Accreditation Education Research & Scientific Service Center, Nepal

Specific Criteria for Accreditation of Medical Laboratory (ISO 15189:2022)

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S. No.	Page No.	Section No.	Issue Date	Issue No.	Revision Detail

Contents

1. Scope

The scope of the accreditation is applicable to the following fields of medical laboratory testing services:

Biochemistry

Includes but not limited to routine and special biochemical tests, hormones, tumor markers, specific proteins, toxicology, therapeutic drug monitoring, ante-natal testing, newborn metabolic screening etc.

Haematology & Immunohematology

Includes but not limited to general hematology, coagulation assays, hemoglobinopathies, flow cytometry for neoplastic and non-neoplastic conditions, blood banking related immunohematological assays, transplantation related immunohematological tests.

Clinical Pathology

Includes but not limited to routine urine analysis, stool for parasites and occult blood, semen analysis.

Microbiology

Includes but not limited to a) bacteriology smear study, manual and automated culture studies, species identification by manual / automated methods, antibiotic sensitivity, film array tests, MALDI, b) Mycobacteriology manual and automated cultures, identification of MTb and MOTT, sensitivity / resistance studies, Molecular studies (GenExpert), c) Mycology d) Parasitology e) Virology including microscopy, and molecular virology.

Serology

(a) Viral serology
(b) Bacterial/parasitic serology

Immunology

(*Note: These tests may be included under any of the other departments depending on the laboratory policy)*

a) Autoimmune serology: ELISA (manual or automated); IFA (manual or automated); RIA; line immunoassay; multiplex assays.
b) Immunochemistry: turbidimetry (automated); ELISA (automated or manual); electrophoresis; immunofixation; radial immunodiffusion; Ouchterlony double diffusion.
c) Flow cytometry
d) Allergen testing
e) Molecular immunology

Histopathology

Includes but not limited to study of paraffin sections, frozen sections, routine H&E stains, special stains, IHC, Immunofluorescence, ISH, Electron microscopy,

Cytopathology (Cytology)

Includes but not limited to

a) Effusion cytology
b) Gynecological cytology
c) Non-gynecological cytology
d) FNAC.

Use of conventional methods and Liquid based cytology, cell blocks. Routine and special staining including immunocytochemistry.

Genetics

Includes but not limited to

a) Cytogenetics
b) Molecular Genetics
c) Molecular Oncology
d) Molecular Hematology

Nuclear Medicine (IVD Only)

POCT /Mobile Laboratories

a) Biochemistry
b) Hematology
c) Microbiology

The scope may be extended for other parameters as and when required. Accreditation is granted to the specific test method followed by the CAB, which was verified during assessment.

The laboratory has the option to not include some of its testing in their scope of accreditation, however local and legal regulations apply. If the regulatory/user requirements mandate accreditation, it is the responsibility of the laboratory to include all the tests in its scope of accreditation.

The accreditation shall be considered only for those tests for which the laboratory has applied for. The laboratory shall enroll itself and successfully participate in an external quality assurance/proficiency program for each test parameter in the scope of application and shall be able to demonstrate competency to perform these tests and compliance to the relevant standards.

The facility for primary sample collection at sites other than its main laboratory shall also comply with the relevant requirements of ISO 15189:2022

2. Normative references

This document is prepared based on the National / International documents and the best practices followed by the Accreditation Bodies and the Medical Laboratories worldwide.

3. Definitions

The terms and definitions in ISO 15189:2022 are all relevant to these requirements.
In this document, the following verbal forms are used:

- 'shall' indicates a requirement;
- 'required to' refer to the expected requirement from the standard;
- 'should' indicates a recommendation; however, the laboratory has to provide a justifiable reason in case it is not implemented;
- 'may' indicates a permission;
- 'can' indicates a possibility or capability.
- 'NOTE' provides explanatory information to the related clauses and can be a requirement.

The following information is referenced to the specific clauses on ISO 15189: 2022. Where there is no additional information, it is considered that the wording in the standard is sufficiently clear not to warrant explanation.

4. General Requirements

4.1 Impartiality

General requirements are as per ISO 15189:2022

I. All potential risks to conducting laboratory activities impartially shall be identified, monitored and any threats mitigated. Threats that can compromise impartiality include commercial relationships, financial arrangements, governance structures, personnel and promoting of laboratory services.
II. All personnel involved in the activities of the laboratory shall declare any conflicts of interest and these need to be managed appropriately.
III. Management commitment to impartiality shall be demonstrated through its policies and processes.

4.2 Confidentiality

4.2.1 Management of information

(General requirements are as per ISO 15189:2022)

I. All patient information obtained or created during the performance of laboratory activities shall be kept confidential. There needs to be robust systems in place to ensure that breaches to confidentiality do not occur.
II. Laboratories are required to inform its users any information it intends to make publicly available.

4.2.2 Release of information

No additional points.

4.2.3 Personnel responsibility

I. All laboratory personnel should sign a confidentiality agreement as part of their induction which clearly defines the information that is required to be kept confidential.

II. Contractors and other external visitors to the laboratory shall be made aware of the confidentiality requirements and where possible, this clause shall be included in the agreement / contract.

4.3 Requirements regarding patients

(General requirements are as per ISO 15189:2022)

I. The well-being, safety and rights of patients shall be the laboratory's primary consideration.

II. The laboratory shall provide patients and requesting clinicians' opportunities to make enquiries or suggestions regarding available tests and the interpretation of test results.

III. Information regarding the range of tests available, associated costs and how long the test results will take, shall be readily and publicly available.

IV. The laboratory shall ensure that minimum number of specimen tubes are collected for tests requested.

5. Structural and Governance requirements

5.1 Legal entity

(General requirements are as per ISO 15189:2022)

Any changes in the license / legal identity of the laboratory shall be notified to AERSSC without delay. The laboratory shall claim accreditation status to the new entity only after obtaining approval from AERSSC.

5.2 Laboratory Director

(General requirements are as per ISO 15189:2022)

5.2.1 Laboratory director competence

Required competence for the post of laboratory director shall be documented.

NOTE 1. There may be more than one person playing the role of Director. The person playing the role of director may be designated in any manner the lab chooses to.

NOTE 2: Competence is a combination of educational qualification, work experience, training and aptitude.

5.2.2 Laboratory director responsibilities

The responsibilities of the laboratory director role shall be clearly documented.

NOTE: Though the prescriptive list of responsibilities of a laboratory director has been removed from the standard, the role of laboratory director Shall be defined by the CAB keeping in mind that the Director / Designate maintains ultimate responsibility for overall operation of the laboratory including risk management application.

5.2.3 Delegation of duties

No additional points.

5.3 Laboratory activities

(General requirements are as per ISO 15189:2022)

5.3.1 General

The laboratory is required to detail all activities for which conformity with this standard is claimed. This includes activities performed outside the main laboratory such as POCT, mobile laboratories and sample collection.

NOTE: The scope may include a summary of activities and services provided and a detailed reference to the applied / accredited scope of testing.

5.3.2 Conformance with requirements

No additional points.

5.3.3 Advisory activities

I. Laboratory management should ensure they have suitably qualified personnel able to provide appropriate advice and interpretation of test results that meet the needs of patients and users of laboratory services.

II. Arrangements for communicating with laboratory users should be established and the effectiveness of the communication forums should be regularly evaluated.

5.4 Structure and authority

(General requirements are as per ISO 15189:2022)

5.4.1 General

I. The laboratory shall define its organizational and management structure in an organizational chart or similar.

II. The relationships between management, clinical and technical personnel, along with any support services, such as Information Technology, shall also be defined.

III. Deputies for key laboratory roles should also be defined.

IV. If the management structure is responsible for a laboratory operating at more than one location, with each one performing tests and issuing test reports, these should be considered as separate laboratories unless agreed otherwise.

V. For individual locations, the laboratory is required to submit a separate application form for accreditation and a separate accreditation certificate will be issued for different locations.

VI. A laboratory that is part of a chain of laboratories with the same quality management system can apply as a unit. However, each location should have an identified person individually responsible for the quality management system and technical SOPs need to be locally specific.

VII. Any change in the structure and authority shall be notified to AERSSC.

5.4.2 Quality management

I. There is now no specific requirement to have an appointed quality manager, however there is a requirement to have personnel that have the training, authority, and resources to carry out the duties of a quality manager.

II. This can be a designated quality manager role, or the duties delegated to a number of defined personnel or roles. This role or roles are required to be defined in the organization structure.

5.5 Objectives and policies

(General requirements are as per ISO 15189:2022)

I. The objectives shall be measurable and be defined in the management system documentation.

II. These shall be relevant to the needs and requirements of the users of the service. The defined objectives shall be regularly monitored and reviewed.

5.6 Risk management

(General requirements are as per ISO 15189:2022)

I. The laboratory is required to establish processes for identifying risks to patients across all activities of the laboratory, including pre-examination, examination, and post-examination.

II. Controls and actions are required to be implemented to mitigate the risks and develop opportunities for improvement.

III. Risk management processes shall be regularly evaluated and updated as required.

6. Resource requirements

(General requirements are as per ISO 15189:2022)

6.1 General

No additional points.

6.2 Personnel

(General requirements are as per ISO 15189:2022)

6.2.1 General

I. The laboratory shall be operated and managed by suitably qualified and competent personnel.

II. Designated personnel with primary responsibility for management, quality, clinical and technical activities of the laboratory shall be defined.

III. Any changes to key personnel shall be notified to AERSSC.

6.2.2 Competence requirements

I. The laboratory is required to specify the competence requirements for managerial, clinical, technical and administration personnel. This includes minimum education and qualifications, along with training required to attain the necessary skills and experience.

Note: The required competence shall be by designation / position and shall be part of the documentation system. Individual staff competence details shall be part of their personal records.

II. During all working hours an accredited laboratory shall have at least one staff member who is competent for the testing work being done.

NOTE: Prior to the assessment visit, AERSSC requires submission of list of laboratory staff details with their working hours for the purpose of accreditation cycle assessment.

III. All technical staff members are required to have a regulatory license to practice as a Laboratory Technologist/Technician as per national / regional regulatory requirements.

IV. Frequency of competency assessments and methods used for demonstrating competencies shall be documented. As a recommendation, for new staff members, competency assessments would be expected not later than three months. Competence evaluation may also follow individual training activities. Once trained and deemed competent, annual competency assessments would be expected.

6.2.3 Authorization

Only authorized personnel shall perform specific laboratory activities, and this shall be clearly defined. This includes but is not limited to approving test methods used, reviewing IQC and EQA results, reporting test results, and access to patient data and information in the LIS along with ability to make amendments. The authorization record may be a consolidated one for all the personnel or separate for every individual as part of the personnel file.

6.2.4 Continuing education and professional development

No additional points.

6.2.5 Personnel records

No additional points.

6.3 Facilities and environmental conditions

(General requirements are as per ISO 15189:2022)

6.3.1 General

I. Specific facility and environmental conditions for the scope of testing provided shall be defined and regularly monitored. This also applies to patient sample collection rooms and premises where POCT is performed.

NOTE: Facilities and environmental condition requirements vary greatly depending on the nature of the samples to be examined or tested and the order of accuracy required of the examinations or tests.

II. The laboratory and its personnel shall follow local and international bio-safety requirements, compliance with conditions required by the test or examination method, and international best practice.

6.3.2 Facility controls

I. The laboratory shall only be accessible to authorized personnel. Appropriate access control systems shall be established.

II. The laboratory shall have adequate lighting, power plugs and uninterrupted power supply (UPS). It is recommended that the UPS supplies and the raw power supply plug points be labelled clearly to avoid mix up in usage. Automated analyzers and data management systems shall be provided with uninterrupted and regulated power supply to prevent compromise of their functioning.

III. The laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure.

IV. Clear segregation and demarcation between 'clean' areas, such as areas used for clerical aspects of laboratory work, and 'dirty areas', such as areas used for testing procedures should be available to avoid contamination and health hazards.

V. Laboratories performing molecular testing shall have designated areas for pre-PCR, PCR, and post- PCR activities with a one-way flow of specimens and personnel.

VI. The appropriate level of containment, including air flow and pressure, shall be maintained when a laboratory is testing for high-risk pathogens. Such examples are Mycobacterium Tuberculosis, Brucella, Meningococcal bacterium, and Coronaviruses.

VII. The laboratory shall ensure that appropriate environmental conditions are maintained to ensure personnel comfort and safety as well as optimal operating of equipment. Temperature and humidity shall be monitored regularly to ensure they are within FDA recommended optimal limits of 20 – 25 ^{0}C for temperature and 30% - 50% for humidity.

VIII. Fire safety devices such as extinguishers / smoke detection systems shall be installed in the laboratory premises. The extinguishers shall be appropriate to the nature of equipment placed in the laboratory.

IX. Air quality checks should meet regulatory Workplace Exposure Standards and shall be performed in various work areas such as Histology laboratories and Microbiology facilities to verify compliance with legislative requirements and as part of good laboratory practice.

X. The laboratory shall provide a quiet and uninterrupted work environment where it is needed.

XI. Safety practices including immunization of personnel against appropriate infections (based on scope of work) shall be followed as per national / regional regulations or as defined by the policy of the laboratory.

6.3.3 Storage facilities

Storage facilities shall be appropriate to the material that is being stored. The laboratory should refer to recommendations provided by the manufacturer / regulatory agencies to ensure that material is stored in a safe manner, and shall avoid contamination / deterioration.

6.3.4 Personnel facilities
No additional points

6.3.5 Sample collection facilities

i. An area separate from the main laboratory area and common waiting area shall be designated for sample collection to ensure appropriate privacy to the patient during collection.
ii. Separate rooms shall be provided for procedures such as FNAC / bone marrow /cervical smears etc.
iii. Environmental conditions shall ensure patient comfort and preservation of sample integrity.

6.4 Equipment
(General requirements are as per ISO 15189:2022)

6.4.1 General
NOTE: Laboratory equipment encompasses all hardware and software of instruments along with any systems or equipment that influences the results of laboratory activities which should be applicable to this clause requirement.

6.4.2 Equipment requirements

i. The laboratory shall have access to equipment required for the provision of specified services. Such equipment may either be owned by the laboratory / leased to it. There may also be situations where certain equipment belonging to a third party are used for certain of the laboratory's activities. Such arrangements shall be through formal agreements and the laboratory shall ensure that all requirements of the standard and this document are complied with. This also applies to any equipment used as POCT which is under the control of laboratory management.
ii. The laboratory shall maintain a register / master list of all equipment used and each item shall be uniquely identified to eliminate confusion and to ensure traceability of records.
iii. All equipment shall be well maintained and replaced as required. Processes for decommissioning of equipment shall also be defined.
iv. Interfacing of key items of equipment should be considered where possible in order to provide a continuous back-up, ready access to data and eliminate the necessity of manual transcriptions.

6.4.3 Equipment acceptance procedure

i. All new equipment used in the laboratory or as POCT, or equipment returned after being sent away for repair or calibration, shall be verified as meeting specified acceptability criteria. Where relevant, the calibration certificate with the returned item of equipment is acceptable as verification.
ii. Acceptance testing shall be comprehensive enough to verify that the equipment is capable of the required measurement accuracy of measurement uncertainty to provide a valid result.

iii. Verification of all automated / semi-automated systems shall be performed by checking precision, accuracy, carryover and if applicable, linearity.
iv. Any changes in key equipment shall be notified to AERSSC along with a commissioning and acceptance testing report.
v. If more than one testing platform is used, or if there is an automated and a manual testing system, for a test or tests, then comparability studies shall be performed, and statistical data produced shall be reviewed and deemed acceptable by an authorised person.

6.4.4 Equipment instructions for use

i. Instructions for use shall be readily accessible for all equipment used in the laboratory and for POCT.
ii. All operators of laboratory equipment and POCT equipment shall be trained and deemed competent prior to being authorized to use it**.**

6.4.5 Equipment maintenance and repair

i. Major analytical instrumentation and any critical items of equipment necessary for testing shall be under preventive maintenance contracts with the suppliers of their authorized agents.
ii. Preventive maintenance programs shall also be established for all major ancillary items of equipment required for testing.
iii. Maintenance schedules for all equipment shall be documented and meet the supplier's recommendations where applicable.
iv. All thermo-regulated equipment (refrigerators, freezers, incubators, water baths) are required to have temperatures monitored and recorded at least once daily.

6.4.6 Equipment adverse incident reporting

No additional points.

6.4.7 Equipment records

No additional points.

6.5 Equipment calibration and metrological traceability

(General requirements are as per ISO 15189:2022)

6.5.1 General

i. All items of equipment that are used in processes to report an examination result and having a direct or indirect effect on the accuracy or validity of the results need to be calibrated to a metrological traceable standard.
ii. The laboratory shall evaluate and determine and document the list of equipment required to be calibrated. Such evaluations require the knowledge on how the measurements obtained using that item of equipment affect the final measurement uncertainty or validity of the final results.
iii. All automated equipment shall be calibrated by the manufacturer.

NOTE 1: The points listed in this commentary pertain mostly to the hardware calibration of analytical and non-analytical equipment. Calibration of individual assays are usually as per recommendations of the kit manufacturer or determined by the laboratory based on QC failures.

6.5.2 Equipment calibration

i. Instructions for calibration procedures shall be documented, including whether it can be performed in-house by suitably trained personnel or shall be performed by an accredited calibration service.

NOTE 1: The laboratory carrying out in-house calibration activities shall comply with Requirements on Metrological Traceability of Measurement Results

ii. All data and records pertaining to equipment calibrations shall be retained, including any correction factors to be applied. Calibration reports shall be verified by authorized laboratory personnel for completeness and accuracy of information contained therein. Evidence of such verification shall be available during assessment.

iii. Guidelines relating to equipment calibration for laboratory equipment are detailed in Table 1. The guidelines set out maximum periods of use before equipment shall be recalibrated or checked. Where a test method or environment requires more frequent calibration, this consideration will over-ride these guidelines.

NOTE: ILAC-G24 provides guidelines for the determination of recalibration intervals of measuring equipment.

iv. It is noted that calibration requirements will vary depending on method specification. For equipment not listed specifically, reference shall be made to manufacturer's specifications.

6.5.3 Metrological traceability of measurement results

a) All measurement results shall have metrological traceability and to International System of Units (SI), through an unbroken chain of calibrations, to a higher order reference material or reference procedures. This includes, where possible, all laboratory results and POCT results.

NOTE 1: The certified values assigned to Certified Reference Materials are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database, website https://www.jctlmdb.org.

NOTE 2: Recognizing that the accreditation of Reference Materials Producers (RMPs) is still developing, and Certified Reference Materials (CRMs) may not be available from accredited RMPs, where CRMs are produced by non-accredited RMPs, the laboratory shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

b) Where it is not possible for quantitative results and for qualitative results, traceability may be established by alternative approaches.

c) Equipment calibration, where relevant, shall be performed by an accredited calibration laboratory.

NOTE 1: ISO/IEC 17025:2017 accredited calibration laboratory is considered to be competent to ensure traceability of equipment measurements. The accreditation certificate of the calibration laboratory is included of scope, range and CMC (Calibration and Measurement Capability) which should be verified against the method tolerance limit prior to put in service.

d) Manufacturers of examination systems often provide information of traceability for calibration material or procedures, which is acceptable if the laboratory operates the system and procedures without modification.

Table 1: Non-analytical equipment calibration guidelines:

Equipment	Calibration Interval	Requirements
Pipettes & Dispensers	Once a year across range of use	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
Pipettes (Used for re constitution of Controls, Calibrators, Reagents & Testing)	Once in Six Months at usage range	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
Data Loggers Thermometers Wireless Thermometer Infrared Thermometer Thermo Hygrometers (Humidity gauges)	Once in Year At Working Ranges	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
Laboratory Refrigerators & Freezers (Laboratories are recommended to use only Medical Laboratory Refrigerator & Freezers for storage of samples, reagents, Calibrators & Controls)	Once during commissioning and when repaired, & shifted Verification once a year at Working Ranges	9/5 Point Temperature Profile check by ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status. External data loggers/Maximum-Minimum temperature devices shall be used to continuously control, monitor and record temperature & are calibrated once in year.

Incubators Water Baths Ovens, Floatation Baths.	Once in Year At Working Ranges	9/5 Point Temperature Profile check by ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status. External data loggers/Maximum-Minimum temperature devices shall be used to continuously control, monitor and record temperature & are calibrated once in year.
(Andrology) Microscope heated stages, Slide warmers	Daily before use	Internal verification ensures working ranges are within limits. Calibration of micrometer if used within laboratory.
Hybridization equipment	Once in six months	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status. or manufacturers recommended procedure
Balances & Weighing Scales	Once in Year At working Ranges	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status. Intermediate checks daily or prior to use with clean stainless mass within the working range are required.
Autoclaves- Temperature, Pressure & Time	Once in Year At working Ranges	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status. Pressure, Temperature & Time shall be calibrated
Centrifuges, Cyto centrifuge Cytospin	Once in Year At working Ranges	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
Timers, Stop Watch Thermo Hygro Clocks	Once in Year At working Ranges	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
Electrophoresis	Once in Year	By ISO/IEC 17025 Accredited Calibration Laboratory by an AB

Device		having ILAC MRA signatory status or Manufactures recommended procedure
Biological Safety Cabinets	Once in Year	Including Sterility check at least once in a week Internally & Recommended By ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status.
pH	Daily prior to use	Internal Verification by Certified Reference Material Agency accredited as per ISO 17034 by an AB having ILAC MRA signatory status.
TDS /Conductivity	As Applicable	As applicable
Fumigation Hood	As Applicable	As Applicable
Tissue Processor	1 Year	As Applicable
Microtome	1 Year	As Applicable
Paraffin Embedding Station	1 Year	As Applicable
Liquid Based Cytology	1 Year	As Applicable
Grossing Station	1 Year	As Applicable
EZ – Retrival (Microwave for IHC)	1 Year	As Applicable
Automated Immunohistochemistry	1 Year	As Applicable
Multistainer	1 Year	As Applicable
All chemistry analyzers Pipette (Reagent probe & Sample probe) calibration Reaction chamber temperature devise calibration	1 Year	Recommended by ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status or Manufactures recommended procedure
All Immunology analyzers Pipette device (Reagent probe & Sample probe) calibration Reaction chamber temperature devise calibration	1 Year	Recommended by ISO/IEC 17025 Accredited Calibration Laboratory by an AB having ILAC MRA signatory status or Manufactures recommended procedure

6.6 Reagents and consumables

(General requirements are as per ISO 15189:2022)

6.6.1 General

No additional points

6.6.2 Reagents and consumables – Receipt and storage

I. All reagents and consumables for laboratory testing and for POCT shall be checked on receipt that they have arrived undamaged, within expiry date and transported within an acceptable temperature range. Date of receipt and acceptance of condition shall be recorded.
II. Storage temperatures shall be regularly monitored and recorded to ensure optimal conditions, as specified by the supplier, are maintained.
III. Any reagents or consumables that are stored outside the laboratory area, such as hospital stores, shall be verified as being optimal conditions for storage.
IV. Stains and reagents shall be labelled with the date opened and stored accordingly to manufacturer's instructions. They should not be used beyond their expiry date or if they show signs of deterioration, such as abnormal turbidity and/or discoloration.

6.6.3 Reagents and consumables – Acceptance testing

Each new lot and shipment of kits, cartridges, reagents and materials, including those prepared in- house, shall be verified for acceptable performance before being put into use.

6.6.4 Reagents and consumables – Inventory management

I. The laboratory shall have an inventory management system that ensures reagents and consumables can be clearly identified as when they were received, their expiry date, acceptance testing completed, and when put into use.
II. A reagent/consumable policy shall be developed regarding use of reagents or consumables that have passed their expiry date. This does not apply to expired QC materials and calibrators which shall not be used after their expiry date.
III. There shall be regular monitoring of expiry dates to prevent use where it may adversely affect testing. This also applies to specimen collection tubes which shall not be used passed their expiry date.

6.6.5 Reagents and consumables – Instructions for use

No additional points.

6.6.6 Reagents and consumables - Adverse incident reporting

No additional points.

6.6.7 Reagents and consumables – Records

When a reagent is made up of a number of components, traceability of the individual component lot number and expiry date details, along with the identity of the person preparing the reagent, shall be maintained.

6.7 Service agreements

(General requirements are as per ISO 15189:2022)

6.7.1 Agreements with laboratory users

i. A contract in its simplest sense involves a test request form presented to the laboratory by a patient or clinician.
ii. The requirements of the users of the laboratory service, both requesters and patients, shall be clearly understood and agreed.
iii. The laboratory shall ensure they have the resources and capability to provide the agreed service.
iv. Information regarding the range of testing that can be requested, testing performed on-site, accreditation status of each test, tests that are referred, expected turnaround times and measurement accuracy shall be readily available.
v. Any changes to the services provided shall be communicated effectively through appropriate channels to the users of the service.
vi. Policies for patient requested examinations shall be defined and understood by all relevant staff members.

6.7.2 Agreements with POCT operators

When POCT is supported by the laboratory there shall be a documented service agreement between the laboratory and relevant parties that clearly defines responsibilities and authorities for POCT activities.

6.8 Externally provided products and services

(General requirements are as per ISO 15189:2022)

6.8.1 General

The laboratory shall maintain a register /record of all externally provided products and services.

6.8.2 Referral laboratories and consultants

i. The laboratory shall have a documented policy and procedure for selecting and referring tests to other laboratories and for second opinion to consultants, including requirement for the referral laboratory to be accredited for ISO 15189. A list of referral laboratories and consultants shall be maintained.

NOTE: Referral laboratory is an external laboratory to which the laboratory management chooses to submit a sample or sub sample for testing which cannot be performed in-house.

ii. It is the responsibility of the referring laboratory to provide the original report from the referral laboratory or to transcribe the test results without alterations of clinical interpretation, with additional remarks if required.
iii. The report, if transcribed, shall clearly identify that the tests were performed by a referral laboratory and the accreditation status of the tests reported.

6.8.3 Review and approval of externally provided services

i. Relevant records relating to the selection and review of externally provided services, including referral laboratories or consultants, shall be retained.
ii. These shall include evaluations against defined criteria, current accreditation status, investigations of complaints and non-conformances, and any actions taken.
iii. Review of performance should be conducted at least annually.

7. Process requirements

(General requirements are as per ISO 15189:2022)

7.1 General

The laboratory is required to identify risks to patient care, which are to be assessed and effective controls implemented, for all pre-examination, examination, and post-examination processes. Risk assessment shall be documented and regularly monitored for effectiveness of mitigation.

7.2 Pre-examination processes

(General requirements are as per ISO 15189:2022)

7.2.1 General

No additional points.

7.2.2 Laboratory information for patients and users

Information relating to the laboratory's scope of activities and requirements relevant to both patients and users shall be available. These may be provided on a website or as a directory or handbook

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7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

i. The test request form may be in hard copy format or electronically requested.
ii. Test request forms shall include at least two unique identifiers which shall also be present on the accompanying specimens collected. Identifiers include full name of the patient, their date of birth and a unique identity number. Test request forms shall be designed to allow the requesting clinician to include all the relevant information, including clinical details.
iii. It is expected that users are consulted prior to any significant changes to the format of request forms.

7.2.3.2 Oral requests

No additional points.

7.2.4 Primary sample collection and handling

7.2.4.1 General

i. It is the responsibility of the laboratory to ensure that primary samples are collected optimally.
ii. Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual / or otherwise labelled. This shall be applicable for the collection facility at the main laboratory and the sites/clinics other than the main laboratory from where samples are collected and sent to the laboratory for testing and reporting.

7.2.4.2 Information for pre-collection activities

For patient self-collected specimens, the instructions provided shall be in a language that is clearly understood by the patient or caregiver. Use of an information sheet or similar, where relevant, regarding pre-collection and collection activities is recommended.

7.2.4.3 Patient consent

The laboratory shall develop a policy on how they obtain informed consent from a patient for specimen collection. For most routine procedures, consent may be inferred by the patient willingly presenting for the collection procedure. However, some special or more invasive procedures, may need documented consent.

7.2.4.4 Instructions for collection activities

i. Patients presenting for specimen collection, once they have given consent, shall be positively identified by the collector by asking them to state their full name and date of birth.
ii. In situations where there is doubt about the identity of the patient, such as when a patient is unconscious or is unable to communicate effectively and consent cannot be obtained, alternative mechanisms shall be used, and the means of identification recorded. This may involve having an appropriate caregiver or family member provide confirmation of identity and consent on behalf of the patient.
iii. Specimens shall all be labelled with at least two identifiers and shall match the details on the request form. When specimens for POCT are collected one patient at a time and the specimen is retained by the collector throughout all stages, labelling requirements may be relaxed.
iv. In general, to minimize errors, specimen collection containers shall not be pre-labelled. An exception may be when a sample container is provided directly to the patient for a non-blood collection. When pre-labelling occurs, adequate systems shall be in place to accurately confirm the identity of the patient and the sample.

7.2.5 Sample transportation

i. Instructions for sample transportation shall ensure the importance of sample integrity and that risk to the general public is recognized.
ii. For samples that are transported from external locations, the temperature of transportation is monitored and recorded. It is advisable for the transport container to have a temperature data logger to confirm that transport conditions have been maintained within an acceptable temperature range.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

i. The laboratory shall have a clearly defined sample acceptance and rejection criteria, which shall be applied to all samples receipted into the laboratory.

ii. Record of time of receipt and the sample details and condition received shall be available as an accession register or in an electronic format.

iii. The identity of the person responsible for taking any aliquots or sub-samples from the primary sample shall be recorded.

7.2.6.2 Sample acceptance exceptions

7.2.6.3 If, having given full consideration to the best interests of the patient, specimens which do not meet

7.2.6.4 Minimum acceptability criteria are accepted and tested, a record shall be kept of the circumstances and any subsequent action taken.

7.2.7 Pre-examination handling, preparation and storage

7.2.7.1 Sample protection

Stored samples for further examinations shall ensure sample integrity is maintained and are readily retrievable.

7.2.7.2 Criteria for additional examination requests

No additional points.

7.2.7.3 Sample stability

i. The sample integrity and stability for each test of stored samples shall be determined by the laboratory.

ii. The laboratory shall define the length of time a sample will be stored after testing. National / regional / legal requirements shall be complied with. In case no regulations exist, the laboratory may define its own policy and adhere to the same. Regardless of the period of retention and justification thereof, additional testing / re-examination shall be carried out based on verified sample stability alone.

7.3 Examination processes

(General requirements are as per ISO 15189:2022)

7.3.1 General

i. A complete audit trail of who has performed each activity in an examination procedure, including for POCT, shall be retrievable. This can either be in hard copy records, such as worksheets, or within the Laboratory Information System (LIS).

NOTE: Accreditation is normally granted only for internationally or nationally standard test procedures or non-standard procedures or in-house methods that have been appropriately validated, and which are performed regularly.

ii. Periodic review of requests and the testing methods provided to evaluate ongoing suitability shall be conducted. The expectation is for these reviews to occur annually as part of overall management review.

7.3.2 Verification of examination methods

i. When standard methods are used or followed, such as reagent kits for autoanalyzer, the laboratory is required to maintain current versions, such as package inserts, of these methods and ensure laboratory procedures are in accordance and updated when required.
ii. Verification of the manufacturer's performance data, and that the examination is suitable for the required performance for the laboratory's users, is required to be conducted. This is expected when a new instrument or new method is introduced, an instrument is relocated, or the manufacturer makes some changes to an existing method.
iii. Verification shall include the following performance characteristics, where relevant: accuracy, precision, limit of detection, linearity, carry over, interfering substances, specificity, selectivity, and sensitivity.
iv. All records pertaining to verification of examination methods shall be retained.
v. Verification for POCT examination methods need to include relevant performance specifications, with comparability to laboratory testing essential.
vi. All verification data shall be reviewed and approved by a pathologist.
vii. Any significant differences between POCT and laboratory test results shall be evaluated and approved or rejected by a pathologist.
viii. If the POCT examination is approved, requesters shall be made aware of the differences.

7.3.3 Validation of examination methods

Commercial test kits, in-house or non-standardised methods will require validation if the laboratory is unable to source the validation data from manufacturers with a recognised quality assurance system or a reputable validation based on collaborative testing.

7.3.4 Evaluation of measurement uncertainty (MU)

i. The laboratory shall identify and control the important sources of uncertainty and devise some parameters/boundaries of the results where practicable.

NOTE 1: The extent to which MU will be applicable in medical laboratories will vary between tests and between disciplines.

NOTE 2: ISO/TS 20914 provided guidance on MU for medical laboratories.

ii. The laboratory shall document how estimates of measurement uncertainty is determined, with reference to published procedures.

iii. Measurement uncertainty shall be estimated for all quantitative tests and qualitative tests based on a quantitative result at the decision/cut-off values. For tests that do not have measurement uncertainty estimated, the rationale for exclusion shall be documented.

NOTE: Measurement uncertainty is often estimated based on QC data or patient replicates as 2 x CV.

iv. Where the laboratory uses different instruments and/or methods for the same test, measurement uncertainty shall be documented for each instrument/method combination.

v. Significant differences in measurement uncertainty will need to be taken into account when interpreting and reporting test results.

7.3.5 Biological reference intervals and clinical decision limits

i. In reviewing biological reference intervals, the laboratory shall in addition to other factors, take into account the intervals used by other laboratories within its geographic and ethnic catchment.

ii. Laboratories shall make all attempts to minimise risk to patients who are commonly tested by more than one laboratory within a region, by avoiding potential confusion amongst clinical requesters when biological reference intervals differ.

7.3.6 Documentation of examination procedures

i. The laboratory will prepare its own document of examination procedures to cover all required aspects of the test / analyte. This is a formal document subject to document control. Cross reference to kit inserts, text books, published literature and other external documents shall be made.

ii. Each new/updated procedure or set of procedures shall be reviewed and approved by an authorized staff member.

iii. All staff members are expected to be aware of any significant changes to relevant procedures, and their familiarity with documented procedures shall be recorded in competency records, manual lists, or similar systems.

iv. Where procedures are not immediately available for use at the workstation or POCT location, they shall be readily accessible either in soft or hard copy format.

7.3.7 Ensuring the validity of examination results

(General requirements are as per ISO 15189:2022)

7.3.7.1 General

i. The procedures for monitoring the validity of results shall include running internal quality control (QC) samples at regular intervals and participating in regular external quality assessments (EQA).

ii. The results shall be recorded in such a way that trends and shifts are readily detectable and appropriate corrective action initiated. QC protocols shall be guided by established best practice in each discipline.

7.3.7.2 Internal quality control (IQC)

i. As appropriate for the test, QC materials shall be combinations of low abnormal, normal, high abnormal; negative and positive; or reactive and nonreactive. Wherever possible, the QC material should be matrix matched to the type of samples being examined.
ii. The frequency of running QC samples shall be based on the stability and robustness of the examination method, along with the hours of operation and number of tests processed. QC shall always be performed after a new reagent kit and after calibration.
iii. There shall be defined criteria for acceptability of QC results and procedures to follow for unacceptable results.
iv. Acceptable ranges for QC results shall be defined for each test parameter that are statistically valid and clinically relevant. Means and standard deviations supplied by the manufacturer of the QC material shall be verified to ensure adequate control of assays is achieved. However, laboratories are required to establish means and standard deviations using their own data to derive performance based acceptable limits.

NOTE: Manufacturer provided ranges are generally too wide to effectively monitor performance of the assay, as they take into consideration different testing platforms and reagents.

7.3.7.3 External quality assessment (EQA)

i. Where applicable, the laboratory shall establish documented plan for the level and frequency of EQA participation within the accreditation cycle based on EIAC certificate validity. The plan shall be reviewed at regular intervals based on key changes which could include but not limited to equipment, methodology, scope, staff etc.
ii. Where available, the laboratory shall participate in an EQA or Proficiency Testing (PT) program for every accredited test, and where suitable, the interpretation of the results, that fulfils ISO/IEC 17043 requirements.
iii. The laboratory shall investigate the EQA programs availability and determine the appropriateness of the available schemes.

NOTE: The primary purpose of EQA or PT programs is to provide information on aspects of uncertainty associated with patient samples, including the competency of staff members carrying out the testing work.

iv. When there is no suitable EQA or PT program, one of the acceptable alternative methods can be adopted. The procedures for any alternate methods shall be documented.
v. All staff members who are directly involved in testing patient samples shall participate fully in the testing of EQA samples.
vi. A secondary purpose of EQA testing is to provide a challenge to staff members for purposes of ongoing training. Consequently, slides and samples may be

examined, tested, and discussed for educational purposes.

vii. EQA/PT reports on interlaboratory comparisons are required to be reviewed by appropriate senior personnel, with any discordant results fully investigated for root cause and clinical significance.

viii. Records of the investigation and any corrective actions shall be maintained.

7.3.7.4 Comparability of examination results

i. When test results can be reported from different methods or instruments, regular patient comparisons shall be performed to determine comparability.

ii. Records of the comparisons shall be maintained with defined acceptable variations.

iii. Where there a clinically significant difference in test results, the users shall be informed and the reference range or interpretation on the test report shall be amended as necessary.

7.4 Post-examination processes

(General requirements are as per ISO 15189:2022)

7.4.1 Reporting of results

7.4.1.1 General

No additional points.

7.4.1.2 Result review and release

i. Persons providing clinical and/or scientific/technical evaluation of results shall be documented and shall be approved as having an appropriate level of competence.

ii. Details of who may release results and/or comments shall be detailed either in procedural documentation or in competency records.

iii. Any manually transcribed test results shall be verified by a second person and an audit trail maintained

7.4.1.3 Critical result reports

i. The laboratory shall determine critical/alert levels for each test where applicable. These levels shall be clearly documented and readily available.

ii. There shall be procedures in place for reporting critical results as soon as possible and all communications shall be recorded.

iii. It may be appropriate to have separate critical/alert levels for hospital and non-hospital patients in discussion with the users of the service.

7.4.1.4 Special considerations for results

No additional points.

7.4.1.5 Automated selection, review, release and reporting of results

It is essential that the integrity of data and confidentiality requirements are met during the transfer of results by any electronic means. A delta check system against predefined criteria, to alert any significant changes in patient's results,

shall be in place.

7.4.1.6 Requirements for reports

i. The laboratory shall have documented reasons for omitting any of the listed requirements for reports

ii. Where relevant, age and gender specific biological reference intervals should be provided when reporting results. Generally, such reference intervals shall be verified or determined by the laboratory.

iii. If a reference interval study is not possible or practical, then the laboratory shall carefully evaluate the use of published data or data provided by the equipment manufacturer for its own reference intervals and retain record of this evaluation.

iv. As appropriate, the description of the examinations performed, their results and reports should follow the vocabulary, syntax and nomenclature recommended by recognized bodies.

7.4.1.7 Additional information for reports

i. Report interpretation comments shall include comments on discrepancies when testing is performed by different procedures or in different locations. All test results performed by POCT shall be clearly identified on the report.

ii. Comments relating to the quality or adequacy of the primary sample, such as 'hemolyzed', should make clear which tests may have been affected and the nature of the likely effects, such as positive or negative interference, if known.

7.4.1.8 Amendments to reported results

i. Authority to make amendments to reported results shall be clearly defined.

ii. When the amended results may alter patient management, the laboratory shall ensure that persons with the authority to take action are contacted and duly informed.

7.4.2 Post-examination handling of samples

i. Storage of primary samples and sub-samples shall be defined in documentation to ensure traceability to the patient is maintained.

ii. The retention time and storage conditions for each sample type shall be defined, along with the stability of the sample for additional testing. Retention times shall comply with local regulations if applicable.

iii. Samples, without prior consent, may be used for research studies or as QC material provided the patient's details are rendered anonymous or samples are pooled.

iv. All biological/medical waste, including liquid waste, shall be disposed of as per local/international and legal regulations after onsite segregation and/or treatment.

7.5 Nonconforming work

(General requirements are as per ISO 15189:2022)

i. Any identified nonconformities shall be investigated and root cause evaluated to determine if the

incident is an isolated occurrence or is a symptom of a more widespread issue.

ii. Risk assessment of all nonconformities shall be completed for any potential impact on patient safety

iii. Appropriate corrective action shall have implemented and the effectiveness to reduce the risk of occurrence shall be evaluated.

iv. A review of nonconforming work for any trends should be presented and discussed at a management review meeting.

7.6 Control of data and information management

(General requirements are as per ISO 15189:2022)

7.6.1 General

Refer to ISO 22367:2020 for risks associated with computerized laboratory information systems.

Refer to ISO/IEC 27001:2022 for security controls to main integrity of information.

7.6.2 Authorities and responsibilities for information management

If the laboratory information management system is subcontracted or maintained off-site, it is still the responsibility of laboratory management that all requirements of this standard are met.

7.6.3 Information systems management

i. The laboratory shall perform data integrity checks of electronically transmitted test reports compared to the original information in the LIS at defined intervals, with at least annual checks performed.

NOTE 1: This interval may vary according to the frequency and mode of transmission and the complexity of the test data

Data integrity checks shall also be completed after any changes made in the LIS and when new equipment interfaces are implemented.

ii. The checks are expected to include biological reference ranges and automated comments.

iii. Records of data integrity checks shall be kept.

7.6.4 Downtime plans

No additional points.

7.6.5 Off site management

No additional points.

7.7 Complaints

(General requirements are as per ISO 15189:2022)

7.7.1 Process

i. Documented processes and procedures shall be available to receive, analyze and handle complaints
ii. Records of all activities related to complaint handling shall be maintained
iii. Evidence of analyzing data from complaints as an improvement tool shall be demonstrated.

7.8 Continuity and emergency preparedness planning

(General requirements are as per ISO 15189:2022)

i. Continuity of services in an emergency situation or other conditions of limited activities needs to focus on testing that is essential or life preserving.
ii. POCT should be available as a contingency option for laboratories providing services for hospital-based care.

8. Management system requirements

(General requirements are as per ISO 15189:2022)

8.1 General requirements

8.1.1 General

i. The management system shall meet the requirements of ISO 15189 and any additional requirements included in this and other related documents, along with ensuring compliance to relevant local and legal regulatory requirements.
ii. The management system (previously referred to as quality management system) shall provide laboratory management with continued confidence that the requirements of this standard and the needs of the users are being met.
iii. The management system shall include actions to address risk and opportunities for improvement.
iv. Any significant change to the management system shall be notified to AERSSC.

8.1.2 Fulfilment of management system requirements

No additional points.

8.1.3 Management system awareness

Laboratory management is responsible to ensure all personnel involved in laboratory activities are fully conversant with the management system requirements and their responsibilities to ensure compliance.

8.2 Management system documentation

(General requirements are as per ISO 15189:2022)

8.2.1 General

The standard no longer prescribes a quality policy or specifically a quality manual. However, procedures still need to be maintained which include objectives and policies.

8.2.2 Competence and quality

No additional points.

8.2.3 Evidence of commitment

i. The management shall provide evidence of its commitment to develop a management system that meets requirements of its users and this standard. Adequate training shall be provided to all staff concerned on its use and continual improvement.
ii. Management staff with the responsibilities of laboratory director and quality manager should have had training in ISO 15189 internal auditing.

8.2.4 Documentation

No additional points.

8.2.5 Personnel access

Reasonable access to relevant parts of management system documents by all staff members shall be assured.

8.3 Control of management system documents

(General requirements are as per ISO15189:2022)

8.3.1 General

No additional points.

8.3.2 Control of documents

i. All controlled documents both external and internal shall be updated, reviewed, and revised as required, with only the authorized and current version available at the place of use.
ii. Internal documents shall be reviewed at least once in 12 months, or according to local regulation.
iii. Work Instructions, posters or flow charts relating to laboratory work shall be considered as controlled documents and shall be traceable to their respective parent documents. All the requirements of document control shall apply.
iv. If a wall poster is only providing information and not instructions, it may not be considered to be a controlled document.
v. Worksheets that contain instructional material and/or calculations shall be controlled in a manner similar to procedural documentation.
vi. Forms used to record results and other relevant information do not need to include full document control parameters expected for instructional material but shall contain sufficient information to preclude inadvertent use of superseded versions.

vii. The laboratory shall have a defined documentation system detailing the different levels or types of documents - both internal and external.

viii. Laboratories with sample collection centres and control of POCT shall also exercise control over documents/instructions provided to these locations.

8.4 Control of records

(General requirements are as per ISO 15189:2022)

8.4.1 Creation of records

i. The laboratory shall retain records of original observations, derived data, and sufficient information to establish an audit trail for all test results reported.

ii. All records shall remain legible and include the identity of the person making each entry.

iii. It is recognized that a number of staff members may be involved in test processes or other laboratory procedures. It is the laboratory's responsibility to identify the critical steps in the procedure and to ensure that the identities of the staff members concerned are recorded.

NOTE: These include activities such as maintenance and QC tasks, result recording and commenting, review and amendment of results, and reporting of results to requestors.

8.4.2 Amendment of records

i. When mistakes occur on paper records, they shall not be erased, made illegible or deleted by such means as correction fluid, but crossed out and the correct value/data or information entered alongside. The identity of person making the amendment shall also be recorded.

ii. In the case of electronic records, equivalent measures shall be taken to avoid loss or change of original data. Spreadsheets may require annotation of the record to effect this expectation.

8.4.3 Retention of records

i. Defined retention times are required to be based on identified risk of early disposal and shall meet the minimum regulatory requirements.

ii. Organizations shall ensure that records stored electronically can be retrieved throughout the stated retention period despite changes in technology that may occur.

iii. Adequate processes shall be in place to ensure all relevant records are appropriately stored prior to disposal, with extra care taken when storing records with sensitive patient information in shared facilities

8.5 Actions to address risks and opportunities for improvement

(General requirements are as per ISO 15189:2022)

8.5.1 Identification of risks and opportunities for improvement

i. Addressing both risks and opportunities for improvement establishes a basis for increasing the effectiveness of the management system.

ii. The laboratory shall complete a risk assessment of all pre-examination, examination, and post-examination activities for impact on patient care and safety, and identifying which risks and opportunities need to be addressed.

8.5.2 Acting on risks and opportunities for improvement
No additional points.

8.6 Improvement
(General requirements are as per ISO 15189:2022)

8.6.1 Continual improvement
The laboratory shall identify, monitor, analyse and take action on quality indicators that are defined taking into account the associated risks. These actions shall demonstrate an improvement in the performance of the laboratory. The improvement plans shall be communicated to the staff concerned.

8.6.2 Laboratory patients, user, and personnel feedback
No additional points.

8.7 Nonconformities and Corrective Actions
(General requirements are as per ISO15189:2022)

8.7.1 Actions when nonconformity occurs
The impact of any nonconformity in relation to risks and opportunities shall be determined.

8.7.2 Corrective action effectiveness
No additional points.

8.7.3 Records of nonconformities and corrective actions
No additional points.

8.8 Evaluations
(General requirements are as per ISO 15189:2022)

8.8.1 General
Evaluations shall be focused on determining that the laboratory's management system and activities meets the needs and requirements of patients and laboratory users.

8.8.2 Quality indicators
The Laboratory shall incorporate salient quality indicators for monitoring its performance. This shall describe the evaluation of various aspects of laboratory function such as, but not limited to, the following: Sample collection and identification, Sample transportation and processing, Sample acceptance and rejection, Equipment downtime, Uncertainty of measurement, Performance in EQA/PT, Analysis and reporting of results, Turnaround times for routine and urgent testing, Turnaround times for routine and urgent testing.

8.8.3 Internal audits

i. The internal audit plan shall ensure all elements of its management system and technical operation are covered with consideration of clause 5.3.2 of ISO 15189: 2022 standard and should include both horizontal and vertical audits.

NOTE: The expectation of internal audit that the main clauses and technical standard operation procedure (SOP) are planned to be audited in monthly basis throughout the whole year.

ii. All elements and the entire laboratory does not necessarily be covered in a single audit but can be spread out across the 12 months.

iii. Comprehensive internal audits for each laboratory discipline, including each collection site and POCT activities, shall be conducted at least annually.

iv. Personnel conducting an internal audit shall have participated in a recognized training course and shall be independent of the area being audited.

v. Use of a checklist or similar is expected to ensure complete coverage of the important aspects of an audit and this also enhances objectivity of findings. A specific checklist may be used for collection sites and POCT activities.

NOTE: In addition to the standard requirement, checklist should include relevant EIAC requirements and local/national regulations.

vi. The laboratory shall determine which elements of its operations are critically important to patient care and focus in particular on these areas.

8.9 Management reviews

(General requirements are as per ISO 15189:2022)

8.9.1 General

i. The overall purpose of management review is to evaluate past and present performance, in order to develop strategies that will optimize the laboratory's contribution to patient care. A management review shall occur at least once in 12 months.

ii. This should be scheduled after internal audit activities for the past year have been completed and prior to the external assessment.

8.9.2 Review input

i. Presentation of summarized data should be presented either prior to the meeting or as a PowerPoint presentation during the meeting.

ii. POCT activities shall also be included as a review input where relevant.

iii. Use of a standard template to facilitate the management review process is expected to be developed, with items to be reviewed and discussed clearly recorded.

8.9.3 Review output

Conclusions and actions arising from management review is required to be communicated to all laboratory personnel.

Annexure A

Additional requirement for Point-of-care Testing (POCT)

i. Service agreements are required between the laboratory and the area where POCT activities are provided, which defines the respective roles and responsibilities.
ii. The laboratory shall appoint a person to be responsible for POCT activities including quality control, EQA and training of personnel who will be performing the testing.
iii. Annual competency reviews shall also be conducted for all operators of POCT instruments.