



PIAWAI BRUNEI DARUSSALAM

MEDICAL LABORATORIES - REQUIREMENTS FOR QUALITY AND COMPETENCE (ISO 15189:2022, IDT)

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The Piawai Brunei Darussalam has been endorsed by Majlis Standard dan Akreditasi Brunei Darussalam and are subject to periodical review according to the current needs of the local industries and to keep abreast of progress in the industries concerned. Suggestion of amendments will be recorded and in due course brought to the notice of the committees concerned.

Any changes made hereafter are documented through the issue of either amendments or revisions.

This PBD ISO 15189:2022 was published in 2024 as a direct adoption, with no modification from ISO 15189:2022.

Attention is drawn to the fact that this Piawai Brunei Darussalam does not confer any immunity from legal obligations in any contract for compliance to the Standard.

Amendments issued since publication

Amd No	Date of issue	Text affected

NATIONAL FORWARD

The Majlis Standard Kebangsaan was formed in 2009 and reinstated as Majlis Standard dan Akreditasi Brunei Darussalam by consent of His Majesty the Sultan and Yang Di-Pertuan of Brunei Darussalam in February 2024. The Council acts as the body responsible for strengthening and monitoring standards and conformance in Brunei Darussalam. Its members encompass multiple agencies across the Government, industry, academia and consumer interests and are envisaged to provide policy direction that will firm up national initiatives to create and stimulate sustainable economic growth. In this endeavor, factors such as the creation and promotion of awareness on consumer safety and interests will also form part of the main scope for the council.

The work of the council is facilitated by the Pusat Standard dan Akreditasi Brunei Darussalam (PSABD), under the Ministry of Finance and Economy. With the main role of strengthening the capacity and sustainability of the national standards infrastructure, PSABD has been instructed to act as the body that provides a platform to complement the formation of the Council.

On matters pertaining to the development of national standards i.e. Piawai Brunei Darussalam (PBD), the management of activities are monitored through the formation of National Standards Committees. Clustered based on the scope of its industry, the work of developing PBD stands guided by international practice with the involvement of multiple agencies across the Government, industry and public as a whole.

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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.

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.]