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Guidance for the Assessment of Laboratories against EN ISO 15189 and EN ISO 22870 Point-of-Care Testing (POCT)

PURPOSE

This guidance document is intended for accreditation bodies (AB) that assess point-of-care testing (POCT) in the field of laboratory medicine and for medical laboratories (conformity assessment body (CAB)), which are responsible for point-of-care testing.
The scope of this document extends to the following:
a) Medical laboratories including both private institutions and government entities who provide POCT within the boundaries of their own organisation
b) Medical laboratories that provide POCT to external organisations. Results from POCT remain under overall responsibility of the medical laboratory.

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The publication has been written by the EA Laboratory Committee working group on Healthcare – Laboratory Medicine.

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The text may be translated into other languages as required. The English language version remains the definitive version.

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1. INTRODUCTION

This guidance document is intended for accreditation bodies (AB) that assess point-of-care testing (POCT) in the medical field and for medical laboratories, which are responsible for point-of-care testing. The guidance document describes the specific criteria, which an AB should take into account when accrediting POCT. The guidance document is issued by the EA Laboratory Committee and it is written by the Health Care Sector Laboratory Medicine working group.

The scope of POCT continues to develop both in the technologies available and the delivery points. Hospitals, private clinics and community based healthcare industries such as pharmaceutical outlets now offer POCT in some respect and it is an increasing concern that this testing is performed with little control or direction. In order to meet the needs of patients and ensure clinical governance, accreditation of POCT providers should be encouraged and promoted by ABs.

2. DEFINITIONS

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

IQA – Internal Quality Assurance - processes established to ensure (and improve) quality of service

IQC – Internal Quality Control – a measure of precision or how well the measurement system reproduces the same result over time and under varying operating conditions. IQC may also provide a comment on accuracy depending on the IQC material available.

EQA - External Quality Assurance – samples distributed by an external provider with known and/or undisclosed content. Results are statistically analysed to present performance in the context of similar/ identical methodologies and / or variance from a known value.

POCT (Point-of-care 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)

POCT provider, organisation providing POCT

POCT head office, legal registered office of POCT provider

POCT customer, patient, health care organisation which contracts POCT provider's services

Medical laboratory, laboratory for examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service, covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation (definition taken from ISO 15189). In the context of this guide, the medical laboratory also provides and maintains overall responsibility for POCT and the results.

Site, a place, where POCT examinations are performed. This can be defined as a ward or clinic e.g. intensive care unit or the location of the clinician e.g. a community physician

Multi-site accreditation, Accreditation of a laboratory (CAB) under a single legal entity for activities carried out at more than one location

Legal entity, an association, corporation, partnership, proprietorship, trust, or an individual, that has legal standing in the eyes of law. A legal entity has legal capacity to enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.

3. ACCREDITATION CRITERIA

The accreditation criteria for POCT are:

- Standard EN ISO 15189, Medical laboratories. Requirements for quality and competence (1) in conjunction with
- Standard EN ISO 22870, Point-of-care testing (POCT). Requirements for quality and competence (2) (References in ISO 22870:2006 are to the version ISO 15189:2007)

4. SCOPE OF STANDARDS

The standard EN ISO 22870 applies to POCT when carried out in a hospital, clinic and also by a healthcare organization providing ambulatory care. It is not intended for patient self-testing in a home or community setting. EN ISO 15189 and EN ISO 22870 are intended for medical laboratories. Therefore the limits to accreditation are defined as only medical laboratories can be accredited according to EN ISO 15189 and EN ISO 22870, as they provide and maintain overall responsibility for POCT. The provision of POCT could be within a clinic/hospital by clinical (hospital) or laboratory personnel.

5. MULTISITE ACCREDITATION

5.1 Multisite organisation

A multisite organisation operates in various sites with one or more sites geographically separated from the head office (Medical laboratory). If the POCT provider operates in different sites, it must meet multisite accreditation criteria.

5.2 Basic requirements for multisite accreditation

When assessing a multisite POCT provider the most relevant requirements are:

- personnel
  - common competence criteria
  - centralized management of resources and competence
  - centralized training and education

- management system
  - common management system, which is implemented in all locations
  - common policies and procedures, common documentation
  - centralized quality assurance
  - implementation of any required corrective action across all sites (as relevant)

- monitoring of the effectiveness of the management system
  - centralized planning for monitoring the effectiveness of a management system
  - audit program covering all locations, comprehensive analysis of audit outcomes

  - centralized following of customer feedback, complaints and non-conformities across all sites
- records available in head office

The initial assessment should cover all sites where key activities are performed. In POCT key activities are interpreted (based on ISO/IEC 17011 definition of key activities) as follows: planning and managing the operation of POCT; evaluation of clinical needs through contract review, defining responsibilities, defining competence of personnel and key qualifications, selecting examination methods and equipment, establishing criteria for quality assurance, controlling records, reviewing results and monitoring the effectiveness of the POCT operation.

5.3 Sampling in multisite POCT accreditation

The AB should have a clear policy for identifying and assessing all key sites of POCT and all sites where POC tests are performed during an accreditation cycle. A plan should be documented by the AB to plan appropriate assessment activities for all sites over the accreditation cycle.

The initial assessment should enable a statement on the overall conformity to standards EN ISO 15189 and EN ISO 22870 for all POCT sites, by selecting a representative sample of the examination procedures and devices in use at each site. The AB can use different tools in assessment activities such as an assessment visit, reviews of records, interview of personnel. The outcome of this assessment together with the assessment of the medical laboratory taking into account all the clauses of both standards can then be used to determine the overall conformity to standards EN ISO 15189 and EN ISO 22870. The AB should define criteria to select representative examples of POCT in different sites. The selecting criteria should ensure that all measurement principles and critical variables in the equipment and examination procedures used plus any key differences in the type of sites are assessed at the initial assessment. The focus should be on those POCT sites and positions, where POCT results are critical to patient care, for example accident and emergency rooms and operating theatres. The POCT provider should set up a list of sites, which it has defined to be critical. After the grant of accreditation, all sites and variables in POCT delivery, including any differences in IT and reporting, must be assessed over a single accreditation cycle.

6. ORGANISATION/LEGAL ENTITY (EN ISO 15189:1, 4.1; EN ISO 22870:1, 4.1)

The POCT provider might be the same legal entity (organization) as its customers (POCT users), but it can also be another legal entity. The AB accredits the legal entity, which takes responsibility for delivery of POCT, for POCT results and for ensuring conformity to EN ISO 15189 and EN ISO 22870. This should be clearly defined. If the POCT equipment is operated by personnel employed by another legal entity, there should be a clear contractual arrangement for the use of these personnel and the competence requirements. This can be considered as ‘contracting in’ the appropriate resources. This needs to be managed in accordance with the requirements of EN ISO 15189/22870 to ensure that it is clearly evident, that the POCT results are issued under the control and responsibility of the accredited body. Any hard copy reports must refer to the accredited body, who is responsible for the results.

POCT providers must be assessed to EN ISO 15189 in conjunction with EN ISO 22870 which has some additional requirements. For example:

- The POCT provider should have a governing body (ultimate responsibility for ensuring appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization), a health professional grouping (medical counselling) and a multidisciplinary POCT management group (operation of POCT).

- Evaluation of the impact of clinical needs, financial implications and technical feasibility, when defining the scope of POCT.

- The formation of a health professional group to define the scope of POCT, which should be offered to customers.

The assessment should cover the roles and operation of these bodies and groups.

7. ROLES AND RESPONSIBILITIES IN POCT

7.1 Quality management system (QMS) (EN ISO 15189:4.2; EN ISO 22870:4.2)

The POCT provider (accredited body) should have a quality management system that fulfils the requirements of standards EN ISO 15189 and EN ISO 22870. The sites under the POCT provider's accreditation should follow this quality management system. The POCT provider should ensure that staff employed by another legal entity is not exposed to requirements from that legal entity, which are contradictory to the requirements in the POCT QMS.

The POCT provider should have a system to monitor the effectiveness and correct operation of POCT including internal audits, handling of non-conformities and customer/co-worker feedback. All information regarding the operation of POCT should be analysed by the POCT provider and necessary actions taken. The role of the multi-disciplinary POCT management group in analysing the information should be defined.

7.2 Document control, record control (EN ISO 15189:4.3, 4.13; EN ISO 22870:4.3, 4.13, 5.6, 5.8)

All documents referred to and required at each site need to be included and considered in the QMS of the accredited POCT provider with respect to document control. If the accredited POCT provider is offering POCT in the facilities of an another organization and the staff must comply with in house policies, then the accredited POCT provider should show that they have considered and reviewed these documents (as relevant external documents) within their document control process. Where required these documents should be supplemented by the POCT provider. Contractual arrangements with customers should define responsibilities where required for the retention of records.

The POCT provider is responsible for all documents within its quality management system and all documents must be issued by competent responsible personnel. All POCT-documents, like all other laboratory documents, must be included in the normal and periodic revision process of the quality management system of the POCT provider.

The POCT provider is responsible for the retention and control of all relevant records. The record control should follow the definitions/requirements set up in cooperation with the customer. All POCT- and laboratory-results/records must be included in patient documentation of the hospital/clinic in electronic or paper form. There must be a clear distinction between POCT- and laboratory results/records. Contractual arrangements should include definitive responsibilities with respect to retention of records. The results/records of quality assurance

controls must be provided to the relevant personnel within the POCT provider. The POCT provider must be able to trace the name of the person who generated the results, verify the ongoing status of the POCT-equipment, analyse the results and determine the expected results of the quality control at the point when the results were generated.

7.3 Competence of personnel (EN ISO 15189:5.1, 4.5; EN ISO 22870:5.1, 4.5)

Only trained and competent personnel should carry out POCT. The multidisciplinary POCT management group should allocate responsibilities and allocate staff to undertake POCT.

The POCT provider is responsible for the provision of management via an assigned skilled staff member/team, in order to ensure that all POCT is performed according to EN ISO 15189 and EN ISO 22870, with the same assurance as would be expected from the medical laboratory. These services may include, but not be limited to, implementation of a quality management system, identification of suitable POCT equipment installation and maintenance, training of personnel, quality control (internal and external), troubleshooting, document control, record control, customer satisfaction.

POCT personnel should have training delivered by qualified personnel, authorized by the POCT provider. The training should at least include:

- theoretical basis of the examination,
- the technology used,
- the nature of biological material,
- material/sample collection,
- transportation and disposal of specimens,
- quality control requirements,
- recording and transfer of the results,
- interpretation of the results (clinical relevance and appropriate actions with respect to the result, especially in cases of non-valid results and non-valid quality control),
- sources of errors,
- basic maintenance and cleaning of equipment,
- health and safety issues

The competence of personnel should be evaluated, reassessed, monitored and relevant records should be maintained. These records may include QA results and non-conformities information. Retraining should occur when necessary.

7.4 Equipment (EN ISO 15189:5.3, 5.9, 5.10; EN ISO 22870:5.3)

POCT providers should maintain records of all POCT equipment including types, locations and date put into service. When equipment is moved between areas, there should be comprehensive decontamination measures, to avoid accidental cross-contamination and the equipment should be checked to the degree necessary to demonstrate that performance has not been affected. The POCT provider is responsible for commissioning, installing and verifying new equipment and for implementing a preventive maintenance plan. If the POCT provider is taking responsibility for POCT, which is already undertaken in a health care unit, it should ensure that the equipment and methods are working correctly and give correct results. Correlation studies between test results obtained by the medical laboratory and POCT are mandatory and the POCT provider should establish acceptance criteria based on clinical need. Whenever equipment is found to be defective or malfunctioning, it should be taken out of service and the POCT provider should be informed immediately. Troubleshooting procedures should be available. Only authorized personnel should operate and maintain the equipment.

Maintenance records should be retained with all the relevant information. Operator's manuals and other working instructions should be part of the quality management system and readily available to users.

Contractual arrangements should ensure that:

- the facilities and equipment where POCT is provided are appropriate for the testing provided
- responsibilities for adequate supplies of consumables and reagents are defined
- responsibilities for calibration, maintenance and service are defined
- familiarization of POCT personnel with equipment is implemented
- POCT equipment should be connected to the laboratory information system (e.g. within a hospital network), where applicable.

Equipment should be suitably calibrated by authorized personnel. If a metrological calibration is not possible, the confidence in the results should be provided in other means according to requirements of EN ISO 15189.

7.5 Accommodation and environmental conditions (EN ISO 15189:5.2 ; EN ISO 22870:5.2)

The POCT provider should determine and manage the work environment in order to establish good working conditions, patient privacy and safety, as well as, conformity to POCT requirements and the device manufacturers' recommendations. Depending on the type of POCT being carried out, access to the testing environment should be restricted to authorized personnel.

Work areas should be clean and tidy. The space allocated should be commensurate with the volume of analyses and the overall needs of the testing offered (including facilities for staff, patients and storage). National legislation, regulations and guidelines, could apply.

Where required the POCT provider should establish a programme that monitors environmental conditions. Special attention should be paid to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration, as appropriate to the technical activities concerned.

7.6 Examination methods (EN ISO 15189:5.5; EN ISO 22870:5.5)

The method selection of a POCT provider is based on the needs of POCT customers (users, health care personnel). The performance characteristics of POCT methods should be considered, when selecting methods to be used for POCT. POCT methods are used to give first-hand (screening) information and they are not intended to be used for a final diagnosis without confirmation, however they do contribute to the clinical evaluation.

As the POCT methods are mainly closed systems, validation process of POCT devices/ equipment is provided by its manufacturers. However, it is the responsibility of the provider to review the validation, done by the manufacturer, as part of establishing the fitness for purpose of the method in the POCT context, and then to determine if any further validation is required. Verification of POCT method is the responsibility of POCT provider. Knowledge in the method/technique within the POCT context together with competence in verification procedures and awareness of ISO 15189 requirements are required in order to effectively verify POCT methods/devices. Selection of the verification criteria depends on the specific POCT method. The accuracy/precision of POCT results should be determined with reference

to external quality assurance results (when available) and comparisons with medical laboratory results of POCT provider.

7.7 Quality assurance (EN ISO 15189:5.6; EN ISO 22870:5.6)

The performance of POCT methods is primarily monitored according to manufacturer's recommendations (according to IVD EC medical devices directive). In those cases where manufacturers do not provide any control or calibration material, the POCT provider should establish other IQC/EQA procedures to review the accuracy/precision of POCT results and the functionality of POCT devices. IQC/EQA plans should be based on recommendations of medical societies, technical literature and experience of POCT provider. Standards EN ISO 15189 and EN ISO 22870 specify requirements for IQC and EQA. The POCT provider has a responsibility for the overall quality assurance strategy and to run the appropriate IQC and EQA program for POCT. Together with the multidisciplinary management group the POCT provider has the responsibility to review/analyse the IQC/EQA results. The IQC/EQA data should also be reviewed with regards to consistency between POCT sites. Included within IQC is the transfer of records IQC/EQA data from POCT devices to the medical laboratory, which then enable effective control by the provider of POCT devices and also monitors the competence of POCT personnel.

7.8 Pre-examination (EN ISO 15189:5.4; EN ISO 22870:5.4)

The POCT provider has a responsibility to define pre-examination procedures. Pre-examination procedures should be described in the POCT provider's quality system, in accordance with requirements of EN ISO 15189. The POCT provider should ensure that these procedures are established and implemented by personnel using POCT equipment. The requirements and specific instructions for proper sample collection and identifying and handling primary samples together with any derived samples should be documented. Clear identification of the patient and traceability to the primary samples should be evident. The requirements for storage and transport of samples usually do not apply since primary samples are usually tested immediately by POCT devices. The requirements for pre-testing, preparation and/or condition of the patient before taking primary samples are however important and documented instructions or information regarding this should be made available by the provider. A procedure describing how to complete and submit requests for POCT should be defined.

7.9 Post-examination, reporting results (EN ISO 15189: 5.7, 5.8, 5.9, 5.10; EN ISO 22870:5.7, 5.8)

The POCT provider is responsible for all POCT results. The patients' clinician (MD) is responsible for the manner in which these results are used. The POCT provider must ensure that appropriate clinical advisory services are provided to enable the correct interpretation of the results.

Consideration must be made to the fact that many POCT results are used directly/ immediately for the treatment of the patient. Therefore the POCT provider reviews and accepts results after issue and interprets them, when necessary, or places them in the context of the treatment of the patient. A software solution and/or an electronic connection to the POCT provider's medical laboratory are desirable, but not essential. However reports are issued (hard copy or electronic), all processes should be defined, validated, and documented.

8. COMPETENCE OF AN ASSESSMENT TEAM

In addition to medical laboratory experience, the competence of an assessment team (technical assessors/experts) should include theoretical and practical knowledge of POCT methods, equipment, quality assurance procedures and both pre- and post-examination procedures. The assessors should also have experience of POCT and managing the whole POCT system.

9. PRESENTATION OF A SCOPE

The AB has to clearly distinguish in the accredited scope examination procedures undertaken in the laboratory from the POCT as well as the sites where POCT examinations are done. The accreditation certificate must refer to both standards EN ISO 15189 and EN ISO 22870.

10. REFERENCES

1) Standard EN ISO 15189, Medical laboratories. Requirements for quality and competence

2) Standard EN ISO 22870, Point-of-care testing (POCT). Requirements for quality and competence

3) In Vitro Diagnostic Medical Devices Directive 98/79/EC