

Quality management and quality assurance standards —

Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

ICS 03.120.10

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

National foreword

This British Standard reproduces verbatim ISO 9000-2:1997 and implements it as the UK national standard. It supersedes BS 5750-4:1994 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standard are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ISO title page, pages ii to iv, pages 1 to 18 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Amendment issued since publications

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Management Systems Sector Board, was published under the authority of the Standards Board and comes into effect on 15 August 1997

© BSI 1998

ISBN 0 580 28081 0

Contents

	Page
National foreword	Inside front cover
ISO text	1

INTERNATIONAL STANDARD

ISO 9000-2

Second edition
1997-06-15

Quality management and quality assurance standards —

Part 2:

Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

Normes pour le management de la qualité et l'assurance de la qualité —

*Partie 2: Lignes directrices génériques pour l'application de l'ISO 9001,
l'ISO 9002 et l'ISO 9003*



Reference number
ISO 9000-2:1997(E)

Contents

	Page
Foreword	iii
Introduction	1
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Quality system requirements	2
4.1 Management responsibility	2
4.2 Quality system	3
4.3 Contract review	4
4.4 Design control	5
4.5 Document and data control	7
4.6 Purchasing	8
4.7 Control of customer-supplied product	9
4.8 Product identification and traceability	9
4.9 Process control	10
4.10 Inspection and testing	11
4.11 Control of inspection, measuring and test equipment	11
4.12 Inspection and test status	12
4.13 Control of nonconforming product	12
4.14 Corrective and preventive action	13
4.15 Handling, storage, packaging, preservation and delivery	14
4.16 Control of quality records	14
4.17 Internal quality audits	15
4.18 Training	16
4.19 Servicing	16
4.20 Statistical techniques	16
Annex A (informative) Bibliography	18

Descriptors: Quality management, quality assurance, quality assurance programme, quality assurance systems, standards, international standards, implementation, rules (instructions).

Foreword

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.

Introduction

This part of ISO 9000 gives guidance for the application of ISO 9001, ISO 9002 and ISO 9003. To facilitate cross-reference to those standards, this part of ISO 9000 has the same clause structure as ISO 9001, ISO 9002 and ISO 9003.

In general, the number and scope of the quality system elements and procedures required for quality assurance are greatest in ISO 9001 and least in ISO 9003. For all clauses, the guidelines of this part of ISO 9000 should be applied in a manner consistent with the scope and requirements of the corresponding clause, if present, in the standard involved (i.e. ISO 9001, ISO 9002 or ISO 9003). Reference should be made to subclause 8.3 of ISO 9000-1:1994 for guidance on the appropriate extent and degree of demonstration.

ISO 9000-1 gives an overview of the ISO 9000 series of International Standards, and explains the use of the entire series. ISO 9004-1 gives guidance for designing and installing a quality management system.

This part of ISO 9000 does not duplicate the guidance to users that is given in other ISO guidance standards such as ISO 9000-1, ISO 9000-3, ISO 9004-1 and ISO 9004-2.

1 Scope

This part of ISO 9000 gives guidance on the application of the 1994 versions of ISO 9001, ISO 9002 and ISO 9003.

It does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 or ISO 9003. In the case of conflicting interpretations of ISO 9001, ISO 9002 or ISO 9003 on the one hand, and ISO 9000-2 on the other, the interpretation of the text in ISO 9001, ISO 9002 or ISO 9003 takes precedence. The use of “should” in this part of ISO 9000 does not weaken the requirements expressed as “shall” in ISO 9001, ISO 9002 and ISO 9003.

This part of ISO 9000 gives guidance for the following users:

- a) suppliers involved in applications of ISO 9001, ISO 9002 or ISO 9003;
- 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 ISO 9000. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9000 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.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing*.

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test*.

3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 8402 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 International 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 ISO 8402.

[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.