



MALAYSIAN STANDARD

MS ISO 9001:2015

**Quality management systems - Requirements
(Second revision)
(ISO 9001:2015, IDT)**

ICS: 03.120.10

Descriptors: requirements, quality management systems

© Copyright 2015

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

The **Department of Standards Malaysia (STANDARDS MALAYSIA)** is the national standards and accreditation body of Malaysia.

The main function of STANDARDS MALAYSIA is to foster and promote standards, standardisation and accreditation as a means of advancing the national economy, promoting industrial efficiency and development, benefiting the health and safety of the public, protecting the consumers, facilitating domestic and international trade and furthering international cooperation in relation to standards and standardisation.

Malaysian Standards (MS) are developed through consensus by committees which comprise balanced representation of producers, users, consumers and others with relevant interests, as may be appropriate to the subject at hand. To the greatest extent possible, Malaysian Standards are aligned to or are adoption of international standards. Approval of a standard as a Malaysian Standard is governed by the Standards of Malaysia Act 1996 [Act 549]. Malaysian Standards are reviewed periodically. The use of Malaysian Standards is voluntary except in so far as they are made mandatory by regulatory authorities by means of regulations, local by-laws or any other similar ways.

For the purposes of Malaysian Standards, the following definitions apply:

Revision: A process where existing Malaysian Standard is reviewed and updated which resulted in the publication of a new edition of the Malaysian Standard.

Confirmed MS: A Malaysian Standard that has been reviewed by the responsible committee and confirmed that its contents are current.

Amendment: A process where a provision(s) of existing Malaysian Standard is altered. The changes are indicated in an amendment page which is incorporated into the existing Malaysian Standard. Amendments can be of technical and/or editorial nature.

Technical corrigendum: A corrected reprint of the current edition which is issued to correct either a technical error or ambiguity in a Malaysian Standard inadvertently introduced either in drafting or in printing and which could lead to incorrect or unsafe application of the publication.

NOTE: Technical corrigenda are not to correct errors which can be assumed to have no consequences in the application of the MS, for example minor printing errors.

STANDARDS MALAYSIA has appointed **SIRIM Berhad** as the agent to develop, distribute and sell Malaysian Standards.

For further information on Malaysian Standards, please contact:

Department of Standards Malaysia
Ministry of Science, Technology and Innovation
Level 1 & 2, Block 2300, Century Square
Jalan Usahawan
63000 Cyberjaya
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 8318 0002
Fax: 60 3 8319 3131
<http://www.jsm.gov.my>
E-mail: central@jsm.gov.my

OR **SIRIM Berhad**
(Company No. 367474 - V)
1, Persiaran Dato' Menteri
Section 2, P. O. Box 7035
40700 Shah Alam
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 5544 6000
Fax: 60 3 5510 8095
<http://www.sirim.my>
E-mail: msonline@sirim.my

Contents

| | Page |
|---|------------|
| Committee representation | iii |
| National foreword | iv |
| Foreword | v |
| Introduction | vi |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Context of the organization | 1 |
| 4.1 Understanding the organization and its context..... | 1 |
| 4.2 Understanding the needs and expectations of interested parties..... | 2 |
| 4.3 Determining the scope of the quality management system..... | 2 |
| 4.4 Quality management system and its processes..... | 2 |
| 5 Leadership | 3 |
| 5.1 Leadership and commitment..... | 3 |
| 5.1.1 General..... | 3 |
| 5.1.2 Customer focus..... | 3 |
| 5.2 Policy..... | 4 |
| 5.2.1 Establishing the quality policy..... | 4 |
| 5.2.2 Communicating the quality policy..... | 4 |
| 5.3 Organizational roles, responsibilities and authorities..... | 4 |
| 6 Planning | 4 |
| 6.1 Actions to address risks and opportunities..... | 4 |
| 6.2 Quality objectives and planning to achieve them..... | 5 |
| 6.3 Planning of changes..... | 5 |
| 7 Support | 6 |
| 7.1 Resources..... | 6 |
| 7.1.1 General..... | 6 |
| 7.1.2 People..... | 6 |
| 7.1.3 Infrastructure..... | 6 |
| 7.1.4 Environment for the operation of processes..... | 6 |
| 7.1.5 Monitoring and measuring resources..... | 7 |
| 7.1.6 Organizational knowledge..... | 7 |
| 7.2 Competence..... | 8 |
| 7.3 Awareness..... | 8 |
| 7.4 Communication..... | 8 |
| 7.5 Documented information..... | 8 |
| 7.5.1 General..... | 8 |
| 7.5.2 Creating and updating..... | 9 |
| 7.5.3 Control of documented information..... | 9 |
| 8 Operation | 9 |
| 8.1 Operational planning and control..... | 9 |
| 8.2 Requirements for products and services..... | 10 |
| 8.2.1 Customer communication..... | 10 |
| 8.2.2 Determining the requirements for products and services..... | 10 |
| 8.2.3 Review of the requirements for products and services..... | 10 |
| 8.2.4 Changes to requirements for products and services..... | 11 |
| 8.3 Design and development of products and services..... | 11 |
| 8.3.1 General..... | 11 |
| 8.3.2 Design and development planning..... | 11 |
| 8.3.3 Design and development inputs..... | 11 |
| 8.3.4 Design and development controls..... | 12 |
| 8.3.5 Design and development outputs..... | 12 |
| 8.3.6 Design and development changes..... | 12 |

| | | |
|-----------|--|-----------|
| 8.4 | Control of externally provided processes, products and services..... | 13 |
| 8.4.1 | General..... | 13 |
| 8.4.2 | Type and extent of control..... | 13 |
| 8.4.3 | Information for external providers..... | 13 |
| 8.5 | Production and service provision..... | 14 |
| 8.5.1 | Control of production and service provision..... | 14 |
| 8.5.2 | Identification and traceability..... | 14 |
| 8.5.3 | Property belonging to customers or external providers..... | 15 |
| 8.5.4 | Preservation..... | 15 |
| 8.5.5 | Post-delivery activities..... | 15 |
| 8.5.6 | Control of changes..... | 15 |
| 8.6 | Release of products and services..... | 15 |
| 8.7 | Control of nonconforming outputs..... | 16 |
| 9 | Performance evaluation..... | 16 |
| 9.1 | Monitoring, measurement, analysis and evaluation..... | 16 |
| 9.1.1 | General..... | 16 |
| 9.1.2 | Customer satisfaction..... | 17 |
| 9.1.3 | Analysis and evaluation..... | 17 |
| 9.2 | Internal audit..... | 17 |
| 9.3 | Management review..... | 18 |
| 9.3.1 | General..... | 18 |
| 9.3.2 | Management review inputs..... | 18 |
| 9.3.3 | Management review outputs..... | 18 |
| 10 | Improvement..... | 19 |
| 10.1 | General..... | 19 |
| 10.2 | Nonconformity and corrective action..... | 19 |
| 10.3 | Continual improvement..... | 19 |
| | Annex A (informative) Clarification of new structure, terminology and concepts..... | 21 |
| | Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176..... | 25 |
| | Bibliography..... | 28 |

Committee representation

The Industry Standards Committee on Quality Management and Quality Assurance (ISC Y) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Construction Industry Development Board Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute of Quality Malaysia
Malaysia Productivity Corporation
Malaysian Agricultural Research and Development Institute
Malaysian Association of Standards Users
Malaysian Institute of Chemistry
Malaysian International Chamber of Commerce and Industry
Medical Device Authority, Ministry of Health Malaysia
National Pharmaceutical Control Bureau
Science and Technology Research Institute for Defence
SIRIM Berhad (National Metrology Laboratory)
SIRIM Berhad (Secretariat)
SIRIM Berhad (Standards Research and Management Centre)
SIRIM QAS International Sdn Bhd
The Electrical and Electronics Association of Malaysia
The Institution of Engineers, Malaysia
Universiti Utara Malaysia

The Technical Committee on Quality Management and Quality Assurance - TC 2 on Quality Systems which recommended the adoption of the ISO Standard as Malaysian Standard consists of representatives from the following organisations:

Construction Industry Development Board Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute of Quality Malaysia
Malaysian Administrative, Modernisation and Management Planning Unit
Malaysian International Chamber of Commerce and Industry
Science and Technology Research Institute for Defence
SIRIM Berhad (Secretariat)
SIRIM QAS International Sdn Bhd
Universiti Utara Malaysia

MS ISO 9001:2015

National foreword

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Quality Management and Quality Assurance - TC 2 on Quality Systems under the authority of the Industry Standards Committee on Quality Management and Quality Assurance.

This Malaysian Standard is identical with ISO 9001:2015, *Quality management systems - Requirements*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, "this International Standard" should read "this Malaysian Standard";
- b) the comma which is used as a decimal sign (if any), to read as a point; and
- c) reference to International Standards should be replaced by corresponding Malaysian Standards as follows:

| <u>Referenced International Standards</u> | <u>Corresponding Malaysian Standards</u> |
|--|---|
| ISO 9000:2015, <i>Quality management systems - Fundamentals and vocabulary</i> | MS ISO 9000:2015, <i>Quality management systems - Fundamentals and vocabulary</i> |

This Malaysian Standard cancels and replaces MS ISO 9001:2008, *Quality management systems - Requirements (First revision)*.

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

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts. It also cancels and replaces the Technical Corrigendum ISO 9001:2008/Cor.1:2009.