TECHNICAL SPECIFICATION

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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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Contents

Page

Foreword

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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.