INTERNATIONAL STANDARD

ISO 7101

First edition
2023-10

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

Reference number
ISO 7101:2023(E)

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

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.

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)

3.26
equitable
<healthcare> providing *healthcare* (3.23) in a manner that is fair and impartial

Note 1 to entry: Impartiality can relate to age, sex, gender, behavioural or clinical diagnosis, race, ethnicity, geographical location, religion, socioeconomic status, linguistic or political affiliation.

3.27
people-centred care
approach to *healthcare* (3.23) delivery that engages patients, families, caregivers and communities, incorporating their unique needs, experiences and preferences

3.28
service user
person or *stakeholder* (3.2) that could or does receive a service that is intended for, or required by, this person or *stakeholder* (3.2)

Note 1 to entry: Similar terms include patient, *healthcare* (3.23) consumer, user, client, and end user.

Note 2 to entry: Service users can include a wide range of individuals including patients, families, caregivers, and their support networks.

3.29
service user experience
perceptions and responses of a *service user* (3.28) that result from the use of a product, system, or service

3.30
workforce
staff
personnel
all individuals employed by the *organization* (3.1)

Note 1 to entry: This concept includes full-time, part-time, casual or contract, clinical and non-clinical workers.

3.31
universal health coverage
all people having access to the *health* (3.32) services they need, when and where they need them, without financial hardship

[SOURCE: World Health Organization, Universal health coverage]

3.32
health
state of complete physical, mental and social *wellbeing* (3.24) and not merely the absence of disease or infirmity

[SOURCE: Preamble to the Constitution of the World Health Organization, 1948]

3.33
co-production
practice of designing and implementing *healthcare* (3.23) service and delivery based on the collaborative relationships and experiences between *healthcare* (3.23) providers, *service users* (3.28), family members, caregivers and advocacy groups

3.34
health literacy
ability of individuals to gain access to, understand and use information in ways which promote and maintain good *health* (3.32) for themselves, their families and their communities

[SOURCE: World Health Organization, Health Literacy]

3.35
dignity
recognition by others of one's inherent value, worth, and right to ethical treatment

3.36
risk assessment
overall *process* (3.8) of *risk* (3.7) identification, risk analysis and risk evaluation

[SOURCE: ISO 31073:2022, 3.3.8]

3.37
risk management
systematic application of management *policies* (3.5), procedures, and practices to the tasks of analysing, evaluating, controlling and *monitoring* (3.21) *risk* (3.7)

[SOURCE: ISO/IEC Guide 63:2019, 3.15]

3.38
health indicator
measure designed to summarize information about a given priority topic in population *health* (3.32) or *healthcare* (3.23) system *performance* (3.11)

Note 1 to entry: Health indicators provide comparable and actionable information across different geographic, organizational or administrative boundaries and/or can track progress over time.

3.39
knowledge management
holistic, cross-functional discipline and set of practices focused on knowledge that improve organizational *performance* (3.11)

Note 1 to entry: Knowledge management includes, but is not limited to, the creation, acquisition, application, maintenance, sharing and protection of knowledge to create organizational value.

[SOURCE: ISO 30400:2022, 3.12.2]

3.40
just culture
atmosphere of trust in which *healthcare* (3.23) workers are supported and treated fairly when something goes wrong in the delivery of care for *service users* (3.28)

3.41
patient safety
service user safety
framework of organized activities that creates cultures, *processes* (3.8), procedures, behaviours, technologies and environments in *healthcare* (3.23) that consistently and sustainably lower *risks* (3.7), reduce the occurrence of an avoidable *harm* (3.47), make an *error* (3.46) less likely and reduce its impact when it does occur

Note 1 to entry: Activities can include the creation of cultures, processes and procedures, behaviours, technologies, and environments in *healthcare* (3.23).

[SOURCE: Global Patient Safety Action Plan 2021-2030: Towards eliminating avoidable harm in health care. (2021)]

3.42
incident
event or circumstance that has caused or could have caused unnecessary *harm* (3.47) to a patient

Note 1 to entry: Incidents include events, near misses, adverse events, and sentinel events.

3.43
credentialing
process (3.8) of establishing the qualifications of licensed medical professionals and assessing their background and legitimacy

3.44
privileging
granting permission to or authorizing an individual to perform specific activities in a hospital or *healthcare* (3.23) *organization* (3.1)

3.45
compassionate care
manner of providing care that seeks to understand another's pain or suffering involving an authentic desire to help

3.46
error
<healthcare> act of mistake or omission that contributes to an *incident* (3.42)

3.47
harm
injury or damage to the *health* (3.32) of people, or damage to property or the environment

3.48
environmentally friendly
pertaining to goods and services, guidelines and *policies* (3.5) that claim reduced, minimal, or no *harm* (3.47) upon ecosystems or the environment

3.49
intelligent kindness
recognizing and bearing in mind the kinship of *service users* (3.28) – being of the same kind, depending on each other for survival, *wellbeing* (3.24), and success – in relationships with each other and those who work to heal or treat service users

[SOURCE: Intelligent Kindness: Rehabilitating the Welfare State]

3.50
human factors
ergonomics
characteristics of individuals, teams, *organizations* (3.1) and systems used in the application of design and evaluation to ensure the compatibility with needs, capabilities and limitations of people

3.51
healthcare associated infection
infection that occurs during the provision of care or during hospitalization that was not present at the time of entry into the *healthcare* (3.23) system

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of the management system for quality in the healthcare organization.

The organization shall determine whether climate change is a relevant issue.

The organization shall be an entity that can be held legally responsible for its activities.

NOTE 1 External context can include factors related to legal, political, technological, clinical, ethical, cultural, religious, socioeconomic conditions, and social determinants of health, whether international, national, regional or local.

NOTE 2 Internal context can include factors relating to the organizational vision, values, goals and objectives, workforce values, culture, power structures, religion, knowledge, access to resources, and social determinants of health.

4.2 Understanding the needs and expectations of stakeholders

The organization shall determine:

— the stakeholders that are relevant to the management system for quality in the healthcare organization;

— the relevant requirements of these stakeholders;

— which of these requirements will be addressed through the management system for quality in the healthcare organization.

NOTE Relevant stakeholders can have requirements related to climate change.

This shall include where applicable global financing partners, governmental, intergovernmental, and non-governmental organizations with whom the organization has stated agreements.

The organization shall monitor stakeholder information and their requirements, maintain documented information, and demonstrate accountability towards agreed-upon expectations of stakeholders.

4.3 Determining the scope of the management system for quality in healthcare organizations

The organization shall determine the boundaries and applicability of the management system for quality in the healthcare organization to establish its scope.

When determining this scope, the organization shall consider:

— the external and internal issues referred to in 4.1;

— the requirements referred to in 4.2;

— the organizational structure of the healthcare system, hospital, clinic or sites where services are provided;

— services, including both clinical and non-clinical activities, that are included within the management system for quality in the healthcare organization.

If items are not included within the scope of the management system for quality in the healthcare organization, the organization shall indicate the reason why and provide this reasoning as documented information.

The scope shall be available as documented information and made available to stakeholders.

4.4 Management system for quality in healthcare organizations

The organization shall establish, implement, maintain and continually improve a management system for quality in the healthcare organization, including the processes needed and their interactions, in accordance with the requirements of this document.

The organization shall have the systems, procedures and documented information as required by this document and have evidence of implementation of the same.

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the management system for quality in the healthcare organization by:

a) defining its mission, vision, and values;

b) defining a code of conduct;

c) ensuring that the healthcare quality policy and objectives are established and are compatible with the strategic direction of the organization;

d) creating a culture of quality by implementing, empowering and rewarding quality monitoring across the organization;

e) establishing quality governance structures and accountabilities for the effective management of the management system for quality across all levels of the organization (e.g. quality plan, quality committees);

f) ensuring the integration of requirements from the management system for quality in the healthcare organization into the organization's services and processes;

g) ensuring that the resources needed for the management system for quality in the healthcare organization are available, including required workforce in terms of numbers and skill levels necessary to safely manage and perform its activities;

h) communicating the importance of effective healthcare quality management and of conforming to the requirements of the management system for quality in the healthcare organization;

i) ensuring that the management system for quality in the healthcare organization achieves its intended results;

j) assigning responsibilities and authorities for persons who contribute to the effectiveness of the management system for quality in the healthcare organization;

k) directing and supporting persons to contribute to the effectiveness of the management system for quality in healthcare organization;

l) promoting continual improvement;

m) supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility;

n) promoting risk-based thinking and risk assessment;

o) promoting safety for service users;

p) promoting safety and wellbeing of the workforce;

q) requesting evidence of compliance with legal and regulatory requirements;

r) ensuring transparency of communication and knowledge management;

s) ensuring impartiality, confidentiality and privacy are maintained and monitored;

t) adopting principles of cultural competence and aligning its services to meet the needs and preferences of service users as to improve care, value diversity, and reduce disparity.

5.2 Healthcare quality policy

Top management shall establish a healthcare quality policy that:

a) is appropriate to the purpose of the organization;

b) provides a framework for setting healthcare quality objectives;

c) includes a commitment to meet applicable requirements;

d) includes a commitment to continual improvement of the management system for quality in the healthcare organization;

e) considers input from stakeholders;

f) expresses a commitment to people-centred care.

The healthcare quality policy shall:

— be available and maintained as documented information;

— be communicated, understood and applied within the organization;

— be available to stakeholders, as appropriate.

Where services are provided at a distance, the healthcare quality policy shall also be communicated, understood, and applied (e.g. mobile and satellite clinics, health outposts, and professionals providing telehealth).

5.3 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities, authorities and accountabilities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility, authority, and accountabilities for:

a) ensuring that the management system for quality in the healthcare organization conforms to the requirements of this document;

b) reporting on the performance of the management system for quality in the healthcare organization to top management;

c) reporting on the performance and status of quality objectives and health indicators at all levels of the healthcare organization and/or healthcare system including primary, secondary, tertiary, quaternary care, and private providers (as appropriate to the healthcare system structure);

d) ensuring the effective functioning of the risk management program;

e) ensuring transparency of reporting based on a just culture;

f) promoting and improving service user experience;

g) proposing and implementing modifications to improve the quality management system;

h) allocating resources and empowering the workforce to carry out their roles and responsibilities in the quality management system.

5.4 Service user focus

Top management shall demonstrate leadership and commitment with respect to service user focus by:

a) meeting requirements of service users;

b) ensuring the rights of service users are clearly known (e.g. patient bill of rights);

c) ensuring methods are in place to listen and respond to the service users' voice;

d) assessing service user experience;

e) using lessons learned from service user experience to facilitate change;

f) creating an environment of co-production that encourages service users to participate in their care.

5.5 Access to care

Top management shall ensure there is access to care in accordance with its defined mandate, taking into consideration the laws and regulations by which it operates.

The organization shall address affordability and accessibility of its services, while minimizing financial risks to service users. This includes consideration of economically challenged underprivileged and vulnerable populations.

The organization should consider how it is working towards universal health coverage.

NOTE 1 United Nations Sustainable Development Goal (SDG) 3, target 3.8 addresses universal health coverage.

NOTE 2 Each country has an individualized path to achieving universal health coverage and deciding what to cover based on the needs of their people and the resources at hand.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 General

When planning for the management system for quality in the healthcare organization, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

— give assurance that the management system for quality in the healthcare organization can achieve its intended result(s);

— prevent, or reduce, undesired effects;

— achieve continual improvement.

The organization shall plan:

a) actions to address these risks and opportunities in a timely manner;

b) how to

  — integrate and implement the actions into its processes for the management system for quality in the healthcare organization;

  — evaluate the effectiveness of these actions.

6.1.2 Risk culture

In order to create an organizational culture in which the values, beliefs, knowledge, attitudes and understanding about risk are shared by everyone, the organization shall:

a) define a risk management program, which is consistent with the organizational vision, mission and values;

b) demonstrate support from top management;

c) continually educate the workforce about the organization's risk management program;

d) develop and maintain documented information of risk management systems and make them accessible as appropriate throughout the organization;

e) measure risk awareness culture at defined intervals.

6.1.3 Risk management processes

The organization shall have a documented system to identify risks and opportunities related to its clinical and non-clinical activities, including environmental risks and unforeseen circumstances (e.g. war, labour strikes, epidemics). Controls shall:

a) assess the risks and opportunities by identifying, analysing and evaluating each risk;

b) develop and maintain a register of risks and opportunities;

c) define a risk criterion that specifies how much risk it can or cannot accept in relation to meeting its different types of clinical and non-clinical objectives;

d) rate risks based on severity, impact or importance;

e) develop risk assessment and treatment tools for monitoring and reporting;

f) define processes to capture and analyse patient safety incidents (near misses, adverse and sentinel events);

g) define responsibilities, authorities and accountabilities for each step of the risk management process;

h) develop risk mitigation plans that specify the options chosen, order of implementation, and how the measures will be integrated into the organizational management plans and processes;

i) monitor and assess risk management interventions to ensure that they are effective and contribute to patient safety and improved quality;

j) define appropriate improvement plans based on the assessments.

The risk management process and its results shall be documented and reported through appropriate mechanisms and discussed during management review meetings.

6.2 Healthcare quality objectives and planning to achieve them

The organization shall establish healthcare quality objectives at relevant functions and levels.

The healthcare quality objectives shall:

a) be consistent with the healthcare quality policy;

b) be measurable (if practicable);

c) take into account applicable requirements;

d) be monitored;

e) be communicated;

f) be updated as appropriate at defined intervals;

g) be available as documented information;

h) include assessment of service user experience;

i) consider factors such as socio-economic status, culture, and diversity of service users;

j) use evidence-informed practice data and established indicators of health outcomes.

When planning how to achieve its healthcare quality objectives, the organization shall determine:

— what will be done;

— what resources will be required;

— who will be responsible;

— when it will be completed;

— how the results will be evaluated.

The organization should consider the United Nations Sustainable Development Goals (SDGs) when establishing healthcare quality objectives.

6.3 Planning of changes

When the organization determines the need for changes to the management system for quality in the healthcare organization, the changes shall be carried out in a planned manner.

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the replication of, and building infrastructure to support, full-scale implementation of best practices beyond project mode;

c) the ability of the management system for quality in the healthcare organization to sustain the changes;

d) the availability of resources;

e) the allocation or reallocation of responsibilities, authorities, and accountabilities;

f) how the changes will be documented, communicated, and implemented at all applicable systems levels (top management, population-based services, preventive services, primary, secondary, tertiary and quaternary care levels) as appropriate.

7 Support

7.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the management system for quality in the healthcare organization.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects its healthcare quality performance;

b) maintain a documented process for recruitment that defines the requirements for competence, education, qualification, training, technical knowledge, skills, and experience;

c) ensure that these persons are competent on the basis of appropriate education, training, or experience;

d) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

e) provide orientation to all workforce at the time of joining the organization which shall include but not be limited to organization's services, rules and regulations, processes, policies and procedures;

f) provide integration into their appointed role and maintain documented procedures for credentialing and privileging of healthcare professionals and support workforce as appropriate;

g) provide ongoing education and training necessary to maintain the required level of performance and competency;

h) perform a documented performance evaluation at defined intervals;

i) provide training on respecting service users' preferences and choices, including their options for care and treatment, components of co-production and compassionate care, and obtaining informed consent;

j) retain documented information as evidence of competence for all workforce members.

NOTE Applicable actions can include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

Persons doing work under the organization's control shall be aware of:

— the healthcare quality policy and the objectives applicable to their role;

— their contribution to the effectiveness of the management system for quality in the healthcare organization, including the benefits of improved healthcare quality performance;

— the implications of not conforming with the requirements of the management system for quality in the healthcare organization.

7.4 Communication

7.4.1 General

The organization shall determine the internal and external communications relevant to the management system for quality in the healthcare organization, including:

— on what it will communicate;

— when to communicate;

— with whom to communicate;

— how to communicate.

7.4.2 Service user communication

Communication processes with service users shall include:

a) providing information relating to services, rights and responsibilities;

b) handling enquiries, agreements or requests, including any actions taken;

c) obtaining service user feedback relating to services, including complaints;

d) ensuring that feedback mechanisms are accessible, understandable, and appropriate to the service user's education level and access to resources (e.g. computer, telephone, literacy level).

7.4.3 Clinical communication

The organization shall have processes in place to ensure effective clinical communication. These processes shall:

a) safeguard the security and privacy of service users' personal information during referrals and transfers between healthcare workers, at shift change, between hospitals and care networks;

b) ensure that oral and telephone orders, and communication of clinical results, are controlled and verified for accuracy;

c) demonstrate the use of comprehensive clinical records that allow for proper tracking of communication between different professionals and service sites;

d) demonstrate that all communications containing personal health information follow national or international standards of privacy;

e) maintain documented information as evidence of employee training on proper clinical communication and privacy requirements.

7.4.4 External communications

The organization shall define communication channels with external parties including stakeholders, global financing partners, government, intergovernmental and non-governmental organizations with whom they have stated agreements.

7.5 Documented information

7.5.1 General

The management system for quality in the healthcare organization shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the management system for quality in the healthcare organization.

NOTE The extent of documented information for a management system for quality in healthcare organizations can differ from one organization to another due to:

— the size of organization and its type of activities, processes, and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating documented information

When creating and updating documented information, the organization shall ensure appropriate:

— identification and description (e.g. a title, date, author, or reference number);

— format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

— review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required by the management system for quality in the healthcare organization and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

— distribution, access, retrieval and use;

— storage and preservation, including preservation of legibility;

— control of changes (e.g. version control);

— periodic review and updating as necessary;

— retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the management system for quality in the healthcare organization shall be identified as appropriate and controlled.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

7.5.4 Information management systems

The organization's information management system(s) shall be validated for its functionality, including the proper functioning of interfaces within the organization information management system, by the organization before use.

Whenever there are changes, including organization software configuration, they shall be authorized, documented, tested, and validated before implementation.

The information management system shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be maintained in a manner that ensures the integrity of data and information;

d) include incidents of any malfunctioning in the recording system;

e) have provisions for backup;

f) have contingency plans so that services are not disrupted;

g) address cybersecurity risk protections.

When an organization's information management system is managed and maintained off-site or through an external provider, the organization shall ensure that the provider of the system conforms to all applicable requirements of this document.

The organization shall have processes in place to consider how and when it will contribute data that can be required for external databases and reporting.

7.5.5 Control and management of electronic information

The organization shall establish and maintain processes for using and safeguarding electronic health information. Actions shall include requirements for:

a) naming files;

b) protection;

c) access;

d) back-up;

e) archive;

f) retrieval;

g) retention time;

h) deletion;

i) integration of documented information generated through different systems and interfaces;

j) maintaining the confidentiality of digital health information.

The organization shall define and document what constitutes a clinical record and maintain complete clinical records for every service user.

The organization shall ensure that both workforce and service users have access to clinical records in a timely manner.

Amendments to records shall be identified and dated, with the individual making the change identified.

NOTE International, national or regional regulations or requirements can also apply.

7.5.6 Audit of records

In order to ensure the integrity of documented information, the organization shall define what is considered both clinical and non-clinical records.

To verify that records are maintained, complete, and accurate, the organization shall:

a) conduct audits of both clinical and non-clinical records periodically to ensure quality of care and services;

b) ensure that clinical records contain the history, results, reports, and sufficient information to facilitate clinical management of the service user;

c) verify that records include the date, time, and identity of the individual responsible for each activity;

d) ensure that clinical records meet any legal requirements;

e) provide documented evidence of the audit of records and the results.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in Clause 6, by:

— establishing criteria for the processes;

— implementing control of the processes in accordance with the criteria.

Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that externally provided processes, products or services that are relevant to the management system for quality in the healthcare organization are controlled. This includes services provided by subcontractors, governmental and non-governmental agencies and relief organizations.

8.2 Healthcare facilities management and maintenance

8.2.1 General

The organization shall determine, provide and maintain the facilities and associated resources necessary to conform to its stated service offerings and the management system for quality in the healthcare organization.

To ensure the safe, proper and continued use of facilities and resources, the organization shall:

a) maintain a scheduled maintenance plan of the facility that describes required facility inspection rounds, including monitoring, inspection, and maintenance activities, and keep documented information of activities and results;

b) monitor turnaround time for breakdown and repair of equipment that affects the provision of uninterrupted service delivery;

c) align its infrastructural needs with possible plans for future expansion (when applicable);

d) maintain as-built drawings for future construction, renovation, and maintenance, as appropriate;

e) ensure that buildings are constructed and maintained per national or international guidelines and provide reasonable access for individuals with disabilities;

f) perform and document preventive maintenance of buildings, firefighting systems, air-conditioning systems, electrical systems, water supply systems and medical gas systems at specified intervals;

g) assess and document risks in terms of safety and infection control in case of renovation and maintenance;

h) supply potable water with appropriate backup for continuous and uninterrupted water supply (whenever possible);

i) adhere to applicable standards for water treatment (e.g. reverse osmosis, distilled water, demineralized water, and soft water) used for clinical and support services;

j) demonstrate that water tanks and sumps are cleaned in accordance with regulatory requirements and best practices;

k) maintain processes to confirm the functionality and availability of ambulances and transport vehicles with appropriate equipment, medications, and supplies for planned and unplanned transfers of patients;

l) confirm the availability of appropriate emergency communication systems at defined intervals;

m) ensure an adequate power supply;

n) ensure airflow of the operating theatre, transplant rooms and other care areas where applicable, meets defined requirements;

o) follow clean air standards with positive pressure and air exchanges to prevent infections;

p) provide negative pressure rooms with adequate air exchanges for isolation rooms (where applicable and dependent on the reasonable resources of the organization);

q) post signs which will be understood by the service user, taking statutory and regulatory requirements into consideration.

8.2.2 Contingency planning for facilities and services

In order to ensure continuation of its services, the organization shall:

a) maintain an emergency response plan that ensures business continuity to manage both natural events and those caused by human beings which impact service delivery (e.g. earthquakes, tornadoes, hurricanes, flooding, terrorism, pandemics, industrial accidents);

b) make adequate infrastructural provisions for early detection, abatement, and containment of fire emergencies;

c) display exit plans and assembly sites taking relevant requirements into consideration, with regular training and testing of emergency plans by conducting mock drills;

d) plan for possible power interruptions, including backup arrangements for continuous and uninterrupted supply;

e) procure, store, handle and distribute medical gases in a safe manner with adequate back up that includes colour coding of the pipelines, pipeline material, connectors, leak detection systems and alarms;

f) have emergency evacuation plans for workforce and service users;

g) address the availability of nutrition and water for service users and workforce needed for survival and continued provision of clinical services;

h) address safety measures that affect physical working conditions (e.g. war times, civil unrest, outbreaks and pandemics, location of workplace).

8.2.3 Equipment

In order to ensure the safe and proper use of equipment required for its operations, and minimize the risk of human factors and errors at the person-machine interface, the organization shall:

a) identify required equipment (including, but not limited to, biomedical equipment, measuring instruments, apparatus, software, reagents, consumables and medical devices);

b) inspect, calibrate, and document relevant equipment traceable to national or international measurement standards or other specified basis for calibration;

c) assess compatibility with existing equipment and devices, software systems and other infrastructure when new procurements are being considered;

d) maintain a list and usage log for identified equipment;

e) ensure that only qualified and trained workforce inspect, maintain, and operate equipment;

f) provide workforce with required personal protective equipment as required when working with equipment.

Equipment and devices shall be identified and controlled for all levels of service delivery (labs, clinics, hospitals, health outposts, diagnostic centres, home visits) as appropriate.

8.3 Waste management

8.3.1 General

The organization shall consider management and life cycle of all types of waste and shall:

a) collect, segregate, treat, store, transport and dispose of waste, taking local regulatory requirements and applicable guidelines into consideration;

b) ensure that individuals responsible for waste disposal (both workforce and external providers) are trained and knowledgeable of how to dispose of wastes and sharps;

c) identify, handle, and properly store hazardous material per safety data sheets or similar documents;

d) define a process for spill management.

8.3.2 Waste reduction

The organization shall have a waste reduction plan.

NOTE Areas of waste reduction can include, but are not limited to, physical wastes such as medical supplies and clinical waste, and administrative wastes including unnecessary clinic visits, strategic employee scheduling, time utilization, duplicate procedures, and reduction of corruption.

8.3.3 Environmental responsibility

The organization shall plan its processes and services in a manner to do the least possible harm to the environment including:

a) take measures to use environmentally friendly chemicals;

b) aim to use environmentally friendly energy sources and monitor the consumption of electricity and water;

c) select materials that are sustainable and environmentally friendly (whenever possible);

d) resell, recycle or donate equipment no longer in use to other facilities or stakeholders (where permitted);

e) reduce, reuse, recycle, rethink, repurpose, and repair as possible;

f) take measures to raise the awareness of environmental responsibility.

8.4 Handling and storage of materials

To ensure the effective and safe preservation of materials incorporated into its process and services, the organization shall have documented information describing how materials are controlled.

NOTE 1 Materials can include, but are not limited to, medical devices and instruments, consumables, medicines, chemicals, and reagents.

NOTE 2 Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5 Service user belongings

The organization shall have a process for managing property belonging to service users if the service user brings it into the facility. The organization shall:

a) maintain a process for recording, storing and safeguarding medications brought by the service user from home;

b) maintain a process for how and where service user items will be stored (e.g. personal wheelchair, medical consumables, assistive breathing devices, linens, clothing);

c) ensure that personal devices requiring the use of electricity do not interfere with the facility's electrical system or capacity;

d) ensure that property does not pose a safety risk;

e) report property that is lost, damaged or found to be unsuitable for use to the service user and document any actions taken.

The organization shall have a documented process for the handling of illegal property brought by the service user, family and caregivers.

8.6 Emerging technologies

Where the organization uses new and emerging technologies to deliver various types of care, the organization shall evaluate and mitigate risks, and define processes to ensure safe, proper, and effective use of such technologies.

Where artificial intelligence is used in healthcare decision making and diagnosis, top management shall ensure that these processes are tested, validated, and controlled.

Where new technologies are used to deliver patient care, the organization shall ensure that the user experience is evaluated, and data used to continually improve user experience.

NOTE In the context of healthcare, emerging technologies include: surgical robots, service robots (transportation and sanitation), social robots, cobots, robots that assist with procedures and assist service users with tasks, wearable devices, communicating with healthcare providers via digital platforms, amongst other emerging technologies.

8.7 Service design in healthcare

Service design process shall take a user-centric approach by considering the needs and requirements of service providers, end users and stakeholders. In order to ensure that design results are user-centric and are in accordance with the organization's mission, healthcare quality objectives and management system, the organization shall:

a) define and document its process for designing or changing a service;

b) identify and engage key stakeholders throughout the process and shall:

   — include multi-disciplinary teams in the process;

   — define the responsibilities and authorities that will be involved in each design project;

   — seek inputs and feedback from service users whenever possible;

c) identify tools and resources necessary to effectively address service design work;

d) adhere to standards or codes of practice that the organization has committed to implement;

e) demonstrate or document compliance with legal or statutory requirements;

f) consider best available medical knowledge and scientific evidence in relation to the service being designed or changed;

g) consider its current and future potential access to resources such as medical devices, medications, vaccinations, adequate workforce, and sufficient space for service users and associated clinical procedures;

h) identify level of risks and maintain a process to control for them;

i) consider workforce and patient safety in the design;

j) consider workforce wellbeing;

k) consider service user access to care settings;

l) consider the need for community outreach and education;

m) consider external and environmental factors.

The organization shall define the controls necessary to ensure all requirements have been adequately addressed and shall retain all relevant documented information.

NOTE Given the challenge in seeking input from end users, it is important to leverage multiple channels or efforts to gain this feedback at the convenience of the end users.

8.8 Supplies and services from external providers

The organization shall ensure that both clinical and non-clinical externally provided services and products conform to stated requirements.

The organization shall:

a) define the criteria for evaluating, selecting, monitoring, and disqualifying its external providers;

b) consider how the product or service affects safety of both workforce and service users;

c) maintain processes in place for receiving and verifying that externally provided equipment, devices, services materials and medications conform to agreed-upon requirements;

d) maintain processes to document and communicate any problems found with externally provided products and services;

e) ensure that services provided externally align with the objectives of the management system for quality in the healthcare organization; including principles of impartiality and confidentiality where applicable;

f) ensure that records of external service provider performance, communications, and corrective actions taken are maintained.

The organization shall document its expectations and agreed-upon contract requirements with partnering stakeholders (governmental, non-governmental, and intergovernmental organizations, funding partners, etc.). Where the stakeholder provides product or services and fails to meet established criteria, the organization shall communicate this to the stakeholder through pre-defined methods.

NOTE Externally provided services and products can include medication, medical equipment and devices, laboratory services, imaging services, consulting services, food and nutritional services, education programs, amongst additional services.

8.9 Provision of services

To ensure a safe, efficient, effective, and timely service, the organization shall define the controlled conditions under which the service is provided. For this purpose, the organisation shall:

a) define and document its scope of services and make this available to service users;

b) provide documented information to service users of their rights and responsibilities;

c) define and document processes and procedures for registration, admission, and discharge of all categories of service users;

d) maintain documented protocols and procedures for recording clinical findings, progress, care provided, follow up details for all categories of service users;

e) maintain documented protocols and procedures for ordering diagnostic investigations, medications, diet, and other clinical needs;

f) provide appropriate personal protective equipment to healthcare workers and service users;

g) use appropriate technology tools in delivery of care (e.g. digital health, telehealth, mobile health);

h) maintain documented processes for patients undergoing sedation, surgeries, and procedures;

i) maintain a documented process for obtaining informed consent in such a manner that the service user clearly understands, and processes for when patients are unable to give verbal consent;

j) maintain documented protocols and procedures for referring service users to other specialists and speciality departments;

k) maintain documented protocols for transfer of service users within the hospital and outside of the hospital for diagnostic and clinical procedures, and for different levels of care;

l) provide a discharge summary, when applicable.

The organisation shall maintain and retain all relevant documented information which demonstrate that all processes and activities have been carried out according to requirements.

8.10 People-centred care

8.10.1 General

Top management shall define the processes and procedures required to endorse and cultivate a culture of people-centred care, taking into consideration the experience of service users, provision of compassionate care, health literacy, as well as the principles of inclusivity and diversity.

8.10.2 Service user experience

8.10.2.1 General

The organization shall have a formal mechanism to routinely assess service user experience in all service areas, including clinical and administrative services, and patient safety perceptions. The organization shall:

a) use a validated and reliable methodology for assessing experience that includes a representative sample of service users, ensuring that all groups are equitably included. This methodology should include qualitative and quantitative components as appropriate;

b) include assessments of family and caregiver experience when possible;

c) encourage input from community groups and external service users;

d) ensure that feedback mechanisms are accessible, understandable, and appropriate to the service user's education level and access to resources (e.g. computer, telephone, literacy level).

8.10.2.2 Service user experience assessment

The service user experience assessment shall determine if:

a) service users, families, and caregivers feel they are treated with respect and dignity;

b) service users' emotional needs, social and cultural needs, preferences, and values are considered;

c) privacy and confidentiality are maintained;

d) all people are treated equally, regardless of sex, gender, age, race, ethnicity, condition, or clinical diagnosis;

e) service users, families and caregivers are included in shared decision making.

Organizational responses shall include action plans to address negative experiences. Actions shall evaluate the need for process changes, corrective and preventive actions, and specify follow-up communication with the service user.

The organization shall determine how experience data can be used to improve clinical outcomes, service delivery, adherence to treatment, and as a mechanism to motivate service users to adopt positive health behaviours.

Evaluation of user experience shall be included in the required management review meeting.

8.10.3 Compassionate care

The organization shall have a process in place to:

a) treat service users and workforce with respect and dignity;

b) foster and promote an environment of kindness among people, families and caregivers;

c) listen to service users and caregivers;

d) educate workforce on how to deliver compassionate care.

Relevant workforce shall be trained in, and aware of, the psychological, social and emotional issues related to end-of-life care.

8.10.4 Inclusivity and diversity

In order to create and foster inclusivity and diversity, the organization shall:

a) adopt principles of cultural competence and align its services to meet the needs and preferences of all people and families as to improve equity of care, value diversity, and reduce disparity for all persons regardless of colour, gender, age, belief, languages, literacy level, racial, ethnic minority groups and other vulnerable populations;

b) provide workforce training on cultural competence;

c) ensure that there is no bias or disparity that influence decision making between the workforce and service users, or between workforce colleagues;

d) maintain processes in place to capture degrees of cultural competence in order to provide feedback and opportunities for improvement.

8.10.5 Health literacy

To foster service user and workforce healthcare literacy, the organization shall:

a) address and integrate health literacy into planning, evaluation measures, patient safety, and quality improvement;

b) educate the workforce to be health literate;

c) include populations served in the design, implementation, and evaluation of health information and services;

d) include caregiver support systems when the patient does not have the capacity to understand information (e.g. paediatric, dementia, and special needs populations);

e) use health literacy strategies in communications and confirm understanding at all points of contact;

f) address health literacy in high-risk situations, including detailed information before performing procedures that require informed consents, care transitions and communications about medication;

g) emphasize people's ability to use health information and focus on the ability to make informed decisions;

h) meet the needs of populations with a range of health literacy skills while avoiding stigmatization;

i) provide service users with education regarding prevention and management of their current or potential conditions.

NOTE Education can be in the form of printed handouts, use of visual aids, verbal counselling, digital platforms, amongst other methods.

8.10.6 Co-production

To co-produce health services the organization shall:

a) work to build trusting, respectful services in partnership with service users;

b) listen to service users and empower them and their support systems to become active in their care;

c) pay attention to service users' lived realities, values, resources, social support, and objectives in seeking care;

d) create a shared decision-making environment in which health professionals engage partners in healthcare service delivery;

e) foster service users' autonomy, identifying objectives that matter to the patient;

f) promote intelligent kindness and mindfulness regarding the kinship of service users and healthcare providers.

8.10.7 Workforce wellbeing

In order to effectively maintain the wellbeing of its workforce, the organization shall:

a) maintain a documented plan to address workforce health and safety to include physical, chemical, biological, ergonomic, and psychosocial components;

b) have processes in place to address workforce wellbeing including stress, burnout, and violence received from service users or co-workers.

8.11 Ethics

The organization shall have defined processes for identifying, investigating, analysing, and addressing ethical dilemmas, including human subject research.

The workforce shall be trained as appropriate on the handling of ethical concerns.

Service users and their family, caregivers, and/or support systems shall be involved in ethical decision making as agreed upon by the service user.

8.12 Patient safety

8.12.1 General

The organization shall have documented processes in place for ensuring patient safety in all healthcare settings in which it provides services.

When deciding on which safety issues to address, the organization shall consider using nationally and internationally recognized objectives and guidelines. To ensure safety in all settings, the organization shall:

a) consider workforce ratios and balance of qualified workforce (interprofessional cadres of health professionals) according to the workload and kind of work;

b) formulate team-based workflow including referral systems in which patients are appropriately transferred to relevant clinical departments for hospitalization and other more specialized medical institutions with corresponding flow of information;

c) assess the patient's experience/journey;

d) consider the existing expertise and capacity of the institutions referring and receiving the patient;

e) define a system for critical incident reporting (see 6.1).

NOTE Healthcare settings include hospitals, speciality clinics, community clinics, health posts, surgery centres, health centres, and non-clinical settings in which health services are provided.

8.12.2 Knowledge and learning in safety

The organization shall:

a) establish an environment to promote continuous learning, knowledge sharing, training, and deployment of relevant and competent workforce to ensure patient safety;

b) define a process for sharing lessons learned;

c) continually collect and analyse data on patient safety to implement improvements.

8.12.3 Patient identification

To ensure accuracy of patient identification, the organization shall develop and implement a process that:

a) requires patient identification at all points of care, and before performing any diagnostic or therapeutic procedure or intervention;

b) requires at least two unique patient identifiers;

c) does not use the patient's room number, bed number or location in the healthcare facility for identification;

d) outlines processes for special circumstances when a patient is unable to confirm their identity (e.g. comatose, disoriented, delirium, new-born that does not yet have a legal name, severe burns).

8.12.4 Medication safety

The organization shall have documented information regarding medication processes including medication choice, prescribing, procurement, pharmacy validation, preparation, storage, dispensing, and administration.

To ensure medication safety, the organization shall:

a) create a list and establish guidelines for the use of high-risk drugs, and implement an alert system (e.g. look-alike and sound-alike drugs, concentrated electrolytes, insulin, antineoplastic drugs, sedatives);

b) institute and enforce practices for rational antibiotics use according to evidence-based guidelines;

c) maintain protocols in place for patient and caregiver education regarding medication;

d) define mechanisms for monitoring and reporting medication errors and medication-related adverse events.

8.12.5 Surgical safety

The organization shall implement systematic safety measures to promote surgical safety in the operating theatre and other areas where a minor surgery is performed by:

a) deploying sufficient workforce considering the required occupational balance (ratio of nurses, physicians, medical engineers and other healthcare workforce);

b) designing infrastructure and implementing a workflow based on human factors;

c) using evidence-based practice for the delivery and monitoring of anaesthesia;

d) ensuring communication and collaboration between surgeons and anaesthesiologists;

e) providing the necessary equipment for patient monitoring during surgery, periodically analysing surgical interventions and related postoperative re-admissions;

f) maintaining processes to prevent wrong patient, wrong kind or wrong site of surgery errors.

NOTE Systematic measures to ensure surgical safety can include tools such as surgical safety checklists, safe childbirth checklists, clinical algorithms and job aides.

8.12.6 Infection prevention and control (IPC)

The organization shall have documented and coordinated processes for an infection prevention and control program that includes:

a) risk identification, setting priorities and definition of strategies;

b) developing and applying indicators, guidelines and operating procedures;

c) a monitoring/audit system for IPC practices, including the development of a tracking system such as a dashboard designed to monitor and minimize impacts;

d) systemic measures for infection prevention and control: hand hygiene, prevention of the emergence and transmission of microorganisms, surveillance of multi-resistant microorganisms, device associated infection prevention, prevention of surgical site infection, isolation measures, cleanliness of environment, and safe and rational use of antibiotics;

e) establishing a system such as committee on IPC to update technical guidance and address emerging challenges by deliberation;

f) developing a surveillance program for healthcare associated infections, health workforce, including the development and implementation of an immunization policy, coordination of biosafety policy, and reporting and management of exposure accidents;

g) conducting annual workforce training program on IPC that reinforces the workforce's critical role in prevention strategies;

h) encouraging service users and their support systems to monitor and enforce compliance to IPC guidelines and regulations;

i) instituting an organizational culture for IPC that can include multimodal strategies such as building champions, feedback, and cross-pollination of best practices.

8.12.7 Prevention of falls, pressure ulcers and thromboembolism

The organization shall have processes in place to prevent patient falls, pressure ulcers and thromboembolism and shall:

a) identify patients who are at risk of pressure injuries, and establish the necessary controls needed to minimize the risk factors;

b) define interventions to maintain skin integrity, and periodically evaluate the implementation and results of the interventions;

c) maintain a comprehensive fall prevention plan and whenever possible use the latest technologies to assist in fall prevention;

d) identify patients who are at risk for thromboembolism and institute evidence-based protocols for prevention and treatment;

e) maintain documented pharmacological protocols for the prevention of thromboembolism that are evidence-based.

8.12.8 Diagnostic safety

To ensure diagnostic safety, the organization shall have processes in place to ensure:

a) accurate and timely laboratory testing, pathology and imaging services;

b) reporting of critical results of tests and diagnostic procedures;

c) timely communication of results to healthcare providers and service users;

d) compliance with applicable regulatory requirements;

e) comprehensive record keeping of diagnostic procedures and test results.

NOTE ISO 15189 provides specific requirements for quality and competence of medical laboratories, and can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

8.12.9 Blood transfusions

The organization shall have established procedures for blood transfusion safety. Documented information shall include:

a) donor education and counselling;

b) cross-matching and typing;

c) accurate, guideline-based protocols for administration of blood products;

d) confirmation of the blood type of the patient and the correct blood to be infused prior to the start of transfusion;

e) screening for transfusion transmissible infections to include at a minimum HIV I/II, hepatitis B, hepatitis C and syphilis;

f) appropriate collection, identification, storage, release, safe administration, assurance of blood and blood products traceability;

g) training and education of workforce on transfusion procedures and the correct handling and disposal of blood;

h) monitoring and reporting of adverse events and reactions.

Wastes and unused blood products generated from blood transfusions shall follow appropriate and well-defined processes from the point of generation to final disposal site.

9 Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

To evaluate its performance, the organization shall establish a healthcare quality monitoring system, which is in accordance with the organization's healthcare quality policy and quality requirements.

Top management shall ensure that the quality monitoring system runs in an effective and efficient manner, producing time-sensitive and usable results.

The organization shall assign responsibilities for the quality monitoring system including:

a) the overall organization as well as for individual departments and services;

b) specific projects identified by the quality monitoring system.

The organization shall define which indicators (clinical and non-clinical) it will use to measure the effectiveness of its operations. Indicators shall be in alignment with recognized national and international health indicators.

The organization shall determine:

— what needs to be monitored and measured;

— the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

— when the monitoring and measuring shall be performed;

— when the results from monitoring and measurement shall be analysed and evaluated.

Documented information shall be available as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the management system for quality in the healthcare organization.

9.1.2 Healthcare quality indicators

The organization shall identify what is to be monitored by the quality monitoring system and shall include:

a) outcomes from clinical and non-clinical services, which examine effectiveness, efficiency and continued appropriateness of the system and its offerings;

b) patient safety issues, risk reduction strategies, adverse events, and results of patient safety interventions;

c) risk (clinical and non-clinical) identification, minimization and mitigation strategies and results;

d) the capacity of the organization to deliver the appropriate and required continuum of care to the patient, including during transfer to other healthcare providers and facilities;

e) wait times as defined by the organization;

f) service user experience;

g) waste reduction efforts;

h) consideration and prioritization of those items that are most critical to the effective functioning of the quality management system.

Where applicable, health indicators shall include morbidity, mortality and quality of life and wellbeing.

NOTE Wait times can include time to initial appointment, time for referrals to specialists, waiting time once arrived for an appointment, amongst other measures.

9.1.3 Methods

The organization shall determine the methods which are to be used by the quality monitoring system, which should include among other sources:

a) internal and external audits;

b) use of clinical and non-clinical indicators (system/organizational/service or program);

c) use of data from internal health information systems;

d) benchmarking.

The data shall be collected and obtained from reliable sources and based on statistical and scientific criteria.

9.1.4 Results

The organization shall ensure that results of the healthcare quality monitoring system are reviewed, analysed and used to inform strategic quality directions of the organization and shall:

a) express if the results meet the objectives set by the organization;

b) define an improvement plan to address cases of nonconformity with stated objectives;

c) share the results and proposals for improvement with appropriate internal and external stakeholders.

9.2 Internal audit

9.2.1 General

The organization shall conduct internal audits at planned intervals to provide information on whether the management system for quality in the healthcare organization:

a) conforms to:

   — the organization's own requirements for the management system for quality in the healthcare organization;

   — the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 Internal audit programme

The organization shall plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting.

When establishing the internal audit programme(s), the organization shall consider the importance of the processes concerned and the results of previous audits.

The organization shall:

a) define the audit objectives, criteria and scope for each audit;

b) select auditors and conduct audits as to ensure objectivity and impartiality of the audit process;

c) ensure that the results of audits are reported to relevant managers in a timely manner;

d) ensure that audits are conducted by trained and qualified individuals;

e) take appropriate corrective actions without undue delay.

Internal audits shall be performed at a minimum once every twelve months.

Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.

9.3 Management review

9.3.1 General

Top management shall review the organization's healthcare quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall include:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the management system for quality in the healthcare organization;

c) changes in needs and expectations of stakeholders that are relevant to the management system for quality in the healthcare organization;

d) information on the performance of the management system for quality in the healthcare organization, including trends in:

   1) nonconformities and corrective actions;

   2) monitoring and measurement results;

   3) audit results;

   4) service user experience and feedback from stakeholders;

   5) the extent to which quality objectives have been met;

   6) the extent to which established health indicators have been met;

   7) process performance and conformity of services;

   8) monitoring and measurement results;

   9) patient safety;

   10) waste management;

   11) the performance of external providers;

e) the adequacy of resources (human and other);

f) internal finances and funding from external partners;

g) accessibility of health services for all people;

h) risk management;

i) opportunities for continual improvement.

9.3.3 Management review results

The results of the management review shall include decisions related to continual improvement opportunities and any need for changes to the management system for quality in the healthcare organization.

Documented information shall be available as evidence of the results of management reviews. Information shall be provided to stakeholders as stated in agreements.

10 Improvement

10.1 Continual improvement

The organization shall continually improve the suitability, adequacy, and effectiveness of the management system for quality in the healthcare organization.

The organization shall consider the results of analysis and evaluation, and the outputs from management review to determine opportunities for improvement.

10.2 Nonconformity and corrective action

10.2.1 General

The organisation shall define the process of identification, management and reporting of non-conformities that could directly or indirectly negatively affect the management system for quality in the healthcare organization. Such nonconformities arise from multiple sources including:

a) process deviations;

b) effectiveness of planning;

c) service user feedback;

d) workforce performance;

e) undesired clinical outcomes;

f) risk management;

g) patient safety incidents and near misses;

h) workforce complaints and grievances;

i) internal audits.

10.2.2 Management of nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable:

   — take action to control and correct it;

   — deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   — reviewing the nonconformity;

   — determining the causes of the nonconformity;

   — determining if similar nonconformities exist, or can potentially occur;

c) implement any action needed, and shall include:

   1) correction, containment, delay or suspension of services;

   2) informing the service user (required if the nonconformity affects the service user);

   3) communicating with those involved with the nonconformity;

   4) fail-proofing or installing equipment and devices that are oriented to quality and safety improvements where feasible;

   5) updating, controlling, and mitigating risks;

   6) planning that considers service user and workforce perspectives;

   7) communicating changes to affected members at all levels of the organization;

8) providing workforce with continued education on changes or new processes;

d) review the effectiveness of any corrective action taken;

e) make changes to the management system for quality in the healthcare organization, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Documented information shall be available as evidence of:

— the nature of the nonconformities and any subsequent actions taken;

— the responsibilities and authorities for the action;

— the results of any corrective action.

At all levels of the healthcare system (i.e. primary, secondary and tertiary), the organization shall empower relevant stakeholders (e.g. healthcare workers, service users and caregivers) to report real and potential nonconformities.

The organization shall consider how it will communicate lessons learned from nonconformities to its workforce.

Bibliography

[1] ISO/IEC Guide 51:2014, *Safety aspects — Guidelines for their inclusion in standards*

[2] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[3] ISO Guide 73, *Risk management — Vocabulary*

[4] ISO 15189, *Medical laboratories — Requirements for quality and competence*

[5] ISO 19011, *Guidelines for auditing management systems*

[6] ISO 22886:2020, *Healthcare organization management — Vocabulary*

[7] ISO 30400:2022, *Human resource management — Vocabulary*

[8] ISO 31073:2022, *Risk management — Vocabulary*

[9] Ballatt J., Campling C., Maloney C., 2020. Intelligent Kindness: Rehabilitating the Welfare State. Cambridge University Press

[10] Global patient safety action plan 2021–2030: Towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO

[11] WHO Quality Toolkit. Available at: https://qualityhealthservices.who.int/quality-toolkit/qt-home

[12] United Nations Sustainable Development Goals, Available at: https://sdgs.un.org/goals

[13] World Health Organization, 1946: Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

[14] World Health Organization, Health Literacy. Available at: https://www.who.int/teams/health-promotion/enhanced-wellbeing/ninth-global-conference/health-literacy

[15] World Health Organization, Universal health coverage. Available at: https://www.who.int/health-topics/universal-health-coverage#tab=tab_1

ICS 03.100.70; 11.020.01

Price based on 35 pages