

Questions and Answers on Quality

Product quality depends on many process variables, such as the caliber of the components or materials used; type of equipment used in design, production, handling, installation, testing and shipping; the equipment calibration and maintenance procedures; the training and experience of production and supervisory personnel; the level of “workmanship”; and sometimes the environmental conditions (temperature, humidity, level of dust particles) in the area where the product is produced. The process, organizational structure, procedures, and resources that manufacturers and suppliers use to control these variables to produce a product or service of consistent quality to meet defined specifications is called a quality system.

In 1979, the International Organization for Standardization (ISO), a worldwide federation of over 90 countries founded in 1946 to promote the development of international standards to facilitate the exchange of goods and services worldwide, formed Technical Committee (TC) 176 on Quality Management and Quality Assurance. The Committee’s purpose was to address the worldwide trend towards increasingly stringent customer demands with regard to quality. This committee was tasked with addressing the growing confusion in the conduct of international trade resulting from differing quality system requirements at national and lower jurisdictional levels. As a result of TC 176’s work, ISO released a series of five standards in 1987, the ISO 9000 Standard Series. These standards provided guidance on selection of and requirements for a basic quality management system.

Soon compliance with the standards became recognized and required by many foreign and domestic buyers and by some governmental regulators. In addition, quality system registration was seen and used by manufacturers as a competitive marketing tool.

Quality system registration or approval entails the assessment and periodic audit of the adequacy of a supplier’s quality system by a third party, known as a quality system registrar. When a supplier’s system conforms to the registrar’s interpretation of an ISO 9000 standard, the registrar issues the supplier a “certificate of registration.” It should be noted that it is the supplier’s quality system that is registered, not an individual product.

This increasing demand for compliance with or registration to the ISO 9000 standards, combined with the lack of adequate and accurate information on the

topic, created significant problems for both U.S. industry and government agencies. To fill this void, NIST published two basic primers on the ISO 9000 Series and the usage of the ISO standards. The two reports, *Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues* [1] and *More Questions and Answers on the ISO 9000 Standard Series and Related Issues* [2], addressed such issues as: the types of requirements included in the standards; how the U.S. registration system operates; how the ISO 9000 standards were being used in the European Union’s new regulatory scheme; mutual recognition efforts at the international level; how federal agencies were using the standards within their regulatory and procurement programs; and information on other ISO 9000 based standards, such as the QS 9000 Standard—a standard published by the auto industry to define a set of quality system requirements for suppliers to the “Big Three” and other auto companies.

The ISO 9000 Standards increased the visibility of and U.S. concerns over the impact of international standards on U.S. competitiveness to a degree never encountered before. The NIST reports provided timely and accurate information that was sorely needed by both the private and government sectors to formulate adequate responses to these issues—information not being provided by the private sector at that time. The reports were written in an easy-to-read question-and-answer format, providing information in a way managers could use to make informed decisions regarding the application of the ISO 9000 Standard Series within company and governmental operations.

The use of the ISO 9000 standards is now a key domestic and international business strategy for many U.S. companies—one that is becoming increasingly necessary for survival. U.S. industry has become acutely aware that information on these and other national and international standards and related conformity assessment activities is vital to ensure continued competitiveness in the U.S. and global marketplaces.

The *Questions and Answers on Quality* reports have been and continue to be widely distributed by NIST and by private sector companies and educational institutions. The popularity of and demand for these reports far exceeded anything that the Office of Standards Services had anticipated or had ever experienced.

These reports are part of NIST's growing effort to respond to the need for accurate and timely information on subjects related to national and international standards and conformity assessment. Other related reports are listed on the Office of Standards Services web site [3]. NIST has also formed federal working groups to address such issues, has responded to many thousands of requests for information on these topics, and has provided staff members to give lectures at numerous workshops and at various public and private sector fora.

Maureen Breitenberg is internationally recognized as a leading authority on conformity assessment issues, standards, guidelines and practices. Her many publications have been used nationally and internationally to address trade-related issues. They have been widely distributed by NIST to private sector organizations, other U.S. federal agencies, state agencies involved in trade development and assistance, U.S. embassies, foreign governments, colleges, universities, and libraries for education and training purposes and for responding to trade related inquiries. Several have been translated and/or reprinted by foreign and domestic government and private sector organizations. Her latest publication, the 1999 edition of SP 739, *Directory of Federal Government Certification and Related Programs* [4], has been highlighted as a very useful resource in terms

of depth of content, authority, and how well the information is presented.

Breitenberg received the NIST Bronze Medal in 1992. She was also elected to the Government and Industry Quality Liaison Panel's Leadership Team, which resulted in harmonizing federal agency quality system requirements for suppliers to the government. The Panel received the Vice President's National Performance Review (Golden Hammer) Award in 1995 for its efforts.

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Bibliography

- [1] Maureen Breitenberg, *Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues*, NISTIR 4721, National Institute of Standards and Technology, Gaithersburg, MD (1991).
- [2] Maureen Breitenberg, *More Questions and Answers on the ISO 9000 Standard Series and Related Issues*, NISTIR 5122, National Institute of Standards and Technology, Gaithersburg, MD (1993).
- [3] NIST publications on standards and conformity assessment activities are listed on the web site (<http://ts.nist.gov>).
- [4] Maureen Breitenberg (ed.), *Directory of Federal Government Certification and Related Programs*, NIST Special Publication 739, 1999 Edition, National Institute of Standards and Technology, Gaithersburg, MD (1999).