**DRAFT INTERNATIONAL STANDARD** ISO/DIS 22870

ISO/TC **212** Secretariat: **ANSI**

Voting begins on: **2004-07-12** Voting terminates on: **2004-12-13**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

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

ICS 03.120.10; 11.100

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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.

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

# Introduction

Traditional testing of a patient's body fluids, excreta and tissues is 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 is gaining more and more 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 testing at, or close to, the location of the patient. Point-of-care/near-patient testing benefits 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.

# 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 with ISO 15189. The requirements of this standard apply when POCT is carried out in a hospital or clinic and may be applied by a healthcare organization providing ambulatory care. It may 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 standard may apply.

Considerations of local, regional, and national regulations shall apply.

## 2 Normative references

The following referenced document is 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
alternative site testing
testing that is performed near or at the site of the 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, documents, and provide resources specific to POCT;

c) required verification, validation, and monitoring of activities specific to POCT; and

d) records to provide evidence that POCT processes and procedures meet requirements.

The governing body of the organization shall be ultimately responsible for ensuring 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 accuracy, precision, detection 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, and the following apply.

The management of laboratory services shall be responsible for the development and implementation of the quality management system and continually improving its effectiveness by:

a) communicating to the organization the importance of meeting healthcare provider and patient requirements;

b) establishing the quality policy;

c) ensuring that quality objectives are established;

d) defining internal audits;

e) conducting management reviews; and

f) ensuring the availability of resources.

## 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; and

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 document.

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:

a) to demonstrate conformity of POCT to the quality system; and

b) to continually improve the effectiveness of the quality management system.

**4.2.3** Documentation requirements

The quality management system documentation shall include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures required by this standard;

d) documents needed by the organization to ensure the effective planning, operation, and control of its processes; and

e) records required by this 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:

a) the size of organization and type of activities;

b) the complexity of processes and their interactions; and

c) 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:

a) that 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; and

c) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**4.2.5** Quality manual

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; and

c) a description of the interaction between the processes of the quality management system.

## 4.3 Document control

**4.3.1** ISO 15189:2003, 4.3, and the following subclauses 4.3.2 and 4.3.3 apply.

**4.3.2** Documents, including records required by the quality management system shall be controlled.

**4.3.3** A documented procedure shall be established to:

a) approve documents for adequacy prior to issue;

b) review and update as necessary and re-approve documents;

c) ensure that changes and the current revision status of documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified, and their distribution controlled; and

g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

## 4.4 Review of contracts

ISO 15189:2003, 4.4, applies.

### 4.5 Examination by referral laboratories

This does not apply to this International Standard.

### 4.6 External services and supplies

ISO 15189:2003, 4.6, applies.

### 4.7 Advisory services

ISO 15189:2003, 4.7, applies.

### 4.8 Resolution of complaints

ISO 15189:2003, 4.8, applies.

### 4.9 Identification and control of nonconformities

**4.9.1** ISO 15189:2003, 4.9, and the following subclauses 4.9.2 to 4.9.4 apply.

**4.9.2** The organization shall ensure that POCT which does not conform to requirements is identified and controlled to prevent its unintended use. The controls and related responsibilities and authorities for dealing with nonconforming POCT shall be defined in a documented procedure.

The organization shall deal with nonconforming POCT by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance; and

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken shall be maintained.

**4.9.3** The organization shall determine, collect, and analyse appropriate data to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement, as well as from other relevant sources.

**4.9.4** The analysis of data shall provide information relating to:

a) healthcare provider/patient/client satisfaction (see 4.12);

b) conformity to POCT requirements (see 4.2);

c) characteristics and trends of POCT, including opportunities for preventive action; and

d) suppliers.

### 4.10 Corrective action

**4.10.1** ISO 15189:2003, 4.10, and the following subclauses 4.10.2 and 4.10.3 apply.

**4.10.2** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

**4.10.3** A documented procedure shall be established to define requirements for:

a) reviewing nonconformities (including healthcare provider/patient/client complaints);

b) determining the causes of nonconformities;

c) evaluating the need for action to ensure that nonconformities do not recur;

d) determining and implementing action needed;

e) records of the results of action taken; and

f) reviewing corrective action taken.

### 4.11 Preventive action

**4.11.1** ISO 15189:2003, 4.11, and the following subclauses 4.11.2 and 4.11.3 apply.

**4.11.2** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

**4.11.3** A documented procedure shall be established to define requirements for:

a) determining potential nonconformities and their causes;

b) evaluating the need for action to prevent occurrence of nonconformities;

c) determining and implementing action needed;

d) records of results of action taken; and

e) reviewing preventive action taken.

### 4.12 Continual improvement

**4.12.1** ISO 15189:2003, 4.12, and the following subclause 4.12.2 apply.

**4.12.2** A quality assurance programme shall periodically document the impact of POCT on patient outcomes, monitor the test ordering patterns, carry out audits to verify record keeping, and review critical value reports.

### 4.13 Quality and technical records

**4.13.1** ISO 15189:2003, 4.13, and the following subclause 4.13.2 apply.

**4.13.2** Records shall be established and maintained to provide evidence of conformity to requirements and of effective operation of the quality management system. Records shall remain legible, readily identifiable, and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

### 4.14 Internal audits

ISO 15189:2003, 4.14, and the following apply.

a) The Laboratory Director, or designated suitably qualified person, and the multidisciplinary POCT management group shall receive and review the reports of the quality assurance programme.

b) Suggested modifications arising from such reviews shall be incorporated into the POCT policy, processes, and procedures.

### 4.15 Management review

**4.15.1** ISO 15189:2003, 4.15, and the following subclauses 4.15.2 to 4.15.4 apply.

**4.15.2** The Laboratory Director, or a designated suitable qualified person, shall implement a periodic management review that includes: a cost-benefit analysis and an evaluation of the clinical need; the clinical effectiveness and the cost efficiency of POCT activities; and identifies opportunities for improvement.

**4.15.3** Input to management review shall include information on:

a) results of audits;

b) healthcare provider/patient/client feedback;

c) process performance and service conformity;

d) status of preventive and corrective actions;

e) follow-up actions from previous management reviews;

f) changes that could affect the quality management system; and

g) recommendations for improvement.

**4.15.4** The Laboratory Director, or designated suitably qualified person, shall make changes to policy, processes, or procedures resulting from the management review.

## 5 Technical requirements

### 5.1 Personnel

ISO 15189:2003, 5.1, and the following subclauses 5.1.1 to 5.1.5 apply.

**5.1.1** The organization shall determine and provide the human resources needed to:

a) implement and maintain the POCT quality management system and continually improve its effectiveness;

b) ensure that required training is provided to personnel performing POCT from all services, programmes and departments; and

c) enhance healthcare provider/patient/client satisfaction by meeting customer requirements.

**5.1.2** ISO 15189:2003, 5.1.3, and the following apply.

The Laboratory Director or another suitably qualified person, shall be responsible for:

a) procuring, evaluating, and selecting all POCT devices, reagents, and systems, including quality control material; and

b) establishing documented quality policy and protocols for the performance of all POCT and associated quality control and quality assurance.

Overall responsibility for the provision of POCT may be delegated to an appropriate laboratory specialist.

**5.1.3** ISO 15189:2003, 5.1.4, and the following apply.

The Laboratory Director or designate shall appoint a member of the POCT management group who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring that processes needed for the POCT quality management system are established, implemented and maintained;

b) reporting on the performance of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of requirements for POCT throughout the organization; and

d) ensuring that users understand the limitations of each POCT device.

**5.1.4** ISO 15189:2003, 5.1.7, and the following apply.

The management group shall allocate responsibilities and designate staff undertaking POCT. The allocation of duties and responsibilities of different groups of staff shall be defined in the operating procedures.

**5.1.5** ISO 15189:2003 5.1.4, 5.1.9, 5.1.11, 5.1.12, and the following apply.

The Laboratory Director, or other suitably qualified person, may appoint a person with appropriate training and experience, to manage the training and competency assessment.

a) The manager shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.

   The manager may assign responsibility for training on a specific POCT instrument/system to an appropriate Technical Specialist or Technologist.

b) Only personnel who have completed the training and demonstrated competence shall carry out POCT. Records of training/attestation and of retraining and re-attestation shall be retained.

c) The content of the training programme and the knowledge/skill level assessment process shall be documented.

NOTE: The knowledge/skill requirements include: ability to demonstrate an understanding of the appropriate use of the device, theory of the measurement system (chemistry and detector) appreciation of the preanalytical aspects of the analysis, including: sample collection; its clinical utility and limitations; expertise in the analytical procedure; reagent storage; quality control and quality assurance; technical limitations of the device; response to results that fall outside of predefined limits; infection control practices; and correct documentation of the results.

d) Retraining intervals and a continuing education programme shall be established by the management group.

e) POCT operator performance shall be monitored as part of the quality assurance programme.

## 5.2 Accommodation and environmental conditions

**5.2.1** ISO 15189:2003, 5.2, and the following subclauses 5.2.2 and 5.2.3 apply.

**5.2.2** The premises in which POCT is undertaken and the equipment used shall conform to applicable national legislation or to regional or local requirements.

**5.2.3** The organization shall determine and manage the work environment needed to achieve conformity to POCT requirements and the device manufacturers' recommendations.

## 5.3 Laboratory equipment

**5.3.1** ISO 15189:2003, 5.3, and the following subclause 5.3.2 apply.

**5.3.2** The Laboratory Director, or designated suitably qualified person, shall be responsible for the selection criteria and for the procurement of equipment, materials, and reagents.

a) An inventory shall be maintained of all POCT equipment including serial number and unique identification, manufacturer, date purchased, and service history, including dates out-of-service.

b) Reagents, kits, and equipment performance shall be verified and results validated prior to routine use.

c) There shall be written procedures for the maintenance and operation of POCT equipment

d) The management group shall recommend that any POCT device or system be withdrawn from service if critical requirements are not met or safety becomes an issue.

e) A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed.

f) Periodic and episodic maintenance of equipment shall be monitored and documented.

## 5.4 Pre-examination procedures

**5.4.1** ISO 15189:2003, 5.4, and the following subclauses 5.4.2 and 5.4.3 apply.

**5.4.2** The organization shall ensure identification of the sample and its clerical traceability to the patient.

**5.4.3** The organization shall exercise care with samples obtained for POCT from its patients while such samples are under the organization's control or are being used by the organization. The organization shall identify and safeguard samples for analysis. If any sample is lost, damaged, or otherwise found to be unsuitable for use, this shall be reported to the responsible healthcare professional and records maintained.

## 5.5 Examination procedures

**5.5.1** ISO 15189:2003, 5.5, and the following subclauses 5.5.2 to 5.5.4 apply.

**5.5.2** Procedure manuals for each POCT system shall be made available to all users.

**5.5.3** Manufacturer's recommendations regarding minimum quality control of a specific instrument system may be accepted, following review.

**5.5.4** Instrument-generated quality control shall be acceptable provided that regulatory authorities have accepted it.

## 5.6 Assuring the quality of examination procedures

**5.6.1** ISO 15189:2003, 5.6, and the following subclauses 5.6.2 to 5.6.8 apply.

**5.6.2** The quality manager is responsible for the design, implementation, and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory. The relationship between values obtained in the laboratory and POCT shall be established, and published, or available upon request.

**5.6.3** The quality manager may assign responsibility for quality control on a specific POCT instrument/system to an appropriately qualified person. When such activities are assigned, the quality manager shall remain accountable to the Laboratory Director, or designated person, for the quality of all POCT testing.

**5.6.4** ISO 15189:2003, 5.6.4, applies.

**5.6.5** Where available, participation in an external quality assessment (EQA) shall be required. (See ISO Guide 43-1.) In the absence of an EQA scheme, the Laboratory Director, or designated person, should establish an internal quality control assessment scheme involving the circulation of samples or replication of the test within the laboratory.

**5.6.6** The Laboratory Director, or designated person, and the multidisciplinary POCT management group shall receive and review the external or internal quality assessment data. Suggested modifications arising from such review shall be incorporated into the POCT policy, processes, and procedures.

**5.6.7** ISO 15189:2003, 5.6.6, applies.

**5.6.8** ISO 15189:2003, 5.6.7, and the following apply.

The laboratory director shall validate the following processes for service provision.

a) Accuracy and, where appropriate, linearity of the instrument response shall be verified by the QC programme.

b) Split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites.

c) Frequency of internal QC should be specified for each device.

d) Corrective action to be taken for out-of-control results shall be documented.

e) Action taken on nonconforming QC results shall be documented.

f) QC results shall be recorded for regular review by the quality manager or designate.

g) Process control for consumable supplies and reagents shall be documented and monitored.

h) In-patient self-testing using POCT devices, if allowed, shall be monitored to validate the accuracy and comparability of the results to those of the central laboratory.

## 5.7 Post-examination procedure

ISO 15189:2003, 5.7, and the following apply.

The organization shall handle and dispose safely of all samples, reagents and kits according to local, regional or national regulations.

## 5.8 Reporting of results

**5.8.1** ISO 15189:2003, 5.8, and the following subclauses 5.8.2 to 5.8.4 apply.

**5.8.2** POCT results shall be reported with necessary detail.

**5.8.3** POCT testing results shall be permanently recorded in the patient's medical record.

The name of the person performing the test should be recorded.

POCT results should be entered where applicable in the hospital and/or laboratory information system.

**5.8.4** The record shall distinguish between POCT results and those from the central laboratory or its satellites.