

## **Amendments to 15189: Annex D (Normative) – Point-of-Care Testing (POCT)**

### **D.1 General**

- D.1.1 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 total quality systems and accreditation of these laboratories is gaining more and more interest. Harmonization of quality systems and of accreditation has been recognized particularly in the European Union.
- D.1.2 Advances in technology have resulted in compact, easy-to-use instruments that make it possible to carry out some testing at, or close to, the location of the patient. Point-of-care/near-patient testing has benefit to the patient and health-care facilities. Benefit lies in speed of generation of the result and convenience. Rarely, demonstrated benefits include improved health outcome for the patient and cost-savings for the facility.
- D.1.3 Risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that provides for:
- 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 re-certification of POCT system operators
  - Quality control and quality assurance
- D.1.4 Bodies that recognise the competence of POCT facilities may use this International Standard as the basis for their activities. If a health care 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.
- D.1.5 Each country or region may have specific regulations or requirements for POCT which apply.
- D.1.6 This annex to ISO 15189 presents matters specific to point-of-care testing which are not included in the main document. The requirements of this standard apply when POCT is carried out in a hospital or clinic and may be applied by a health care organisation 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 the standard may apply.

**D.2 Normative references**

Those given in ISO 15189 apply.

**D.3 Terms and definitions**

**point of care testing**

near patient testing

alternative site testing

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

**D.4 Management requirements**

**D.4.1 Organisation and management**

**D.4.1.1** *[EN ISO 15189 subclause 4.1.1 applies]*

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;
- d) records needed to provide evidence that the realization processes and resulting services 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 health-care organization.

**D.4.1.2** *[EN ISO 15189 subclause 4.1.2 applies]*

A health professional grouping, which includes laboratory representation (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, financial implications, technical feasibility, and the ability of the organization to fulfil the need.

**D.4.1.3** *[EN ISO 15189 subclause 4.1.5 applies]*

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 health care provider and patient requirements,
- b) establishing the quality policy.
- c) ensuring the quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

**D.4.2 Quality management system**

*[EN ISO 15189 subclause 4.2 applies]*

**D.4.2.1** The management of laboratory services shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

**D.4.2.1.1** 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, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

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

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

- D.4.2.1.2 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.

#### D.4.2.2 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 controls of its processes, and
- e) records required by this standard.

NOTE 1 Where the term “documented procedure” appears within this Annex this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can 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.

NOTE 3 The documentation can be in any form or type of medium.

#### D.4.2.3 Quality manual

*[EN ISO 15189 subclause 4.2.4 applies]*

D.4.2.3.1 The organisation 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.

D.4.2.3.2 The Laboratory Director or suitably qualified designate shall ensure that POCT quality objectives are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy.

D.4.2.3.3 The Laboratory Director or designate shall ensure that

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

### **D.4.3 Document control**

*[EN ISO 15189 subclause 4.3 applies]*

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

### **D.4.4 Review of contracts**

*[EN ISO 15189 subclause 4.4 applies]*

D.4.4.1 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.

- D.4.4.2 The management group shall ensure that responsibilities and authorities are defined and communicated within the organisation.
- D.4.4.3 The management group shall assist in evaluating and selecting POCT equipment and systems.
- D.4.4.4 The management group shall consider all proposals to introduce any product, device or system for POCT.

**D.4.5 Examination by referral laboratories**  
This does not apply to this Annex

**D.4.6 External services and supplies**  
This does not apply to this Annex

**D.4.7 Advisory services**  
*[EN ISO 15189 subclause 4.7 applies]*

**D.4.8 Resolution of complaints**  
*[EN ISO 15189 subclause 4.8 applies]*

**D.4.9 Identification and control of nonconformities**  
*[EN ISO 15189 subclause 4.9 applies]*

- D.4.9.1 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
- 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.

D.4.9.2 The organization shall determine, collect and analyse appropriate data to and 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 and from other relevant sources.

D.4.9.3 The analysis of data shall provide information relating to

- a) health care 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.

#### **D.4.10 Corrective action**

*[EN ISO 15189 subclause 4.10 applies]*

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.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including health care 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.

#### **D.4.11 Preventive action**

*[EN ISO 15189 subclause 4.11 applies]*

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.

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.

#### **D.4.12 Continual improvement**

*[EN ISO 15189 subclause 4.12 applies]*

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

#### **D.4.13 Quality and technical records**

*[EN ISO 15189 subclause 4.13 applies]*

Records shall be established and maintained to provide evidence of conformity to requirements and of the 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.

#### **D.4.14 Internal audits**

*[EN ISO 15189 subclause 4.14 applies]*

- 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.

**D.4.15 Management Review**

*[EN ISO 15189 subclause 4.15 applies]*

D.4.15.1 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.

The input to management review shall include information on

- a) results of audits,
- b) health care 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.

D.4.15.2 The Laboratory Director or designated suitably qualified person, shall make changes to policy, processes, or procedures resulting from the management review.

**D.5 Technical Requirements**

**D.5.1 Personnel**

*[EN ISO 15189 subclause 5.1 applies]*

D.5.1.1 The organization shall determine and provide the resources needed

- a) to implement and maintain the POCT quality management system and continually improve its effectiveness, and

- b) ensuring that all personnel from all services, programmes, and departments, who perform POCT have the required training and proficiency
- c) to enhance health care provider/patient/client satisfaction by meeting customer requirements.

D.5.1.2 *[EN ISO 15189 subclause 5.1.3 applies]*

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

- a) evaluating and selecting all POCT equipment reagents and systems including quality control material
- b) establishing documented quality policy and protocols for the performance of all POCT and associated quality control and assurance.

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

D.5.1.2 *[EN ISO 15189 subclause 5.1.4 applies]*

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, and
- c) ensuring the promotion of awareness of POCT requirements throughout the organization.
- d) Ensuring that clients understand the limitations of POCT

D.5.1.3 *[EN ISO 15189 subclause 5.1.7 applies]*

The POCT management group shall ensure that appropriate communication processes are established within the organization. This shall include the effectiveness of the quality management system.

- a) The management group shall allocate responsibilities and designate staff undertaking POCT.

- b) The allocation of duties and responsibilities of different groups of staff shall be defined in the operating procedures.

**D.5.1.4** [EN ISO 15189 subclause 5.1.4 applies]

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

**D.5.1.5** [EN ISO 15189 subclauses 5.1.9, 5.1.10, 5.1.11 and 5.1.12 apply]

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

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

- b) Only designated health care professionals who have completed the training and demonstrated competence shall carry out POCT. Records of training/attestation and of retraining and re-attestation shall be kept.
- 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, appreciation of the pre-analytical aspects of the analysis including sample procurement, 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 for certified staff shall be established.

**D.5.2 Accommodation and environmental conditions**

[EN ISO 15189 subclause 5.2 applies]

- D.5.2.1** The premises in which POCT is undertaken and the equipment used shall conform to appropriate national legislation or to regional or local requirements.

D.5.2.2 The organization shall determine and manage the work environment needed to achieve conformity to POCT requirements.

### **D.5.3 Laboratory equipment**

*[EN ISO 15189 subclause 5.3 applies]*

D.5.3.1 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. Reagents, kits and equipment performance shall be verified and results validated prior to routine use.
- b) There shall be written procedures for the maintenance and operation of POCT equipment.
- c) 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.
- d) A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed.
- e) POCT operator performance shall be monitored as part of the quality assurance programme.
- f) The Laboratory Director, or designated suitable qualified person, shall appoint a person with appropriate training and experience, as quality manager responsible for POCT quality including review of the requirements related to POCT.

### **D.5.4 Pre-examination procedures**

*[EN ISO 15189 subclause 5.4 applies]*

D.5.4.1 The organisation shall identify the product by suitable means and ensure its traceability to the primary sample and the patient/client.

Note: The product of POCT is the value of the measurand as determined by the POCT device in use.

D.5.4.2 The organization shall exercise care with samples obtained for POCT from its patients or clients while such samples are under the organization's control or 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 health care professional and records maintained.

**D.5.5 Examination procedures**

*[EN ISO 15189 subclause 5.5 applies]*

D.5.5.1 Procedure manuals for each POCT instrument/system shall be made available to all users.

D.5.5.2 Manufacturer's recommendations regarding minimum quality control of a specific instrument system may be accepted following review.

D.5.5.3 Instrument-generated quality control shall be acceptable if regulatory authorities have accepted it as valid.

D.5.5.4 Periodic and episodic maintenance of equipment shall be monitored and documented.

**D.5.6 Assuring the quality of examination procedures**

*[EN ISO 15189 subclause 5.6 applies]*

D.5.6.1 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.

D.5.6.2 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.

D.5.6.3 *[EN ISO 15189 subclause 5.6.4 applies]*

- D.5.6.4 Where available, participation in an external quality assessment (EQA) shall be required. In the absence of an EQA scheme, the Laboratory Director, or designated person, should establish an internal assessment scheme involving the circulation of samples or replication of the test within the laboratory.
- D.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.
- D.5.6.6 *[EN ISO 15189 subclause 5.6.6 applies]*
- D.5.6.7 *[EN ISO 15189 subclause 5.6.7 applies]*

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) Corrective action to be taken for out-of-control results shall be specified.
- d) Action taken on non-conforming results shall be documented.
- e) QC results shall be recorded for regular review by the quality manager or designate.
- f) Process control for consumable supplies and reagents shall be documented and monitored.
- g) In-patient self-testing, if allowed using POCT devices, shall be monitored to validate the accuracy and comparability of the results to those of the central laboratory.

#### **D.5.7 Post-examination procedure**

*[EN ISO 15189 subclause 5.7 applies]*

- D.5.7.1 The organisation shall handle and dispose safely of all samples, reagents and kits according to local, regional or national regulations.

**D.5.8 Reporting of results**

*[EN ISO 15189 subclause 5.8 applies]*

- D.5.8.1 POCT results shall be reported with a minimum of necessary detail.
- D.5.8.2 POCT testing results and their traceability shall be recorded permanently in the patient's medical record and the name of the person performing the test entered to the laboratory record.
- D.5.8.3 The record shall distinguish between POCT results and those from the central laboratory or its satellites.
- D.5.8.4 POCT results shall be entered in the hospital and/or laboratory information system. The source of the result shall be indicated.

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