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Guidance for supervisors and operators of point-of-care testing (POCT) devices

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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, *Clinical laboratory testing and in vitro diagnostic test systems.*

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.

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 significant civil and/or legal implications 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 point of care 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, paramedics, 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 have a negative effect on the patient in terms of health outcomes or punitive action taken.

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.

It is recommended that manufacturers and their distributors draw this this document to the attention of purchasers of POCT equipment and encourage them to follow this document.

NOTE 1 The Annexes provide detailed information and add context that is not included in the main body of this document. Therefore, to appreciate this document fully the reader is encouraged to ensure the relevant annexes are read in conjunction with main body of this document.

NOTE 2 It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

NOTE 3 In some sections readers of this document are referred to medical laboratory professionals. Medical laboratory professionals with the required competence to offer advice can be found in laboratories adhering to international standards including ISO 15189, *Medical laboratories — Requirements for Quality and Competence* and ISO 22870, *Point-of-care testing (POCT) — Requirements for quality and competence.*

Guidance for supervisors and operators of point-of-care testing (POCT) devices

1 Scope

This document gives guidance 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 terminological databases for use in standardization at the following addresses:

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

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

3.1
analyte
item that is being measured, tested or calculated

EXAMPLE Glucose, troponin, concaine, 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

Note 1 to entry: A reference interval is composed of the values or range for an *analyte* (3.1) that are expected for a “healthy person”. They are sometimes called "normal" values. Whilst “normal” ranges can give an indication about the wellbeing of a *patient* (3.10), things which should be considered are that a result within the “normal” range does not necessarily mean the *patient* (3.10) is healthy, or a result outside of the “normal” range does not necessarily mean the *patient* (3.10) is unhealthy. It is also important to note that “normal ranges” can differ from *equipment* (3.6) to *equipment* (3.6) and population to population.

Note 2 to entry: In some cases, such as drugs of abuse testing the normal value should be negative or not detected.

[SOURCE: ISO 15189:2012, 3.4, modified — NOTE 1 to NOTE 4 have been deleted and Note 1 to entry has been added.]

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.

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 POCT result

[SOURCE: ISO 15189:2012, 3.5, modified — "to produce an accurate POCT result" has been added and "NOTE" has been deleted.]

3.5
critical results
results outside defined limits which may indicate a life-threatening situation and require immediate notification of the referring doctor

3.6
equipment
any device or apparatus which can be used to perform a *POCT* (3.11)

Note 1 to entry: Examples include simple colour changing urine test strips for glucose to more complex electronic hand held 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 *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 manufacturers and/or laboratories may be able to offer assistance with *sample* (3.13) exchange programs.

3.8
interference factors
a 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.

3.9
internal quality control (IQC)
quality control (QC)
internal procedure which monitors the testing process 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 *POCT* (3.11)

Note 1 to entry: For this document the term patient has been used for consistency.

Note 2 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.

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 *POCT* (3.11)

3.13
sample
primary sample
specimen
discrete portion of a body fluid (e.g. blood, urine, saliva), breath, hair or tissue taken from the human body for *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

Note 2 to entry: The source of blood samples (whether arterial, venous or capillary) is another important consideration as POCT results for capillary specimens may 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

3.15
validation
process of establishing the performance characteristics and limitations of *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).

3.16
verification
process of demonstrating the performance criteria to which the method has been validated have been met by the *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;
— confirmatory testing and/or referral for appropriate or necessary additional testing;
— 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;
— appropriate and effective clinical handover; and
— 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.

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; and
  - the significance of each step;
- ensures the operators can produce reliable results;
- describes the requirements for use of internal quality control and external quality assessment programs and ensure they are used (if available); and
- 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 needs to 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.

5 Point-of-care testing equipment selection

Selection of POCT equipment shall be based on:

— scope and purpose of the POCT Service;

— performance specifications of the equipment;

— reliability of the equipment when used;

— needs of those to be tested;

— other third party needs e.g. employer request; and

— local and national regulatory requirements.

Whilst POCT equipment may not meet every desirable attribute that has been identified, the equipment that is the most appropriate for a given testing scenario should be considered fit-for-purpose.

Lack of understanding of the testing requirements can result in selection of equipment that is not fit-for-purpose. Selection of inappropriate equipment can impact patient safety.

Before equipment is purchased and testing is implemented, the POCT equipment shall be approved by the supervisor as being fit-for-purpose.

NOTE Annex B provides advice for selecting POCT equipment that is fit-for-purpose.

6 Point-of-care testing process management

6.1 General

The testing process consists of three stages: pre-testing, testing and post-testing.

Pre-testing includes all activities performed up to the point of performing the test.

Testing includes using the patient sample and POCT equipment to generate a test result.

Post-testing includes review, interpretation and reporting of results as well as disposal of residual samples, collection equipment and restoring the testing environment and equipment to its pre-testing stage.

All three stages contribute to the quality of the test results.

6.2 Pre-testing stage

6.2.1 General

The majority and often most serious errors (e.g. misidentified patient, insufficient sample, unsuitable sample, improper sample handling) occur in the pretesting stage. If errors occur in this stage, the reliability and accuracy of test results are affected no matter how good the testing or post-testing processes are.

Testing on the wrong patient will always mean the wrong result is produced. As such the wrong treatment might be provided to the wrong patient or a patient can miss the treatment needed causing harm.

6.2.2 Planning and development of the POCT service

The planning and development of the POCT service shall consider

— the reasons for testing including potential outcomes to those being tested;

— what patient population is the POCT service directed toward;

— who is eligible to be tested;

— the criteria for selecting appropriate testing methods, equipment and the tests to be provided;

— who can request the test;

— who can receive test results;

— personnel resources;

— appropriate methods to assure the POCT service is performing as expected;

— evaluation of failures and their consequences to patients and POCT service;

— requirements for quality including internal quality control and external quality assessment;

— storage of equipment, reagents and consumables; and

— regulatory requirements.

Medical and/or Medical laboratory professionals should be available to provide consultation and advice.

6.2.3 Suitable testing environment

A testing environment shall be available which is suitable for POCT. Such an environment shall provide safety for patients and operators, suitable accommodation and sufficient space for testing operations and privacy to maintain patient confidentiality according to ethical and cultural considerations.

6.2.4 Availability and adequacy of test consumables

6.2.4.1 General

Test consumables shall be available and adequate for the test to be performed. This includes sample collection devices, test tubes, test strips or test cards as well as reagents, labels and writing instruments to label samples.

Availability of extra consumables could be appropriate in case of contamination or loss of supplies while POCT is being performed.

All consumables shall be handled in accordance with manufacturers recommendations.