



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of ISO/IEC TS 17021-15:2023.

The UK participation in its preparation was entrusted to Technical Committee CH/304, Healthcare Organization Management.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 25444 0

ICS 03.120.20

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 December 2023.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

**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*





COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Generic competence requirements	1
5 Competence requirements for auditors and audit teams in management systems for quality in healthcare organizations	2
5.1 General.....	2
5.2 Knowledge of healthcare delivery requirements outlined in ISO 7101.....	2
5.3 Context of the organization.....	2
5.4 Client outcomes, services, processes and organization.....	3
6 Competence requirements for other personnel	3
6.1 General.....	3
6.2 Competence of personnel reviewing audit reports and making certification decisions.....	3
Annex A (informative) Knowledge for auditing and certification of management systems for quality in healthcare organizations	4
Bibliography	5