000 standards focus on the supplier organization functions that most directly affect product quality. The ISO 9000 standards are intended for implementation by the large majority of supplier organizations. By contrast, the purposes of the award criteria are (1) to select, from among all the supplier organizations in a nation or region, those few organizations that exemplify the very best level of achievement in quality management and (2) to provide criteria and guidelines for other organizations that may wish to improve in the direction of becoming best of the best and are willing to make the substantial investment to achieve that lofty level of quality performance.

Relationship to ISO 9001. ISO 9001 is a requirements standard for two-party contractual or third-party registration use in support of international trade. Commensurate with this role, ISO 9001 focuses only on the functions that most directly affect product quality. It does not, therefore, deal with questions of economic effectiveness and cost efficiency. It deals only with specific personnel aspects and specific sales and marketing aspects that directly affect product quality. Thus, the *scope* of ISO 9001 is narrower than the scopes of the cited national awards. For example, the MBNQA criteria examine many specific items in seven broad categories of an organization's activities. These seven categories are: leadership, information and analysis, strategic planning, human resource development and management, process management, business results, and customer focus and satisfaction. The ISO 9001 requirements give greatest emphasis to the process management category of MBNQA, and have lesser emphasis on the other categories.

In view of the differing purposes of ISO 9001 and the award criteria, there is a difference also in the *depth* of examination of the supplier organization's quality management system. The MBNQA and ISO 9001 both embrace the concept that all work is accomplished by a process and that an organization's activities can be viewed as a network of processes. Both MBNQA and ISO 9001 recognize the need to examine the approach, the deployment, and the results (Marquardt 1996b) in the examination of a process.

In the late 1980s the author developed Table 11.8 to describe the relative depth of expectations in terms of the appropriate assessment questions at various levels, including ISO 9001 and award criteria. Questions are shown for approach, deployment, and results.

It is instructive to compare ISO 9000 registration (specifically ISO 9001 or ISO 9002) to the achievement of an MBNQA award. As described in Table 11.9, ISO 9000 registration has in many ways more modest requirements, but it does emphasize to a greater degree the necessity of a consistent, disciplined, documented quality system, with periodic internal and external audits that serve to hold the gains and institutionalize continuous improvement.

Relationship to ISO 9004. ISO 9004 is the standard in the ISO 9000 family that provides to organizations quality management guidelines that cover a *wider scope* and *greater depth* than the requirements in ISO 9001. The additional scope and depth go part way toward the scope and depth of award criteria such as the MBNQA. In keeping with the purpose of the ISO 9000 standards, the scope and depth is at a level that is achievable by a large proportion of organizations in the global economy. Thus, ISO 9004 is deliberately positioned in an intermediate range, between ISO 9001 and the award criteria. The marketplace uniqueness of ISO 9004 is that it offers to organizations a framework for building a quality management system that will be effective and efficient and that will focus on features that have a direct effect on product quality, features that are fully consistent with ISO 9001, ISO 8402, and other standards in the ISO 9000 family. This enables the organization to use one consistent set of terminology that is internationally standardized and one consistent framework.

Many organizations worldwide have adopted the strategic perspective that ISO 9001 provides for them minimum adequate criteria for effective operation and for meeting the marketplace

TABLE 11.8 Assessment Questions (for Any Process in a Quality Management System)

Approach	Deployment	Results
First level of depth		
Is there a defined process?	Is the process fully deployed?	Are the results meeting requirements?
Second level of depth (e.g., ISO 9001 requirements)		
Is the process appropriate to the needs of the function? Is there documentation appropriate to each person's needs at each organizational level? Is the documentation controlled (accurate, up-to-date, available when and where needed)?	Is a process used wherever this generic function is implemented in the organization? Is every involved person trained (understands the process, why it exists, how to use it)? Does every person have value for the function?	Have quantitative metrics been defined? Are the metrics understood and used by those involved? Do the values of the metrics show that the process is appropriate to the function for both quality management and quality assurance purposes?
Third level of depth (National or International Award Criteria)		
Is the process state of the art, world class, best of the best for this function? Is there innovation, technology advantage, cost advantage, functional superiority in this process? Does the excellence in this process provide superior value that is perceived by the customer as exceeding expectations?	Is the process deployed consistently and universally to accomplish this function in a standard way with consistent, transferable training everywhere? Does the consistency of the results of this process provide superior value that is perceived by the customer as exceeding expectations?	Are the metrics designed and implemented in a way that elicits value-adding behavior responses? Do the values of the metrics clearly portray continuous improvement and world-class status? Do the financial results demonstrate that customers perceive superior value?

TABLE 11.9 ISO 9000 Registration in Relation to Malcolm Baldrige Award

ISO 9000 requires:
- Adequate quality systems
- Objective evidence for every requirement
- Complete, controlled, up-to-date documentation
- Periodic surveillance audits that verify continuing compliance to requirements

MBNQA looks for:
- Best-of-the-best quality systems
- Clear evidence of product quality superiority
- Clear evidence of customer perception of superiority
- Historic trends that lend credence to one-time audit

requirements for quality. ISO 9004 provides a guideline to enrich and enhance the ISO 9001 baseline, and to take deliberate, planned initiatives that build upon the baseline in the direction of TQM. The award criteria, such as those of MBNQA, provide a comprehensive operational statement of full-scale TQM. With this insight, the standards and the award criteria are compatible and complementary. Both are necessary in the global economy.

REFERENCES

Kolesar, P. J. (1994). "What Deming Told the Japanese in 1950." *Quality Management Journal,* vol. 2, issue 1, pp. 9–24.

Marquardt, D. W. (1994). "Credibility of Quality Systems Certification: How to Deal with Scopes of Certification, Conflicts of Interest and Codes of Conduct." In Peach, R. W. (ed.), *ISO 9000 Handbook,* 2d ed. Irwin Professional Publishing, Fairfax, VA, chap. 17.

Marquardt, D. W.(1995). "The Missing Linkage in ISO 9001: What's Being Done About It?" *ASQC 49th Annual Quality Congress Proceedings,* American Society for Quality Control, Milwaukee, pp. 1056–1061.

Marquardt, D. W. (1996a). "The Importance of Linkages in ISO 9001." *ISO 9000 News,* vol. 5, no. 1, pp. 11–13.

Marquardt, D. W. (1996b). "The Functions of Quality Management in Relation to the P-D-C-A Management Cycle." Manuscript submitted for publication.

Marquardt, D. W., et al. (1991). "Vision 2000: The Strategy for the ISO 9000 Series Standards in the '90s." *Quality Progress,* May, pp. 25–31. Reprinted in *ISO 9000 Quality Management* (an ISO standards compendium containing all standards in the ISO 9000 family, plus the Vision 2000 paper), 5th ed. (1994), ISO Central Secretariat, Geneva. Also reprinted in a number of other countries and languages, and in the *ISO 9000 Handbook,* op cit., chap. 11.