



# **Guidance for the Implementation of a Medical Laboratory Accreditation System**

**ILAC-G26:07/2012**

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**The ILAC Secretariat**  
PO Box 7507  
Silverwater NSW 2128  
Australia  
Fax: +61 2 9736 8373  
Email: [ilac@nata.com.au](mailto:ilac@nata.com.au)

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## PREAMBLE

ISO 15189 *Medical laboratories – Particular requirements for quality and competence* is a standard that contains the requirements necessary for diagnostic 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 members of the International Laboratory Accreditation Cooperation (ILAC). Clinical personnel responsible for patient care can be confident that medical laboratories accredited to ISO 15189 are competent to produce timely and reliable diagnostic examination results.

## PURPOSE

This is a practical guide for accreditation bodies implementing a medical laboratory accreditation system 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 program that is based on ISO 15189.

## AUTHORSHIP

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

## 1. ISO 15189 and Medical Laboratories

Medical laboratory services are essential to patient care in the 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. ISO 15189 is for use by medical laboratories in developing their management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognizing their competence.

## 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 particular to medical laboratories. It addresses competence of personnel involved in medical laboratory examinations, physical facilities, equipment, reagents and supplies, pre-analytical factors, analytical factors, quality assurance considerations, and post-analytical factors.

The management system requirements in ISO 15189 are written in a language relevant to medical laboratory operations and meet the principles of ISO 9001. The technical requirements are a comprehensive set of elements essential to consistently deliver valid test results.

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 Programs

### 3.1 Policy

Accreditation bodies wishing to develop programs to assess medical laboratory conformance to ISO 15189 should investigate and analyze the potential market as well as the existence of other established programs before developing their own program.

National legislation should also be taken into consideration.

### 3.2 Development Plan

Accreditation bodies should plan the delivery of ISO 15189 programs 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) program 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) program 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 program concerned (see ISO/IEC 17011).*

### **3.3 Verification and maintenance of the accreditation program**

Accreditation bodies should design and conduct an evaluation of newly implemented programs, 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 process, accreditation criteria, procedures, guidance and adequacy of other relevant documents. Based on the evaluation results, accreditation bodies should make necessary changes to their program.

## **4. Factors for Accreditation Bodies to Consider When Implementing an ILAC Accreditation System 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 program.

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 program. Challenges may be encountered in convincing powerful medical and government authorities, of the value of accreditation. Prior to designing a medical laboratory accreditation program 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 program. Effective engagement with these bodies may facilitate acceptance/endorsement of an accreditation program.
- ◆ 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 within ISO 15189.

## 4.2 What is a Medical Laboratory?

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, for the purpose of providing information for the diagnosis, prevention and treatment 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 micro-organisms. Medical laboratories will also provide a consultant advisory service covering all aspects of laboratory investigation, 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 in the absence of 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/prepare/transport samples, or act as a mailing, or distribution centre are not considered as stand-alone medical laboratories, although they may be part of a larger laboratory network or system.

## 4.3 Management System

Accreditation bodies may inform or educate 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 Personnel (Staffing)

It is important for accreditation bodies to be familiar with the professional qualifications and where relevant other specified requirements 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 need to ensure that staff working evenings or nights receive the same training, ongoing education and professional development as staff working during the day.

#### **4.5 Accommodation and Environmental Conditions plus Safety Considerations**

National, regional and local governments may establish regulations that dictate building codes and other safety considerations such as fire, electrical, chemical, biohazards, etc and shall be followed. International and national standards bodies are sources of helpful information.

Due to the nature of specimens examined by medical laboratories, safety considerations cannot be ignored. ISO 15190: *Medical laboratories — Requirements for safety* is a useful reference in determining safety requirements.

#### **4.6 Laboratory Equipment**

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 and that appropriate materials are purchased.

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 ensuring that manufacturers' performance claims are met, and that calibration services provided by manufactures meet needs. The fitness to the intended use should be ensured.

#### **4.7 Pre-examination Procedures**

The results of medical examinations are one of the important elements necessary for care givers (physicians and others) to decide on treatment policy and follow-up. The majority of laboratory examinations are conducted by specialized medical laboratories. Exceptions may exist in physician offices and clinics employing point-of-care testing devices.

Medical laboratory staff may not collect all or any samples for examination. However, laboratories are still responsible for ensuring that samples received are not compromised. 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 and transport as well as ensure that specimen acceptance criteria has been established. 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.

#### **4.8 Examination Procedures and Quality Assurance**

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 and ISO/IEC 17043



*Conformity assessment – general requirements for proficiency testing* can be useful in successfully implementing an ISO 15189 accreditation program.

Accreditation bodies need to establish participation criteria when proficiency testing (PT) or external quality assessment (EQA) schemes are available, appropriate and at a frequency that reflects best practices and/or best local norms. When establishing appropriate frequency of PT/EQA, accreditation bodies need to take into account the test range, method capabilities and pre-established regulatory limits, where available.

Medical laboratories have well-defined quality control and quality assurance practices but such practices might not be incorporated into a comprehensive scheme for verifying the quality of results as required by ISO 15189. In addition, medical laboratory personnel may be unfamiliar with traceability and uncertainty of measurement concepts.

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

Medical laboratories with limited testing menus 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. According to the definition in ISO 15189, a referral laboratory is an external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report. The purpose and definition of referral laboratories are different from those of subcontractors, but there may be other times when medical laboratories use subcontractors. Unless it is specified by regulation, accreditation bodies may extend the relevant requirements for a referral laboratory to the subcontractor when medical laboratories subcontract their examinations due to limitation of competence, resource, time, etc.

*Note*

*Referral laboratory means the external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report.*

*In general, subcontractor means 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).*

#### **4.9 Post-examination Procedures 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.

## 5. Companion Documents

ISO 15189 includes annexes on ethics and laboratory information systems. These are not normative (or mandatory) but they constitute important direction on practices in these areas for medical laboratories.

Competent laboratory information systems are very important in ensuring that samples are appropriately entered into the laboratory records and able to be tracked. This is particularly important in medical laboratories with high sample volumes. Accreditation bodies may utilize these annexes into accreditation programs.

While ISO 15189 touches on safety considerations for equipment, the laboratory environment and its facilities, additional safety considerations contained in ISO 15190 *Medical laboratories – Requirements for safety* should not be ignored. Accreditation bodies may incorporate these requirements into assessment programs.

When medical laboratories direct point-of-care testing (POCT) activities occurring within the hospital or facility served by the laboratory, requirements of ISO 22870 *Point-of-care testing (POCT) – Requirements for quality and competence* should apply and an accreditation body should incorporate these requirements into its assessment program.

## 6. 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*.

## 7. Scope of Accreditation

As with any accreditation model, accreditation bodies need to determine the method for describing the scope of accreditation. For diagnostic medical laboratories, this includes decisions regarding the discipline of practice, sample type and techniques employed. For detail, refer to ILAC G18: *Guideline for the Formulation of Scopes of Accreditation for Laboratories*.

## ANNEX A – Key Differences Between ISO 15189:2007 and ISO/IEC 17025:2005

### What is the same?

The outline of ISO 15189 is similar to ISO/IEC 17025.

Much of the content and requirements are the same, even if different wording is used. What follows here points out specific ISO 15189 requirements that are different from ISO/IEC 17025.

The numbers used in this annex relate to the clause numbers of ISO 15189.

### What is different? – A section-by-section review of ISO 15189 compared to ISO/IEC 17025

#### 1. Scope

While the description of scope in ISO 15189 is much shorter than in ISO/IEC 17025, the general intent of each is the same – both standards specify requirements for quality and competence and are intended for use by laboratories and accreditation bodies that are confirming or recognizing competence of laboratories.

The difference is that ISO/IEC 17025 is directed to laboratories performing tests and/or calibrations while ISO 15189 is directed to medical laboratories.

#### 2. Normative references

ISO/IEC 17025 is cited as a normative reference in ISO 15189. Therefore, ISO/IEC 17025 is considered ‘indispensable’ for applying ISO 15189. Some of the calibration and traceability issues cannot be equally applied to medical laboratory testing.

#### 3. Terms and definitions

ISO/IEC 17025 refers to ISO/IEC 17000 and ISO/IEC Guide 99:2007, but does not define any specific terms. ISO 15189 defines 19 specific terms.

One of these terms is “medical laboratory” and this definition is significant. It is synonymous with “clinical laboratory” and means a diagnostic medical laboratory, which performs examinations on human samples of biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, or pathological nature for diagnosis, prevention and treatment of disease or assessment of health. This is the applicant laboratory for accreditation to ISO 15189.

#### 4. Management Requirements – the content of specific requirements do not necessarily match. While each standard contains essentially the same requirements, here are the specific additional points included in ISO 15189, by the section and requirement numbers.

4.1 ISO 15189 uses the title “Organisation and management” to replace the ISO/IEC 17025 title “Organisation”.

4.2 ISO 15189 uses the title “Quality management system” to replace the ISO/IEC 17025 title “Management system”.

- 4.2.2 ISO 15189 includes an additional requirement that specifies the QMS shall include internal quality control and participation in organized interlaboratory comparison such as external quality assessment schemes. Medical laboratories participate in extensive internal quality control and proficiency testing/external quality assessment, and need to ensure that manage these activities in an integrated fashion.
- 4.2.3 ISO 15189 requires that the quality policy statement includes the scope of service the laboratory provides.
- 4.2.4 ISO 15189 provides a point-by-point sample of table of contents for a quality manual, which is much more prescriptive than in ISO/IEC 17025.
- 4.3 Document Control
- 4.3.3 ISO 15189 includes two minor points about the identification of controlled documents: in addition to the date of issue and/or revision, page numbering, number of pages, and the authority for issue that are specified in ISO/IEC 17025, ISO 15189 specifies “title” and “source identification” shall be identified. Interpret the latter as being the internal or external, or the author.
- 4.4 ISO 15189 uses the title “Review of contracts” to replace the ISO/IEC title “Review of requests, tenders and contracts”. However there is really only one difference:
- 4.4.1 ISO 15189 does not include the note explaining that a contract may be any written or oral agreement. Accreditation bodies may need to specify that the term “contract” does not only apply to a legal document.
- 4.5 ISO 15189 uses the title “Examination by referral laboratories” to replace the ISO/IEC 17025 title “Subcontracting of tests and calibrations” and therefore the focus is slightly different. It outlines the need to review arrangements with referral services (laboratories performing supplementary or confirmatory testing) as well as consultants who provide second opinions. Specifically it states:
- 4.5.2 Arrangements need to be reviewed so it is clear what is expected of the referral laboratory or consultant, including who is responsible for interpretation of results.
- 4.5.4 The referring laboratory and not the referral laboratory is responsible for reporting the findings. Note: national, regional and local regulations may apply and these will need to be considered during conformity assessment.
- 4.6 ISO 15189 uses the title “External services and supplies” to replace the ISO/IEC 17025 title “Purchasing services and supplies”.
- 4.6.3 ISO 15189 has changed this requirement about purchasing records, using it to specify that there shall be an inventory control system for supplies and records maintained.
- 4.7 ISO 15189 uses the title “Advisory services” to replace the ISO/IEC 17025 title “Service to the customer”. ISO 15189 specifies that appropriate professional staff shall provide advice on choice of tests to be ordered, the frequency with which they should be reordered, and the appropriate sample to be tested. It also states that an interpretation of the results is to be provided (when appropriate).

Another component of this requirement is to specify that laboratory professional staff meet with

clinical staff regarding use of laboratory services and to consult on scientific matters and these meetings documented. In addition, professional staff are to participate in clinical rounds.

- 4.8 ISO 15189 uses the title “Resolution of complaints” to replace the ISO/IEC 17025 title “Complaints”.
- 4.9 ISO 15189 uses the title “Identification and control of nonconformities” to replace the ISO/IEC 17025 title “Control of nonconforming testing and/or calibration work”.
- 4.9.1 ISO 15189 specifies that policies and procedures must consider the “medical significance” of nonconforming examinations, and if necessary, notify the requesting clinician.
- 4.10 ISO 15189 section 4.10 is “Corrective action”, which is section 4.11 in ISO/IEC 17025.
- 4.11 ISO 15189 section 4.11 is “Preventive action”, which is section 4.12 in ISO/IEC 17025.
- 4.12 ISO 15189 section 4.12 is “Continual Improvement, which is section 4.10 “Improvement” in ISO/IEC 17025. ISO 15189 does not necessarily contain anything different, but it is more prescriptive in what this involves.
- 4.12.1 Specifies a systematic review at regular intervals to be defined in the QMS with the purpose of identifying potential sources of nonconformance or opportunities for improvement, with documented action plans.
- 4.12.2 Specifies that laboratory management shall evaluate the effectiveness of action.
- 4.12.3 Specifies results of actions shall be included in management review.
- 4.12.4 Specifies quality indicators to be implemented to evaluate the laboratory’s contribution to patient care, which may identify opportunities for improvement in or outside the laboratory and deal with issues related to patient care outcomes.
- 4.12.5 Specifies that laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel and relevant users of laboratory services.
- 4.13 ISO 15189 uses the title “Quality and technical records” to replace the ISO/IEC 17025 title “Control of records”, but it does deal with “control” issues like procedures for identification, collection, indexing, access, storage, maintenance and safe disposal.

A shopping list of records to which this section applies is provided.

- a) request forms
- b) examination results and reports
- c) instrument printouts
- d) examination procedures
- e) laboratory workbooks or sheets
- f) accession records
- g) calibration functions and conversion factors
- h) quality control records
- i) complaints and action taken

- j) records of internal and external audits
- k) external quality assessment records/interlaboratory comparisons
- l) quality improvement records
- m) instrument maintenance records, including internal and external calibration records
- n) lot documentation, certificates of supplies, package inserts
- o) incident/accident records and action taken
- p) staff training and competency records

4.13.3 Notes that national, regional and local regulations may dictate retention time for various records.

4.14 ISO 15189 specifies that “Internal audits” need to emphasize areas critically important to patient care (4.14.1). Requirement 4.14.3 links internal audit findings directly to management review.

4.15 ISO 15189 specifies that “Management review” is an activity that ensures continuing stability and effectiveness in support of patient care.

4.15.2 Contains a longer list of what shall be taken account of during management review (complete list shown here, only those with an asterisk \* are not included in ISO/IEC 17025):

- a) follow-up of previous management reviews
- b) status of corrective actions taken and required preventive action
- c) reports from managerial and supervisory personnel
- d) the outcome of recent internal audits
- e) assessment by external bodies
- f) the outcome of external quality assessment and other forms of interlaboratory comparison
- g) any changes in the volume and type of work undertaken
- h) feedback, including complaints and other relevant factors, from clinicians, patients and other parties
- i) quality indicators for monitoring the laboratory’s contribution to patient care \*
- j) nonconformities
- k) monitoring of turnaround time \*
- l) results of continuous improvement processes
- m) evaluation of suppliers \*

4.15.3 Specifies that the quality and appropriateness of the laboratory’s contribution to patient care is to be monitored and evaluated objectively.

5. Technical Requirements – ISO 15189 has no “General” section as in ISO/IEC 17025

5.1 Personnel requirements are laid out quite differently in ISO 15189 than in ISO/IEC 17025, include specific requirements for the laboratory director, and in general are more prescriptive.

5.1.2 Under records, it is noted that “Other records available to authorized persons relating to personnel health may include records of exposure to occupational hazards and records of immunization status”.

- 5.1.4 Specifies the responsibilities of the laboratory director or designees for professional, scientific, consultative or advisory organization, administrative and educational matters relevant to the laboratory's service. It says that these people need appropriate training and background for these duties:
- a) providing advice about the choice of tests, use of the laboratory and interpretation of test data
  - b) serving as an active member of the medical staff for those facilities served by the laboratory
  - c) liaising with accreditation and regulatory agencies, administrative officials, the healthcare community, patients
  - d) defining, implementing and monitoring standards
  - e) implementing the QMS
  - f) monitoring all laboratory work for reliability of data
  - g) ensuring sufficient personnel with adequate training and experience
  - h) planning and goal-setting, resource allocation in the medical environment
  - i) administration of the medical service (including budgeting)
  - j) educating medical and laboratory staff, participating in education programs in the institution
  - k) research and development
  - l) selecting and monitoring referral services
  - m) safety
  - n) addressing complaints, suggestions or requests from users of laboratory services
  - o) ensuring good staff morale
- 5.1.5 Specifies adequate staff resources.
- 5.1.6 Specifies that personnel be trained specifically in quality assurance and the QMS.
- 5.1.9 Specifies a continuing education program to be in place, for staff at all levels.
- 5.1.10 Specifies employees are to be trained to prevent or contain effects of adverse incidents.
- 5.1.11 Is more prescriptive than ISO/IEC 17025 by stating "The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary".
- 5.1.12 Specifies that personnel making professional judgments about testing (opinions, interpretations, predictions) have theoretical and practical background and experience. It is noted that national, regional and local regulations may apply.
- 5.1.13 Specifies that confidentiality of patient information to be maintained by all personnel.
- 5.2 ISO 15189 requirements for "Accommodation and environmental conditions" are essentially the same as those in ISO/IEC 17025 section 5.3, with these additions:
- 5.2.2 Laboratory design to consider minimizing risk of injury and occupational illness, patient, employee and visitor safety (protecting from recognized hazards).
- 5.2.3 "When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions."

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- 5.2.4 In the consideration of design, it is important that the environment does not affect the performance of specimen collection and the equipment utilized for this purpose.
- 5.2.8 “Communication systems within the laboratory shall be those appropriate to the size and complexity of the facility and the efficient transfer of messages.”
- 5.2.9 “Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results.”
- 5.2.10 “Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations.”
- 5.3 ISO 15189 uses the title “Laboratory equipment” to replace the ISO/IEC 17025 title “Equipment (section 5.4).
- 5.3.4 The list of maintenance considerations in ISO 15189 is a bit longer, specifically mentioning:
- c) manufacturer’s contact person and telephone number, as appropriate
  - f) condition when received
  - h) equipment performance records that confirm the equipment’s suitability for use
  - k) predicted replacement date, if possible
- 5.3.8 Specifies that measures to reduce contamination must be available and that personnel have space for repairs and personal protective equipment.
- 5.4 ISO 15189 uses the title “Pre-examination procedures” to replace the ISO/IEC 17025 title “Sampling” (section 5.7), and it contains elements of ISO/IEC 17025 section 5.6 “Measurement traceability” as well as section 5.8 “Handling of test and calibration items”. This section contains requirements specific to medical laboratories, and it is worth noting them as worded in the standard:
- 5.4.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data. National, regional or local requirements shall apply.

The request form or an electronic equivalent should allow space for the inclusion of, but not be limited to, the following:

- a) unique identification of the patient;
- b) name or other unique identifier of physician or other person legally authorized to request examinations or use medical information together with the destination for the report; the requesting clinician’s address should be provided as part of the request form information;
- c) type of primary sample and the anatomic site of origin, where appropriate;
- d) examinations requested;
- e) clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes;
- f) date and time of primary sample collection;
- g) date and time of receipt of samples by the laboratory.



The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services.

- 5.4.2 Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection. These instructions shall be contained in a primary sample collection manual.
- 5.4.3 The primary sample collection manual shall include the following:
- a) copies of or references to lists of available laboratory examinations offered, consent forms, when applicable, 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;
  - b) procedures for preparation of the patient (e.g. instructions to caregivers and phlebotomists), identification of primary sample, primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives;
  - c) instructions for completion of request form 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, refrigeration, warming, immediate delivery, etc.), labeling of primary samples, clinical information (e.g. history of administration of drugs), positive identification, in detail, of the patient from whom a primary sample is collected, recording the identity of the person collecting the primary sample, safe disposal of materials used in the collection;
  - d) instructions for storage of examined samples, time limits for requesting additional examinations, additional examinations, repeat examination due to analytical failure or further examinations of sample primary sample.
- 5.4.4 The primary sample collection manual shall be part of the document control system.
- 5.4.5 Primary samples shall be traceable, normally by request form, to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.
- 5.4.6 The laboratory shall monitor the transportation of samples to the laboratory such that they are transported:
- a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned,
  - b) within a temperature interval specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples,
  - c) in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional or local regulatory requirements.
- 5.4.7 All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded.

- 5.4.8 Criteria shall be developed and documented for acceptance or rejection of primary samples. If compromised primary samples are accepted, the final report shall indicate the nature of the problem and, if applicable, that caution is required when interpreting the result.
  - 5.4.9 The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.
  - 5.4.10 Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.
  - 5.4.11 The laboratory shall, if relevant, have a documented procedure for the receipt, labeling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labeling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used and any special criteria to be followed.
  - 5.4.12 Sample portions shall also be traceable to the original primary sample.
  - 5.4.13 The laboratory shall have a written policy concerning verbal requests for examinations.
  - 5.4.14 Samples shall be stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.
- 5.5 ISO 15189 uses the title “Examination procedures” to replace the ISO/IEC 17025 title “Test and calibration methods and method validation”, and in this section ISO 15189 addresses verification of trueness, calibration, and traceability that is covered in the ISO/IEC 17025 section 5.6 titled “Measurement traceability”.

A few specific differences exist:

- 5.5.3 ISO 15189 is a bit more specific when referring to ensuring current procedures are available for staff performing the work. (ISO/IEC 17025 covers document control of procedures in section 4.3.2). ISO 15189 addresses a common practice for staff to use “quick reference” cards or abbreviated procedures posted as reminders. The requirement says “Card files” or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.

ISO 15189 includes a few additional items in the list of inclusions to a procedure, specifically interferences (e.g. lipaemia, haemolysis, bilirubinemia) and cross reactions, alert/critical values, laboratory interpretation, and safety precautions.

- 5.5.5 Here ISO 15189 refers to biological reference intervals (i.e., normal reference ranges), noting that they need to be reviewed periodically and when testing changes are introduced, to ensure they remain appropriate for the patient population served.

- 5.6 ISO 15189 uses the title “Assuring quality of examination procedures” to replace the ISO/IEC 17025 titles “Measurement traceability” (section 5.6) and “Assuring the quality of test and calibration results” (section 5.9). Specific differences of note are:
- 5.6.2 This is where ISO 15189 addresses the need to determine uncertainty of measurement (ISO/IEC 17025 section 5.4.6).
  - 5.6.3 This is where ISO 15189 addresses calibration and verification of trueness (ISO/IEC 17025 section 5.6.2.1).
  - 5.6.4 This is where ISO 15189 addresses interlaboratory comparison requirements (ISO/IEC 17025 section 5.9). It refers to ISO/IEC Guide 43-1 for criteria of acceptable programs. It states “External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures”.
  - 5.6.5 ISO 15189 acknowledges that formal interlaboratory comparisons are not available for all examinations included in the scope of testing for medical laboratories. Here it states “Whenever a formal interlaboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilize externally derived challenge materials such as exchange of samples with other laboratories. Laboratory management shall monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions”.
- 5.7 ISO 15189 includes a section to address “Post-examination procedures” that is not included in ISO/IEC 17025. This is exactly what it says:
- 5.7.1 Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of results.
  - 5.7.2 Storage of the primary sample and other laboratory samples shall be in accordance with approved policy. *Note that this is addressed in ISO/IEC 17025, section 5.8.4.*
  - 5.7.3 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 ISO 15189 uses the term “Reporting of results to replace the ISO/IEC 17025 title “Reporting the results” (section 5.10). It requires many of the same things, but with different language.

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

- 5.8.3 The list of what an examination report contains also includes:
  - e) date and time of primary sample collection as well as time of receipt
  - f) date and **time** of release of report
  - i) biological reference intervals
  - l) identification of the person authorizing the release of results

- 5.8.4 This requirement refers to a number of associations who might dictate a standard vocabulary in the description of examinations or tests, most of them specific to laboratory medicine.
- 5.8.7 “The laboratory shall have procedures for immediate notification of a 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.”
- 5.8.8 “In order that local clinical needs can be served, the laboratory shall determine the critical properties and their “alert/critical” intervals, in agreement with the clinicians using the laboratory. This applies to all examinations, including nominal and ordinal properties.”
- 5.8.9 “For results transmitted as an interim report, the final report shall always be forwarded to the requester.”
- 5.8.10 “Records 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. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.”
- 5.8.11 “Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.
- “There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to it shall be monitored, recorded and reviewed by laboratory management. Where necessary, corrective action shall be taken to address any problems so identified.
- “This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.”
- 5.8.12 “When examination results from a referral laboratory need to be transcribed by the referring laboratory, procedures for verifying the correctness of all transcriptions shall be in place.”
- 5.8.13 “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.”
- 5.8.14 “The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Results provided verbally shall be followed by a properly recorded report.”
- 5.8.16 “Results that have been available for clinical decision-making and revised shall be retained in subsequent cumulative reports and be clearly identified as having been revised. If the reporting system cannot capture amendments, changes or alterations, an audit log shall be used.”

6. Annex B – ISO 15189 contains an informative Annex B titled “Recommendations for protection of laboratory information systems (LIS)”. It provides a list of considerations that accreditation bodies would be wise to include as requirements for laboratory assessment, which will require the inclusion of knowledgeable technical personnel on the team.
7. Annex C – ISO 15189 contains an informative Annex C titled “Ethics in laboratory medicine”. For accreditation bodies not familiar with laboratory medicine, this informative annex provides an insight into ethical considerations in the practice of laboratory medicine. Relevant provisions in national legislation need to be also taken into consideration.

**REFERENCES**

- [1] ISO/IEC 17043:2010 Conformity assessment - General requirements for proficiency testing
- [2] ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- [3] ISO 9000:2000, Quality management systems — Fundamentals and vocabulary” and “ISO 9001:2000, Quality management systems — Requirements” after “ISO 5725-1, Accuracy (trueness and precision) of measurement methods and results -- Part 1: General principles and definitions”
- [4] ISO 15189:2007 Medical laboratories — Particular requirements for quality and competence
- [5] ISO 15190:2003, Medical laboratories — Requirements for safety
- [6] ISO 22870:2006 Point-of-care testing (POCT) – Requirements for quality and competence
- [7] ILAC P9:11/2010 ILAC Policy for Participation in Proficiency Testing Activities
- [8] ILAC P10:2002 ILAC Policy on Traceability of Measurement Results
- [9] ILAC G11:2006 ILAC Guidelines on Qualifications & Competence of Assessors and Technical Experts
- [10] ILAC G18:2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories.
- [11] ILAC G22:2004 — Use of Proficiency Testing as a Tool for Accreditation in Testing
- [12] EA-4/17:2008 EA Position Paper on the description of scopes of accreditation of medical laboratories