BSI Standards Publication

Medical laboratories — Requirements for quality and competence

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National foreword

This British Standard is the UK implementation of EN ISO 15189:2022+A11:2023. It is derived from ISO 15189:2022. It supersedes BS EN ISO 15189:2022, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

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

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31 December 2023	Implementation of CEN amendment A11:2023: Annex ZA added.

EUROPÄISCHE NORM

November 2023

ICS 03.120.10; 11.100.01

Supersedes EN ISO 15189:2012, EN ISO 22870:2016

English Version

Medical laboratories - Requirements for quality and competence (ISO 15189:2022)

Laboratoires de biologie médicale - Exigences concernant la qualité et la compétence (ISO 15189:2022)

Medizinische Laboratorien - Anforderungen an die Qualität und Kompetenz (ISO 15189:2022)

This European Standard was approved by CEN on 15 November 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 15189:2022 E

European foreword

This document (EN ISO 15189:2022) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by December 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15189:2012 and EN ISO 22870:2016.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 15189:2022 has been approved by CEN as EN ISO 15189:2022 without any modification.

European foreword to amendment A11

This document (EN ISO 15189:2022/A11:2023) has been prepared by Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 15189:2022 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by November 2026.

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This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document.

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Annex ZA
(informative)

Relationship between this European Standard and the requirements of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 aimed to be covered

This European Standard has been prepared under Commission Implementing Decision C(2021)9277 of 17.12.2021 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards accreditation and conformity assessment in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council (M/580), to provide one voluntary means of conforming to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 [OJ L 218].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table Z confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 [OJ L 218]

Requirement of Regulation (EC) 765/2008	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Article 8(10)	4 General requirements 5 Structural requirements 6 Resource requirements 7 Process requirements 8 Management system requirements	In addition to the accreditation of laboratories in line with Article 5(5)(c) of Regulation (EU) 2017/746

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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Foreword

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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).

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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.

Medical laboratories — Requirements for quality and competence

1 Scope

This document specifies requirements for quality and competence in medical laboratories.

This document is applicable to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.

This document is also applicable to point-of-care testing (POCT).

NOTE International, national, or regional regulations or requirements can also apply to specific topics covered in this document.

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/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

NOTE ISO/IEC Guide 99 is also known as the Joint Committee for Guides in Metrology (JCGM) 200.

ISO/IEC 17000:2020, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following 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/

3.1
bias
measurement bias
estimate of a systematic measurement error

Note 1 to entry: This definition only applies to quantitative measurements

[SOURCE: ISO/IEC Guide 99:2007, 2.18, modified — Note 1 to entry has been added.]