

INTERNATIONAL STANDARD

ISO
15189

Fourth edition
2022-12

Medical laboratories — Requirements for quality and competence

*Laboratoires de biologie médicale — Exigences concernant la qualité
et la compétence*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

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	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	8
4.1 Impartiality.....	8
4.2 Confidentiality.....	8
4.2.1 Management of information.....	8
4.2.2 Release of information.....	9
4.2.3 Personnel responsibility.....	9
4.3 Requirements regarding patients.....	9
5 Structural and governance requirements	9
5.1 Legal entity.....	9
5.2 Laboratory director.....	10
5.2.1 Laboratory director competence.....	10
5.2.2 Laboratory director responsibilities.....	10
5.2.3 Delegation of duties.....	10
5.3 Laboratory activities.....	10
5.3.1 General.....	10
5.3.2 Conformance with requirements.....	10
5.3.3 Advisory activities.....	10
5.4 Structure and authority.....	11
5.4.1 General.....	11
5.4.2 Quality management.....	11
5.5 Objectives and policies.....	11
5.6 Risk management.....	12
6 Resource requirements	12
6.1 General.....	12
6.2 Personnel.....	12
6.2.1 General.....	12
6.2.2 Competence requirements.....	12
6.2.3 Authorization.....	13
6.2.4 Continuing education and professional development.....	13
6.2.5 Personnel records.....	13
6.3 Facilities and environmental conditions.....	13
6.3.1 General.....	13
6.3.2 Facility controls.....	14
6.3.3 Storage facilities.....	14
6.3.4 Personnel facilities.....	14
6.3.5 Sample collection facilities.....	14
6.4 Equipment.....	15
6.4.1 General.....	15
6.4.2 Equipment requirements.....	15
6.4.3 Equipment acceptance procedure.....	15
6.4.4 Equipment instructions for use.....	15
6.4.5 Equipment maintenance and repair.....	15
6.4.6 Equipment adverse incident reporting.....	16
6.4.7 Equipment records.....	16
6.5 Equipment calibration and metrological traceability.....	17
6.5.1 General.....	17
6.5.2 Equipment calibration.....	17

6.5.3	Metrological traceability of measurement results	17
6.6	Reagents and consumables	18
6.6.1	General	18
6.6.2	Reagents and consumables — Receipt and storage	18
6.6.3	Reagents and consumables — Acceptance testing	18
6.6.4	Reagents and consumables — Inventory management	18
6.6.5	Reagents and consumables — Instructions for use	19
6.6.6	Reagents and consumables — Adverse incident reporting	19
6.6.7	Reagents and consumables — Records	19
6.7	Service agreements	19
6.7.1	Agreements with laboratory users	19
6.7.2	Agreements with POCT operators	19
6.8	Externally provided products and services	20
6.8.1	General	20
6.8.2	Referral laboratories and consultants	20
6.8.3	Review and approval of externally provided products and services	20
7	Process requirements	21
7.1	General	21
7.2	Pre-examination processes	21
7.2.1	General	21
7.2.2	Laboratory information for patients and users	21
7.2.3	Requests for providing laboratory examinations	21
7.2.4	Primary sample collection and handling	22
7.2.5	Sample transportation	23
7.2.6	Sample receipt	24
7.2.7	Pre-examination handling, preparation, and storage	24
7.3	Examination processes	25
7.3.1	General	25
7.3.2	Verification of examination methods	25
7.3.3	Validation of examination methods	25
7.3.4	Evaluation of measurement uncertainty (MU)	26
7.3.5	Biological reference intervals and clinical decision limits	26
7.3.6	Documentation of examination procedures	27
7.3.7	Ensuring the validity of examination results	27
7.4	Post-examination processes	30
7.4.1	Reporting of results	30
7.4.2	Post-examination handling of samples	32
7.5	Nonconforming work	33
7.6	Control of data and information management	33
7.6.1	General	33
7.6.2	Authorities and responsibilities for information management	33
7.6.3	Information systems management	34
7.6.4	Downtime plans	34
7.6.5	Off site management	34
7.7	Complaints	34
7.7.1	Process	34
7.7.2	Receipt of complaint	35
7.7.3	Resolution of complaint	35
7.8	Continuity and emergency preparedness planning	35
8	Management system requirements	35
8.1	General requirements	35
8.1.1	General	35
8.1.2	Fulfilment of management system requirements	36
8.1.3	Management system awareness	36
8.2	Management system documentation	36
8.2.1	General	36
8.2.2	Competence and quality	36

8.2.3	Evidence of commitment.....	36
8.2.4	Documentation.....	36
8.2.5	Personnel access.....	36
8.3	Control of management system documents.....	37
8.3.1	General.....	37
8.3.2	Control of documents.....	37
8.4	Control of records.....	37
8.4.1	Creation of records.....	37
8.4.2	Amendment of records.....	37
8.4.3	Retention of records.....	38
8.5	Actions to address risks and opportunities for improvement.....	38
8.5.1	Identification of risks and opportunities for improvement.....	38
8.5.2	Acting on risks and opportunities for improvement.....	38
8.6	Improvement.....	39
8.6.1	Continual improvement.....	39
8.6.2	Laboratory patients, user, and personnel feedback.....	39
8.7	Nonconformities and corrective actions.....	39
8.7.1	Actions when nonconformity occurs.....	39
8.7.2	Corrective action effectiveness.....	40
8.7.3	Records of nonconformities and corrective actions.....	40
8.8	Evaluations.....	40
8.8.1	General.....	40
8.8.2	Quality indicators.....	40
8.8.3	Internal audits.....	40
8.9	Management reviews.....	41
8.9.1	General.....	41
8.9.2	Review input.....	41
8.9.3	Review output.....	41
Annex A (normative) Additional requirements for Point-of-Care Testing (POCT).....		43
Annex B (informative) Comparison between ISO 9001:2015 and ISO 15189:2022 (this document).....		44
Annex C (informative) Comparison between ISO 15189:2012 and ISO 15189:2022 (this document).....		54
Bibliography.....		61

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15189:2012), which has been technically revised. It also replaces ISO 22870:2016.

The main changes are as follows:

- Alignment with ISO/IEC 17025:2017 resulted in the management requirements now appearing at the end of the document;
- Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated;
- Increased emphasis on risk management.

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.

Introduction

The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories.

This document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. Benefits of this approach include: increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment.

The requirements for risk management are aligned with the principles of ISO 22367.

The requirements for laboratory safety are aligned with the principles of ISO 15190.

The requirements for sample collection and transport are aligned with ISO 20658.¹⁾

This document contains the requirements for point-of-care testing (POCT) and supersedes ISO 22870, which will be withdrawn upon publication of this document.

The format of this document is based on ISO/IEC 17025:2017.

The medical laboratory is essential to patient care; activities are provided within an ethical and governance framework, that recognizes the obligations of healthcare providers to the patient. These activities are undertaken in a timely manner to meet the needs of all patients and the personnel responsible for the care of those patients. Activities include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, processing of patient samples, selection of examinations that are fit for intended use, examination of samples, sample storage, as well as subsequent interpretation, result reporting and advice to laboratory users. This may also include the provision of results to the patient, arrangements for urgent testing and the notification of critical results.

While this document is intended for use throughout the currently recognized medical laboratory disciplines, it can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

The use of this document facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

The comparability of patient examination results between medical laboratories, regardless of city or country, is facilitated when medical laboratories conform to this document.

When a laboratory seeks accreditation, it should select an accreditation body which operates in accordance with ISO/IEC 17011, and which takes into account the particular requirements of medical laboratories.

Comparisons between this document, ISO 9001:2015 and ISO/IEC 17025:2017 are in [Annex B](#). The comparison of ISO 15189:2012 to ISO 15189:2022 (this document) is in [Annex C](#).

1) First edition under preparation (previous edition was a Technical Specification). Stage at the time of publication: ISO/DIS 20658:2022.