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Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment

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National foreword

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Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment

Exigences et recommandations pour les superviseurs et les opérateurs de tests biologiques effectués près du patient (POCT)

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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).

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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems.*

This second edition cancels and replaces the first edition (ISO/TS 22583:2019), which has been technically revised.

The main changes are as follows:

— title changed from *Guidance for supervisors and operators of point-of-care testing (POCT) devices* to *Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment;*

— insertion of a paragraph in the Introduction to include reference to the COVID-19 pandemic;

— removal of refences to ISO 22870, *Point of care testing (POCT) — Requirements for quality and competence* (withdrawn document).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Due to the ease of use and rapidness of point-of-care-testing (POCT), POCT equipment is widely used as a tool for making decisions related to the health, management or care needs of patients. Such decisions can include admission to hospital, evacuation to more appropriate care environments and directed patient management. There can also be either significant civil or legal implications, or both that arise from POCT such as cessation or termination of employment, family court rulings or revocation of bail or parole.

The availability of simple-to-use POCT equipment has led to continuous development in POCT, examples include testing for diabetes management, blood clotting factors, infectious disease markers, haemoglobin, white blood cell counts, pregnancy tests, cardiac markers, illicit drug use and performance enhancing chemical testing.

Whilst examinations of a patient's body fluids, excreta and tissues have been performed traditionally in the controlled and regulated environment of a medical laboratory, globally, POCT is increasingly being performed outside of a traditional laboratory setting and by operators without medical laboratory support.

Circumstances where POCT testing can occur include, but are not limited to, hospitals, medical practices, pharmacies, ambulances, long-term care facilities, outreach clinics in remote and rural settings, in emergency and natural disasters and community settings such as law enforcement, workplace health and safety, sporting facilities, academia, the military and public areas such as shopping centres.

As POCT results can be used to make important decisions about patients, it is vital that the equipment works properly to yield the correct results and that the operators are trained and competent. This requires that a quality testing structure is provided by supervisors and made available to the operators.

Testing should be of benefit to the patient being tested. If the testing is not performed within a defined quality testing structure, then incorrect results can be obtained which can have a negative effect on the patient in terms of health outcomes or punitive action taken.

During the COVID-19 pandemic, the importance and context of POCT increased substantially. Testing was used to determine whether a patient could leave their residence, attend work or travel within and/or outside their country on a simple POCT, often self-conducted. The need for accurate POCT results in this context was never more obvious due to the profound effect an incorrect result could have on a patient.

This document has been written in easy to understand language. Its purpose is to provide supervisors and operators of POCT services guidance for assessing the appropriateness of proposed POCT, test and equipment selection, as well as skill requirements for technical performance and result interpretation that will ensure that the reliability, quality and interpretation of the results produced is of a quality appropriate to the intended use.

Manufacturers and their distributors should draw this document to the attention of purchasers of POCT equipment and encourage them to follow this document.

NOTE 1 Annexes A to E provide detailed information and add context that is not included in the main body of this document.

NOTE 2 Reference is made to medical laboratory professionals in 4.1, 6.2.2, 6.2.6.3, 6.2.9, 6.3.5, 6.4.2, 6.4.3.2, 6.5, 7.1, B.1.1 and D.1. Medical laboratory professionals with the required competence to offer advice can be found in laboratories adhering to international standards, e.g. ISO 15189.

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Requirements and recommendations for supervisors and operators of point-of-care testing (POCT) equipment

1 Scope

This document provides requirements and recommendations for supervisors and operators of point-of-care testing (POCT) services where POCT is performed without medical laboratory training, supervision or support. It includes the key components that should be considered to provide safe and reliable POCT results.

Self-testing is excluded from this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
analyte
item that is being measured, tested or calculated

EXAMPLE Glucose, troponin, cocaine, HIV antibodies.

3.2
biological reference interval
reference range
normal range
normal value
specified interval of the distribution of values taken from a biological reference population

[SOURCE: ISO 15189:2022, 3.2, modified — Notes 1 to 4 have been deleted.]

3.3
clinical handover
patient handover
handover
transfer of professional responsibility and accountability for some or all aspects of care for a *patient* (3.10) to another person or professional group on a temporary or permanent basis

Note 1 to entry: Transferring all or part of a *patient's* (3.10) care between healthcare providers or locations is a high-risk situation and a failure in clinical handover is a major source in preventable *patient* (3.10) harm.

Note 2 to entry: Effective clinical handover, which is structured and standardised, can reduce communication errors and improve *patient* (3.10) safety.

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Note 3 to entry: A simple example of clinical handover is ensuring critical result notification to an appropriate person is performed in a timely manner to minimise harm to the *patient* (3.10).

3.4
competence
demonstrated ability to apply knowledge and skills to produce an accurate *point-of-care testing (POCT)* (3.11) result

[SOURCE: ISO 15189:2022, 3.5, modified — "to produce an accurate POCT result" has been added.]

3.5
critical results
results outside defined limits which may indicate a life-threatening situation and require immediate notification of the referring doctor, nurse or physician's assistant

3.6
equipment
any device or apparatus which can be used to perform a *point-of-care testing (POCT)* (3.11)

Note 1 to entry: Examples include simple colour changing urine test strips for glucose to more complex electronic handheld or bench top analysers such as glucometers, lipid analysers and alcoholmeters.

Note 2 to entry: For the purposes of this document equipment includes any reagents or consumables required to perform the test.

3.7
external quality assessment
EQA
proficiency testing
PT
process where *samples* (3.13) of known values are tested periodically and the results are not known to the operator at the time of testing

Note 1 to entry: The results obtained are then compared against others testing the same *sample* (3.13) with the same *point-of-care testing (POCT)* (3.11) *equipment* (3.6) type giving the participant the ability to evaluate their performance against others.

Note 2 to entry: Commercially available EQA programmes are recommended but are not always available. Where these are not available, either manufacturers or laboratories, or both, can be able to offer assistance with *sample* (3.13) exchange programs.

3.8
interference factors
substance or process which falsely alters a test result

Note 1 to entry: Interference can be significant.

Note 2 to entry: Interfering substances can be endogenous [substances found naturally in the *patient* (3.10) *sample* (3.13) such as lipids, proteins, antibodies] or exogenous (substances not naturally found in the patient's sample such as drugs, poisons or medications).

Note 3 to entry: The most common interfering factors are haemolysis (the rupturing of red blood cells and the release of their contents into surrounding fluid, e.g. blood plasma/serum), hyperbilirubinemia (a yellow or green pigmentation of the blood plasma/serum due to high bilirubin) and lipaemia (an abnormally high concentration of lipids in the blood, characteristically the blood plasma can appear white or milky in colour due to the presence of fat).

Note 4 to entry: The type of collection tube can also cause test interference as these often contain additive components.

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3.9
internal quality control
IQC
quality control
QC
internal procedure which monitors the testing process which can be used to decide if the system is working correctly and gives confidence that the results are reliable enough to be released

Note 1 to entry: IQC *samples* (3.13) have known quantities of the *analyte* (3.1) being tested. The result obtained is expected to be close to the known value and within an acceptable range. Where results fall outside the acceptable range, action to rectify the issue needs to occur before *patients* (3.10) are tested.

3.10
patient
individual undergoing *point-of-care testing (POCT)* (3.11)

Note 1 to entry: It should be noted that an individual who undergoes *POCT* (3.11) may not have an ongoing disease and therefore may not be a patient as such. They can be clients or employees being tested for reasons other than to receive medical care, such as community screening, pre-employment testing or assessing the use of performance-enhancing drugs or chemicals.

Note 2 to entry: For this document the term patient has been used for consistency.

3.11
point-of-care testing
POCT
near-patient testing
testing that is performed near or at the site of a *patient* (3.10)

3.12
point-of-care testing service provider
POCT service provider
individual or organisation responsible for providing *point-of-care testing (POCT)* (3.11)

3.13
sample
specimen
discrete portion of a body fluid (e.g. blood, urine, saliva), breath, hair or tissue taken from the human body for *point-of-care testing (POCT)* (3.11) which is assumed to represent the whole patient

Note 1 to entry: In some countries, the terms “specimen” or “primary sample" are used instead of sample. For the purpose of this document the terms “sample”, “primary sample” and “specimen” should be considered interchangeable, however for the purpose of this document only “sample” is used.

Note 2 to entry: The source of blood samples (whether arterial, venous or capillary) is another important consideration as POCT results for capillary specimens can differ from arterial, venous values for certain tests and in certain circumstances.

3.14
urgent results
results needed for the care management of a patient within a minimal time period, e.g. Troponin

3.15
validation
process of establishing the performance characteristics and limitations of *point-of-care testing (POCT)* (3.11) *equipment* (3.6) and the identification of the influences which can change these characteristics and to what extent

Note 1 to entry: Which *analytes* (3.1) it can measure and in which *sample* (3.13) type (blood arterial, venous or capillary, plasma, urine) in the presence of which *interferences* (3.8) are important considerations.

Note 2 to entry: The process for confirming that a method is fit-for-purpose (is appropriate for its intended use).

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3.16
verification
process of demonstrating the performance criteria to which the method has been validated have been met by the point-of-care testing (*POCT) service provider* (3.12) prior to introducing into routine use

4 Personnel

4.1 Supervisor

There shall be an appointed person(s) (supervisor) who has the authority and takes responsibility for, the quality of the service and is competent to supervise the testing provided.

The supervisor is responsible for the quality, timeliness, accuracy and safe delivery of the POCT, which includes hazard analysis (see 9.2.5).

The supervisor shall define the roles and responsibilities of POCT operators.

The supervisor shall ensure implementation of the following:

— selection of appropriate tests in consultation with a medical professional, when indicated;

— maintaining privacy, safety and confidentiality of personal information and test results of patients undergoing testing;

— availability of appropriate result interpretation;

— access to advisory services;

— either confirmatory testing or referral for appropriate or necessary additional testing, or both;

— selection of suitable testing equipment;

— identification and adherence to applicable guidelines;

— performance and review of quality control with corrective actions;

— establishment and maintenance of internal instructions or processes;

— operator training and competency assessment;

— appropriate environment for testing;

— inventory control management processes;

— monitoring and reporting medical device adverse events;

— appropriate and effective clinical handover;

— appropriate biosafety and infection control procedures.

The supervisor shall ensure procedures are in place and appropriate for the POCT service provided and that operators adhere to all instructions and procedures relating to POCT.

The supervisor should ensure there is access to medical experts and medical laboratory professionals to provide consultation as needed.

4.2 Operators

4.2.1 General

There shall be an appointed person(s) (operator) who has been trained and has demonstrated the competence required to perform testing. A supervisor may also be an operator.

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4.2.2 Training

An operator training program shall be implemented that

— describes the key aspects of the testing process including:

  — the intent of the testing process;

  — its essential steps;

  — the significance of each step;

— ensures the operators can produce reliable results;

— describes the requirements for use of IQC and EQA programs and ensure they are used (if available);

— states the importance of following policies, procedures and instructions for use.

All operators are required to have successfully completed the training program.

The training program shall be updated when changes to the testing service occur (e.g. new equipment or procedure is introduced) and operators shall be trained to the new processes.

The training program shall be evaluated periodically for effectiveness.

NOTE Aspects of the testing process to consider in training programs are described in Annex A.

4.2.3 Competence

Operators shall be assessed for competence after training and before being allowed to perform testing.

Operators not deemed competent shall not perform any testing until they have been retrained and deemed competent.

The competence of operators shall be reassessed at planned intervals. The interval for competence reassessment should be based on the following:

— test volume and frequency;

— frequency of individual operator involvement in testing;

— complexity of testing (degree of difficulty);

— quality assessment data (e.g. more errors can require more frequent training and a search for root cause).

Where patient testing does not occur immediately after competence has been granted, the POCT service should consider a reasonable timeframe whereby the operator is still deemed competent to test and competence reassessment does not need to occur. After this time, however, the operator should be reassessed for competence.

Generally low volume or less frequent testing requires more frequent competency assessment.

The volume and frequency of tests and the frequency of operator involvement in POCT can determine an operator's ability to remain competent. The complexity of the POCT can influence this as more complex tests are often more difficult to perform correctly, especially when performed rarely. Therefore, planned reassessment intervals should take into account how often and how many POCT an operator performs, i.e. 1 test, 10 tests, 100 tests performed daily, weekly, monthly or yearly in conjunction with the degree of difficulty of the POCT. Each competency assessment shall be recorded against a predetermined set of realistic and measurable targets as defined by the supervisor.

When operators are deemed not competent after training, the training program should be evaluated and improved as necessary.

NOTE Aspects of the testing process to consider in competence assessment programs are described in Annex A.

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