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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

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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..

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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.

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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

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.

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