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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 healthcare quality management systems for quality in healthcare organizations

DTS stage

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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~~ JWG 63~~, *Healthcare organization management*.

A list of all parts in the ISO/IEC 17021~~-1~~ series can be found on the ISO ~~website~~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 ~~the quality~~ requirements for management system ~~(QMS) requirements~~ for quality in healthcare systems and organizations of all sizes and structures. Healthcare organizations are complex and the delivery of healthcare is equally complex involving multiple stakeholders, its own terminology and indicators, high levels of quality, risk and safety, diverse governance structures (public, private, public-private partnerships), and a highly unique human element from the service user perspective and from staff. ~~Personnel certifying the management systems for quality in healthcare organizations need to have generic competencies described in ISO/IEC 17021-1, as well as the specific management system competencies described in this document.~~

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 interested parties, 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 ~~allowed to conduct quality management system (QMS) audits~~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.

~~It is intended that all personnel involved in certification functions possess the generic competence described in ISO/IEC 17021-1, as well as the specific QMS knowledge described in this document.~~

Certification bodies ~~will need to~~must identify the specific audit team competence needed for the scope of each ~~QMS~~ audit based on the complexity of the healthcare organization. The selection of ~~a QMS~~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 ~~healthcare quality~~ management systems for quality in healthcare organizations

1 Scope

This document specifies ~~additional~~ competence requirements for personnel involved in the audit and certification process for ~~healthcare quality~~ management systems ~~and~~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 ~~quality~~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~~ 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~~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 ~~Healthcare QMS~~ 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 ~~healthcare quality management systems~~ 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 ~~healthcare quality~~ knowledge of management systems ~~knowledge~~ for quality in healthcare organizations described in 5.2 to 5.~~9~~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 ~~needs to~~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 or 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 diverse and important factors.

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

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

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

~~c)~~ c) terms and definitions around people-~~centered~~centred care, such as equity, vulnerable populations, inclusivity, health literacy and co-production of care;

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

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

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

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

~~h)~~ h) application of risk ~~-~~based thinking, including the determination of risks and opportunities;

~~i)~~ i) application of the PDSA (~~plan, do, study, act~~Plan-Do-Study-Act) cycle;