Guidance for the Implementation of a Medical Accreditation Scheme

ILAC-G26:11/2018

About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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TABLE OF CONTENTS

PREAMBLE

ISO 15189 *Medical laboratories – Requirements for quality and competence* is a standard that contains the requirements necessary for medical laboratories to demonstrate their competence to deliver reliable services.

The scope of ISO 15189 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 should select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories". Therefore, laboratories that meet its management and technical requirements qualify for recognition by accreditation bodies that are signatories of the ILAC mutual recognition arrangement. Clinical personnel responsible for patient care can be confident that medical laboratories accredited to ISO 15189 are competent to produce timely and reliable examination results.

PURPOSE

This is a practical guide for accreditation bodies implementing a medical accreditation scheme using ISO 15189. It identifies key aspects of the standard, points out its unique elements, and provides advice for the development and maintenance of an accreditation scheme that is based on ISO 15189.

AUTHORSHIP

This guideline was prepared by Working Group (WG) 6 (Accreditation in the Medical Field) of the Accreditation Committee (AIC) of the International Laboratory Accreditation Cooperation (ILAC).

1. Medical Laboratories and ISO 15189

Medical laboratory services are essential to patient care in the prevention, diagnosis and assessment of the health of human beings. Medical laboratory services encompass arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent result validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work. Medical laboratory services need to therefore meet the needs of all patients, other customers and the clinical personnel responsible for patient care.

ISO 15189 contains the elements essential for medical laboratories to demonstrate the quality and competence of their services as well as to consistently deliver technically valid test results.

2. Unique Elements of ISO 15189

ISO 15189 is based on ISO/IEC 17025 and ISO 9001, and provides requirements for competence and quality that are specific to medical laboratories. It addresses competence of personnel involved in patient care and medical laboratory examinations and includes requirements concerning physical facility maintenance, management of equipment, reagents and supplies, pre-analytical processes, examination processes, quality assurance, post-analytical processes and reporting of results.

The technical requirements are a comprehensive set of elements essential to consistently deliver valid test results.

The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001, *Quality management systems —Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué).

Therefore, accreditation to ISO 15189 demonstrates that medical laboratories comply with comprehensive management and technical requirements that ensure their competence to provide timely, accurate and reliable results.

3. Development and Maintenance of Accreditation Scheme

3.1 General

Accreditation bodies wishing to develop schemes to assess medical laboratory conformance to ISO 15189 should investigate and analyze the potential market as well as the existence of other established schemes before developing their own schemes. National legislation should also be taken into consideration.

3.2 Development Plan

Accreditation bodies should plan the delivery of ISO 15189 schemes and target markets based on the contents of prior research. The development plan should consider:

a) accreditation policy,
b) development issues (see note 1),
c) development tasks (see note 2),
d) development schedule, and

e) proposed structure and allocation of roles.

Note 1: Development issues may include broader subjects requiring consultation with regulatory authorities, educational institutions, and professional associations.

Note 2: Development tasks include:
a) scheme values and accreditation processes
b) criteria, forms, procedures and guidance for applicant laboratories
c) local regulations
d) record keeping or database
e) competence criteria of personnel needed for assessment activities
f) scheme manual and informative documents necessary for laboratories and assessors
g) organization and member-mix of approval, advisory and technical committees and
h) other development items necessary for the accreditation scheme concerned (see ISO/IEC17011).

3.3 Verification and maintenance of the accreditation scheme

Accreditation bodies should design and conduct an evaluation of newly implemented scheme, which should occur at the earliest possible time after implementation. This will require the setting of performance goals, evaluation criteria, and possibly the collection of baseline data. The evaluation should consider the adequacy of the processes, accreditation criteria, procedures, guidance and adequacy of other relevant documents. Based on the evaluation results, accreditation bodies should make necessary changes to their schemes.

4. Factors for Accreditation Bodies to Consider When Implementing an ILAC Accreditation Scheme for Medical Laboratories using ISO 15189

4.1 Government Regulation and Professional Governance

Accreditation bodies need to understand the overall structure within which medical services are delivered in the applicable country/economy in order to offer value-added accreditation services for medical laboratories. Governments and other regulatory authorities may wish to mandate medical laboratory accreditation, and accreditation bodies should provide these authorities with sufficient information to substantiate the added value of an ISO 15189 accreditation scheme.

Accreditation bodies should investigate and attempt to understand the professional/legislative structure within which medical services are delivered, to define the most suitable structure for delivery of medical laboratory accreditation for the country/economy.

Some form of professional review of the quality of medical services may already exist, which accreditation bodies should consider when developing a medical laboratory accreditation scheme. Challenges may be encountered in convincing powerful medical and government authorities, of the value of accreditation. Prior to designing a medical laboratory accreditation scheme the following areas should be investigated and understood.

- Stakeholder and special interest bodies who may need to be consulted in the design of an accreditation scheme. Effective engagement with these bodies may facilitate acceptance/endorsement of an accreditation scheme.

- Existing government regulations to be incorporated into the requirements for accreditation of medical laboratories. Harmonizing the goals of accreditation with the goals of the regulator will aid in resolving any conflicts between pre-existing regulations and the requirements of ISO 15189.

4.2 Medical laboratory services

Medical laboratories perform examinations for the biological, microbiological, immunological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological or other investigation of materials derived from the human body and/ or direct testing on the human body, for the purpose of providing information for the diagnosis, prevention treatment and /or monitoring of disease in (or assessment of the health of) human beings. These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

In addition, the standard ISO 15189 is also intended for use in other disciplines such as clinical physiology, medical imaging and medical physics, which could also find it useful and appropriate.

Medical laboratories will also provide a consultant advisory service covering all aspects of laboratory examination, including the interpretation of results and advice on further appropriate investigation.

Medical laboratories may be stand-alone institutions or part of a larger organization such as a hospital or clinic. Impartiality needs to be established. Management and personnel must be free from any commercial, financial or other pressures that may affect technical judgments. Potential conflicts of interest due to financial or referral arrangements need to be avoided.

Facilities that only collect or prepare specimens that are linked to a medical laboratory or a network of medical laboratories can be considered if they are included in the management system of the entity being accredited.

4.3 Management System

Accreditation bodies may inform medical laboratories on the purpose, benefits and elements of a management system. Emphasis should be placed on continual improvement and risk management. General guidance on the contents of a quality manual, the role of a quality manager/coordinator, internal auditing and management review may be necessary in order to prepare laboratories to successfully meet the management requirements of ISO 15189.

4.4 Examination by referral laboratories

Medical laboratories with limited offer of examinations may seek the cooperation of other laboratories in performing all the requested examinations on samples received. ISO 15189 specifies the relevant requirements for referral laboratories and referral

consultants. According to the definition in ISO 15189, a referral laboratory is an external laboratory to which a sample is submitted for examination.

This includes the external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report; as well as the external organization which performs subcontract work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements).

Medical laboratories can only claim accreditation for examinations they have performed by themselves and not for examinations referred to other laboratories.

4.5 Personnel (Staffing)

It is important for accreditation bodies to be familiar with the professional qualifications and where relevant other specified requirements including local legally binding regulations for personnel involved in the delivery of medical laboratory services.

Accreditation bodies need to understand the existing relationship between laboratory examinations and physician authority/responsibility in the practice of medicine. Medical laboratories should be sufficiently independent so that no one outside of the laboratory can change examination results.

In many economies, there are qualification schemes for scientists/technicians/technologists.

Common educational requirements may be established, and entry-to-practice requirements defined. Accreditation bodies need to be aware of existing qualification schemes, and that such laboratory professionals may require additional training in management systems in order to fully implement the requirements of ISO 15189.

Medical laboratories may be staffed 24 hours per day, seven days per week. Accreditation bodies shall consider if the laboratory can provide sufficient training, ongoing education and professional development for the working in evenings or at nights.

Accreditation bodies may need to consider making arrangements to observe testing activities in the evening hours or nights when certain testing is only performed during those shifts.

All competency assessment including that for professional judgment should be designed as specific and fit for purpose.

4.6 Accommodation, environmental conditions and considerations

National, regional and local governments may establish regulations that dictate building codes and other safety considerations such as fire, electrical, chemical, biohazards, conditions for the clinical laboratory, allocated space and area separation, temperature, humidity, etc. and shall be followed. International and national standards bodies are sources of helpful information.

4.7 Laboratory equipment, reagents, and consumables

Within facilities with medical laboratories, the purchasing and control of equipment, reagents and supplies may be controlled by materials management or engineering

personnel but accreditation bodies should examine these practices to ensure conformity to ISO 15189.

The purchase of equipment and consumables may be undertaken by other agencies outside the laboratory. Laboratories need to be able to demonstrate they have input, evaluate the purchase process and that appropriate materials are purchased.

The accreditation body should be aware of national and local regulations affecting procurement of equipment, reagents and consumables.

Medical laboratories often have back-up or duplicate equipment. When laboratories use different equipment or examination methods, the comparability of these different examination systems needs to be assured.

Medical laboratories are responsible for verifying that manufacturers' performance claims are met, and that calibration services provided by manufacturers meet needs. The fitness to the intended use should be ensured.

The accreditation body should confirm that adverse incidents and accidents that could be attributed directly to specific equipment be investigated and reported to the manufacturer and appropriate authorities, as required.

The traceability of measurements is a fundamental part of accreditation and accreditation bodies should provide guidance to laboratories on traceability and measurement uncertainty taking into consideration ILAC P10. In biological sample examination, traceability may be more difficult to establish (e.g. due to the lack of available international reference materials) and accreditation bodies should be aware of any special challenges encountered by medical laboratories in assuring the quality of examination results.

4.8 Pre-examination processes

Medical laboratories need to ensure that collection instructions and collection manuals are available to all personnel collecting samples for the laboratory. In case the laboratory is directly responsible for the collection of samples, accreditation bodies need to assess specimen collection, specimen storage after collection and transport as well the specimen reception has fulfilled the criteria established by the laboratory.

In cases where samples are not collected by the medical laboratory staff, laboratories are still responsible for ensuring that samples received are not compromised.

Personnel records including training and qualifications should be reviewed and collection techniques by the laboratory's own staff should be witnessed.

Wherever the collection work is performed, the collection sites should be evaluated when accrediting medical laboratories and all the typical collection sites should be covered during the whole accreditation cycle.

4.9 Examination processes and quality assurance

Laboratories shall validate examination procedures when using non-standard methods, laboratory designed or developed methods, standard methods used outside their intended scope and validated methods subsequently modified.

Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.

Accreditation bodies need to understand the methodology, instrumentation and quality assurance/control involved in producing timely, accurate and reliable test results.

Familiarity with national and local generally accepted principles of good practice can be useful in successfully implementing an ISO 15189 accreditation scheme.

Medical laboratories shall participate in PT activities as specified in ILAC P9. Whenever interlaboratory comparison is not available or possible, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.

To ensure quality of results, medical laboratories shall document a designed quality control procedures to verify the attainment of the intended quality of results.

Where medical laboratories conduct point-of-care testing (POCT) activities, requirements of ISO 22870 Point-of-care testing (POCT) should be applied if those activities are not under the direct responsibility of the laboratory.

4.10 Post-examination processes and reporting of results

It is important for accreditation bodies to understand the reporting processes and clinical consultation practices, the use of referral laboratories and consulting services, who can order/receive results of examinations, and the impact of testing on clinical management of patient care. Other factors to consider are safe disposal of biological samples and contaminated materials, in accordance with local regulations or recommendations for waste management.

4.11 Risk management

Risk management is the identification, assessment, and prioritization of risks followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events or to maximize the realization of opportunities.

The accreditation body should confirm the laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety, personnel safety and process effectiveness, and confirm the laboratory modifies processes to reduce or eliminate the identified risks and document decisions and actions taken.

4.12 Ethics

ISO 15189 addresses “Ethics in laboratory medicine”. For accreditation bodies not familiar with laboratory medicine, an insight into ethical considerations in the practice of laboratory medicine is needed. Some examples: the impact of results being sent directly to the patient without a clinician interpretation; the use of social media or web based communication by medical laboratory professionals and patients with sharing of images.

Relevant provisions in national legislation need to be also taken into consideration.

The accreditation body should confirm the laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user.

The accreditation body needs to confirm the laboratory has a documented procedure and that it has been effectively implemented, to ensure that the confidentiality of patient information is maintained at all times.

4.13 Laboratory information management

Laboratory information system (LIS) is a class of hardware and software that receive, process, and store information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as hospital information systems (HIS). A LIS is a highly configurable application which is customized to facilitate a wide variety of laboratory workflow models.

Note
Information system includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems.
Computerized systems can include those integral to the functioning of laboratory equipment and stand-alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.

5. Assessment Teams

To ensure that conformity to each clause of ISO 15189 is assessed, accreditation bodies should ensure that there is sufficient expertise on each assessment team. This includes experts in quality management systems, management of laboratory operations, and technical expertise in each discipline of practice to be included in the scope of accreditation, e.g. biochemistry, medical genetics, hematology, blood transfusion, immunology, etc.

In particular, the assessment team should have an understanding sufficient to make reliable assessments of the competence of the laboratory to operate within its scope of accreditation. Refer to ILAC G11:*ILAC Guidelines on Qualifications & Competence of Assessors and Technical Experts.*

6. Scope of Accreditation

As with any accreditation model, accreditation bodies need to determine the method for describing the scope of accreditation. For medical laboratories, this includes decisions regarding the discipline of practice, sample type and techniques employed.

Accredited laboratories may apply for flexible scope of accreditation which allow laboratories to modify their own laboratory-developed methods or to use updated versions of standard methods and standards they are accredited for and to introduce similar new methods without having to report to the accreditation body in advance, provided that these modifications and updated versions or new methods do not incorporate new measurement principles that are not covered by the original scope of accreditation.

For details, refer to ILAC G18: *Guideline for the Formulation of Scopes of Accreditation for Laboratories*.

REFERENCES

For dated references only the edition cited applies. For undated references, the latest edition of the referenced document (including amendments) applies.

[1] ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing

[2] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

[3] ISO 9000 Quality management systems — Fundamentals and vocabulary

[4] ISO 9001 Quality management systems — Requirements

[5] ISO 15189:2012 Medical laboratories —Requirements for quality and competence

[6] ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities

[7] ILAC P10:01/2013 ILAC Policy on Traceability of Measurement Results

[8] ILAC G18:04/2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories.

[9] CLSI AUTO 10-A *Auto-verification of Clinical Laboratory Test Results; Approved Guideline*

[10] ISO/IEC 17011 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

[11] ISO 22870:2016 Point of care testing (POCT) - Requirements for quality and competence

APPENDIX A

Revision Table – The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
Whole document.	General review of the document taking into account the applicable requirements from reference documentation. Improvement of the document's wording making it consistent with ISO 15189 language and less connected to any specific version of ISO 15189. Deletion of the old Annex A (differences between ISO 15189:2007 and ISO/IEC 17025:2005). Redundancies have been removed.
Clause 1 Medical Laboratories and ISO 15189	Editorial changes.
Clause 2 Unique Elements of ISO 15189	Improvement of the wording concerning requirements of personnel competence.
Clause 3 Development and Maintenance of Accreditation Scheme	Editorial changes.
Clause 4.2 Management system	Improvement of the wording concerning the definition of a medical laboratory, extending it to other potential activities (i.e. medical imaging). Remarks concerning laboratories that only collect or prepare specimens and that are linked to a medical laboratory.
Clause 4.4 Examination by referral laboratories	The previous requirements concerning "Examination by referral laboratories" (4.8) has been now put in this new clause 4.4. Enhanced clarification concerning claiming accreditation by laboratories.
Clause 4.5 (Old 4.4) Personnel (staffing)	Inclusion of arrangements for assessment of laboratory activities in evenings/nights. Competency assessment should include professional judgment, where applicable.
Clause 4.6 (Old 4.5) Accommodation, environmental conditions and considerations	Reference to ISO 15190 has been removed.
Clause 4.7 (Old 4.6) Laboratory equipment, reagents, and consumables	Added new requirements concerning purchasing of reagents and consumables Inclusion of requirements for ABs to the CAB's management of adverse incidents and accidents. Concerning traceability: - requirements for traceability have been moved here from old clause 4.8. - reference to ILAC P10 has been included.

Clause 4.8 (Old 4.7) Pre-examination processes	First paragraph has been removed (redundant).
Clause 4.9 (Old 4.8) Examination processes and quality assurance	Reference to ISO 17043 has been removed. Traceability requirements have been moved to clause 4.7. Added references to ILAC P9 and ISO 22870 POCT (where applicable). Requirements concerning validation and verification of examination procedures have been included. The requirements on traceability and referral laboratories have been moved to Clauses 4.7 and 4.4.
Clause 4.11Risk management	New clause concerning CAB's risk identification and management.
Clause 4.12 Ethics	New clause concerning Ethics requirements.
Clause 4.13 Laboratory information management	New clause concerning requirements on Laboratory information management.
Old Clause 5 Companion documents	Paragraph has been removed. ISO 22870 requirements (POCT) has been moved to Clause 4.9 References to Ethics and Safety have been moved resp. to Clauses 4.12 and 4.7.
Clause 5 (Old 6) Assessment Teams	Editorial changes.
Clause 6 (Old 7) Scope of accreditation	References to flexible scope have been added.
Old Annex A Differences between ISO 15189:2007 and ISO/IEC 17025:2005.	The paragraph has been removed.
References	References have been updated.
Appendix A	Revision table has been added.