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Point-of-care testing (POCT) — Requirements for quality and competence (ISO 22870:2016)

National foreword

This British Standard is the UK implementation of EN ISO 22870:2016. It supersedes BS EN ISO 22870:2006 which is withdrawn.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 secretary.

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Point-of-care testing (POCT) - Requirements for quality and competence (ISO 22870:2016)

Examens de biologie médicale délocalisée (EBMD) - Exigences concernant la qualité et la compétence (ISO 22870:2016)

Patientennahe Untersuchungen (point-of-care testing, POCT) - Anforderungen an Qualität und Kompetenz (ISO 22870:2016)

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European foreword

This document (EN ISO 22870:2016) 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of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by November 2019.

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This document supersedes EN ISO 22870:2006.

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The text of ISO 22870:2016 has been approved by CEN as EN ISO 22870:2016 without any modification.

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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 22870:2006), of which it constitutes a minor revision.

The changes compared to the previous edition are as follows:

— inclusion of cross-references to the applicable clauses in ISO 15189:2012.

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, installation and maintenance of equipment,

— maintenance of consumable supplies and reagents,

— training, certification and recertification of POCT system operators, and

— quality control and quality assurance.

Bodies that recognize the competence of POCT facilities may use this document 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 document gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. This document 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 document can be applicable.

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

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 15189:2012, *Medical laboratories —Requirements for quality and competence*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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 15189:2012, 4.1.1.2, 4.1.1.3 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 15189:2012, 4.1.2.2, and the following subclauses 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 15189:2012, 4.1.1.1 applies.

4.2 Quality management system

4.2.1 ISO 15189:2012, 4.1.2.3, 4.1.2.4, 4.1.2.6 and the following 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 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 document,

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

e) records required by this document.

NOTE Within this document, 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 the organization and type of activities,

— the complexity of processes and their interactions, and

— 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 15189:2012, 4.1.2.3, 4.1.2.4 and the following apply.

The laboratory director or suitably qualified designate shall ensure that

a) POCT quality objectives are established and 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 ISO 15189:2012, 4.2.2 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 interactions between the processes of the quality management system.

4.3 Document control

ISO 15189:2012, 4.3 applies.

4.4 Service agreements

ISO 15189:2012, 4.4 applies.

4.5 Examination by referral laboratories

This does not apply to this document.

4.6 External services and supplies

ISO 15189:2012, 4.6 applies.

4.7 Advisory services

ISO 15189:2012, 4.7 applies.

4.8 Resolution of complaints

ISO 15189:2012, 4.8 applies.

4.9 Identification and control of nonconformities

4.9.1 ISO 15189:2012, 4.9 and the following apply.

4.9.2 The organization shall ensure that POCT that 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 and acceptance;

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/customer 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 15189:2012, 4.10 and the following 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 15189:2012, 4.11 and the following 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 15189:2012, 4.12, 4.14.6, 4.14.7 and the following apply.

4.12.2 A quality assurance programme shall periodically review the relative benefits of POCT, 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 15189:2012, 4.13 and the following 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 15189:2012, 4.14.1, 4.14.5 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, if approved, shall be incorporated into the POCT policy, processes and procedures.

4.15 Management review

4.15.1 ISO 15189:2012, 4.15 and the following apply.

4.15.2 The laboratory director, or a designated suitably 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

— the identification of opportunities for improvement.

NOTE See Reference [7].

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 15189:2012, 4.1.1.4, 5.1 and the following 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 The laboratory director, or other 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 15189:2012, 4.1.2.5 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.

5.1.4 ISO 15189:2012, 5.1.2, 5.1.6, 5.1.8 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 (or certification) and of retraining and re-attestation (or recertification) shall be retained.

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

   The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system (chemistry and detector) and appreciation of the pre-analytical aspects of the analysis, including

   — a 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 and maintenance of the results.

d) Retraining/recertification 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 15189:2012, 5.2 and the following apply.

5.2.2 The premises, in which POCT is undertaken and the equipment are 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 good working conditions as well as conformity to POCT requirements and the device manufacturer's recommendations.

5.3 Equipment

5.3.1 ISO 15189:2012, 5.3, 5.9.2, 5.10 and the following 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/supplier, date purchased and service history, including dates out-of-service.

b) Reagents, kits and equipment shall be verified 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 15189:2012, 5.4.1, 5.4.4.2 and the following 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 15189:2012, 5.5 and the following apply.

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

5.5.3 The manufacturer's recommendations regarding minimum quality control of a specific instrument system may be accepted, following documented 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 15189:2012, 5.6 and the following 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 Where available, participation in an external quality assessment (EQA) shall be required (see ISO/IEC 17043). In the absence of an EQA scheme, the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of the test within the laboratory.

5.6.5 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.

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

a) Trueness and precision 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 designated person.

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

5.7.1 ISO 15189:2012, 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.

5.7.2 Where repeat testing is clinically indicated, the original sample shall be used where available. Otherwise, a new sample shall be obtained.

5.8 Reporting of results

5.8.1 ISO 15189:2012, 5.8, 5.9 and the following apply.

5.8.2 POCT results shall be reported with necessary details.

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

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

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

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