
**Healthcare organization
management — Management systems
for quality in healthcare organizations
— Requirements**

*Management des organisations de soins de santé — Systèmes de
management pour la qualité dans les organisations de soins de santé
— Exigences*



This document is a preview generated by ELS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	7
4.1 Understanding the organization and its context	7
4.2 Understanding the needs and expectations of stakeholders	8
4.3 Determining the scope of the management system for quality in healthcare organizations	8
4.4 Management system for quality in healthcare organizations	8
5 Leadership	9
5.1 Leadership and commitment	9
5.2 Healthcare quality policy	10
5.3 Roles, responsibilities and authorities	10
5.4 Service user focus	10
5.5 Access to care	11
6 Planning	11
6.1 Actions to address risks and opportunities	11
6.1.1 General	11
6.1.2 Risk culture	12
6.1.3 Risk management processes	12
6.2 Healthcare quality objectives and planning to achieve them	12
6.3 Planning of changes	13
7 Support	13
7.1 Resources	13
7.2 Competence	14
7.3 Awareness	14
7.4 Communication	14
7.4.1 General	14
7.4.2 Service user communication	15
7.4.3 Clinical communication	15
7.4.4 External communications	15
7.5 Documented information	15
7.5.1 General	15
7.5.2 Creating and updating documented information	16
7.5.3 Control of documented information	16
7.5.4 Information management systems	16
7.5.5 Control and management of electronic information	17
7.5.6 Audit of records	17
8 Operation	18
8.1 Operational planning and control	18
8.2 Healthcare facilities management and maintenance	18
8.2.1 General	18
8.2.2 Contingency planning for facilities and services	19
8.2.3 Equipment	19
8.3 Waste management	20
8.3.1 General	20
8.3.2 Waste reduction	20
8.3.3 Environmental responsibility	20
8.4 Handling and storage of materials	20

8.5	Service user belongings.....	21
8.6	Emerging technologies.....	21
8.7	Service design in healthcare.....	21
8.8	Supplies and services from external providers.....	22
8.9	Provision of services.....	23
8.10	People-centred care.....	23
8.10.1	General.....	23
8.10.2	Service user experience.....	23
8.10.3	Compassionate care.....	24
8.10.4	Inclusivity and diversity.....	24
8.10.5	Health literacy.....	25
8.10.6	Co-production.....	25
8.10.7	Workforce wellbeing.....	25
8.11	Ethics.....	26
8.12	Patient safety.....	26
8.12.1	General.....	26
8.12.2	Knowledge and learning in safety.....	26
8.12.3	Patient identification.....	26
8.12.4	Medication safety.....	27
8.12.5	Surgical safety.....	27
8.12.6	Infection prevention and control (IPC).....	27
8.12.7	Prevention of falls, pressure ulcers and thromboembolism.....	28
8.12.8	Diagnostic safety.....	28
8.12.9	Blood transfusions.....	28
9	Performance evaluation.....	29
9.1	Monitoring, measurement, analysis, and evaluation.....	29
9.1.1	General.....	29
9.1.2	Healthcare quality indicators.....	30
9.1.3	Methods.....	30
9.1.4	Results.....	30
9.2	Internal audit.....	31
9.2.1	General.....	31
9.2.2	Internal audit programme.....	31
9.3	Management review.....	31
9.3.1	General.....	31
9.3.2	Management review inputs.....	31
9.3.3	Management review results.....	32
10	Improvement.....	32
10.1	Continual improvement.....	32
10.2	Nonconformity and corrective action.....	33
10.2.1	General.....	33
10.2.2	Management of nonconformity and corrective action.....	33
	Bibliography.....	35

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 304, *Healthcare organization management*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

Healthcare systems and organizations of all sizes and structures embrace a culture of quality and continual improvement with the objective of providing timely, safe, effective, efficient, equitable and people-centred care. Given the current and future challenges in healthcare, more than ever it is vital to improve service user experience, quality of care, and provide sustainable solutions.

Healthcare organizations around the world have been facing significant threats such as decreasing financial resources, workforce shortages, increase in the number of people needing care as a result of ageing populations, increasing rates of chronic disease, lack of shared data for decision making, scarcity or inadequacy of medical equipment and medications, and an absence of clear healthcare system governance. Many countries have embarked on universal health coverage, while others struggle with rising healthcare costs. To compound this, a global pandemic has highlighted the importance of virtual healthcare, new technologies, and the need to create and adapt approaches to healthcare management and delivery. These health and organizational challenges require bold and innovative steps to improve healthcare quality around the world.

This document provides requirements for management systems for quality in healthcare organizations. As such, its target audience is broad, including any healthcare system, organization, or entity that aims to increase the quality of its healthcare delivery and care outcomes. This includes ministries of health, public and private healthcare systems, hospitals, clinics, non-governmental organizations and agencies that provide healthcare services, and more.

This document conforms to ISO's requirements for management system standards. These requirements include a harmonized structure, identical core text, and common terms with core definitions, designed to benefit users implementing multiple ISO management system standards.

This document contains the requirements used to assess conformity. An organization that wishes to demonstrate conformity with this document can do so by:

- making a self-determination and self-declaration;
- seeking confirmation of its conformity by parties having an interest in the healthcare organization, such as service users;
- seeking confirmation of its self-declaration by a party external to the organization; or
- seeking certification/registration of its management system for quality in the healthcare organization by an external organization.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is intended to assist the understanding or use of this document

0.2 Aim of a management system for quality in healthcare organizations

The aims of a management system for quality in healthcare organizations include the following:

- create a culture of quality starting with strong top management;
- embrace a healthcare system based on people-centred care, respect, compassion, co-production, equity and dignity;

- identify and address risks;
- ensure patient and workforce safety and wellbeing;
- control service delivery through documented processes and documented information;
- monitor and evaluate clinical and non-clinical performance;
- continually improve its processes and results.

0.3 Success factors

The success of a management system for quality in a healthcare organization depends on the commitment from all levels and functions of the organization, led by top management. The top management structure of the organization can create a culture of quality by including quality principles in the organization's strategic direction, decision making, and aligning them with other operational priorities. Successful implementation of this document can demonstrate to stakeholders that an effective management system for quality in the healthcare organization is in place.

The level of detail and complexity of a management system for quality in the healthcare organization varies depending on the context of the organization, the scope of its work, its regional, national, and international conformity obligations, the nature of its activities, services provided, and resources available.

0.4 Plan-Do-Study-Act model

The approach underlying a management system for quality in healthcare organizations is based on the concept of Plan-Do-Study Act (PDSA) (see [Figure 1](#)). The PDSA model provides an iterative process used by organizations to achieve continual improvement through cycles of ongoing measurement of performance and assessment of changes. It can be applied to a management system for quality in healthcare organizations and is briefly described as follows.

- Plan: establish healthcare quality objectives and processes necessary to deliver results in accordance with the organization's healthcare quality policy ([Clause 6](#)).
- Do: implement the processes as planned ([Clauses 7 and 8](#)).
- Study: monitor, measure and assess processes against the organization's policies, including its commitments, objectives and operating criteria and report the results ([Clause 9](#)).
- Act: take actions to continually improve ([Clause 10](#)).



Figure 1 — Elements of a management system for quality in healthcare organizations

Healthcare organization management — Management systems for quality in healthcare organizations — Requirements

1 Scope

The purpose of this document is to provide organizations with requirements to deliver high-quality healthcare and specifies requirements for management systems for quality in healthcare organizations when an organization desires to:

- a) demonstrate its ability to consistently meet service user, stakeholder, and applicable statutory and regulatory requirements;
- b) enhance service user experience during the continuum of care and continually improve healthcare quality; and
- c) create and maintain processes that ensure timely, safe, effective, efficient, equitable, and people-centred care.

The requirements of this document are based on recognized best practices and are intended to be applicable to any organization providing healthcare services, regardless of its type, size, or the services it provides.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term “organization” refers only to the part of the larger entity that is within the scope of the *healthcare* (3.23) *quality management system* (3.4).

Note 3 to entry: In the case of *healthcare* (3.23), the organization is developed for the delivery of *healthcare* (3.23) services by specialized *workforces* (3.30) to defined communities, populations, individuals or markets.