

INTERNATIONAL STANDARD

ISO 15189

First edition
2003-02-15

Corrected version
2003-07-15

Medical laboratories — Particular requirements for quality and competence

*Laboratoires d'analyses de biologie médicale — Exigences particulières
concernant la qualité et la compétence*



Reference number
ISO 15189:2003(E)

© ISO 2003

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2003

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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 Management requirements	4
4.1 Organization and management	4
4.2 Quality management system	4
4.3 Document control	6
4.4 Review of contracts	7
4.5 Examination by referral laboratories	7
4.6 External services and supplies	8
4.7 Advisory services	8
4.8 Resolution of complaints	9
4.9 Identification and control of nonconformities	9
4.10 Corrective action	9
4.11 Preventive action	10
4.12 Continual improvement	10
4.13 Quality and technical records.....	10
4.14 Internal audits.....	11
4.15 Management review	11
5 Technical requirements.....	12
5.1 Personnel	12
5.2 Accommodation and environmental conditions.....	14
5.3 Laboratory equipment	15
5.4 Pre-examination procedures.....	17
5.5 Examination procedures	19
5.6 Assuring quality of examination procedures.....	21
5.7 Post-examination procedures	22
5.8 Reporting of results	22
Annex A (normative) Correlation with ISO 9001:2000 and ISO/IEC 17025:1999	25
Annex B (informative) Recommendations for protection of laboratory information systems (LIS)	29
Annex C (informative) Ethics in laboratory medicine	33
Bibliography	36