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Medical Laboratory Accreditation Requirements

Applies to medical laboratories seeking accreditation for defined examinations and to point-of-care testing activities under the laboratory's governance where included.

Primary standard	**ISO 15189:2022**
Document owner	International Services for Certification Bodies
Review trigger	Standard, scheme, regulatory or ISCB process change

Document status and use

This ISCB applicant guide states the evidence and operating controls normally expected for this programme. It does not reproduce or replace the applicable ISO or ISO/IEC standard. Applicants must hold an authorised current copy and comply with all applicable requirements, legislation, scheme rules and formally issued ISCB criteria.

References to IAF or ILAC publications identify technical criteria that may be relevant. They do not by themselves state or imply that ISCB is an IAF or ILAC arrangement signatory.

01

Applicable framework

The assessment hierarchy begins with the primary standard and includes applicable normative, regulatory, scheme-owner and ISCB documents. ISCB will identify the controlling criterion if requirements conflict.

- ISO 15189:2022 is the primary quality and competence standard.
- ISO/IEC 17011:2017 governs ISCB's accreditation process and decisions.
- Applicable legal, ethical, patient-safety, confidentiality and professional requirements remain binding in each jurisdiction.

02

Core organisational requirements

Legal status and responsibility

Be a legally identifiable entity, or a defined part of one, that can be held responsible for conformity-assessment activities, contracts and decisions.

Impartiality and independence

Identify, analyse, treat, monitor and record threats from ownership, finance, relationships, consultancy, commercial pressure and self-review.

Confidentiality and information security

Protect confidential information, personal data, intellectual property and electronic records; control any legally required disclosure.

Organisation and governance

Define authority, responsibilities, reporting lines and safeguards; assign technical work, review and decisions to competent and appropriately independent functions.

Competence and resources

Set role-specific competence criteria; evaluate, authorise, monitor and re-evaluate personnel; control facilities, equipment, software and external resources.

Controlled operations

Accept work only after confirming capability; use controlled methods and records; handle deviations; review outputs; base decisions on sufficient objective evidence.

Management system

Maintain document and record control, risks and opportunities, complaints, appeals, nonconforming work, corrective action, internal audit, management review and improvement.

Accreditation claims

Limit certificates, symbols and claims to the granted scope and amend them immediately after suspension, reduction, withdrawal or expiry.

03 Service-specific technical requirements

1. Define the requested scope by discipline, examination, specimen, method or platform and location.

2. Control pre-examination, examination and post-examination processes, including patient preparation, collection, transport, acceptance, critical results and report authorization.

3. Verify or validate examination procedures and demonstrate measurement uncertainty or other appropriate evaluation of result quality where applicable.

4. Maintain internal quality control and suitable external quality assessment or interlaboratory comparison coverage.

5. Manage biological reference intervals, clinical decision limits, metrological traceability, reagents, equipment, information systems and data integrity.

6. Apply risk management, continuity planning and patient-impact evaluation to nonconforming work and significant changes.

04 Minimum application and readiness evidence

Submit current, approved documents and representative implementation records. Templates without operational evidence are not sufficient.

01	Legal identity, governance and medical leadership responsibilities
02	Scope schedule, examination directory and referral arrangements
03	Personnel qualifications, competence and authorization records
04	Method verification/validation, uncertainty and reference-interval evidence
05	IQC and EQA performance with follow-up actions
06	Sample pathway, critical-result and information-system controls
07	Internal audit, management review, risk and improvement records
08	Representative authorized reports and user communications

05

Assessment, decision and continued accreditation

Application and scope review

ISCB reviews legal identity, requested scope, locations, resources, readiness and applicable criteria before quotation and assessment planning. Acceptance of an application is not a promise of accreditation.

Assessment

Assessment may include document review, office or remote assessment, on-site technical assessment, witnessing, interviews, record tracing and evaluation of representative activities. The mix depends on scope and risk.

Nonconformities and decision

The applicant must determine causes, correct the issue, implement proportionate corrective action and provide evidence of effectiveness within the notified period. Accreditation decisions are independent from assessment and limited to demonstrated competence.

Maintenance

Accredited bodies must remain competent, comply with surveillance and reassessment, notify significant changes without delay, cooperate with witnessing and record access, address complaints and nonconformities, and control all accreditation claims.

06

Principal references

- ISO 15189:2022
- ISO/IEC 17011:2017
- ILAC P9 and P10, where applicable
- Applicable national medical laboratory and patient-data requirements

External editions can change. The edition stated in the accreditation agreement, transition notice or other formal ISCB communication controls the assessment. Verify current editions before use.

Prepare	Complete the readiness assessment and organise objective evidence.
Apply	Submit the application and proposed scope for formal review.