Οι Βασικές Απαιτήσεις του CYS ISO 7101:2023 “Management systems for quality in healthcare organizations - Requirements”

Έλενα Δημοσθένους
Λειτουργός Τυποποίησης CYS

ISO TC 304 Healthcare Organisation Management

Καθεστώς CYS στην ολομέλεια:

- παρατηρητής 2017 - 2019
- πλήρες μέλος από το 2020 – σήμερα

ISO TC 304 / WG5 – Healthcare Quality Management (2021 -2023)

- Εκπόνησε το ISO 7101:2023
- 29 Επίσημες Διαδικτυακές Συνεδριάσεις
- 70 εμπειρογνώμονες από 30 χώρες
- Διαλύθηκε τον Μάιο 2023

ISO TC 304 Healthcare Organisation Management

Published Standards

- ISO 5258:2022 Healthcare organization management — Pandemic response (respiratory) — Drive-through screening station
- ISO 5472:2022 Healthcare organization management — Pandemic response (respiratory) — Walk-through screening station
- ISO 5741:2023 Healthcare organization management — Pandemic response — Temporary medical facility
- ISO 6028:2023 Healthcare organization management — Pandemic response — Functional requirements for self-symptom checker app
- ISO 7101:2023 Healthcare organization management — Management systems for quality in healthcare organizations — Requirements
- ISO/TS 17371:2023 Healthcare organization management — Infection prevention and control (IPC) measures for cross-border workers
- ISO/PAS 18999:2024 Healthcare organization management — Pandemic response —Guidelines for respiratory infection prevention and control in hospitals
- ISO 22886:2020 Healthcare organization management — Vocabulary
- ISO 22956:2021 Healthcare organization management — Requirements for patient-centred staffing
- ISO 23447:2023 Healthcare organization management — Hand hygiene performance

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- **Το πρώτο πρότυπο συστήματος διαχείρισης στο είδος του καθώς**
  - **Αφορά σε συγκεκριμένο τομέα**
  - **Είναι συμβατό με όλα τα πρότυπα συστημάτων διαχείρισης**
  - **Λαμβάνει υπόψη τους Στόχους Βιώσιμής Ανάπτυξης**
  - **Καλύπτει όλο το εύρος υπηρεσιών υγείας**

Δεδομένα – Παραδοχές για τις Υπηρεσίες Υγείας

- Πολυπλοκότητα
- Πολλά ενδιαφερόμενα μέρη
- Εξαρτήσεις – Συνεργάτες - Προμηθευτές - Υπεργολάβοι
- Ανάγκη προστασίας ασθενών – προσωπικού – οργανισμού
- Ανάγκη απόδειξης επιπέδου υπηρεσιών και ανταγωνιστικότητας
- Αδυναμία στην παρακολούθηση και μέτρηση
- Κενά στις τεκμηριωμένες πληροφορίες
- Κόστος Κακής Διαχείρισης και Έλλειψης Ποιότητας

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Elements of a management system for quality in healthcare organizations

Plan: establish healthcare quality objectives & processes necessary to deliver results in accordance with the organization's healthcare quality policy (Clause 6).

Do: implement the processes as planned (Clauses 7 & 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).

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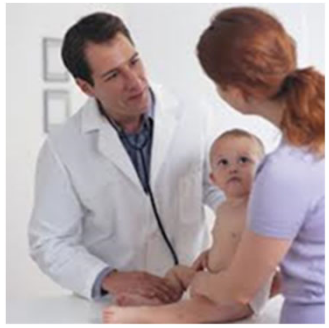

Contents (6/6)

5.1 Leadership and commitment

- Mission / Vision / Values / Code of Conduct
- Quality governance structures and accountabilities
- Resources needed including required workforce in terms of numbers and skill levels necessary
- Responsibilities and authorities' assignment
- Promotion of risk-based thinking and risk assessment
- Safety for service users
- Safety and wellbeing of the workforce
- Transparency of communication and knowledge management
- Impartiality, confidentiality and privacy monitoring and maintenance
- Etc…..

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. Controls shall:

- assess the risks and opportunities by identifying, analysing and evaluating each risk
- develop and maintain a register of risks and opportunities
- define a risk criterion that specifies how much risk it can or cannot accept
- rate risks based on severity, impact or importance
- develop risk assessment and treatment tools for monitoring and reporting
- define processes to capture and analyse patient safety incidents (near misses, adverse and sentinel events)
- define responsibilities, authorities and accountabilities for each step of the risk management process
- develop risk mitigation plans
- monitor and assess risk management interventions
- 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.

7.2 Competence

The organization shall:

- determine the necessary competence of person(s) doing work under its control
- maintain a documented process for recruitment that defines the requirements for competence, education, qualification, training, technical knowledge, skills, and experience
- ensure that these persons are competent on the basis of appropriate education, training, or experience
- provide orientation to all workforce at the time of joining the organization
- maintain documented procedures for credentialing and privileging of healthcare professionals and support workforce as appropriate

- provide ongoing education and training necessary to maintain the required level of performance and competency
- perform a documented performance evaluation at defined intervals
- 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
- retain documented information as evidence of competence for all workforce members.

7.4.3 Clinical communication

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

- 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
- ensure that oral and telephone orders, and communication of clinical results, are controlled and verified for accuracy
- demonstrate the use of comprehensive clinical records that allow for proper tracking of communication between different professionals and service sites
- demonstrate that all communications containing personal health information follow national or international standards of privacy
- maintain documented information as evidence of employee training on proper clinical communication and privacy requirements.

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.

7.5.5 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:

- naming files / protection / access / back-up / archive / retrieval / retention time / deletion
- integration of documented information generated through different systems and interfaces
- 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.

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:

- conduct audits of both clinical and non-clinical records periodically to ensure quality of care and services
- ensure that clinical records contain the history, results, reports, and sufficient information to facilitate clinical management of the service user
- verify that records include the date, time, and identity of the individual responsible for each activity
- ensure that clinical records meet any legal requirements
- provide documented evidence of the audit of records and the results.

8.9 Provision of services (1/2)

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:

- define and document its scope of services and make this available to service users
- provide documented information to service users of their rights and responsibilities
- define and document processes and procedures for registration, admission, and discharge of all categories of service users
- maintain documented protocols and procedures for recording clinical findings, progress, care provided, follow up details for all categories of service users
- maintain documented protocols and procedures for ordering diagnostic investigations, medications, diet, and other clinical needs

8.9 Provision of services (2/2)

- provide appropriate personal protective equipment to healthcare workers and service users
- use appropriate technology tools in delivery of care
- maintain documented processes for patients undergoing sedation, surgeries, and procedures
- 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
- maintain documented protocols and procedures for referring service users to other specialists and speciality departments
- 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
- 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.

8.12 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. To ensure safety in all settings, the organization shall:

- consider workforce ratios and balance of qualified workforce
- 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
- assess the patient's experience/journey
- consider the existing expertise and capacity of the institutions referring and receiving the patient
- define a system for critical incident reporting

8.12 Patient safety

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:

- 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);
- institute and enforce practices for rational antibiotics use according to evidence-based guidelines;
- maintain protocols in place for patient and caregiver education regarding medication
- define mechanisms for monitoring and reporting medication errors and medication-related adverse events.

8.12 Patient safety

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

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 etc.

9.1.2 Healthcare quality indicators

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

- outcomes from clinical and non-clinical services
- patient safety issues, risk reduction strategies, adverse events, and results of patient safety interventions
- risk (clinical and non-clinical) identification, minimization and mitigation strategies and results
- wait times as defined by the organization
- service user experience
- waste reduction efforts
- 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.

9.3.2 Management review inputs (1/2)

The management review shall include:

- the status of actions from previous management reviews
- changes in external and internal issues & in needs and expectations of stakeholders
- information on the performance of the management system for quality in the healthcare organization, including trends in:
  - nonconformities and corrective actions
  - monitoring and measurement results
  - audit results
  - service user experience and feedback from stakeholders
  - the extent to which quality objectives have been met
  - the extent to which established health indicators have been met
  - process performance and conformity of services
  - monitoring and measurement results
  - patient safety
  - waste management
  - the performance of external providers

e)

9.3.2 Management review inputs (2/2)

The management review shall include:

- the adequacy of resources (human and other)
- internal finances and funding from external partners
- accessibility of health services for all people
- risk management
- 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.

10.2.2 Management of nonconformity and corrective action (1/2)

When a nonconformity occurs, the organization shall:

- react to the nonconformity, and as applicable take action to control and correct it & deal with the consequences
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere
- implement any action needed and shall include …….
- review the effectiveness of any corrective action taken
- 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.

10.2.2 Management of nonconformity and corrective action (2/2)

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.


Effective
People-centred
Timely
Safe
Equitable
Efficient
PLAN 6
DO 7,8
STUDY 9
ACT 10
LEADERSHIP 5

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ISO/IEC TS 17021-15:2023 Conformity assessment requirements for bodies providing audit and certification of management systems — Part 15: Competence requirements for auditing and certification of management systems for quality in healthcare organizations

TRAINING AND CONSULTING

ACCREDITATION OF CERTIFICATION BODIES

CERTIFICATION BODY

AUDITOR

IMPLEMENTATION AND AUDIT AGAINST THE STANDARD

Σας ευχαριστώ