EUROPEAN ACCREDITATION

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Guidance for the assessment of laboratories against EN ISO 15189:2022 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 organizations who provide POCT within the boundaries of their own organization.
b) Medical laboratories that provide POCT to external organizations. Results from POCT remain under overall responsibility of the medical laboratory (POCT provider).

Authorship

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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

Accredited or applicant medical laboratories for Point-of-Care Testing (POCT) shall comply with all the requirements of the EN ISO 15189:2022 standard. This guidance document describes the specific criteria and the risks which an AB should take into account when accrediting or assessing POCT activities. This version of the document is based on the EN ISO 15189:2022 standard and focuses only on the clauses where there are specific additional risks or a higher risk related to POCT activities compared to activities performed in a traditional medical laboratory setting. For ease of reference, these risk factors are summarized in tables below.

The scope of POCT continues to develop both in the technologies available and in the number and complexity of delivery points (mobile or fixed). Hospitals, private clinics and even community-based healthcare industries such as pharmaceutical outlets offer POCT activities.

In this document the following verbal forms are used:

"shall" indicates a requirement

"should" indicates a recommendation

"may" is used to indicate that something is permitted

"can" is used to indicate that something is possible, for example, that an organization or individual is able to do something as defined in the ISO/IEC Directives, Part 2 (1).

2 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions from EN ISO 15189: 2022 standard (2) and the following ones apply:

Point-of-Care Testing (POCT): see clause 3.22 EN ISO 15189:2022.

POCT provider: medical laboratory providing POCT.

POCT manager: person responsible for POCT quality, see Annex A.3 EN ISO 15189: 2022.

POCT user: health care organization which contracts POCT provider's services.

POCT site: location (e.g. such as one building from a hospital), where POCT is carried out. In one POCT site, several delivery points could be included.

Delivery points (DP): facilities (wards, clinics, and emergency care rooms etc.) where POCT is performed.

It may also include mobile delivery points such as ambulance, helicopter, or other vehicle.

Medical laboratory: see clause 3.20 EN ISO 15189:2022.

Internal Quality Control (IQC): see clause 3.13 EN ISO 15189:2022.

External Quality Assessment (EQA): see clause 3.10 EN ISO 15189:2022.

3 ACCREDITATION CRITERIA

The accreditation criteria for POCT are defined in the EN ISO 15189: 2022 Standard, Medical laboratories — Requirements for quality and competence.

4 SCOPE OF STANDARD

The EN ISO 15189: 2022 standard applies to POCT wherever it is delivered, for example in a hospital, clinic or by a healthcare organization providing ambulatory care. Patient self-testing is excluded. Only medical laboratories can apply the EN ISO 15189: 2022 standard. Therefore, only medical laboratories can be accredited for POCT activities according to EN ISO 15189:2022, as they provide and maintain overall technical and organizational responsibility for POCT. In general, POCT is performed within a clinic or hospital environment or pharmaceutical outlets, and it is performed by clinical/hospital personnel or laboratory personnel or healthcare personnel.

All ABs should define and document their own policies concerning POCT accredited according to the EN ISO 15189:2022 standard, taking into account local legislation and requirements (especially in case of delivery points being located in different organizations).

5 RISK FACTORS

5.1 Governance (EN ISO 15189: 2022; clause 5 & Annex A.2)

A POCT site can be part of the same organization as the POCT provider (e.g. in a hospital) or located in a different organization (as explained in Annex A, clause A1& A2 of the EN ISO 15189:2022 standard) if allowed by local legislation. In all cases, the POCT activities at that site and the results issued shall be under the responsibility of the POCT provider.

The POCT provider shall have service agreements with all POCT users covering all POCT sites and delivery points. The requirements are applicable for each organization contracting with the POCT provider.

The following potential risk factors should be considered when assessing/accrediting a POCT activity:

Items	Potential Risk factors
Organization[1]	- Organization of the activity: o Complexity of the organization: delivery points at one or several organizations (see service agreement); contractualization; local regulation o Suitability of management

[1] See Appendix

	○ Number of sites/type of delivery points and staff involved (number of delivery points and/or organizations) ○ Instability, maturity of the management system
Responsibilities	- Undefined responsibilities: ○ POCT manager and responsibilities in the delivery points (samples, results, equipment maintenance, ...) ○ Multidisciplinary group (if existing) and responsibilities (Impartiality, financial criteria and approval: equipment/reagents purchase; costs; ...) if one or several organizations ○ Number of persons responsible for clinical approval of the contract ○ Delegation of responsibilities (if one or several organizations) ○ Authority to issue instructions to the POCT operators
Impartiality & confidentiality	- Loss of confidentiality (dissemination of data, ...) and impartiality: ○ Turnover of the personnel ○ Shared personnel ○ Unauthorized personnel ○ One or several organizations ○ One or several IT systems (access to patient data, ...)

5.2 Personnel (EN ISO 15189: 2022; clause 6.2 & Annex A.4)

The POCT provider is responsible for the provision and ongoing management of POCT by an authorized competent staff member or team. Appropriate training and competency assessment processes shall be in place for all POCT operators (**6**) in each delivery point. Relevant records of training and competence evaluation shall be maintained.

The following potential risk factors should be considered when assessing/accrediting a POCT activity:

Items	**Potential Risk factors**
Responsibilities	- See clause 5.1
Confidentiality/Impartiality	- See clause 5.1

Training and documentation	- Failure to recognize inconsistent or incorrect results and insufficient warning of possible method/instrument malfunction: o Content of the training not updated (analytical instructions, QC, maintenance, NC, continuity plan, results...) o Lack of training (personnel untrained, ...) o Lack of competency assessment, high turnover, low frequency o Multiplicity of procedures
Resources	- Lack of personnel/inability to meet customer needs: o Number of POCT operators o Turnover of the personnel o Shared personnel o Number and Type of location (sites, delivery points), Any mobile delivery point o Task description partially or not defined: QC, maintenance, ... - Lack of personnel responsible for POCT in the POCT provider (POCT manager, ...) and in the associated delivery points - Lack of personnel responsible for training, clinical approval of the contract and if necessary, financial approval (equipment/reagents purchase; costs; ...)

5.3 Service agreement (EN ISO 15189: 2022; clause 6.7.2)

The service agreement may be defined in a simplified way by the POCT provider if the POCT users are within the same organization.

Items	Potential Risk factors
Responsibilities	- See clause 5.1
Location of POCT	- Needs of the POCT users not met: o Number of POCT sites and delivery points o Any mobile delivery point
Confidentiality/Impartiality	- See clause 5.1

Resources	- Needs of the POCT users not met: o Type of equipment: Responsibilities, QC, maintenance o Continuity and emergency procedure (equipment, IT system...) o Number of equipment (in a site or in each delivery point) o Availability of resources (equipment, personnel, facilities, reagent and consumable storage, maintenance and modification...)
Training and Documentation	- See clause 5.2

5.4 Ensuring the validity of examination results (EN ISO 15189: 2022; clause 7.3.7)

The POCT provider shall participate in EQA programmes (or equivalent) that are suitable for the examinations and interpretation of the results for all POCT examination procedures.

The POCT provider shall draw up a plan for participation in EQA schemes for POCT activities, and define criteria using a risk-based analysis.

According to the specifications of ILAC document P9 (3), ABs expect medical laboratories to define groups of technical competence areas. The EQA performance achieved within a defined area can be directly correlated with the other combinations of test or measurement methods, characteristics and products included in the same technical competence area. For this reason, not all individual POCT devices need to be subject to EQA, provided that equivalence is demonstrated through IQC performance, correlation and risk analysis results.

The following potential risk factors should be considered when assessing/accrediting a POCT activity:

Items	**Potential Risk factors**
Organization	- See clause 5.1
Personnel	- Misinterpretation of test results and release of incorrect patient results: o See clause 5.2
Preanalytical conditions	- Inadequate conditions of sampling: o Stability of the analyte and matrix
Methodology/Test	- Inadequate verification of method and lack of performance control: o Number of equipment: backup, same equipment or not

	○ Number of POCT sites/ delivery points ○ Complexity and robustness of the methodology ○ Number and frequency of tests undertaken ○ Known stability/instability of the test or measurement technique ○ Suitability of EQA material (i.e. same sample type as the POCT sample) ○ Comparability of equipment/IQC

5.5 Continuity and emergency preparedness planning (EN ISO 15189: 2022; clauses 7.8 and 7.6.4)

A strategy for service continuity and emergency preparedness shall be established by the POCT provider. The POCT users should be informed of this strategy (see clause 5.3), which takes into account the scope of the POCT activity provided and the potential clinical risk and impact on patients if the continuity of the activity is unavailable.

The POCT provider shall identify the risks for each and adapt the continuity and emergency planning to the different organizations.

Items	Potential Risk factors
Location of the breakdown	- Total or partial breakdown ○ POCT provider ○ POCT sites: number of POCT sites/delivery points impacted
IT system	- Failures due to breaches in cybersecurity (7): ○ One or different systems ○ Responsibilities of the POCT provider or/and in the delivery points (see clause 5.1) ○ Role of the ICT department ○ POCT devices coupled to the LIS
Documentation	- Inadequate documentation or absence: ○ Provision of the breakdown of the activity: responsibilities, multiplicity of procedures
Equipment/reagent	- Inability in emergency situations to process samples of urgent diagnostic need, leading to delay in diagnosis and patient treatment:

	○ Number of equipment impacted: backup, ... ○ Number of POCT sites/ delivery points ○ Supplier: service agreement, time response - Disruption of reagent or consumable supply chain leading to service interruption (see clause 5.3)
Personnel	- Lack of personnel: ○ See clause 5.2

5.6 Control of data and information management (EN ISO 15189:2022; clause 7.6)

The following risks should be considered in relation to control of data and information system particularly where there are multiple systems:

Items	Potential Risk factors
Organization	- Insecure data transfer/loss of organization: ○ Complexity and responsibilities (see clause 5.1), service agreement (see clause 5.3) ○ Same vs different IT systems, number of systems ○ System: Manual recording vs automated system (connected to the LIS)
Results/report	- Potential software issues impacting digital process interpretation to the right person at the right time/Failure to deliver the right information: ○ Communication between delivery points and POCT provider (integrity of the data), mobile delivery points ○ POCT report ○ See clauses 5.1, 5.4 and 5.5
User access control and traceability of records	- Confidentiality - Integrity of the data - POCT results and report - Cloud, shared system (if one or several organizations: confidentiality)

6 COMPETENCE OF AN ASSESSMENT TEAM

The expertise of the assessment team should include practical and/or theoretical knowledge of POCT and should cover all stages of the process (pre-examination, examination, post-examination process; quality assurance procedure).

Lead assessors and technical assessors shall have knowledge of the requirements of EN ISO 15189:2022 and the AB's processes and policies, as for all assessments.

7 PRESENTATION OF A SCOPE

The scope of accreditation of the POCT provider shall refer to the EN ISO 15189:2022 standard; and ensure conformity to document EA-4/17M (**4,5**) for further details concerning the description of scopes of accredited medical laboratories.

The AB shall define the level of flexibility authorized concerning POCT (activities, equipment, …) but flexibility can never include the addition of a new POCT site. This level of flexibility shall be represented in the scope of accreditation.

8 SAMPLING AND ASSESSMENT

The AB should have a policy for assessment of POCT sites and/or delivery points in a representative manner over the accreditation cycle. The initial assessment should include all POCT activities.

The sampling strategy of the AB may differ between POCT sites and also from the other sites of the medical laboratories because the risks associated with each could be different.

The AB could also define, as a basis of its sampling strategy, clusters corresponding to groupings of POCT delivery points such as wards and clinics, where critical variables such as IT interfaces, purpose of POCT (for example emergency care) are the same. A cluster could be over more than one POCT site. However, the assessment approach should ensure that all the POCT sites are separately considered.

To establish the competence of the POCT provider, the AB should ensure that the accreditation cycle includes at least a representative sample of all sites and clusters with a selection of delivery points and high risk activities.

As part of the risk-based assessment programme, the AB should define how delivery points, in clusters or POCT sites, are chosen to be assessed and which sampling criteria are to be used (see Appendix).

For ease of reference, these major criteria and risk factors are summarized in tables below:

Criteria for sampling	Issues to consider when assessing Risk
Number of POCT sites	- Located within the same or different organizations - Different organizations/different local management - Same or different LIS
Number of POCT delivery points	- Same POCT site - Different POCT sites - Criticality of delivery points for patient care (paediatric, intensive care ...)
Type of tests	- Same or different tests - Same or different matrix - Same or different producer/ model number of equipment - Number of tests - Preanalytical criteria/sampling method - Participation in EQA - Reporting of the results (automated, verbal, interim reports) - Complexity of tests - Equipment turnover/replacement rate
Personnel	- Same or different personnel - Frequency of changing POCT operators - Shifting of POCT operators - Personnel with specified authorization

The AB can use different tools in assessment activities such as:

- Assessment visit,
- Observation of activity on delivery point,
- Review of records,
- Interview of personnel.

9 REFERENCES

(1) ISO/IEC DIR 2:2021 - ISO/IEC Directives Part 2 Principles and rules for the structure and drafting of ISO and IEC documents.

(2) EN ISO 15189:2022 Standard, Medical laboratories - Requirements for quality and competence.

(3) ILAC P9:01/2024 – ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.

(4) EA-2/15 M - EA Requirements for the Accreditation of Flexible Scopes.

(5) EA-4/17 M - Description of scopes of accreditation of medical laboratories.

(6) ISO/TS 22583:2024 Standard, Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment.

(7) ISO/IEC 27001:2022 Standard, Information security, cybersecurity and privacy protection — Information security management systems — Requirements

10 APPENDIX

The example provided below illustrates how a sampling strategy could be defined for delivery points and POCT sites, but it is not intended for this to be the definitive approach for all ABs. Sampling strategy could be different in initial assessment, surveillance assessment and reassessment.

Example:

The POCT provider in hospital H (POCT user) is accredited according to EN ISO 15189:2022 standard. The hospital has two sites (POCT site I and site II) with several POCT delivery points (DP). The POCT provider has confirmed that the same management system is applied in each POCT site.

The POCT sites and delivery points are organized as described below. The **critical activities** and **changes** since the last assessment are in bold and highlighted:

Delivery point (Numbers DP)	**Number of POCT equipment**	**Test**	**Activity (number of POCT tests/year)**	**IT – type, linked with LIS or manual transcription**	**Types of staff delivering POCT**
POCT-site I					
Haematology clinic (2 DP)	2	Anticoagulant levels (to provide dosing information)	350	System A, not linked	Nurses
Intensive care ward adults (1 DP)	2	Electrolytes, urea, kidney function parameters	500	System A, linked	Senior nurses
POCT-site II					
Paediatric theatre (1 DP)	2	Blood gases	500	**NEW system B linked**	Nurses and operating theatre assistants **30% turnover**
Emergency vehicles (5 DP)	5	Blood gases	780	Manual, not linked	Nurses/healthcare assistants/ clinicians **3 new vehicles**

The AB identified the major risks of this organization (**+**) and applied its sampling strategy on the basis of the following risk analysis:

Criteria for sampling	Risk factors	Impact	SITE/DP assessed
Number of POCT sites: **2**	- One legal entity	0	
	- Same governance that the accredited laboratory	0	
	- Same management system	0	Sites I & II
	- Different LIS: o manual o System A not linked o **NEW system B linked** o **Manual system not linked (vehicles)**	**+**	Site II/ **Paediatric theatre (1 DP)**; **Emergency vehicles (2 DP)**
Number of POCT delivery points: **9**	- In different POCT sites	0	
	- Criticality of delivery points for patient care: o paediatric o intensive care o emergency vehicles (**3 new vehicles**)	**+**	Site II/ **Paediatric theatre (1 DP)**; **Emergency vehicles (2 DP)**
Type of tests	- Different tests	0	Site II/ **Paediatric theatre (1 DP)**; **Emergency vehicles (2 DP)**
	- Activity (Number of tests)	**+**	Site II/ **Emergency vehicles (2 DP)**
	- Complexity of tests	0	
	- Same or different producer/ serial number of equipment	0	
	- Preanalytical criteria/sampling method	0	
	- Participation in EQA	0	
	- Reporting of the results (automated, verbal, interim reports)	**+ (different LIS)**	Site II/ **Paediatric theatre (1 DP)**; **Emergency vehicles (2 DP)**
	- Equipment turnover/replacement rate	0	
Personnel	- Same employer	0	
	- Shifting of POCT operators	**+ 30% turnover**	Site II/**Nurses and operating assistants' paediatric theatre (1 DP)**
	- Personnel with specified authorization	0	

The sampling plan showed that there are 3 delivery points (site II: pediatric theatre (1) and emergency vehicles (2)) assessed out of 9 potential delivery points operated by the POCT provider of hospital H. If every delivery point is located in one building (e.g. in the new building) and all POCT systems are linked to the LIS of the medical laboratory, then the assessment plan could be simplified.