Accreditation Education Research & Scientific Service Center, Nepal

Specific Criteria for Accreditation of Medical Laboratory (ISO 15189:2012)

Document No. – AERSSC 22

Issue No.: 11 **Issue Date:** 31st March 2024
Amendment No.: 0 **Amendment Date:**

Amendment Records

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

Contents

1. Introduction

The scope of ISO 15189:2012 states the standard is for "use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories. The introduction states: "if a laboratory seeks accreditation, it shall select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories".

Laboratory accreditation activities are administered under the Accreditation Education Research and Scientific Service Center (AERSSC) in Nepal involving Assessment Team and Accreditation Committee as well as Accreditation Board. AERSSC is Associate Member of International Laboratory Accreditation Cooperation (ILAC) and Asia Pacific Accreditation Cooperation (APAC) and planning to be a signatory to APAC and ILAC.

The Specific Criteria document provides an interpretation of ISO 15189:2012 and describes specific requirements for those clauses which are general in nature. Further, the laboratory shall follow National Mandatory Laws and Regulations.

2. Scope

The scope of the accreditation is applicable to the following Medical Laboratory Services as follows:

i. Clinical Biochemistry
ii. Clinical Pathology
iii. Hematology
iv. Immunology
v. Histopathology
vi. Cytopathology
vii. Serology

The accreditation will be considered only for those tests, which the laboratory is in itself equipped and competent to carry out.

3. Description and Type of Laboratory

The requirements given in this document are applicable to all Medical Laboratories (private/government) existing in Nepal applying for AERSSC accreditation regardless of the level as well as location. Each and every Health/Medical laboratory has to be registered from National Public Health Laboratory under the Ministry of Health, Government of Nepal which has classified five types of medical laboratories on basis of their existing equipment as mentioned in Annexure 1 and facilities which are as follows:

E group Laboratory:
Human resource: minimum two.

Services to be provided by these laboratories include designated test in the field of Hematology, Biochemistry, Microbiology and routine urine analysis, routine stool analysis etc.

D group Laboratory:
Human resource: minimum four, one of whom shall be lab technologist or above.
Services to be provided by these laboratories include designated test in the field of Hematology, Biochemistry, Microbiology, Serological tests in addition to designated test for group E.

C group Laboratory:
Space with designated areas for sample collection, sample processing and reporting (applicable to 50 beds General Hospital);
Human resource: Minimum six with at least 50% technical manpower shall be having Bachelor's Degree or above with at least one having Master's degree or above depending upon the nature of tests.
Services to be provided by these laboratories include designated test in the field of Hematology, Biochemistry, Microbiology, Histopathology/Cytopathology in addition to designated test for group D.

B group laboratory:
Space with adequate rooms required for all specialized laboratory services (depending on type of services (applicable to 51 to 200 beds General Hospital);
Human resource: twelve or four per discipline with 50% technical manpower shall be having bachelor's Degree or above with at least three having Master's degree or above depending upon the nature of tests.
Services to be provided by these laboratories include designated test in the field of Haematology, Biochemistry, Microbiology, Histocytology tests in addition to designated test for group C;
All stand-alone laboratories providing specialized or super specialized services shall be of B group.

A group Laboratory:
Space depending upon the number of specialized services. There shall be adequate space for sample collection, information/reception/cash counter/ reporting room, QC unit, library, meeting hall and office;
Human resources: minimum 24 or six per discipline with 50% technical manpower shall be having Bachelor's Degree or above with at least one per department having Master's Degree or above depending upon the nature of tests.
Services to be provided by these laboratories include designated test in the field of Hematology, Biochemistry, Microbiology, Histocytopathology tests in addition to designated test for group B.

Classification of Type of laboratory as per no of samples received as follows:
Small Sized Laboratory: A laboratory receiving up to 100 patients per day.
Medium Sized Laboratory: A laboratory receiving up to 101-200 patients per day.
Large Sized Laboratory: A laboratory receiving up to 201 – 400 patients per day.
Very Large Sized Laboratory: A laboratory receiving more than 400 patients per day.

Other mandatory requirements to be fulfilled by each and every medical laboratory under guidelines published by the National Public Health Laboratory under the Ministry of Health, Nepal are as follows:

- Easily accessible
- Well ventilated
- Sufficient light
- Controlled environment
- Adequate water supply
- Uninterrupted electricity supply –back up if needed
- Efficiency and quality of laboratory operations
- Sterilization facility
- Proper waste management facility
- Proper storage for transportation of biological/clinical samples and reagents
- Data storage, recording and data management
- Safety of personnel and environment
- Quality of reagent/chemical used
- Logical flow of work for separate activities
- Free from contamination problem
- Other facilities e.g. refreshment/rest room/etc.

4. Management Requirement

4.1 Organization and management

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.2 Quality management system

(The main test of this clause is the text of the same clause of ISO 15189:2012).

4.3 Document control

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.4 Review of contracts

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.5 Examination by referral laboratories

(The main text of this clause is the text of the same clause of ISO 15189:2012).

Laboratory shall have documented policy and procedure for selection and evaluation of referral laboratories. Samples may be referred to another laboratory when the main equipment is under break down or maintenance and consultants are selected for getting second opinion.

Laboratory management has to take responsibility for selecting and monitoring the quality of referral laboratories and consultants.

4.6 External services and supplies

(The main text of this clause is the text of the same clause of ISO 15189:2012).

Purchased items like reagents, antibiotic shall be checked before being placed in service as per the policy and procedure of the laboratory.

4.7 Advisory Services

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.8 Resolution of Complaints

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.9 Identification and control of nonconformities

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.10 Corrective action

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.11 Preventive action

(The main text of this clause is the text of the same clause of ISO 15189:2012).

4.12 Continual improvement

(The main text of this clause is the text of the same clause of ISO 15189:2012).

All operational procedures shall be systematically reviewed by laboratory management annually, as defined in the quality management system, in order to identify any potential sources of non-conformities and opportunities for improvement of technical practices.

Further, the laboratory must have the comprehensive program for Quality improvement which will describe the evaluation of various aspects such as,

- Sample collection and identification;
- Transportation and processing;
- Analysis and reporting of results;
- Turnaround time;
- Equipment downtime;
- Uncertainty of measurements (monthly % cv);
- Performance in EQAS/NEQAS

4.13 Quality and technical records

(The main text of this clause is the text of the same clause of ISO 15189:2012).

The laboratory shall decide the retention time of records as per the National regulations.

4.14 Internal audits

(The main text of this clause is the text of the same clause of ISO 15189:2012).

The laboratory must have documented policy and procedures regarding:

- Quality Policy
- Quality Manual;
- Quality Plan
- Standard and corrective action Procedures;

- Standard Operating Procedures;
- Design forms and records;
- Participation in NEQAS/EQA Programs

4.15 Management review

(The main text of this clause is the text of the same clause of ISO 15189:2012).

5. Technical Requirement

5.1 Personnel

The authorized signatories shall demonstrate knowledge and competence in the concerned specialty.

5.2 Accommodation and environmental conditions

(The main text of this clause is the text of the same clause of ISO 15189:2012).

5.3 Laboratory Equipment

(The main text of this clause is the text of the same clause of ISO 15189:2012).

The mandatory requirement for the equipment as per NPHL Guidelines has to be followed by each and every health laboratory before registration has been attached as Annexure.

All reagents/stains/media/kits/antimicrobial discs shall be procured from standard reputed sources.

All laboratory specific items like reagents, lab ware, lab equipment etc shall be received directly at lab.

Each new lot number reagents/kits/antibiotic sensitivity will be checked for performance and suitability for the intended use per procedure defined in SOP on new reagent/kit/antibiotic sensitivity lot verification. Temperature controlled items like reagents, clinical reference material (like controls and calibrators) are immediately stored at appropriate temperatures (refrigerated at 2-8 C or frozen at -20 C) as mentioned by the manufacturer on the surface of packaging.

Further, the laboratory must have documented procedure related to the following:

- Calibration, performance, verification/validation and proper operation as per manufacturers Guideline;
- Calibration of automated instrument such as cell counters, clinical biochemistry autoanalyzer, automated haematology analysers and ELISA readers etc.
- Maintenance Plan including Annual Maintenance Contract (AMC);
- Training of Concerned staff for the operation of Equipment;
- Inventory log of new equipment with date of purchase including status of the equipment new/used/repaired one.

Generally, in the use of analytical systems such as automated analyzers the frequency of calibration will be as per manufacturer's guidelines.

Analytical instrument such as pH meter, spectrophotometer and colorimeter, HPLC can be calibrated primarily in-house by use of certified reference materials traceable to National/International Standards.

Temperature controlled equipment such as water baths, incubators, ovens and refrigerators etc. shall be monitored routinely to ensure compliance with the temperature requirements of test methods. Temperature recording devices shall be checked at six monthly intervals against a reference thermometer and the results shall be recorded.

5.4 Pre-examination Procedures

(The main text of this clause is the text of the same clause of ISO 15189:2012).

Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual including the following at least:

- Copies of or references to list of available laboratory examinations offered, consent forms, information and instructions provided to patients in relation to their own preparation before primary sample collection, information for users of laboratory services on medical indications and appropriate selection of available procedures;
- Instructions for completion of request from or electronic request, type and amount of the primary sample to be collected, special timing of collection, if required, any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigerants, warming, immediate delivery etc.) labelling of primary samples, clinical information (e.g. of history of administration of drugs in detail of the patient from whom a primary sample is collected, safe disposal of materials used in the collection;
- Instructions for storage of examined samples, time limits for requesting additional examinations, repeat examination due to analytical failure or further examinations of primary sample;
- Rejection of sample if there is lacking of proper identification or not traceable by request form;
- Concerning verbal requests for examinations;
- Monitoring the transportation of samples within a timeframe/temperature interval with designated preservatives to ensure the integrity of samples.

  Storage period of examined specimen

The examined samples shall be stored for a specific time as described in the procedure under conditions that ensure stability of sample properties to enable any retesting or add on tests if required.

5.5 Examination Procedures

(The main text of this clause is the text of the same clause of ISO15189:2012).

Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations. The documentation shall include, when applicable to the examination procedure the following,

- Purpose of the examination
- principle and method of the procedure used for examination;
- Performance Characteristics

Laboratory shall not use reagents/consumables or methods that have not been extensively validated by the manufacturer for their intended use and clinic-pathologic correlation.

In case lab modifies the reagent use for concentrations/dilutions other than mentioned in the manufacturer provided reference literature, the same shall be extensively validated under close supervision of Lab Director.

5.6 Assuring Quality of Examination Procedures

(The main text of this clause is the text of the same clause of ISO15189:2012).

The laboratory must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving "out of control" situations as well as procedure for applying one level QC or 2 levels of QC once a day or at least twice a day on the basis of number of patient samples analysed. The laboratory must have its procedures for Internal Quality Control, so as to verify the quality of test results before they are released. The laboratory shall incorporate in the procedure, the multi-control QC rules used to detect systematic (trend or shifts) and random errors.

Lab process the internal quality control practices prior to the analysis of patient samples so that equipment and reagent functionality is verified as per manufacturer's specification. As per ISO 15189:2012 "External quality assessment programs provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

Laboratory shall participate in formal EQAS programs with National/International level. The results shall be documented and if any deviations are noted necessary corrective actions has to be implemented and documented. Wherever EQAS program is not available lab shall participate Inter Laboratory Comparison (ILC) with two accredited labs.

5.7 Post-Examination Procedures

(The main text of this clause is the text of the same clause of ISO15189:2012).

Authorized personnel shall systematically review the results of examination, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of results.

Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.

5.8 Reporting results

(The main text of this clause is the text of the same clause of ISO15189:2012).

However, there are some additional requirements that address the urgency of some medical samples, the need to determine and monitor turnaround times, as well as confidentiality of information, they are:

- Turnaround time for release of report: as per defined by the responsible laboratory in compliance with the test;
- Quality check/review of results to confirm accuracy of report;
- Retention of sample and softcopy/hardcopy of the report;
- Method of communicating results to physician and date management, e.g. email, fax, hard copy;

"The laboratory shall have procedures for immediate notification of Physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established "alert or critical intervals'. This includes results received on samples sent to referral laboratories for examination.

Results of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible staff member, person notified and examination results.

"The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.

The laboratory shall have clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall also include guidelines for the release of results directly to patients".

The list of what an examination report contains also includes:

a) Detailed description of the laboratory including registration number and category;
b) Date and time of primary sample collection as well as time of receipt;
c) Referred/requested by;
d) Test date and test description;

e) Test Method
f) Test results with interpretation (with normal values where applicable);
g) Biological reference intervals;
h) Date and time of release of report;
i) Authorized signature with qualification and respected council registration number.

6. References

1. ISO15189:2012 Medical Laboratories – requirements for quality and competence;
2. ILAC P10:07/2020 ILAC Policy on Traceability of Measurement of results;
3. ISO/IEC 17011:2017 Conformity assessment requirements for accreditation bodies accrediting conformity assessment bodies;
4. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories;
5. ILAC G 26:11/2018 Guidance for the implementation of a Medical Accreditation Scheme;
6. Guideline on Health Laboratory Establishment and Operation 2017, Published by National Public Health Laboratory on 12th May 2017 under Ministry of Health, Government of Nepal.

Annexure 1

List of Equipment

l. "E" Category laboratory

All "Basic Equipment's", consumables, reagent/kits

Basic equipment's include:

- Centrifuge
- Colorimeter
- Water bath
- VDRL shaker
- Hot air oven
- incubator
- Micropipettes
- DC counter
- Refrigerator
- Power backup

Glassware's-- Khan Tubes, Test tubes, petridishes, etc.

Consumables- Disposable syringes, vacutainers, Gloves and masks.

2. "D" Category laboratory

All "E" category, PLUS Semi-automated: Biochemistry analyser etc.

3. "C" Category laboratory

All "D" category, PLUS Automated hematology analyser, Coagulomater, Electrolyte analyser, ELISA etc.

4. "B" Category laboratory

All "C" category, PLUS Fully Automated Biochemistry analyser, CLIA etc.

5. "A" Category laboratory

All "B" category, PLUS Basic molecular facility (PCR- Conventional/Real Time) etc.

Source: Guideline on Health laboratory establishment and Operation 2017.

Annexure 2

List of routine and special tests

Clinical Biochemistry

Routine tests: Plasma/ Serum: glucose, urea, creatinine, total protein, albumin, bilirubin, AST, ALT, LDH, alkaline phosphatase, acid phosphatase, CK & CK MB, electrolytes, calcium, phosphorus, cholesterol, triglycerides, HDL cholesterol, uric acid, amylase, T3, T4, TSH, FSH and LH (except by RIA). Urine: 24 hours for biochemical examination, CSF: glucose, protein, chloride. Effusion fluid and Ascitic fluid: glucose, protein; Calculi analysis

Special tests The tests other than those mentioned above.

Haematology

Routine tests Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), Malaria/Filarial Parasite, Blood grouping, Compatibility testing for transfusion, D-Dimer/FDP, PT, APTT, Fibrinogen, Bleeding time, Anti globulin (Coombs) test (direct and indirect), G6 PD screen, sickling test,

Special tests The tests other than those mentioned above.

Microbiology and Serology Routine Tests: Urine routine stool routine, Examination of direct smear and stain preparation under microscope in bacteriology, mycology and parasitology.

Slide and agglutination reaction, ELISA and automated serological reactions

Special tests: The tests other than those mentioned above

Histopathology: All tests are considered special.

Cytopathology: All tests are considered special.

Genetics / molecular: All tests are considered special.

Source: Guideline on Health laboratory establishment and Operation 2017.