NISTIR 4721

Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues

Maureen Breitenberg

U.S. DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Standards Code and Information Program
Office of Standards Services
Gaithersburg, MD 20899

U.S. DEPARTMENT OF COMMERCE
Robert A. Mosbacher, Secretary
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
John W. Lyons, Director

NIST

NISTIR 4721

Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues

Maureen Breitenberg

U.S. DEPARTMENT OF COMMERCE
National Institute of Standards
and Technology
Standards Code and Information Program
Office of Standards Services
Gaithersburg, MD 20899

November 1991

U.S. DEPARTMENT OF COMMERCE
Robert A. Mosbacher, Secretary

NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
John W. Lyons, Director

FOREWORD

The Standards Code and Information Program periodically publishes information on various aspects of conformity assessment for use by those who operate or benefit from such systems. Recently there has been considerable interest in the content and application of international standards related to quality management, i.e., the so-called ISO 9000 series. This report provides answers to some of the most often asked questions on this topic. This material is intended for those who are concerned about the ISO 9000 standards and should help foster a wider interest in the use of quality systems in general. This document also references other publications and services provided by this office which readers may find useful.

The reader is also invited to share any comments on the material presented in this document. The attainment of quality is a dynamic and evolving process, and its continued maturation depends on feedback from those involved in the process.

ACKNOWLEDGEMENTS

I would like to thank Mary Saunders, International Trade Administration's Office of European Community Affairs; Mr. Charles Hyer, the Marley Organization; Mr. Donald Mackay, Air-Conditioning and Refrigeration Institute; Dr. Curt Reimann and Dr. Robert Chapman, NIST's Office of Quality Programs; Patricia Kopp, American Society for Quality Control; and NIST's Standards Code and Information staff for their careful review of and comments on this document.

Maureen A. Breitenberg
Standards Code and Information

ABSTRACT

This report provides information on the development, content and application of the ISO 9000 standards to readers who are unfamiliar with these aspects of the standards. It attempts to answer some of the most commonly asked questions on quality; quality systems; the content, application and revision of the ISO 9000 standards; quality system approval/registration; European Community requirements for quality system approval/registration; and sources for additional help.

Key Words: conformity assessment; EN 29000; ISO 9000; quality assurance; quality control; quality system; quality system registration

TABLE OF CONTENTS

INTRODUCTION

This report was designed to answer the most commonly asked questions on quality; quality systems; the content, application and revision of the ISO 9000 standards; quality system approval/registration; European Community requirements for quality system approval/registration; and related topics. The Standards Code and Information Program at the National Institute of Standards and Technology (NIST) has received an increasing number of inquiries on these topics, which is indicative of the expanding interest in quality by many sectors of the economy. This report has been prepared to provide basic information in this area.

WHAT IS QUALITY?

Quality improvement has now become both the corporate and international business strategy of the 1990's. Cadillac and Milliken and Company each advertise winning the Malcolm Baldrige Award for quality. Ford Motor Company publicizes a "Quality is Job 1" slogan, and many other companies are following suit. At the international level, interest has mushroomed in quality systems as a means of assuring the consistent conformity of products or services to a given set of standards or expectations.

There has, however, been little agreement among either corporate management or professionals in the field regarding the meaning of "quality." The International Organization for Standardization (ISO) Standard 8402 defines quality as: "the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs." However, there are problems with this definition. Whose needs does the service or product address? Who are its customers? In the testing services field, for example, totally erroneous test results may satisfy a client's needs quite well if the faulty test report can be used to allow him to sell his product, especially if an accurate test report would not. Nevertheless, such results are unlikely to satisfy the needs of the potential buyers of the product or of the agency responsible for regulating the product.

Customers for a product or service produced by a company can be located within or outside the company or both, depending on the product or service. A product or service may be provided by one company unit to another solely for the latter's use, or for subsequent delivery to a customer outside the organization. It has been said that most product or service defects (no matter where they occur in the service or manufacturing process) usually find their way to the point of interface between a company and its outside customers.

In an attempt to address this problem, ISO has added seven footnotes to its definition, including that: "in a contractual environment, needs are specified, whereas in other environments, implied needs

should be identified and defined" and that "needs can change with time." Needs can be defined in terms of safety; usability; availability; versatility; compatibility with other products; reliability; maintainability; overall cost (including purchase price, maintenance costs, and product life); environmental impact; or other desired characteristics.

Even if all "needs" can be identified and adequately defined (often no easy task), what about the issue of an "acceptable quality level (AQL)" -- the maximum percentage of nonconforming products or service units that should be considered satisfactory as a process average? Stated in other words, how many (if any) mistakes can you make and still produce a "quality" product or service? A manufacturer's production system may be considered by his customers to produce a "quality" product if the AQL is 0.1%, that is only one in 1,000 products contains defects. Yet a 1 in 1,000 error rate for nurses whose job it is to hold babies (they only drop one out of a thousand) or for containers which hold highly toxic or hazardous materials (only one serious leak gets by for every 1,000 containers produced) are obviously not acceptable. There is a belief among many quality experts and their disciples that the only acceptable quality level for any manufactured product or service is 100% ("zero defects"), and that any failure to "do it right" the first time is not tolerable. This is not a universally held opinion.

WHAT IS A QUALITY SYSTEM?

Product quality depends on many 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 employed; 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 of consistent quality which meets defined specifications is called a **quality system.** [1] The

---

[1]/ Note this definition is somewhat different from the ISO definitions. ISO Standard 9000-1987 defines quality system as: "the organization, structure, responsibilities, procedures, processes and resources for implementing quality management." The standard defines quality management as : "that aspect of the overall management function that determines and implements quality policy." The standard defines quality policy as: "the overall intentions and directions of an organization as regards quality, as formally expressed by top management." These ISO definitions also include several additional footnotes.

standards that are being adopted globally for quality systems are the ISO 9000 standards.

WHAT IS ISO?

ISO is the International Organization for Standardization, founded in 1946 to promote the development of international standards and related activities, including conformity assessment, [2] to facilitate the exchange of goods and services worldwide. ISO is composed of member bodies from over 90 countries, the U.S. member body being the American National Standards Institute (ANSI). ISO's work covers all areas except those related to electrical and electronic engineering, which are covered by the International Electrotechnical Commission (IEC). The results of ISO's technical work are published as International Standards or Guides.

WHAT ARE THE ISO 9000, ANSI/ASQC Q 90, AND CEN/CENELEC EN 29000 STANDARDS?

In 1987, the ISO published a series of five international standards (ISO 9000, 9001, 9002, 9003, and 9004), developed by ISO Technical Committee (TC) 176 on quality systems. This series, together with the terminology and definitions contained in ISO Standard 8402, provides guidance on the selection of an appropriate quality management program (system) for a supplier's operations.

The ISO 9000 standards were intended to be advisory in nature and were developed primarily for use in two-party contractual situations or for internal auditing. However, the standards are currently being applied under a much broader range of conditions and circumstances. In some cases, compliance with one of the ISO 9000 standards (or their equivalent) has been or will be mandated by a U.S., foreign national, or regional government body. Conformance to ISO 9000 standards is also being required in purchasing specifications with increasing frequency.

The ISO 9000 Standard Series has been adopted in the United States as the ANSI/American Society for Quality Control (ASQC) Q 90 Series. In Europe, it has been adopted by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) as the European Norm (EN) 29000 Series. According to a recent survey by ISO, forty-three (43) countries have

---

[2]/ Conformity assessment includes testing, inspection, laboratory accreditation, certification, quality system assessment, and other activities intended to assure the conformity of products to a set of standards and/or technical specifications.

national standards that are identical or equivalent to the ISO 9000 Standard Series. Additional countries are considering their adoption.

WHAT SORT OF INFORMATION IS CONTAINED IN EACH ISO 9000 STANDARD?

The ISO 9000 Standard Series is generic in scope. Each standard addresses a different aspect of quality assurance, depending on the needs of the user.

ISO 9001, 9002 and 9003 describe three distinct quality system models of varying stringency for use in different applications. Common elements in ISO 9001, 9002, and 9003 include the need for: an effective quality system; ensuring that measurements are valid, that measuring and testing equipment is calibrated regularly; the use of appropriate statistical techniques; having a product identification and traceability system; maintaining an adequate record keeping system; having an adequate product handling, storage, packaging and delivery system; having an adequate inspection and testing system as well as a process for dealing with nonconforming items; and ensuring adequate personnel training and experience.

ISO 9000 (ANSI/ASQC Q 90), Quality Management and Quality Assurance Standards - Guidelines for Selection and Use, explains fundamental quality concepts; defines key terms; and provides guidance on selecting, using, and (if necessary) tailoring ISO 9001, 9002, and 9003.

ISO 9001 (ANSI/ASQC Q 91), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing, is the most comprehensive standard in the series. ISO 9001 covers all elements listed in ISO 9002 and 9003. In addition, it addresses design, development, and servicing capabilities.

ISO 9002 (ANSI/ASQC Q 92), Quality Systems - Model for Quality Assurance in Production and Installation, addresses the prevention, detection, and correction of problems during production and installation. It is more extensive and more sophisticated than ISO 9003.

ISO 9003 (ANSI/ASQC Q 93), Quality Systems - Model for Quality Assurance in Final Inspection and Test, is the least comprehensive standard. It addresses requirements for the detection and control of problems during final inspection and testing.

ISO 9004 (ANSI/ASQC Q 94), Quality Management and Quality System Elements - Guidelines, provides guidance for a supplier to use in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. ISO 9004 examines each of the quality system elements (cross-referenced in the other ISO 9000 standards) in greater detail and can be used for internal and external auditing purposes.

WHERE CAN COPIES OF THESE STANDARDS BE OBTAINED?

Copies of ISO draft/final standards and European standards (ENs) can be purchased from: The American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, Phone: (212) 642-4900, Fax: (212) 302-1286.

ARE THE ISO 9000 STANDARDS SUBJECT TO CHANGE?

According to ISO procedures, all ISO standards, including those in the ISO 9000 series, must be reviewed and revised or reaffirmed at least once every five years. ISO has already begun to revise and supplement the ISO 9000 series. Some of these standards/guidelines will supplement ISO 9000 and ISO 9004, while others will be included in the new ISO 10000 series. Both series have been reserved for use by ISO TC 176.

Recently released ISO standards and guidelines in the quality area include: ISO 9000-3, Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software; ISO 9004-2, Quality Management and Quality System Elements - Part 2: Guidelines for Services; ISO 10011 Part 1, Guidelines for Auditing Quality Systems - Auditing; ISO 10011 Part 2, Guidelines for Auditing Quality Systems - Qualification Criteria for Auditors; ISO 10011 Part 3, Guidelines for Auditing Quality Systems - Managing Audit Programs; and ISO 10012-1, Quality Assurance Requirements for Measuring Equipment - Part 1: Management of Measuring Equipment.

In addition, ISO/DIS (Draft International Standard) 8402-1 Quality Systems Terminology; and DIS 9000-2 Addendum to 9000 on Guidelines for Implementing 9001-2-3; DIS 9004-3 Addendum to 9004 on Processed Materials are under review by ISO TC 176. ISO TC 176 is also considering committee draft (CD) 9004-4 Addendum to 90004 on Quality Improvement; guidance documents on project management, quality plans, quality manuals, the economics of quality, and configuration management; documents covering revisions to ISO 9000, 9001-2-3; and 9004; and a working draft (WD) 10012-2: Quality Assurance Requirements for Measuring Equipment - Part 2: Measuring Equipment.[3]

Some national and regional standards bodies are developing supplemental guidance for the application of the ISO 9000 series to specific industries. CEN and CENELEC, for example, are developing more specific requirements for the application of the ISO 9001 to the

---

[3]/ Information on drafts or proposed standards work was provided by Patricia Kopp, Standards Coordinator at the American Society for Quality Control (ASQC) in Milwaukee, WI, Phone: 414-272-8575.

medical device industry. [4] The U.S. Food and Drug Administration (FDA) is also considering replacing its current good manufacturing practices (GMP) regulations for medical devices with the ISO 9000 standards with appropriate guidance for their application. The International Organization for Legal Metrology (OIML) is developing a document entitled: "Quality Assurance as Applied for Initial Verification of Measuring Instruments," which provides guidance on the applicability and use of the ISO 9000 Standard Series in the manufacture of measuring instruments.

DOES TC 176 HAVE A PLAN FOR REVISING AND SUPPLEMENTING THE ISO 9000 STANDARDS?

Vision 2000 - A Strategy for International Standards' Implementation in the Quality Arena During the 1990s is a long range plan through the year 2000 developed by an Ad Hoc Task Force of ISO TC 176. The plan includes providing additional guidance on how to apply the ISO 9000 series standards to four generic product categories (hardware, software, processed materials, and services), as well as providing guidance on related issues, such as quality system auditing. As noted above, these documents are in various stages of development. Minor modifications in the original ISO 9000 series are expected in 1993, with major revisions in 1997. The long range goal, according to Vision 2000, is to have a single Total Quality Management Standard by the year 2000.

WHAT IS THE ISO 9000 FORUM?

ISO has established a forum which will serve the needs of ISO 9000 users by: providing information (such as a newsletter); facilitating international discussions on new developments and issues affecting the application of the ISO 9000 standards; promoting the exchange of experience in such areas as training, promotion and operation of relevant schemes; harmonizing practices in the application and interpretation of the ISO 9000 standards; providing advice to ISO TC 176 or the relevant ISO decision making body.

HOW DO THE ISO 9000 CRITERIA COMPARE WITH CRITERIA USED IN THE MALCOLM BALDRIGE NATIONAL QUALITY AWARD PROCESS?

The Malcolm Baldrige National Quality Award process is designed to recognize and award those firms with outstanding records of quality

---

[4]/ CEN and CENELEC have issued a draft European standard, EN 46001 - Specific Requirements for the Application of EN 29001 to Medical Devices. Medical device manufacturers doing business in the EC will have to comply with the quality system requirements of EN 46001.

performance. The purpose of the program is therefore very different from the purpose behind the development of the ISO 9000 criteria. While the use of the ISO 9000 standards may be a good starting point in establishing a quality system, the criteria used in evaluating candidates for the Baldrige Award are much more detailed and extend beyond those areas covered by the ISO 9000 series. The Baldrige Award criteria are results oriented and cover all operations, processes, and work units of a company. The evaluation procedures emphasize the dynamics involved in the integration of all aspects of a firm's quality system and the firm's continuous improvements in quality.

WHAT IS QUALITY SYSTEM REGISTRATION?

Quality system registration or approval (sometimes misnamed "quality system certification" [5]) involves 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." **Interpretations of an ISO 9000 standard may not be consistent from one registrar to another.**

Note that the supplier's quality system is registered, not an individual product. **Consequently, quality system registration does not imply product conformity to any given set of requirements.** Registration programs can be conducted in conjunction with or independently from a certification [6] program. Registrars may or may not concurrently operate a product certification program.

WHO EVALUATES QUALITY SYSTEMS?

A manufacturer may choose to evaluate his own quality system. Such self-audits are usually major components of the quality system itself. Such self-audits can increase the confidence of management in its production system and demonstrate to its personnel that the firm is committed to quality management.

"Second party" evaluations are also common. In these cases, it is usually the buyer who requires and conducts quality system evaluations of his suppliers. These evaluations are mandatory only for companies wishing to become suppliers to that buyer.

---

[5]/ ISO/IEC Guide 48 uses the term "register," though many Europeans continue to use the term "certify."

[6]/ Certification is defined in ISO Guide 2-1991 as the: "procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements."

"Third party" quality system evaluations and registrations may be voluntary or mandatory and are conducted by persons or organizations independent of both the supplier and the buyer. According to a recent ISO survey, 31 countries reported the existence of one or more third party registration schemes in their countries.

WHAT IS THE "NEW APPROACH" FOR CONFORMITY ASSESSMENT OF REGULATED PRODUCTS?

The Government of the European Community (EC) has established a conformity assessment scheme for EC-regulated [7] products. The EC has specified conformity assessment methods in terms of eight "modules," such as self-certification (also called "manufacturer's declaration"), type testing, quality system approval, or final product verification by a third party. Each "new approach" directive specifies the alternative means (set of modules) which suppliers must use to certify their products as being in conformance with the "essential requirements" spelled out in each directive.

When EC directives require the use of a third party in the conformity assessment process, each member country government must provide the EC government with a list of such bodies. Each member country government must determine that the bodies it notifies, referred to as a "notified bodies," are competent to declare that a regulated product is in conformity to the "essential requirements" spelled out in a particular directive. Member states notify bodies by both conformity assessment method (module) and by directive to the EC, which is then responsible for compiling a list of all such bodies.

Each EC country must accept the results of conformity assessments by notified bodies in all other EC countries unless there is cause to believe that the product was improperly tested. Each EC country is responsible for assuring that the bodies it designates as notified bodies comply with the criteria for competence of testing laboratories, certification and laboratory accreditation bodies, and quality system registrars spelled out in the European EN 45000 series of standards.

WILL QUALITY SYSTEM APPROVALS BE MANDATORY IN THE EC?

Having an approved quality system will not be a blanket requirement for all products. However, for suppliers of medical devices, construction products, industrial safety equipment, telecommunications

---

[7]/ Regulated products are those for which the EC Commission has developed or is developing an EC-wide technical harmonization directive which provides manufacturers with a single set of requirements that must be met to place their products on the EC market.

terminal equipment, gas appliances, commercial scales, and possibly other products, approval of a supplier's quality system will be a key component of the EC's legal requirements for safety certification, as specified in the EC directives pertaining to those products. In other directives, such as the Council Directive dated June 14, 1989 on machinery (89/392/EEC), manufacturers of some products will be permitted to self declare that their product conforms to the requirements of the directive and to place the European Community (CE) mark on the product. However, such machinery manufacturers must maintain a file on the manufacture of those products, including information on "the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive" -- in other words, on the manufacturer's quality system. It is possible that the ISO 9000 (EN 29000) Series Standards could be used within the European Community to evaluate the adequacy of such quality systems.

WHO WILL BE ABLE TO CONDUCT MANDATORY EC QUALITY SYSTEM APPROVALS?

At the present time, notified bodies must be physically located within the geographical boundaries of the European Community. The EC has developed a draft document entitled, Working Document on Negotiations with Third Countries Concerning the Mutual Recognition of Conformity Assessment, which provides guidance for the establishment of mutual recognition agreements with third countries. Until the final version of that document is available and one or more mutual recognition agreements are subsequently established between the United States and the European Community, there can be no notified bodies in the United States. A mutual recognition agreement would allow U.S. entities to perform all required conformity assessment procedures included within the scope of the agreement.

There remains the possibility that some conformity assessment tasks may be subcontracted by notified bodies to bodies outside the EC, including organizations in the United States. Such subcontracting would be done at the discretion of the notified body, which would continue to be responsible for the final assessment of product conformity. Subcontractors must comply with all requirements of the EN 45000 series. Though drafts of Guiding Principles for Subcontracting by "Notified Bodies" pursuant to the Council Resolution of 13 December 1990 Concerning the Modules for the Various Phases of the Conformity Assessment Procedures have been circulated, final EC guidance on subcontracting is still pending. Permission for subcontracting certain testing functions has already been given by the EC Council of Ministers.

WILL QUALITY SYSTEM REGISTRATION BE REQUIRED FOR NONREGULATED PRODUCTS IN THE EC AND ELSEWHERE?

In the nonregulated product area, producers desiring to do business in the European Community (EC) and elsewhere may be required by procurement authorities or buyers to be audited and registered as being in compliance with an ISO 9000 standards. Such requirements will result from marketplace demands, as opposed to regulatory requirements.

It should be noted that in the United States, the U.S. Department of Defense is expected to replace the use of some of its military quality standards (MIL-Q-9858A and MIL-I-45028A) with the ISO 9000 standards. Other foreign government procurement authorities have already or are likely to follow suit.

WHAT IS THE EOTC AND HOW DOES IT FIT INTO THE PICTURE?

The European Organization for Testing and Certification (EOTC) was created by the EC in April 1990 under a memorandum of understanding with the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Free Trade Association (EFTA) countries. The EOTC was formed to promote the mutual recognition of test results, certification procedures, and quality system assessments and registrations in nonregulated product areas throughout the EC and EFTA. The EOTC will also be responsible for providing technical assistance to the EC Commission in the implementation of some EC legislation, especially in the preparation of mutual recognition agreements with non-EC countries. It is anticipated that there will be a Specialized Committee of the EOTC in the area of Quality Assurance. However, this committee will not be established until after December 31, 1992. Nevertheless the need for expert advice in this area was recognized by the EOTC in July 1991. The European Organization for Quality (EOQ) and the European Committee for Quality System Assessment and Certification (EQS) have been offered observership status in EOTC to fill this need. The EOTC is expected to be fully operational by the end of 1992. For further information on the EOTC, contact: EOTC, Rue Stassart 33, 2nd Floor, B-1050 Brussels, Belgium, Phone: 32 2 519 6969, Fax: 32 2 519 69 17/19.

DOES THE U.S. HAVE A SCHEME FOR QUALITY SYSTEM REGISTRATION?

Until recently, U.S. companies relied on quality system registration firms in Europe and Canada to register their quality systems, but this is no longer the case. Today, the number of U.S.-based organizations offering consulting services, assessment and/or quality system registration is growing rapidly.

WHO EVALUATES THE COMPETENCE OF REGISTRARS?

In 1989, the Registration Accreditation Board (RAB) was established as an affiliate of the American Society of Quality Control (ASQC) to develop a program to evaluate the quality of services offered by registrars. RAB issued its first approval in March 1991, and several more firms have been approved since then. Talks are underway between the RAB and ANSI to place the RAB program under ANSI. Information on the RAB program is available from: the RAB, c/o ASQC, 611 East Wisconsin Ave., Milwaukee, WI 53202, Phone 414-272-8575.

Programs similar to that of the RAB have been underway in Canada, in a number of European countries, and elsewhere in the world for some time.

WHERE CAN U.S. INDUSTRY GO TO GET ADDITIONAL HELP?

Additional information is available from:

National Center for Standards and Certification Information (NCSCI)
National Institute of Standards and Technology (NIST)
TRF Bldg. Room A163
Gaithersburg, MD 20899
Phone: (301) 975-4040 Fax: (301) 926-1559

and from

Office of EC Affairs
International Trade Administration, Room 3036
14th and Constitution Ave., SW
Washington, DC 20230
Phone: (202) 377-5276 Fax: (202) 377-2155

Both agencies are located in the Department of Commerce and can refer interested parties to other sources of information within and outside the federal government.

APPENDIX
INFORMATION AND PUBLICATIONS AVAILABLE FROM

Standards Code and Information Program (SCI)
National Institute of Standards and Technology
Administration Building, Room A629
Gaithersburg, MD 20899
(301) 975-4040

o The ABC's of Standards-Related Activities in the United States (NBSIR 87-3576)
This report is an introduction to voluntary standardization, product certification and laboratory accreditation for readers not fully familiar with these topics. It stresses some of the more important aspects of these fields; furnishes the reader with both historical and current information on these topics; describes the importance and impact of the development and use of standards; and serves as background for using available documents and services.
Order as PB 87-224309 from NTIS.

o The ABC'S of Certification Activities in the United States (NBSIR 88-3821)
This report, a sequel to NBSIR 87-3576, The ABC'S of Standards-Related Activities in the United States, provides an introduction to certification for readers not entirely familiar with this topic. It highlights some of the more important aspects of this field, furnishes the reader with information necessary to make informed purchases, and serves as background for using available documents and services.
Order as PB 88-239793 from NTIS.

o Laboratory Accreditation in the United States (NISTIR 4576)
This report, a sequel to NBSIR 87-3576 The ABC'S of Standards-Related Activities in the United States and NBSIR 88-3821 The ABC'S of Certification Activities in the United States, is designed to provide information on laboratory accreditation to readers who are new to this field. It discusses some of the more significant facets of this topic, provides information necessary to make informed decisions on the selection and use of laboratories, and serves as background for using other available documents and services.
Order as PB 91-194495 from NTIS.

o Directory of International and Regional Organizations Conducting Standards-Related Activities (NIST SP 767)
This directory contains information on 338 international and regional organizations which conduct standardization, certification, laboratory accreditation, or other standards- related activities. It describes their work in these areas, as well as the scope of each organization, national affiliations of members, U.S. participants, restrictions on membership, and the availability of any standards in English.
Order as SN 003-003-02937-8 from GPO.

o Directory of European Regional Standards-Related Organizations (NIST SP 795)

This directory identifies more than 150 European regional organizations - both governmental and private - that engage in standards development, certification, laboratory accreditation and other standards-related activities, such as quality assurance. Entries describe the type and purpose of each organization; acronyms; national affiliations of members; the nature of the standards-related activity; and other related information.
Order as SN 003-003-03038-4 from GPO.

o Standards Activities of Organizations in the United States (NIST SP 806)

The directory identifies and describes activities of over 750 U.S. public and private sector organizations which develop, publish, and revise standards; participate in this process; or identify standards and make them available through information centers or distribution channels. NIST SP 806, a revision of NBS SP 681, covers activities related to both mandatory and voluntary U.S. standards. SP 806 also contains a subject index and related listings that cover acronyms and initials, defunct bodies and organizations with name changes.
Copies not available from SCI. Order as SN 003-003-03070-8 from GPO.

o Directory of Private Sector Product Certification Programs (NIST SP 774)

This directory presents information from 132 private sector organizations in the United States which engage in product certification activities. Entries describe the type and purpose of each organization, the nature of the activity, product certified, standards used, certification requirements, availability and cost of services, and other relevant details.
Copies not available from SCI. Order as SN 003-003-02984-0 from GPO.

o Directory of Federal Government Certification Programs (NBS SP 739)

This directory presents information on U.S. Government certification programs for products and services. Entries describe the scope and nature of each certification program, testing and inspection practices, standards used, methods of identification and enforcement, reciprocal recognition or acceptance of certification, and other relevant details.
Order as SN 003-003-02852-5 from GPO.

o Directory of Federal Government Laboratory Accreditation/ Designation Programs (NIST SP 808)

This directory provides updated information on 31 federal government laboratory accreditation and similar type programs conducted by the federal government. These programs, which include some type of assessment regarding laboratory capability, designate sets of laboratories or other entities to conduct testing to assist federal agencies in carrying out their responsibilities. The directory also lists 13 other federal agency programs of possible interest, including

programs involving very limited laboratory assessment and programs still under development.
Order as SN 003-003-03069-4 from GPO.

o Directory of State and Local Government Laboratory Accreditation/ Designation Programs (NIST SP 815)
This directory provides updated information on 21 state and 11 local government laboratory accreditation and similar type programs. These programs, which include some type of assessment regarding laboratory capability, designate private sector laboratories or other entities to conduct testing to assist state and local government agencies in carrying out their responsibilities. Entries describe the scope and nature of each program, laboratory assessment criteria and procedures used in the program, products and fields of testing covered, program authority, and other relevant details.
Order from SN 003-003-03093-7 GPO.

o Barriers Encountered by U.S. Exporters of Telecommunications Equipment (NBSIR 87-3641)
This report addresses the perceived institution of unreasonable technical trade barriers by major European trading partners to the export of telecom products and systems by U.S. companies. The GATT technical office, which has responsibilities to assist U.S. exporters to take advantage of trade opportunities, informally contacted over a period of six months, telecom companies and agencies to assess the extent of unreasonableness in foreign national standards, regulations, testing and certification requirements, and accreditation procedures.
Order as PB 88-153630 from NTIS.

o A Review of U.S. Participation in International Standards Activities (NBSIR 88-3698)
This report describes the role of international standards, their increasingly significant importance in world trade, and the extent of past and current U.S. participation in the two major international standardization bodies - ISO and IEC. The degree of U.S. participation covers the 20 year period 1966-1986. A coarse analysis of data indicates some correlation between U.S. participation and recent export performance for several major product categories.
Order as PB 88-164165 from NTIS.

o An Update of U.S. Participation in International Standards Activities (NISTIR 89-4124)
This report presents updated information on the current level of U.S. participation in ISO and IEC (reference: NBSIR 88-3698).
Order as PB 89-228282/AS from NTIS.

o A Summary of the New European Community Approach to Standards Development (NBSIR 88-3793-1)
This paper summarizes European Community (EC) plans to aggressively pursue its goal of achieving an "internal market" by 1992 and the standards-related implications of such a program on U.S. exporters.
Order as PB 88-229489/AS from NTIS.

o Trade Implications of Processes and Production Methods (PPMs) (NISTIR 90-4265)

This report discusses processes and production methods (or PPM's) and their relationship to trade, the GATT Agreement on Technical Barriers to Trade, and traditional product standards used in international commerce. The report provides background information on PPM's, a suggested definition, and the possible extension of their application from the agricultural sector to industrial products. Order as PB 90-205485 from NTIS.

[SEE LAST PAGE FOR NTIS AND GPO CONTACTS]

The following documents are available upon request from OSCI.

o tbt news

This newsletter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). tbt news reports on the latest notifications of proposed foreign regulations; bilateral consultations with major U.S. trade partners; programs of interest to U.S. exporters; and availability of standards and certification information. Subscription is free upon request.

o Technical Barriers to Trade

This booklet explains the basic rules of the international Agreement on Technical Barriers to Trade negotiated during the Tokyo Round of the Multilateral Trade Negotiations (MTN), and describes Title IV of the U.S. Trade Agreements Act of 1979 which implements the United States' obligations under the Agreement. The Agreement, popularly known as the Standards Code, was designed to eliminate the use of standards and certification systems as barriers to trade. The booklet describes the functions of the Departments of Commerce and Agriculture, the Office of the U.S. Trade Representative, and the State Department in carrying out the U.S.'s responsibilities.

o "GATT Standards Code Activities"

This brochure gives a brief description of NIST's activities in support of the Standards Code. These activities include operating the U.S. GATT inquiry point for information on standards and certification systems; notifying the GATT Secretariat of proposed U.S. regulations; assisting U.S. industry with trade-related standards problems; responding to inquiries on foreign and U.S. proposed regulations; and preparing reports on the Standard Code.

o GATT Standards Code Activities of the National Institute of Standards and Technology

This annual report describes the GATT Standards Code activities conducted by the Standards Code and Information Program for each calendar year. NIST responsibilities include operating the GATT inquiry point, notifying the GATT Secretariat of proposed U.S. Federal government regulations which may affect trade, assisting U.S. industry

with standards-related trade problems, and responding to inquiries about proposed foreign and U.S. regulations.

o Free handout material on office activities and standards-related information such as: government sources of specifications and standards; foreign standards bodies; U.S. standards organizations; and a brochure on the National Center for Standards and Certification Information (NCSCI).

In addition to general inquiry services, the following assistance is also available:

o EC Hotline
This hotline reports on draft standards of the European Committee on Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). It also provides information on selected EC directives. The recorded message is updated weekly and gives the product, document number and closing date for comments. The hotline number is (301) 921-4164 (not toll-free).

o GATT Hotline
A telephone hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations which may significantly affect trade. The recorded message is updated weekly and gives the product, country, closing date for comments (if any) and Technical Barriers to Trade (TBT) notification number. The hotline number is (301) 975-4041 (not toll-free).

o NCSCI provides assistance to U.S. and foreign exporters in obtaining current standards, regulations and certification information for the manufacture of products. To aid foreign exporters, NCSCI also provides directory information of state offices prepared to respond to queries concerning conditions to be met by goods for sale in their state.

Publication Ordering Information

NTIS - National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Telephone: (703) 487-4650
Fax: (703) 321-8547

GPO - Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
Telephone: (202) 783-3238
Fax: (202) 275-2529

NIST-114A
(REV. 3-90)

U.S. DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

BIBLIOGRAPHIC DATA SHEET

1. PUBLICATION OR REPORT NUMBER
NISTIR 4721

2. PERFORMING ORGANIZATION REPORT NUMBER

3. PUBLICATION DATE
November 1991

4. TITLE AND SUBTITLE

Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues

5. AUTHOR(S)

Maureen Breitenberg

6. PERFORMING ORGANIZATION (IF JOINT OR OTHER THAN NIST, SEE INSTRUCTIONS)

U.S. DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
GAITHERSBURG, MD 20899

7. CONTRACT/GRANT NUMBER

8. TYPE OF REPORT AND PERIOD COVERED

9. SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS (STREET, CITY, STATE, ZIP)

Same.

10. SUPPLEMENTARY NOTES

11. ABSTRACT (A 200-WORD OR LESS FACTUAL SUMMARY OF MOST SIGNIFICANT INFORMATION. IF DOCUMENT INCLUDES A SIGNIFICANT BIBLIOGRAPHY OR LITERATURE SURVEY, MENTION IT HERE.)

This report provides information on the development, content, and application of the ISO 9000 standards to readers who are unfamiliar with these aspects of the standards. It attempts to answer some of the most commonly asked questions on quality; quality systems; the content, application and revision of the ISO 9000 standards; quality system approval/registration; European Community requirements for quality system approval/registration; and sources for additional help.

12. KEY WORDS (6 TO 12 ENTRIES; ALPHABETICAL ORDER; CAPITALIZE ONLY PROPER NAMES; AND SEPARATE KEY WORDS BY SEMICOLONS)

Conformity assessment; EN 29000; ISO 9000; quality assurance; quality control; quality system; quality system registration

13. AVAILABILITY

XX	UNLIMITED
	FOR OFFICIAL DISTRIBUTION. DO NOT RELEASE TO NATIONAL TECHNICAL INFORMATION SERVICE (NTIS).
	ORDER FROM SUPERINTENDENT OF DOCUMENTS, U.S. GOVERNMENT PRINTING OFFICE, WASHINGTON, DC 20402.
X	ORDER FROM NATIONAL TECHNICAL INFORMATION SERVICE (NTIS), SPRINGFIELD, VA 22161.

14. NUMBER OF PRINTED PAGES
23

15. PRICE
A02

ELECTRONIC FORM