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

Examens de biologie médicale délocalisée (EBMD) — Exigences concernant la qualité et la compétence

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Contents

Page

Foreword

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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;