



Additional Standards for Point-of-Care Testing (POCT) facilities

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1 Introduction

These Standards for Point-of-Care testing are based upon the requirements of the International Standard, ISO 22870:2006 – Point-of-care Testing (POCT) – Requirements for quality and competence. The requirements of the International Standard are intended ‘to apply when POCT is carried out in a hospital, clinic or by a healthcare organisation providing ambulatory care’ and makes it clear that they are not intended for application to patient self testing in a home or community setting. Readers of these Standards are required to purchase and read the International Standard, ISO 22870:2006 in preparing for accreditation of their facilities.

As ISO 22870:2006 gives ISO 15189:2003 Medical laboratories – Particular requirements for quality and competence as a normative reference, the requirement is that in order to fulfil the requirements for POCT, the organisation wishing to have its POCT facilities accredited shall also meet the requirements of the current edition of ISO 15189.

As the CPA (UK) Ltd ‘Standards for the Medical Laboratory’ incorporate the requirements of ISO 15189:2007; it follows that for any POCT to be in conformity with these Additional Standards it shall also meet the requirements of CPA’s Standards for the Medical Laboratory.

2 Scope and purpose

These Additional Standards are intended for use by those laboratories that wish to include POCT within their accreditation scope. They specify additional requirements for the quality and competence of Point-of-Care Testing.

3 References

The following references are the source material used in the writing of these standards.

ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence

ISO 22870:2006 Point-of-care Testing (POCT) – Requirements for quality and competence

4 Terms and definitions

For purposes of this document the following terms and definitions apply. If a term and its definition are based on a source material reference (see 3), this is acknowledged in square brackets following the definition.

4.1 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 [ISO 22870:2006]

4.2 healthcare professional grouping

A high level group responsible for governance and risk issues

4.3 POCT Management group

A group responsible for operational management of POCT which should have representation, where appropriate, from the laboratory, administration, and clinical programmes including nursing to advise on the provision of POCT.

5 The Standards

These standards are additional to CPA's Standards for the Medical Laboratory and define the requirements for the organisation and management of POCT. They should be used in conjunction with the CPA Standards for the Medical Laboratory 2009.

A ORGANISATION AND QUALITY MANAGEMENT SYSTEM

CPA Standards for the Medical Laboratory section A and the following apply:

A1 Organisation and management

A 1.6 (POCT) Laboratory management shall ensure that POCT is organized and operates in conformity with these Additional Standards and the CPA (UK) Ltd 'Standards for the Medical Laboratory'

A 1.7 (POCT) Top management of the organisation within which POCT is provided, shall ensure that there are procedures in place to monitor the quality of the service.

A 1.8 (POCT) The organisation within which POCT is provided, shall ensure that there is a healthcare professional grouping (e.g. a governance group) responsible to its top management for defining the scope of POCT. The scope of POCT shall take into account:

- a) the clinical need
- b) its financial implications
- c) technical feasibility and
- d) the resources available.

A 1.9 (POCT) The laboratory director or designee, in conjunction with organisation management, shall appoint a multidisciplinary **POCT management group** to advise on the management and provision of POCT. The group shall ensure that:

- a) the responsibilities, authority and interrelationships of all personnel involved in POCT are specified and communicated within the organization
- b) staff performing POCT receive appropriate training, supervision and competence testing.
- c) all proposals to introduce any product, device, or system for POCT are evaluated for their clinical effectiveness and cost efficiency the selection of POCT devices and systems includes their practicability and the comparability of their results with those obtained in the laboratory.

- d) the selection of POCT devices and systems includes their practicability and the comparability of their results with those obtained in the laboratory.
- e) the reports of the POCT quality assurance programme(s) are reviewed by the group and advice on improvement is provided and implemented.

A2 Needs and requirements of users

A 2.5 (POCT) Where the laboratory provides POCT to another healthcare organization, (a separate (legal) entity), and uses resources, including staff, provided by that organisation, the ultimate responsibility for the examination results/reports shall be defined in a formal agreement (see A 2.4).

A4 Quality management system

A 4.4 (POCT) Laboratory management shall establish a quality management system for POCT.

A7 Quality manager

A 7.4 (POCT) Laboratory management shall appoint an individual with defined responsibility for ensuring that the POCT quality management system is implemented and maintained.

A8 Document control

A 8.4 (POCT) Manuals and instructions for use of POCT shall be subject to document control and readily available to users.

A11 Management review

A 11.4 (POCT) Laboratory management shall conduct an annual review of POCT. The review shall include:

- a) the clinical need for POCT
- b) the clinical effectiveness of POCT
- c) the cost effectiveness of POCT

B PERSONNEL

CPA Standards for the Medical Laboratory section B and the following apply:

B1 Laboratory Director

B 1.6 (POCT) The laboratory director or designee shall appoint a multidisciplinary POCT management group (A 1.9)

B 1.7 (POCT) The laboratory director or designee shall implement a periodic management review that includes an ongoing evaluation of the clinical effectiveness and

cost efficiency of POCT activities provided and identifies opportunities for improvement.

B2 Staffing

B 2.4 (POCT) The POCT management group shall ensure that there are appropriate numbers of staff to implement the POCT Quality Management system and provide training to personnel performing POCT.

B6 Staff records

B 6.3 (POCT) The POCT management group shall designate staff performing POCT and maintain a record of their competency.

B9 Staff training and education

B 9.7 (POCT) The POCT training programme shall, as appropriate, include the following:

- a) the context and clinical utility of POCT
- b) the theoretical aspects of the measuring system
- c) sample collection and handling
- d) reagent storage
- e) quality control
- f) infection control
- g) limitations of the measuring systems
- h) response to results outside predefined limits
- i) documentation and reporting of results

B 9.8 (POCT) Competency to perform POCT tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary. Records of competency assessments shall be kept (B6).

C PREMISES AND ENVIRONMENT

CPA Standards for the Medical Laboratory section C and the following apply:

C1 Premises and environment

C 1.5 (POCT) The healthcare organization shall ensure the premises within which the POCT is performed, provide a working environment in which staff can undertake required functions in accordance with national legislation and guidelines.

D EQUIPMENT, INFORMATION SYSTEMS AND MATERIALS

CPA Standards for the Medical Laboratory section D apply

E PRE EXAMINATION PROCESS

CPA Standards for the Medical Laboratory section E and the following apply

E3 Specimen collection and handling

E 3.4 (POCT) Where a POCT sample may be unsuitable for analysis there shall be procedures to report this to the POCT user and records shall be maintained.

F EXAMINATION PROCESS

CPA Standards for the Medical Laboratory section F and the following apply

F3 Ensuring the quality of examinations

F 3.6 (POCT) Where results are obtained by POCT and the laboratory, the comparability between the methods used shall be determined and made available to users upon request.

G THE POST EXAMINATION PHASE

CPA Standards for the Medical Laboratory section G and the following apply

G2 The report

G 2.6 (POCT) Results of POCT shall be recorded in the patient's medical record and be distinguishable from results provided by the laboratory. A record shall be kept of the person performing the POCT.

H EVALUATION AND QUALITY ASSURANCE

CPA Standards for the Medical Laboratory section H and the following apply

H5 External quality assessment

H 5.5 (POCT) There shall be participation in external quality assessment schemes. Where such a scheme is not available an alternative internal quality assessment scheme shall be implemented [NOTE]

NOTE 1.

This may involve circulation of a sample to multiple POCT analysers and comparison of results.