Supplementary Requirements for Accreditation of Medical Testing Laboratories

Foreword

This Philippine Accreditation Bureau (PAB) Supplementary Requirements for Accreditation of Medical Testing Laboratories (LA/SR08) was developed by the Laboratory Accreditation Technical Committee (LATC) – Medical Testing to supplement ISO 15189 requirements by providing specific technical criteria and guidelines for both assessors and for laboratories carrying out medical testing.

The numbering in the text of this document follows system of the ISO 15189 numbering system.

1 Scope

All applicant and accredited Medical Testing Laboratories are required to meet this supplementary requirement in addition to the requirements for the quality and competence of medical testing laboratories ISO 15189.

This document describes additional, specific accreditation requirements for laboratories performing all types of human pathology testing and therefore often need to be interpreted with respect to the type of testing concerned, and the techniques involved. Also, this document provides an explanation of the application of ISO 15189 for medical testing laboratories.

The following information is referenced to specific clauses in ISO 15189. Where a clause is not listed, it is considered that the wording is sufficiently clear not to warrant explanation and that there are no supplementary requirements related to this clause.

2 Authorship

This document was prepared by the PAB LATC for Medical Testing. It is based on deliberation by the group of experts and stakeholders convened by the PAB.

3 Terms and definitions

The word “shall” describes mandatory criteria for accreditation. The word “should” is used where guidance is provided but does not preclude other acceptable practices. Where a smaller size font has been used this indicates matters of an advisory or informative nature.

Where the words “policy” and “procedure”’ are used in ISO 15189 it is possible that one document may meet the requirements of the standard. This will be determined at assessment.

4 Management requirements

4.1 Organization and management responsibility

4.1.1.2 Legal entity

It is the responsibility of the laboratory to carry out its work in accordance with relevant Laws and Regulations applicable to its economy.

4.1.1.3 Ethical conduct

The Laboratory shall have documented evidence of conformity to follow policies and procedures on ethical conduct. Preservation of proprietary rights shall be included in the policies and procedures on ethical conduct.

4.1.1.4 Laboratory director

There shall be an official appointment of laboratory director or its equivalent by the management.

4.1.2 Management responsibility

4.1.2.2 Needs of users

The laboratory shall have documented list of services, turnaround time, preparation of patients, sample volume requirements, purchase requirement (i.e. suppliers and service providers), and adequate resources (i.e. employees).

4.1.2.6 Communication

Means of communication include but not limited to memo, email, bulletin boards, logbook and the like.

4.1.2.7 Quality manager

The scope of responsibilities and authority of the quality manager shall be clearly defined and documented. The responsibilities of the quality manager shall include the following functions:

a) maintenance of the quality manual and associated operation documentation;
b) monitoring of laboratory practices to verify continuing compliance with documented policies and procedures;
c) selection, training and evaluation of internal auditors;
d) scheduling and coordination of internal audits and management reviews;
e) review of feedback received from clients;
f) proposal of corrections and improvements to the management system;
g) ensuring instruments are calibrated and maintained according to schedules;

4.4 Review of Contracts

4.4.1 Establishment of service agreements

When reviewing contracts, laboratories shall ensure that the examinations requested relate to the needs of customers for the intended purposes. As far as practicable, laboratories should give advice to customers and help them determine their needs.

Contracts within a medical laboratory may include but are not limited to:

- request forms signed by the requesting clinicians;
- contracts or tenders with customer groups;
- add-on requests (verbal or written);
- consultancy arrangements; and
- arrangements where supervision is provided by a person who is not employed/ affiliated to/by laboratory or hospital management.

Where a laboratory is a part of a hospital and provides in-house services to the hospital, the internal arrangement between the hospital management and the laboratory management may be considered as the contract and the requirements of this clause apply. The arrangement may be in the form of a memorandum, circular, letter, minutes of a meeting etc., which shall be controlled.

4.4.2 Review of service agreements

The laboratory shall inform the customer concerned of any deviation from the contract within a reasonable time to minimize adverse effects on patient care or health services that may ensue.

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

A competent referral laboratory is a laboratory accredited by PAB or one of PAB's mutual recognition partners for the tests referred.

4.5.2 Provision of examination results

There must be a procedure for the follow-up of results from the referral laboratory in a timely manner.

Where tests are reported electronically, the requirement for traceability shall be maintained.

Note: Medical Testing Laboratories in the Philippines shall follow Department of Health (DOH) Administrative Order 2007-0027 on Releasing of Reports from Referral Laboratories.

4.6 External services and supplies

There are two commonly encountered situations where a laboratory needs to seek external services and supplies:

a) Purchase of consumables or perishable items (e.g. media, reagents, calibrators, controls, etc.):

   Records shall be kept of the different brands of these items which bear a critical influence on the examination results. These records shall, where appropriate, include results of acceptance tests on each new batch and/or delivery prior to use. When a particular brand shows an undesirably high rejection rate, consideration shall be given to excluding it from the list of acceptable source of supplies.

   Expiry dates of purchased consumables or perishable items/materials shall be recorded in addition to the other details listed in the Standard.

b) Purchase of equipment:

   Separate records shall be kept for each manufacturer supplying major items of equipment. The records shall include results of the acceptance tests and the subsequent maintenance history of their products. Manufacturers whose products consistently do not meet their stated performance specification and/or show undesirably high proportion of instrument down time and/or are not supported by good after-sale service shall be noted and their names removed from the list of currently approved suppliers.

4.7 Advisory services

Pathologist(s) and/or appropriate specialist(s) shall be available to provide clinical advice prior to test ordering and to advise on the interpretation of all test results. This may entail referring the clinician to an appropriate specialist in another laboratory or institution. A laboratory handbook, developed in conjunction with appropriate pathologist(s) or specialist(s), may be seen as a convenient means of providing guidance to clinician(s) on the choice of tests, etc. However, this does not negate the need to provide direct access for clinician(s) to special advice as needed. Freedom consultation between pathologist, specialist, and clinician (including that required to gain a second opinion), must not be hindered by commercial or financial consideration, when applicable.

4.10 Corrective action

Corrective actions may be identified through internal audits, external audit by accreditation and certification bodies, customer and staff feedback and complaints, analysis of quality control data, performance in proficiency testing programs, incidence of nonconforming work, etc. Corrective actions shall be evaluated, prioritized and implemented according to an agreed timescale. ~~Their~~ Effectiveness of corrective actions taken shall be monitored.

4.11 Preventive action

Preventive actions shall be taken against needed improvements and potential nonconformities. This highlights the need for identifying potential problems and opportunities for improvement. In other words, the laboratory shall take a proactive approach rather than a passive and reactive approach.

Note: Total quality management tools such as brainstorming, flowcharting, pareto charts and similar problem-solving tools and techniques may assist this process.

4.12 Continual improvement

Upon review of the processes, identified actual or potential sources of nonconformance or other opportunities for improvement in the quality management system or technical practices shall be subject to quality improvement studies focused on the processes, assessment and performance.

Note: a) Continual quality improvement activities may be based on the plan-do-check-act (PDCA) cycle framework and result in feasible action plans.
b) Educational and Training opportunities regarding continual improvement can be availed through various national quality organizations, professional organizations or academic institutions.

4.13 Control of records

All records shall include the identity and signature of the person making the record and the date the record is made. It is recognized that a number of personnel may be involved in the 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 personnel concerned are recorded. For electronic records, in lieu of a signature, traceability of critical steps in a procedure to personnel performing or taking part in the process should be ensured.

Alterations to data must include the date the change was made and the identity of the person making the change.

The record system shall include a copy of each report issued or shall allow one to be reproduced. Test request form may be in either hard copy or electronic copy.

Minimum retention periods for patient records and specimens shall conform to relevant national guidelines where applicable (*e.g. The Revised Disposition Schedule of Medical Records Amending Ministry Circular 77 s. 1981*). Where not applicable, consult national and international standards of medical professional societies.

The record system shall include but not limited on the following:

a) specimen identification;

b) test methodology and/or test equipment (if relevant);
c) date of test;
d) name of tests;
e) original test observations and calculations;
f) identity of the person performing the test;
g) an indication that calculations and manual data transfer have been checked;
h) identity of the person reviewing quality control results; and
i) any other information specified in the test method, other contractual documents or relevant statutory regulations.

5 Technical requirements

5.1 Personnel

5.1.8 Continuing education and professional development

Laboratory staffs (i.e. pathologists, scientists, and other appropriate staff) shall attend the minimum requirement on professional development set by the applicable legislation.

Note: Any education program should include in-house and external components and there should be access to appropriate reference texts and journals.

Components of in-house education may include:
- *regular educational presentations;*
- *journal article reviews;*
- *case presentations;*
- *review of QAP educational material; and*
- *review of interesting or abnormal blood films, cultures etc.*

Components of external continuing education may include:
- *membership in relevant professional societies; and*
- *attendance at meetings, conferences, trainings and workshops.*

5.2 Accommodation and environmental conditions

The laboratory shall have appropriate documentation to contain the details of policies and procedures in relation to health and safety, accommodations and environmental conditions. This shall be made aware to all relevant personnel. The manual shall be reviewed, the frequency of which is to be determined by the organization, based on applicable laws and relevant references. Reference may be made to the following documents:

a) WHO Laboratory Biosafety Manual;
b) Policies & Guidelines on Effective and Proper Handling, Collection, Transport, Treatment, Storage and Disposal of Healthcare Waste.
c) DOH Manual of Standards on Laboratory Biosafety and Biosecurity;
d) ISO 15190 (a related standard on requirements for safety in medical laboratories);
e) Biosafety in Microbiological and Biomedical Laboratories by the CDC-NIH

5.3 Laboratory equipment, reagents, and consumables

5.3.1 Equipment

5.3.1.4 Equipment calibration and metrological traceability

It should be noted that calibration requirements would vary depending on method specifications. Laboratory shall have well defined systems of calibrations and intermediate checks.

Note: a) Calibration is a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand. (VIM-6.13 reference)

b) Check is a measurement of at least one point in a range of a measuring instrument or system or material against a known value to confirm that it has not deviated significantly from its original calibrated value. It is also an examination of the condition of an artifact to determine that it has not been adversely affected by constant use.

Laboratory equipment calibration and check programs should cover:

a) commissioning of new equipment (including initial calibration and checks after installation);
b) operational checking (checking during use with reference standards or reference materials);
c) periodic checking (interim but more extensive checking, possibly including partial calibration);
d) scheduled maintenance by in-house or specialist contractors; and
e) complete recalibration.

For calibration interval of common testing equipment in medical laboratories refer to LA/SR07 Supplementary Requirements for Accreditation in the Field of Calibration, Appendix A-Equipment Calibration Intervals.

The following can be calibrated primarily in-house by use of reference materials of known composition.

Chromatographs

a) Gas chromatographs

Instrument performance shall be routinely monitored during use with reference materials. System components (e.g. integrators, ovens, electronic appliers and detectors) shall also be checked periodically, and records kept.

b) Liquid chromatography, including high performance (or high pressure) liquid chromatography (HPLC) and ion chromatography

The total system shall be monitored during use with reference materials. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) must be subject to periodic checks and details must be recorded.

The following section details general checks and maintenance requirements or equipment and instrumentation in Medical Testing laboratories.

Flow cytometry

Performance of the photomultiplier tubes should be monitored daily to ensure that the correct alignment is maintained between calibrations and that the settings in use are still within the monthly calibration parameter limits.

Temperature-controlled equipment

Recorded checks of the temperature must be performed on each day of laboratory operation. The use of continuous temperature monitors is recommended where temperature control is critical. Maximum/minimum thermometers must be used where appropriate.

Corrective action must be taken when temperatures fall outside acceptable limits with records kept.

The thermometers used to monitor the performance of temperature-controlled equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods.

5.4 Pre-examination processes

5.4.4 Primary sample collection and handling

5.4.4.1 General

The laboratory's collection procedures shall include 'order of draw'.

Note: Blood collection tubes must be drawn in a specific order to avoid cross contamination of additives between tubes.

Documented instructions should be available for self-collect samples (e.g. midstream urine, semen) in languages appropriate for the patient population.

5.4.4.2 Instructions for pre-collection activities

Sample collection containers shall not be labeled before collection.

5.4.4.3 Instructions for collection activities

a) On presentation for collection, all patients shall be positively identified by the collector without prompts e.g. by asking 'What is your name?'

   Note: Where identification of the patient by the above means is not possible, e.g. unconscious patients, non-English/ non-Filipino speakers etc., other mechanisms would be necessary to ensure correct identification.

e) The minimum requirements for labeling samples are two identifiers attributable to the patient. Generally these will be patient's full name and either date of birth or medical record number. Where point-of-care testing is performed, labeling requirements may be relaxed; where a delay in testing occurs there must be labeling of the syringe or tube as above. Samples which are not labeled with two identifiers are considered to be inadequately labeled.

f) Where inadequately labeled samples are received and accepted for testing, the laboratory must assure itself of the identity of the sample. If samples that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of any subsequent action taken.

Where the labeling of a sample has been corrected or amended by collection staff, a comment indicating the original identification of the sample shall be recorded.

There may be special circumstances where the identity of the patient will not be revealed to the laboratory. In such cases, adequate precautions shall be taken to maintain unique identification of the sample at all stages.

5.4.6 Sample reception

Documented sample reception procedures must include the action to be taken in the event that an unsuitable sample is received.

As requirement for public health monitoring such as in HIV, Emerging and re-emerging infections, the national guidelines for testing and referral system shall be followed.

In-house laboratory procedures should be applied for research purposes only.

5.4.7 Pre-examination handling, preparation and storage

Samples and associated records (worksheets, slides etc.) shall be uniquely identified during all stages of testing.

Note: This may be achieved by the use of a unique laboratory number. This is usually the most practical option especially where large numbers of samples are processed. Alternatively, samples and associated records can be uniquely identified by the use of two patient identifiers (e.g. patient's name and either date of birth or medical record number). The uniqueness of a numbering system should take into consideration the sample storage time and ensure two samples with the same number cannot be in the laboratory at the one time.

5.5 Examination process

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

There shall be a policy or procedure for the introduction of new methodology. Appropriate records of validation or verification studies must be kept and be available for review at assessment. The results of these studies shall be evaluated and the method authorized for use prior to introduction for patient testing. Evidence of this evaluation shall be available. The documentation of the validation or verification process should include a description of the studies carried out, the results obtained, comments concerning the suitability of the method for use in the laboratory and any relevant limitations of the method.

5.5.1.2 Verification of examination procedures

Verification of methods prior to use shall include statistical correlation with existing validated methods. A statistically significant number of samples must be used in the evaluation process and these must cover the full range of results for the intended use of the assay. Precision and accuracy studies shall also be considered. For qualitative and semi-quantitative methods concordance

studies with existing validated methods are required. Clinical sensitivity and specificity shall be considered.

5.5.1.3 Validation of examination procedures

Any deviation from manufacturers' instructions shall be validated and the validation data shall be evaluated and retained as above.

5.5.2 Biological reference intervals or clinical decision values

The sources of biological reference intervals and/or medical decision points shall be documented and should include references to the information used in deciding the intervals, any statistical processes used, literature studies considered and the personnel involved in deciding the intervals. Where possible and relevant, customers of the laboratory with appropriate expertise should also be involved in the determination of reference intervals. Consideration should be given to adopting intervals/decision points consistent with those in other laboratories, where possible and appropriate.

Age, gender and other relevant information shall be considered when establishing reference intervals.

Changes to reference intervals must be documented in the same manner as changes in procedures. Where such changes could result in a different interpretation of test results, these should be communicated to users of the laboratory service in the same manner as other significant method changes.

5.6 Ensuring quality of examination results

5.6.2.2 Quality control materials

The quality control materials used shall cover the analytical concentrations encountered. Low/normal/high, normal/abnormal, positive/negative, reactive/non-reactive controls, as appropriate for the test, shall be performed. For most analytes, a minimum of two levels of quality control is recommended. Where possible the analyte concentrations should be at the clinically relevant levels.

It is recommended that controls independent of those produced by the manufacturer of the test or analyzer are used. If independent commercial quality control material is unavailable, the use of controls from the manufacturer of the reagents or calibrator may be considered. If manufacturer control is also unavailable, patient pool samples may be used.

Where calibration of an assay is required, appropriate material shall be used as a calibrator. If the material selected is not intended for use as a calibrator, assigned calibration values must be substantiated.

Mean, standard deviations (SD) and ranges supplied by manufacturers may not always provide adequate control of assays. Acceptable ranges (confidence limits) shall be defined for internal quality control material. Where acceptable ranges are set to limits other than +/- 2SD based on current analytical performance, the rationale for the limits should be documented.

Controls materials should be matrix matched where possible e.g. urine based control should be used for assay of urine analytes.

5.6.2.3 Quality control data

Numerical QC results shall be presented graphically to assist in the early detection of trends.

The laboratory shall have a system of long-term monitoring of internal quality control results to assess method performance.

There shall be documented evidence of review of internal quality control results.

A protocol for action to be taken where QC results fall outside acceptable ranges shall be documented. This shall include consideration as to whether test results should be withheld and whether previously issued results should be recalled.

Additional disciple-specific QC shall be required and laboratory shall define and implement QC procedures as appropriate.

5.8 Reporting of results

5.8.3 Report content

The identification of the laboratory on the test report shall include the PAB accreditation number. Refer to the Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol LA/SR11.

5.9 Release of release reports

5.9.1 General

d) Test reports may be issued upon completion of components of the test request. Such hard copy reports shall be labeled ‘interim’ and shall not include invalidated results. The laboratory shall have a documented protocol for issuing interim test reports.

   If interim reports are accessible to an enquirer via a computer terminal, the status of the report must be apparent to the enquirer.

e) The laboratory must have a documented protocol for the verbal release of results.

<u>Reports from other laboratories</u>

A test report may include results of tests performed by another laboratory provided that the source of those test results is clearly identified on the test report. Where testing is performed within a laboratory group, the group must be able to identify the laboratory in which testing was performed.

Note: A ‘laboratory group’ is defined as a group of laboratories with the same name and/or the same corporate accreditation number.

5.9.2 Automated selection and reporting of results

Test reports may be electronically issued (including from a site other than the accredited laboratory) provided that the reports have been appropriately authorized for release. The adequacy of such arrangements will be reviewed at assessment.

Copies (hard copy or computer records) of test reports shall be retained at the accredited laboratory. Care must be taken to ensure that copies of handwritten comments are also retained by the issuing laboratory.

The laboratory shall be able to demonstrate appropriate controls over the electronic generation, access, storage and backup of results and reports and program controls such as password protection. If the report is to be accessed from a website by the client there must be an appropriate control in place to ensure the report can only be downloaded in a protected format.

6 References

6.1 ISO 15189 : 2012 Medical laboratories - Particular requirements for quality and competence

6.2 Requirements on the Use of PAB Laboratory and Inspection Body Accreditation Symbol, LA/SR11/Issue 1/January 2015

6.3 DOH Administrative Order 2012- 27 and its Inspection Tool. “Rules and Regulation Governing Licensure and Operation of Clinical Laboratories”

6.4 Joint DOH/DENR AO no. 02 S 2005, “Policies & Guidelines on Effective and Proper Handling, Collection, Transport, Treatment, Storage and Disposal of Healthcare Waste”

6.5 DOH Manual of Standards on Laboratory Biosafety and Biosecurity

6.6 The Revised Disposition Schedule of Medical Records Amending Ministry Circular 77s.1981).

6.7 AS 4633 (ISO 15189) Field Application document-Supplementary requirements for accreditation in field of Medical Testing, NATA

6.8 SC 2 Specific criteria for accreditation in the field of medical testing- DSM Malaysia

6.9 Statistical quality control for quantitative measurements - Principles and definitions; approved guidelines (C24- A3)

6.10 Uncertainty of Measurement in Quantitative Medical testing-A Laboratory Implementation Guide-Australasian Association of Clinical Biochemists-2004

ISSUE AND AMENDMENT RECORD

Title	Issue	Date	Amendment
Supplementary Requirements for Accreditation of Medical Testing Laboratories	01	January 2015	Initial Issue
	02	January 2017	Redundant information and numbering system was aligned to ISO 15189:2012.