
**Point-of-care testing (POCT) —
Requirements for quality and competence**

*Analyses de biologie délocalisées (ADBD) — Exigences concernant la
qualité et la compétence*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 22870 was prepared by Technical Committee ISO/TC TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

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Introduction

Traditional examinations of a patient's body fluids, excreta and tissues are carried out generally in the controlled and regulated environment of a recognized medical laboratory. The introduction of quality management systems and accreditation of these laboratories are gaining increasing interest.

Advances in technology have resulted in compact, easy-to-use *in vitro* diagnostic (IVD) medical devices that make it possible to carry out some examinations at, or close to, the location of the patient. Point-of-care/near-patient testing may benefit the patient as well as healthcare facilities.

Risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates:

- evaluation of new or alternative POCT instruments and systems,
- evaluation and approval of end-user proposals and protocols,
- purchase and installation of equipment,
- maintenance of consumable supplies and reagents,
- training, certification and recertification of POCT system operators,
- quality control and quality assurance.

Bodies that recognise the competence of POCT facilities may use this International Standard as the basis for their activities. If a healthcare facility seeks accreditation for a part or all of its activities, it should select an accreditation body that operates in a manner which takes into account the special requirements of POCT.

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Point-of-care testing (POCT) — Requirements for quality and competence

1 Scope

This International Standard gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this International Standard apply when POCT is carried out in hospital, clinic and by a healthcare organization providing ambulatory care. This International Standard can be applied to transcutaneous measurements, the analysis of expired air, and *in vivo* monitoring of physiological parameters.

Patient self-testing in a home or community setting is excluded, but elements of this International Standard can be applicable.

NOTE Local, regional, and national regulations are to be taken into consideration.

2 Normative references

The following referenced documents are indispensable for the application 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 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

point-of-care testing

POCT

near-patient testing

testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient

4 Management requirements

4.1 Organization and management

4.1.1 ISO 15189:2003, 4.1.1, and the following apply.

The management of laboratory services shall plan and develop the processes needed for POCT.

The following shall be considered, as appropriate:

- a) quality objectives and requirements for POCT;

- b) the need to establish processes and documents, and provide resources specific to POCT;
- c) required verification, validation, and monitoring of activities specific to POCT;
- d) records to provide evidence that POCT processes and procedures meet requirements.

The governing body of the organization shall be ultimately responsible for ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization.

4.1.2 ISO 15189:2003, 4.1.2, and the following subclauses 4.1.2.1 to 4.1.2.5 apply.

4.1.2.1 A health professional grouping (e.g. Medical Advisory Committee) shall be responsible to the governing body, for defining the scope of POCT to be made available. This shall take into consideration the clinical need for POCT, its financial implications, technical feasibility, and the ability of the organization to fulfil the need.

4.1.2.2 The laboratory director or designate shall appoint a multidisciplinary POCT management group with representation from the laboratory, administration, and clinical programmes including nursing to advise on the provision of POCT.

4.1.2.3 The management group shall ensure that responsibilities and authorities are defined and communicated within the organization.

4.1.2.4 The management group shall assist in evaluating and selecting POCT devices and systems. Performance criteria for POCT devices should include consideration of trueness, precision, detection limits, use limits, and interferences. Practicability should also be considered.

4.1.2.5 The management group shall consider all proposals to introduce any product, device, or system for POCT.

4.1.3 ISO 15189:2003, 4.1.3 applies.

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4.2 Quality management system

4.2.1 ISO 15189:2003, 4.2, and the following subclauses 4.2.2 to 4.2.5 apply.

4.2.2 The management of laboratory services shall establish, document, implement and maintain a quality management system and continually improve its effectiveness.

4.2.2.1 The management of laboratory services shall

- a) identify the processes needed for the quality management system for POCT throughout the organization,
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyse these processes,
- f) implement actions necessary to achieve planned results and continual improvement of these processes,
- g) appoint a person with appropriate training and experience, as quality manager responsible for POCT quality, which includes review of the requirements related to POCT.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, service provisions, and measurement provisions.

4.2.2.2 The management of laboratory services shall plan and implement the monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of POCT to the quality system.

4.2.3 The quality management system documentation shall include:

- a) documented statements of a quality policy and quality objectives;
- b) quality manual;
- c) documented procedures required by this International Standard;
- d) documents needed by the organization to ensure the effective planning, operation, and control of its processes;
- e) records required by this International Standard.

NOTE Within this International Standard, the term “documented procedure” means that the procedure is established, documented, implemented, and maintained.

The extent of the quality management system documentation may differ from one organization to another, due to:

- the size of organization and type of activities;
- the complexity of processes and their interactions;
- the competence of personnel.

The documentation may be in any form or type of medium that can be maintained and retrieved up to the specified retention times, which is dependent upon local, regional, and national requirements.

4.2.4 ISO 15189:2003, 4.2.3, and the following apply.

The laboratory director or suitably qualified designate shall ensure that:

- a) POCT quality objectives are established that are measurable;
- b) the planning of the quality management system is carried out in order to meet the requirements of the service, as well as the quality objectives;
- c) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

4.2.5 ISO 15189:2003, 4.2.4, and the following apply.

The organization shall establish and maintain a quality manual that includes:

- a) the scope of the quality management system;
- b) the documented procedures established for the quality management system, or reference to them;
- c) a description of the interaction between the processes of the quality management system.