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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

Exigences relatives à l'évaluation de la conformité pour les organismes procédant à l'audit et à la certification des systèmes de management —

Partie 15: Exigences de compétence pour l'audit et la certification des systèmes de management de la qualité dans les organismes de santé

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document 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 or www.iec.ch/members_experts/refdocs).

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This document was prepared by the ISO Committee on Conformity Assessment (CASCO), in collaboration with ISO Technical Committee ISO/TC 304, *Healthcare organization management*.

A list of all parts in the ISO/IEC 17021 series can be found on the ISO and IEC websites.

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 and www.iec.ch/national-committees..

Introduction

ISO 7101 sets out requirements for management systems for quality in healthcare organizations of all sizes and structures. Healthcare systems and organizations are complex, and the delivery of healthcare is equally complex. The healthcare sector involves multiple stakeholders, its own terminology and indicators, high levels of risk and safety considerations, diverse governance structures (public, private, public-private partnerships) and a highly unique human element from the perspectives of both the service user and the workforce.

This document is intended to be used in conjunction with ISO/IEC 17021-1. In particular, it clarifies the requirements for the competence of personnel involved in the certification process set out in ISO/IEC 17021-1:2015, Clause 7 and Annex A.

Certification bodies have a responsibility to stakeholders, including their clients and the customers of the organizations whose management systems are certified, to ensure that only those auditors who demonstrate the relevant competence are permitted to conduct management system audits. Personnel certifying the management systems for quality in healthcare organizations must possess the generic competencies described in ISO/IEC 17021-1, as well as the specific competencies described in this document.

Certification bodies must identify the specific audit team competence needed for the scope of each audit based on the complexity of the healthcare organization. The selection of an audit team will depend upon various factors, including the client's technical area and specific healthcare processes.

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.

Further details can be found in the ISO/IEC Directives, Part 2.

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

1 Scope

This document specifies competence requirements for personnel involved in the audit and certification process for management systems for quality in healthcare organizations. It complements the existing requirements of ISO/IEC 17021-1.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7101, *Healthcare organization management — Management systems for quality in healthcare organizations — Requirements*

ISO/IEC 17021-1:2015, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17021-1 and ISO 7101 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/

4 Generic competence requirements

The certification body shall define the competence requirements for each certification function as referenced in ISO/IEC 17021-1:2015, Table A.1. When defining these competence requirements, the certification body shall take into account all the requirements specified in ISO/IEC 17021-1, as well as those specified in Clauses 5 and 6 of this document that are relevant for the specific healthcare sector, as defined by the certification body.

NOTE 1 Annex A provides a summary of the knowledge required for auditing and certification of management of quality in healthcare organizations.

NOTE 2 ISO 19011 provides information on the principles of auditing.

5 Competence requirements for auditors and audit teams in management systems for quality in healthcare organizations

5.1 General

An audit team shall be composed of auditors (and technical experts, as necessary) having the collective competence to undertake the audit. This shall include the generic competence described in ISO/IEC 17021-1 and the knowledge of management systems for quality in healthcare organizations described in 5.2 to 5.4.

NOTE It is not necessary for each member of the audit team to have the same competence, however, the collective competence of the audit team must be sufficient to achieve the audit objectives.

5.2 Knowledge of healthcare delivery requirements outlined in ISO 7101

Healthcare delivery is a complex system involving multiple stakeholders, its own terminology and indicators, high levels of risk, diverse governance structures (public, private, public-private partnerships) and a highly unique human element. It is necessary for the auditor to have a sound understanding of these important and varied factors.

The audit team involved in the auditing of management systems for quality in healthcare organizations shall have knowledge of:

a) fundamental concepts and principles of management of quality in healthcare organizations;

b) terms and definitions related to healthcare delivery and management;

c) the delivery of people-centred care, as well as the application of themes such as service user experience, compassionate care, inclusivity and diversity, health literacy, co-production of care and workforce wellbeing;

d) the application of risk-based thinking as it applies throughout the continuum of healthcare design, planning, and delivery, including the determination of risks and opportunities;

e) scopes and their applicability to a healthcare organization's management system for quality;

f) the process approach, including related monitoring and measurement;

g) the role of leadership in a healthcare organization and its impact on the management system;

h) application of the PDSA (Plan-Do-Study-Act) cycle;

i) tools, methods and techniques related to management of quality, and their application.

5.3 Context of the organization

The audit team shall have healthcare sector knowledge within the geographical area to determine whether an organization has appropriately defined:

a) the external and internal issues relevant to its purpose and its strategic direction, and that affect its ability to achieve the intended result(s) of its management system for quality;

b) the needs and expectations of stakeholders relevant to the organization's management system for quality, including the requirements for the products and services of the organization;

c) the boundaries and applicability of the management system for quality to establish its scope;

d) the skills (tact) and attributes (empathy) to understand the clinical condition of patients to be able to involve them, their carers and family members in interviews and maintain confidentiality, including when talking to the workforce in the presence of patients;

e) the implementation of patient safety processes.

NOTE A healthcare sector is understood to be an economic activity where the delivery of services covers a broad range of care, e.g. primary, secondary and/or tertiary.

5.4 Client outcomes, services, processes and organization

The audit team shall have knowledge of:

a) terminology and technology specific to the healthcare sector;

b) statutory and regulatory requirements applicable to the delivery of the type of healthcare, product or service;

NOTE Statutory and regulatory requirements can be expressed as government policy, or legal requirements of the country where the healthcare facility is situated.

c) characteristics of outcomes, services and processes specific to the healthcare setting;

d) the infrastructure and environment for the safe operation of processes affecting outcomes and service quality;

e) the provision of externally provided processes, outcomes and services;

f) the impact of organization type, size, governance, structure, functions and relationships on development and implementation of the management system for quality, its documented information and certification activities;

g) healthcare indicators, methods and practices for monitoring, measuring and reporting.

6 Competence requirements for other personnel

6.1 General

Personnel involved in other certification functions shall have the collective competence sufficient to undertake those functions. This shall include the generic competence described in ISO/IEC 17021-1 and the knowledge of healthcare delivery requirements described in 6.2.

6.2 Competence of personnel reviewing audit reports and making certification decisions

Personnel reviewing audit reports and making certification decisions shall have knowledge of:

a) fundamental concepts and principles of management of quality in healthcare organizations;

b) terms and definitions related to healthcare delivery and management;

c) the application of risk-based thinking, including the determination of risks and opportunities throughout the continuum of healthcare design, planning and delivery;

d) the process approach, including related monitoring and measurement;

e) the role of leadership in a healthcare organization and its impact on the management system for quality;

f) application of the PDSA cycle;

g) tools, methods and techniques related to management of quality, and their application in healthcare;

h) people-centred care themes, such as service user experience, compassionate care, inclusivity and diversity, health literacy, co-production of care and workforce wellbeing.