

CHAPTER 74

Standardization, Certification, and Stretch Criteria

HARRISON M. WADSWORTH, JR.
Georgia Institute of Technology

1. INTRODUCTION	1966	3.7. Product Realization	1971
1.1. Definitions	1966	3.8. Measurement, Analysis, and Improvement	1971
1.2. Reasons for Quality Management System Standards	1967	4. ISO 9004-21972	1972
2. HISTORY OF QUALITY MANAGEMENT SYSTEM STANDARDS	1967	5. OTHER STANDARDS AND GUIDES IN THE ISO 9000 FAMILY	1972
2.1. American Standards	1967	6. STANDARDS DEVELOPED BY OTHER ORGANIZATIONS	1973
2.2. European Standards	1968	6.1. ANSI/ASQ/Z1.11, <i>The Application of ISO 9001 to Educational Institutions</i>	1973
2.3. International Standards	1968	6.2. QS 9000, <i>Quality System Requirements</i>	1973
3. DETAILS OF THE ISO 9001:2000 STANDARD	1969	6.3. Other Quality Management Requirement Documents	1973
3.1. Process Model	1969	7. REGISTRATION TO QMS STANDARDS	1973
3.2. Scope	1969	REFERENCES	1974
3.3. Principles of Quality Management	1969		
3.4. QMS Requirement	1970		
3.5. Management Responsibility	1970		
3.6. Resource Management	1971		

1. INTRODUCTION

This chapter will discuss international and national standards for quality management systems. After defining some terms and concepts, it will consider the need for such standards and how they are used.

The history and evolution of these standards will then be presented, leading up to the current ISO standards, which have revolutionized quality management. The requirements in the latest version (2000) of the QMS standards will be presented. The topic of registration to these standards will be discussed. This includes reasons for registration and means for becoming registered. Similar standards for environmental management, the ISO 14000 family of standards, were discussed in Chapter 39 of this handbook.

1.1. Definitions

The definitions given here are taken from ISO/DIS 9000-2000, which is the latest version of the terminology standard as of the writing of this chapter. This standard will be discussed later. It su-

persedes and replaces the previous terminology standard, ISO 8402-1994, and its American counterpart, ANSI/ISO/ASQ A8402-1994.

A quality management system is defined in this standard as a “system to establish quality policy and quality objectives and to achieve those objectives” (2.2.3).

Quality policy is defined in the standard as the “overall intentions and direction of an organization related to quality as formally expressed by top management” (2.2.4).

Quality objective is defined as “something sought, or aimed at, related to quality” (2.2.5).

Other terms that are useful for the presentation given in this chapter are:

- Quality management: “coordinated activities to direct and control an organization with regard to quality” (2.2.8)
- Quality control: “part of quality management focused on fulfilling quality requirements” (2.2.10)
- Quality assurance: “part of quality management focused on providing confidence that quality requirements are fulfilled” (2.2.11)

1.2. Reasons for Quality Management System Standards

There are several reasons for standards for quality management systems. As indicated, quality assurance involves the demonstration of good-quality products and services. The quality management system is the organization that enables this assurance to be accomplished. Quality management system standards provide a guideline for a manufacturing or service company to determine if proper quality assurance requirements can be met.

The first reason for such standards is to provide these guidelines. While each organization is different and thus has different needs for quality assurance, there are many elements that are fundamental to all organizations. These elements can be standardized and are found in such standards. This provides internal quality assurance.

In addition, quality management system standards provide a means to evaluate an organization’s quality management system and thus its ability to provide high-quality products. This is the provision of external quality assurance by a supplier of a product or service. In an increasing number of situations, customers require, for contractual purposes, the registration or certification of their suppliers’ quality systems. Such registration must use standards for guides.

As we move into a global marketplace, we find the need for standardization increases. Without such internationally recognized standardization we cannot communicate with suppliers or customers in other countries.

These needs for standardization have been recognized by international and national standards writing bodies. The present standards for quality systems and quality assurance are the results of this recognition. More will be said about the development of such standards in the next section.

2. HISTORY OF QUALITY MANAGEMENT SYSTEM STANDARDS

2.1. American Standards

For the marketplace, standardization is a necessity. Product standards, monetary standards, measurement standards, and so forth have been with us for thousands of years. This chapter does not address these standards, however. It addresses generic quality standards that are not product or industry specific. The earliest quality management system standards were developed for contractual purposes. Such standards, for example MIL-Q-9858A (1963) and MIL-I-45208A (1981), were developed by the United States Department of Defense (DoD). These are mandatory standards created for the purpose of assuring the defense procurement agencies of the United States that a supplier has the ability to provide high-quality weapons systems. Other countries developed similar standards for quality management systems.

In the United States, voluntary national standards (as opposed to the mandatory standards) have been published by several organizations. The most prominent publishers of such standards are the American Society for Testing Materials (ASTM), the American Society of Mechanical Engineers (ASME), the Institute of Electrical and Electronic Engineers (IEEE), the American Society for Quality (ASQ), and others. All of these technical societies publish many of their standards under the auspices of the American National Standards Institute (ANSI). ANSI approves such standards, and most of them carry a dual designation of both the writing organization and ANSI. There are currently more than 11,000 ANSI standards, most of which are product-specific standards. ANSI itself consists of individual members, approximately 1,000 companies, 30 government agencies, and 250 professional, technical, trade, labor, and consumer organizations.

ANSI is the sole U.S. representative to international standards writing bodies such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the Pacific Area Standards Congress (PASC). To facilitate the development of standards dealing with quality assurance and quality control, the American Society for Quality was accredited as a standards-writing body in 1974 by ANSI, with its Standards Committee charged with promoting such standards. Later, in 1978, the ANSI Accredited Standards Committee Z1 was established, with the ASQ holding its Secretariat.

One of the early voluntary quality system standards developed in the United States was ANSI Standard Z1.8-1971, *Specification of General Requirements for a Quality Program*. This was written by the ASQ and later revised as ANSI/ASQC C1 in 1985. A later, much more detailed standard was published by the ASQ as ANSI/ASQC Z1.15-1979, *Generic Guidelines for Quality Systems*. This latter standard was written by a subcommittee of the ANSI Accredited Standards Committee Z1. It was the basis for international standard ISO 9004, published in 1987. In the United States it has been superseded by the American version of ISO 9004, which is designated ANSI/ISO/ASQ Q9004. The third revision of this standard has now been completed and published as ISO 9004-2000. Its American counterpart will be ANSI/ISO/ASQ Q9004-2000. This edition of the standard will be reviewed later in this chapter.

2.2. European Standards

Other single-level standards similar to MIL-Q 9858A and ANSI/ASQC Z1.15 were being developed at the same time by other countries. A partial list of such early standards is:

<u>Country</u>	<u>Standard</u>
United Kingdom	BS4891:1972, <i>A Guide to Quality Assurance</i>
France	AFNOR NFX50-110, <i>Recommendations for a System of Quality Management for the Use of Companies</i>
France	AFNOR NFX50-111, <i>Quality Assurance Systems for the Use of Companies</i>
Germany	DIN 55-355, <i>Basic Elements of Quality Assurance Systems</i>

Some standards developed during this time were multilevel standards. That is, they have several levels of quality assurance standards that depend on the requirements placed on the supplier. They were chiefly developed for use in contractual situations. The following are some of these standards:

<u>Country</u>	<u>Standard</u>
United Kingdom	BS 5750-1979, <i>Specification for Design, Manufacture, and Installation</i>
Canada	CSA Z299-1978, <i>Quality Assurance Program Requirements</i>
Norway	NVS-S-1594, <i>Requirements of the Contractor's Quality Assurance Program</i>
South Africa	SABS 0157-1979, <i>Code of Practice for Quality Management Systems</i>
Australia	AS 1821-1975, <i>Suppliers Quality Control System</i>

2.3. International Standards

In 1979, ISO formed Technical Committee 176, with Secretariat given to Canada. The scope of this Technical Committee, as stated in the 1989 Momento of ISO, is "Standardization in the field of generic quality management, including quality systems, quality assurance, and generic supporting technologies, including standards which provide guidance on the selection and use of these standards." The Technical Committee published six standards in 1986-1987. Since then, other standards have been published, bringing the total to 27 as of 1999. The six original standards were the principal accomplishments of the committee. The first of the six standards published in 1986 was ISO 8402, *Vocabulary*. This standard consisted of 22 terms. It was revised in 1994 with 67 terms. The 2000 edition of the standard, now designated as ISO 9000-2000, has 87 terms. As with the 1994 edition, the terms are divided into 10 sections as follows:

- Seven terms related to quality
- Fourteen terms related to management
- Seven terms related to organization
- Eight terms related to process and product
- Five terms related to characteristics
- Thirteen terms related to conformity
- Six terms related to document
- Six terms related to examination

- Thirteen terms related to audit
- Eight terms related to quality assurance for measurement processes

Many of the standards in the ISO 9000 family will be discontinued following publication of the new edition of the basic standards, ISO 9000, ISO 9001, and ISO 9004. The original 9002 and 9003 standards will be merged with ISO 9001. ISO 9000-1 will be merged with 8402 and designated 9000. ISO 9004-1, 9004-2, 9004-3, and 9004-4 will be merged and designated ISO 9004. ISO 10011-1, 10011-2, and 10011-3 on auditing have been merged with auditing standards for environmental management. The new standard is designated 19011. The remaining members of the ISO 9000 family are as follows:

Core standards

ISO 9000:2000, *Quality Management Systems—Fundamentals and Vocabulary*

ISO 9001:2000, *Quality Management Systems—Requirements*

ISO 9004:2000, *Quality Management Systems—Guidelines for Performance Improvements*

ISO 19011, *Guidelines for Auditing Management Systems*

Other international standards

ISO 10012, *Guidelines for Quality Assurance for Measuring Equipment*

ISO 10015, *Quality Management—Guidelines for Training*

Technical reports

ISO 10006, *Guidelines to Quality in Project Management*

ISO 10007, *Guidelines for Configuration Management*

ISO 10013, *Guidelines for Developing Quality Manuals*

ISO 10014, *Guidelines for Managing the Economics of Quality*

ISO 10017, *Guidance on Statistical Techniques for ISO 9001*

The only standard in this family that may be used for registration of a quality management system is ISO 9001. In previous editions there were three such requirements standards, ISO 9001, 9002, and 9003. The 9001 standard was the most complete in that it covered all parts of a quality management system. ISO 9002 was identical to 9001 except that the design function was not included. Several other functions were omitted from the 9003 standard. The 2000 edition of ISO 9001 allows for the tailoring of the standard to delete requirements such as design when they do not apply to an organization.

3. DETAILS OF THE ISO 9001:2000 STANDARD

3.1. Process Model

This edition of the standard is based on a process approach to quality management. Any activity that receives inputs and converts them to outputs is a process. Most processes are linked in that outputs from one process are often the inputs to other processes. The systematic identification and management of the processes employed within an organization is the process approach.

This edition of ISO 9001 is considered as one part of a consistent pair of standards, the other being ISO 9004:2000. The two standards have identical clause structures, an important property that was missing in earlier editions. ISO 9004:2000 gives guidance on a wider application of a quality management system meant to improve the organization's overall performance beyond that required by ISO 9001:2000. It is not a guideline for implementing ISO 9001:2000 and is not intended for certification or other contractual use. The ISO 9001:2000 standard also has an identical clause structure with ISO 14001:1996 in order to improve the compatibility between registration of quality and environmental management systems.

3.2. Scope

ISO 9001:2000 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets requirements of customers and regulatory agencies. It also addresses customer satisfaction through the requirements for continual improvement and the prevention of nonconformities.

3.3. Principles of Quality Management

ISO 9000:2000 lists the following steps that might be used to develop a quality management system:

1. Determine the needs of the customer.
2. Establish the quality policy and quality objectives of the organization.
3. Determine the processes needed to implement the quality objectives.
4. Develop measures for the effectiveness of each process towards the attainment of the objectives.
5. Develop means of preventing nonconformities.
6. Look for opportunities to improve the effectiveness and efficiency of processes.
7. Determine and prioritize proposed improvements.
8. Plan strategies, processes, and resources to obtain improvements.
9. Implement the plan.
10. Monitor the improvements.
11. Assess the results against expected outcomes.
12. Determine follow-up actions.

An organization that adopts the 12 steps outlined above creates confidence in the capability of its processes and provides a basis for continual improvement. This, in turn, leads to increased customer satisfaction and the success of the organization.

3.4. QMS Requirements

Clause 4 of ISO 9001:2000 presents some general requirements of the quality management system. These include requirements dealing with the identification and management of the processes in the system. General documentation requirements are also discussed in this clause. These include the requirements for documented procedures, work instructions, and manuals. The actual, detailed requirements of the standard are stated in four clauses:

- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis, and Improvement

Each of these clauses is discussed briefly in the following sections.

3.5. Management Responsibility

Clause 5 of the standard is entitled "Management Responsibility." It designates a requirement for management commitment to high quality. It states that this management commitment must be highly visible. This is done by the establishment of a quality policy, setting of quality objectives, and a description of the quality system that emphasizes problem prevention rather than dependence on detection after a problem occurs.

Management must develop and state its corporate policy as it relates to quality. This quality policy must be consistent with all other corporate policies. It is the responsibility of management to ensure that its quality policy is understood, implemented, and maintained. The policy contains management's definition of good quality and its goals for quality improvement.

Quality objectives must be explicitly stated. These include the key elements of quality, such as fitness for use, performance, safety, and reliability.

Management's responsibilities also include the organization and operation of the quality system. This responsibility includes the provision of all necessary resources. Management is responsible for seeing that the quality system functions in such a manner that the system is well understood and effective, confidence is provided that products or services satisfy requirements and customer expectations and that its emphasis is on prevention of problems rather than problem detection.

The clause also requires the appointment of a management representative charged with the operation and maintenance of the quality system. The management representative must have direct access to top management. A manual must be developed by management that describes the quality system and includes references to appropriate documented procedures. The manual and the procedures must be controlled using a document control procedure.

Top management shall review the quality management system at prescribed intervals to ensure its continuing effectiveness. These reviews shall include results of audits, customer feedback, process performance and product conformance, status of corrective and preventive actions, and changes that could affect the quality management system.

3.6. Resource Management

Clause 6 of the standard requires the provision of resources needed to maintain the quality management system. These include human resources, requiring the identification of competency needs for personnel, the provision of training to satisfy these needs, evaluation of the effectiveness of this training, and the maintenance of appropriate records of education, training, and qualifications of all personnel. There is also a requirement for the maintenance of a proper work environment and all facilities needed to provide high-quality products and services.

3.7. Product Realization

The last two clauses, 7 and 8, are large and include a number of subclauses. The first subclause of clause 7 deals with quality planning. This requires a statement of the quality objectives for the product or project and the processes needed. These plans are to be recorded in the form of quality plans, and they include any inspection or tests needed to verify the product quality. The second clause, 7.2, requires the organization to determine all customer requirements. It also requires a review of product requirements prior to a commitment to produce a product to ensure the organization is able to meet the requirements. The organization is also required to implement arrangements for adequate communication with the customer, including customer feedback or complaints.

Clause 7.3 deals with the design of a product or service. This clause contains all the requirements of earlier editions of the standard regarding design and development. An appropriate planning activity is required that controls the entire design process. Design input states that inputs must be defined and documented, including all functional, regulatory, and legal requirements. The organization must document that knowledge from prior design activities is used when it is available. Design output must be such that verification against input requirements is feasible. The output must give the necessary requirements for production operations, address product acceptance criteria, and explain how the product may be used safely and correctly. The output documents must be approved before publication.

The standard requires design reviews at suitable stages using a review team made up of representatives of all functions associated with the product. There must be a verification stage during which the output is matched to the design input. There must also be a validation stage during which the final product's performance is compared to requirements. Finally, all design changes must be documented and controlled.

Clause 7.4 covers the control of the purchasing function to ensure that purchased product meets the specified requirements. Criteria for the selection and periodic evaluation of suppliers shall be defined and results recorded. The organization shall identify and implement all activities necessary for the verification of purchased product.

Clause 7.5 is entitled Production and Service Operations. The first subclause in this section requires the control of operations relevant to production and service by making available information including all specifications about the product, work instructions, devices needed for measuring and monitoring, and instructions for release and post delivery activities. The second subclause requires product to be identified and traceable throughout production. Clause 7.5.3 requires the organization to protect and control any customer-owned property used in production. This includes customer-owned tooling, shipping containers, and intellectual property that may be provided in confidence.

Clause 7.5.4 requires the organization preserve the property during all internal processing and delivery to the final destination. Subclause 7.5.5 requires the validation of all production and service processes that cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies may not be detected until after the product is put in use. The last subclause, 7.5.6, in this section deals with the control of measuring and monitoring devices. The devices must be controlled, serviced at regular intervals, and protected from damage. The results of calibration must be recorded and corrective action taken whenever a device is found to be out of calibration.

3.8. Measurement, Analysis, and Improvement

Clause 8 contains five subclauses, the first of which, 8.1, states that the organization shall define, plan, and implement the measuring and monitoring activities needed to ensure conformity and improvement. Clause 8.2 on measurement and monitoring requires the organization to measure customer satisfaction, conduct internal audits, and measure and monitor all processes and the product. The internal audits must be performed at regular intervals and must assess whether the quality management system is effective and conforms to the standard.

Clause 8.3 is on control of nonconformity. This is a requirement to identify and control product that is in nonconformance and to take appropriate action to see that such product does not reach the customer. The next subclause requires data dealing with the quality system to be collected and analyzed. These data include customer satisfaction and dissatisfaction, conformance to requirements, characteristics of processes and products, and suppliers.

Clause 8.5 requires the organization to plan for continual improvement of the quality system through the “use of quality policy, objectives, audit results, analysis of data, corrective and preventive action, and management review.” The last two subclauses in clause 8.5 are entitled Corrective and Preventive Action. These two requirements were a single clause in the 1994 edition of the standard. This led to some confusion among users of the standard as to the difference between them. Corrective action includes the correction of problems that have occurred, whereas preventive action deals with potential problems that may have never occurred.

4. ISO 9004-2000

ISO 9004-2000 is a guidance document that provides more information regarding the quality management system. As stated earlier, the clause structure of this standard is the same as that of 9001-2000. The title of this standard is *Quality Management Systems—Guidelines for Performance Improvements*. It is, however, based on the same quality management principles as ISO 9001-2000. The focus of this standard is the improvement of the processes of an organization in order to enhance its performance.

When ISO 9001-2000 and ISO 9004-2000 are used together, the benefits to an organization are likely to be greater than if only one is used. The two standards have identical structures but different scopes. ISO 9004 is not intended to be used as guidance document for compliance to ISO 9001. The purpose of ISO 9001 is to define the minimum requirements needed to achieve customer satisfaction by meeting specified product requirements. The purpose of ISO 9004 is to provide guidance on the application and use of a quality management system to improve the overall performance of an organization.

The clauses of ISO 9001-2000 are included in a box within the clauses of 9004 for immediate reference for users of ISO 9004. The verb used in ISO 9001 is “shall,” whereas that used in 9004 is “should.” The clauses of ISO 9004-2000 are based on the following eight quality management principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, and mutually beneficial supplier relationships.

A clause in the measurement and monitoring section provides a means for self- assessment of an organization’s quality system. The actual methodology along with appropriate questions to be answered are included in an annex to the standard.

5. OTHER STANDARDS AND GUIDES IN THE ISO 9000 FAMILY

In addition to the three standards discussed above, ISO 9000-2000, 9001-2000, and 9004-2000, there are three other standards, five technical reports, and three brochures in the 2000 edition of the ISO 9000 family. Some of these documents have not been revised to agree with the 2000 editions of the basic standards at the time of the publication of this chapter. The three additional standards are:

- ISO 19011, *Guidelines for Auditing Management Systems*
- ISO 10012, *Quality Assurance Requirements for Measuring Equipment*
- ISO 10015, *Quality Management—Guidelines for Training*

The five technical reports are:

- ISO 10006, *Quality Management—Guidelines to Quality in Project Management*
- ISO 10007, *Quality Management—Guidelines for Configuration Management*
- ISO 10013, *Guidelines for Developing Quality Manuals*
- ISO/TR 10014, *Guidelines for Managing the Economics of Quality*
- ISO/TR 10017, *Guidance on Statistical Techniques for ISO 9001-1994*

The three brochures are:

- *Quality Management Principles and Guidelines on Their Application*
- *Selection and Use of Standards*
- *Small businesses*

Two other standards were formerly in the 9000 family. The first of these is ISO 9000-3:1997, *Quality Management and Quality Assurance Standards—Part 3: Guidelines for the Application of ISO 9001:1994 to the Development, Supply, Installation, and Maintenance of Computer Software*. This standard was transferred to ISO/IEC JTC/SC7, who will update it to correspond to the 2000 edition of ISO 9001. The second is ISO 9000-4:1993, *Quality Management and Quality Assurance*

Standards— Part 4: Guide to Dependability Program Management. This standard has been transferred to IEC/TC 56, Dependability, who is updating it for the 2000 edition of ISO 9001. The following standards in the 9000 family have been dropped:

- ISO 8402:1994, *Vocabulary*—now part of ISO 9000-2000
- ISO 9000-1:1994, *Selection and Use of ISO 9000 Standards*—now part of ISO 9000-2000
- ISO 9002:1994, *Model for Quality Assurance*—now part of ISO 9001-2000
- ISO 9003:1994, *Model for Quality Assurance*—now part of ISO 9001-2000
- ISO 9004-1:1994, *Quality Management and Quality System Elements*—Part 1: Guidelines, now designated as ISO 9004-2000
- ISO 9004-2:1991, *Quality Management and Quality System Elements*—Part 2: Guidelines for Services—now included in ISO 9004-2000
- ISO 9004-3:1993, *Quality Management and Quality System Elements*—Part 3: Guidelines for Processed Materials—now included in ISO 9004-2000
- ISO 9004-4:1993, *Quality Management and Quality System Elements*—Part 4: Guidelines for Quality Improvement—now included in ISO 9004-2000
- ISO 10005:1995, *Quality Management—Guidelines for Quality Plans*—now included in ISO 10013

6. STANDARDS DEVELOPED BY OTHER ORGANIZATIONS

6.1. ANSI/ASQ/Z1.11, *The Application of ISO 9001 to Educational Institutions*

This standard is an American National Standard, published by the American Society for Quality. The standard, now being updated to the 2000 edition of ISO 9001, was written to assist educational institutions conform to the requirements of ISO 9001. The current edition contains the ISO 9001:1994 standard in the left column of each page, with the corresponding clauses of ANSI/ASQ/Z1.11 on the right. The Z1.11 standard puts the 9001 standard in terms recognizable to persons dealing with education.

6.2. QS 9000, *Quality System Requirements, 3d Ed., 1998*

This document is not really a standard, in that it was not developed using a consensus procedure. It is a set of requirements, in addition to the ISO 9001 requirements, that have been developed by the Automotive Industry Action Group. The actual set of requirements were developed by representatives of Chrysler, Ford, and General Motors in 1994. The second edition was published in 1995 and the third edition published in 1998. The clause structure corresponds to that of ISO 9001:1994. In fact the ISO standard is printed in italics within each clause, while the additional requirements are in roman letters. Since 1994, the document has been printed in five languages in at least 63 countries. The original equipment manufacturers in the automotive industry have required their suppliers to be registered to this document in order to sell their product to them.

The additional requirements of this document consist of additional statistical requirements, such as requirements for statistical process control, gage repeatability and reproducibility studies, and failure mode and effects analyses. Other requirements imposed by the automotive group are also included. Most of the additional requirements are discussed in a set of supplementary manuals entitled *Statistical Process Control Reference Manual, Production Part Approval Process Reference Manual, Measurement Systems Analysis Reference Manual, Advanced Product Quality Planning and Control Plan Reference Manual, and the Failure Mode and Effects Analysis Reference Manual*. Organizations wishing to be registered to QS 9000 must be familiar with all of the supplementary manuals as well as the basic set of requirements. QS 9000 is to be replaced in 2000 by ISO/TS 16949, which is the result of cooperation of both European and American automotive industry groups.

6.3. Other Quality Management Requirement Documents

Taking an approach similar to that taken by the automotive industry, the aerospace industry has developed a set of requirements entitled AS 9100 and the telecommunication industry has developed TL 9000. Both of these documents are based on ISO 9001:1994 and contain additional requirements considered necessary for quality management systems in their industry.

7. REGISTRATION TO QMS STANDARDS

Since the original adoption of the ISO 9000 standards in 1987, the registration of companies to the standards has become an accepted practice throughout the world. As of the end of 1998, there were 271,966 certificates of conformance issued in 143 countries on every continent, according to data

released by the International Organization for Standardization. The number of certified organizations has increased rapidly over the years, indicating that the interest in registration is increasing. As an indication of the growth rate, the September 1999 issue of *Quality Systems Update* reports there were 27,816 certificates in January 1993; 70,364 certificates in June 1994; 127,353 in December 1995; 162,704 in December 1996; and 223,403 certificates in December 1997. The 1998 data also show there were 7,887 registrations to ISO 14001, the environmental management standard.

These registrations represent every possible industry, from service industries to heavy manufacturing organizations. According to the ISO report, there were 573 registrars listed in 1999. This number had grown from 309 in 1995. During the same period the number of countries with registrars grew from 73 to 93. The directory lists 52 registrars operating in the United States. The number of accreditation agencies that accredit the registrars has increased from 33 in 1995 to 40 in 1999. Usually there is no more than one accreditation agency in any country. Some accreditation agencies operate in several countries.

Of the more than 270,000 registered companies, 36,653 are from the electrical and optical equipment industries, 28,885 from the basic metal and fabricated metal products industries, 20,275 from the machinery and equipment industries, 19,768 from the construction industries, and 16,451 from wholesale and retail trade. More than 61% of the registrations have been issued to organizations in Europe. In the United States, the accreditation agency is the Registrar Accreditation Board, a wholly owned subsidiary of the American Society for Quality and the American National Standards Institute. However, several other accreditation agencies operate in the United States, most notably the Raad voor Accreditatie (RVA) of the Netherlands.

There are several reasons for an organization to consider registration to these standards. The most commonly quoted reason is that their customers require it. In many instances, customers require extensive audits and/or surveys from their suppliers. These are often waived if the supplier is registered to ISO 9001. Of course, the principal reason is that the company will be a better company if it conforms to the standard, even if it is not registered. However, registration is an indication that this conformance has been met.

REFERENCES

- American Society for Quality, (ASQ) (1979), ANSI/ASQC Z1.15-1979, *Generic Guidelines for Quality Systems*, ASQC, Milwaukee.
- American Society for Quality, (ASQ) (1996), ANSI/ASQC C1-1996, *Specifications of General Requirements for a Quality Program* (also designated as Z1.8-1971), ASQC, Milwaukee.
- Automotive Industry Action Group (AIAG) (1992), *Statistical Process Control Reference Manual*, 2nd Ed., AIAG, Detroit.
- Automotive Industry Action Group (AIAG) (1994), *Advanced Product Quality Planning and Control Plan Reference Manual*, AIAG, Detroit.
- Automotive Industry Action Group (AIAG) (1995a), *Measurement Systems Analysis Reference Manual*, 2nd Ed., AIAG, Detroit.
- Automotive Industry Action Group (AIAG) (1995b), *Potential Failure Mode and Effects Analysis Reference Manual*, 2nd Ed., AIAG, Detroit.
- Automotive Industry Action Group (AIAG) (1995c), *Production Part Approval Process*, 2nd Ed., AIAG, Detroit, 1995.
- Automotive Industry Action Group (AIAG) (1998a), *Quality System Assessment*, 2nd Ed., AIAG, Detroit.
- Automotive Industry Action Group (AIAG) (1998b), *QS9000, Quality System Requirements*, 3rd Ed., AIAG, Detroit.
- International Organization for Standardization (ISO) (1989), *ISO Momento*, ISO, Geneva.
- International Organization for Standardization (ISO) (1999), ISO/TS 16949, *Quality Systems—Automotive Suppliers—Particular Requirements for the Application of ISO 9001:1994*, ISO, Geneva.
- International Organization for Standardization (ISO) (2000a), ISO 19011, *Guidelines for Auditing Management Systems*, ISO, Geneva.
- International Organization for Standardization (ISO) (2000b), ISO 9000-2000, *Quality Management Systems—Fundamentals and Vocabulary*, ISO, Geneva.
- International Organization for Standardization (ISO) (2000c), ISO 9001-2000, *Quality Management Systems—Requirements*, Geneva.
- International Organization for Standardization (ISO) (2000d), ISO 9004-2000, *Quality Management Systems—Guidelines for Performance Improvements*, ISO, Geneva.
- United States Department of Defense (1963), MIL-Q-9858A, *Quality Program Requirements*, 1963.
- United States Department of Defense (1981), MIL-I-45208A, *Inspection Systems Requirements*, 1981.