

ANSI/ISO/ASQ Q9000-2-1997

***Quality management and quality assurance
standards—Part 2: Guidelines for implementing
ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002
and ANSI/ISO/ASQC Q9003***

ANSI/ISO/ASQ Q9000-2-1997

Approved as an American National Standard by:

American Society for Quality



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AMERICAN NATIONAL STANDARD

Quality Management and quality assurance standards Part 2: Guidelines for implementing ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 and ANSI/ISO/ASQC Q9003

Approved as an American National Standard by:
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An American National Standard Approved on February 20, 1998

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10 9 8 7 6 5 4 3 2 1

Printed in the United States of America

♾ Printed on acid-free paper

Published by:

American Society for Quality



Quality Press
611 East Wisconsin Avenue
Milwaukee, Wisconsin 53201-3005
800-248-1946
Web site <http://www.asq.org>
<http://standardsgroup.asq.org>

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Foreword

(This Foreword is not a part of American National Standard ANSI/ISO/ASQ Q9000-2, Quality management and quality assurance standards—Part 2: Guidelines for implementing ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002, ANSI/ISO/ASQC Q9003).

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

International Standard ISO 9000-2 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition cancels and replaces the first edition (ISO 9000-2:1993), which has been technically revised. ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*.

- *Part 1: Guidelines for selection and use*
- *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*
- *Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*
- *Part 4: Guide to dependability management*

Annex A of this part of ISO 9000 is for information only.

Comments concerning this standard will be welcome and considered in future standards development and revision. They should be sent to the Standards Administrator, American Society for Quality, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

Introduction

This part of ANSI/ISO/ASQC Q9000 gives guidance for the application of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 and ANSI/ISO/ASQC Q9003. To facilitate cross-reference to those standards, this part of the ANSI/ISO/ASQC Q9000 has the same clause structure as the ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 and ANSI/ISO/ASQC Q9003.

In general, the number and scope of the quality system elements and procedures required for quality assurance are created in ANSI/ISO/ASQC Q9001 and least in ANSI/ISO/ASQC Q9003. For all clauses, the guidelines of this part of the ANSI/ISO/ASQC Q9000 should be applied in a manner consistent with the scope and requirements of the corresponding clause, if present, in the standard involved (i.e. ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 and ANSI/ISO/ASQC Q9003). Reference should be made to subclause 8.3 of ANSI/ISO/ASQC Q9000-1-1994 for guidance on the appropriate extent and degree of demonstration.

ANSI/ISO/ASQC Q9000-1 gives an overview of the series of American National Standards, and explains the use of the entire series. ANSI/ISO/ASQC Q9004-1 gives guidance for designing and installing a quality management system.

This part of ANSI/ISO/ASQC Q9000 does not duplicate the guidance to users that is given in other ANSI/ISO/ASQC standards such as ANSI/ISO/ASQC Q9000-1, ANSI/ISO/ASQC Q9000-3, ANSI/ISO/ASQC Q9004-1 and ANSI/ISO/ASQC Q9004-2.

ANSI/ISO/ASQ Q9000-2-1997

QUALITY MANAGEMENT AND QUALITY ASSURANCE STANDARDS—PART 2: GENERIC GUIDELINES FOR THE APPLICATION OF ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 AND ANSI/ISO/ASQC Q9003

1 SCOPE

This part of ANSI/ISO/ASQC Q9000 gives guidance on the application of the 1994 versions of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 and ANSI/ISO/ASQC Q9003.

It does not add to, or otherwise change, the requirements of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003. In case of conflicting interpretations of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003 on the one hand, and ANSI/ISO/ASQC Q9000-2 on the other, the interpretation of the text in ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003 takes precedence. The use of "should" in this part of the ANSI/ISO/ASQC Q9000 does not weaken the requirements expressed as "shall" in ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003.

This part of ANSI/ISO/ASQC Q9000 gives guidance for the following users:

- a) suppliers involved in applications of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003;
- b) customers and third parties.

2 NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ANSI/ISO/ASQC Q9000. At the time of publication, the editions indicated were valid. All standards are subject to revisions, and parties to agreements based on this part of ANSI/ISO/ASQC Q9000 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ANSI/ISO/ASQC A8402-1994, *Quality management and quality assurance — Vocabulary*.

ANSI/ISO/ASQC Q9001-1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

ANSI/ISO/ASQC Q9002-1994, *Quality systems — Model for quality assurance in production, installation and servicing*.

ANSI/ISO/ASQC Q9003-1994, *Quality systems — Model for quality assurance in final inspection and test*.

3 DEFINITIONS

For the purposes of this part of ANSI/ISO/ASQC Q9000 the definitions given in ANSI/ISO/ASQC A8402 and the following apply.

3.1 contract: Agreed requirements between a supplier and customer transmitted by any means.

[ISO 9001]

3.2 product: Result of activities or processes.

NOTE 1 A product may include service, hardware, processed materials, software or a combination thereof.

NOTE 2 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

NOTE 3 For the purposes of this American National Standard, the term 'product' applies to the intended product offering only and not to unintended 'by-products' affecting the environment. This differs from the definition given in ANSI/ISO/ASQC A8402.

[ISO 9001]

3.3 specified requirements

- 1) Product requirements prescribed by the customer and agreed by the supplier.
- 2) Requirements prescribed by the supplier that are perceived as satisfying a market need.

3.4 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

[ISO 9001]

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4 QUALITY SYSTEM REQUIREMENTS**4.1 Management responsibility****4.1.1 Quality policy**

The supplier's management with executive responsibility (see 4.1.2.1) is required to develop and define its quality policy, quality objectives and commitment in (a) recorded statement(s). This is required to be relevant to its organizational goals, and the expectations and needs of its customers. The statement(s) should be published throughout the organization and be seen to be fully supported by the management.

All employees, including newly hired, part-time and temporary employees, should be trained so that they understand the objectives of the organization and the commitment required to achieve these objectives. The policy should be expressed in language that is easy to understand and the objectives should be achievable, planned and periodically reviewed.

Management should continuously demonstrate visible commitment to the quality policy by activities which may include, but not be limited to, the following:

- ensuring that the organization's personnel understand and implement the quality policy;
- ensuring that the organization's personnel have quality objectives consistent with the organization's overall objectives;
- initiating, managing and following up on the implementation of the quality policy, including implementation and maintenance of the quality system;
- not accepting deviations from the quality policy in any part or aspect of the organization;
- providing adequate resources and training to support quality system development and implementation. (See 4.1.2.2.)

4.1.2 Organization**4.1.2.1 Responsibility and authority**

Management with executive responsibility is that person or group of persons within an organization with the necessary level of authority for making policy and setting objectives, planning their implementation, reviewing achievement and taking corrective action. The supplier should clearly identify those persons having such executive responsibility.

In particular the personnel having the responsibility and authority to make decisions that control all the elements of the quality system and processes should be identified and the job requirements defined and documented (see 4.18).

4.1.2.2 Resources

Consideration needs to be given by the supplier's management to the identification and provision of adequate resources needed to implement its quality policy and achieve its objectives as well as to satisfy customer needs and expectations. The following should be considered:

- personnel to plan, manage, perform work, control and carry out verification activities;
- awareness of standards, procedures and other documented practices that are needed;
- training and qualifications (see 4.18);
- planning design, development and production activities to allow sufficient time to perform the work;
- equipment and processes, including acquisition of new equipment or technology;
- means to access quality records.

4.1.2.3 Management representative

Within the supplier's organization, a management representative with delegated authority is required to be appointed for arranging and overseeing the working of the quality system. This management representative is required to be appointed by management with executive responsibility.

The functions of the management representative may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If the management representative has other functions to perform, there should be no conflict of interest between the responsibilities for the other functions and those for the quality system. The management representative should have the authority to ensure that the requirements of ANSI/ISO/ASQC Q9001, ANSI/ISO/ASQC Q9002 or ANSI/ISO/ASQC Q9003 are satisfied and that compliance is maintained, together with the responsibility to ensure that they are operated throughout the organization.

The defined role should include reporting on the suitability and effectiveness of the quality system as a