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# 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*



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# Foreword

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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).

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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).

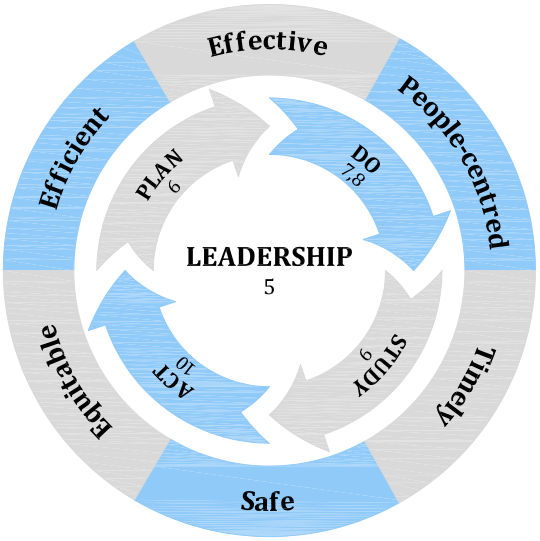


**Figure 1 — Elements of a management system for quality in healthcare organizations**

# 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.

**3.2**
**stakeholder**
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note 1 to entry: Stakeholders can include but are not limited to: Ministry or Department of Health, Finance, Treasury, Education; non-governmental organizations and not-for-profit sector; community groups and civil society organizations; local government, health insurance groups and other healthcare funders; donor and aid agencies, UN agencies (including the WHO), health professions associations, regulatory bodies, health workers' organizations and networks; patients, families, caregivers, and other health *service users* (3.28).

**3.3**
**top management**
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Note 3 to entry: In some countries, and within differing organizational structures, additional terms can be used such as "board", "board of directors", "trustees", or "governance."

**3.4**
**management system**
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those *objectives* (3.6)

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.



**3.5**
**policy**
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

**3.6**
**objective**
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organization-wide or specific to a project, product or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as a *healthcare* (3.23) quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *healthcare* (3.23) quality *management systems* (3.4), *healthcare* (3.23) quality objectives are set by the *organization* (3.1), consistent with the *healthcare* (3.23) quality *policy* (3.5), to achieve specific results.

**3.7**
**risk**
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73) and consequences (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73) of occurrence.

**3.8**
**process**
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

**3.9**
**competence**
ability to apply knowledge and skills to achieve intended results

**3.10**
**documented information**
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

a) the *management system* (3.4), including related *processes* (3.8);

b) information created in order for the organization to operate (documentation);

c) evidence of results achieved (records).



**3.11**
**performance**
measurable result



Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

**3.12**
**continual improvement**
recurring activity to enhance *performance* (3.11)

**3.13**
**effectiveness**
extent to which planned activities are realized and planned results are achieved

**3.14**
**effective**
producing a desired or intended result

**3.15**
**requirement**
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1) and *stakeholders* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.10).

**3.16**
**conformity**
fulfilment of a *requirement* (3.15)

**3.17**
**nonconformity**
non-fulfilment of a *requirement* (3.15)

**3.18**
**corrective action**
action to eliminate the cause(s) of a *nonconformity* (3.17) and to prevent recurrence

**3.19**
**audit**
systematic and independent *process* (3.8) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

**3.20**
**measurement**
*process* (3.8) to determine a value



**3.21**
**monitoring**
determining the status of a system, a *process* (3.8) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.



**3.22**
**safe**
free from *risk* (3.7) which is not tolerable

Note 1 to entry: In the *healthcare* (3.23) setting, "safe" refers to circumstances and services affecting all *stakeholders* (3.2), not only patients.

[SOURCE: ISO/IEC Guide 51:2014, 3.14, modified — The term has been changed from "safety" to "safe"; in the definition, "freedom" has been changed to "free"; note 1 to entry has been added.]

**3.23**
**healthcare**
organized provision of services to individuals or a community in order to address, manage and improve their physical, mental, and social *wellbeing* (3.24)

**3.24**
**wellbeing**
state of optimal physical, mental, emotional and social *health* (3.32)

[SOURCE: ISO 22886:2020, 3.11.4]

**3.25**
**efficient**
<healthcare> using inputs to the *health* (3.32) system (in the form of expenditure and other resources) in a way to secure valued *healthcare* (3.23) system *objectives* (3.6)