

Accreditation of Medical Laboratories as per ISO 15189 - New the 4th Version Changes from 2012 – 2022



Tomáš Zima

Institute of Medical Biochemistry and Laboratory Diagnostics, 1st Faculty of Medicine, Charles University and General University Hospital, Prague, Czech Republic phone: +420-22496 2841, e-mail: zimatom@cesnet.cz

One and key of the priorities in laboratory medicine is improvement of quality management system for patient safety. Quality in the health care is tightly connected to the level of excellence of the health care provided in relation to the current level of knowledge and technical development.

Accreditation is an effective way to demonstrate competence of the laboratory, is a tool to recognize laboratories world-wide, is linked to periodical audits stimulating to keep and improve the quality, leads to high standard of services for clients (patients, health care providers, etc.). Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks, it is an independent process and there is only one recognized national accreditation body in each country.

The history of quality systems in labs has started many decades ago. The first steps are implementation of internal (IQA) and external quality control (EQA) systems and their basic principles in daily laboratory practice.

An importance set of criteria was done in EN 45 001 (European Standard), specifying general criteria for the operation of a testing laboratory. Next step for accreditation was documented in ISO 17025 (General Requirements for the Competence of Testing and Calibration Laboratories). This standard is widely used for testing laboratories in whole world in industry and also in medicine. This standard requires a management system and how the laboratory be found competent to perform specific tests/calibrations or types of tests/calibration.

The strategic plans of IFCC and EFLM include focusing on accreditation of labs based on ISO standards and cooperation with regional accreditation bodies and national accreditation bodies. IFCC and EFLM recognised that ISO 15189 Medical laboratories – Requirements for quality and competence is precisely describing standard for labs and has been widely accepted. The first issue of standard was in 2003, 2007 next 2012 and in December 2022 was issued the last the 4th version.

Main principles for the revision of ISO 15189 and new ISO 15189:2022 version

- **ISO/IEC 17025 is the normative reference to ISO 15189** and the 2017 revision of ISO/IEC 17025 informs the revision of ISO 15189 (restructured according ISO 17025); therefore, the common structure of ISO CASCO standards (ISO CASCO PROC 33) has been implemented in the new draft of ISO 15189. Mandatory language coming from PROC 33 was integrated into the document and will continue to be highlighted throughout the relevant parts of the document.
- **The revised ISO 15189 will consider other relevant published ISO documents** with the aim of avoiding redundant repetitions, as well as synchronizing relevant clauses in the following: ISO 15190, ISO 22367, ISO TS 20658, ISO 17511, ISO TS 20914, and the suite of molecular diagnostic standards developed by ISO TC 212 WG 4.
- **The revised ISO 15189 should be less prescriptive** risk based and linked to patient care.
- **The revised ISO 15189 will include relevant aspects of POCT** performed under the control of the laboratory.

Main changes in ISO 15189: 2022

- New part of ISO/IEC includes part – impartiality (Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality) Confidentiality (The laboratory shall be responsible, through legally enforceable commitments, for the management of all patient information obtained or created during the performance of laboratory activities) and ethical conduct.
- More ethical issues - timely satisfaction of the needs of patients and medical staff
- Complexity of services from preparation of patient to interpretation of results
- Better communication between labs and other health care providers – harmonization of processes
- Management system – in accordance with the principles of ISO 9001:2015. The laboratory shall establish, document, implement and maintain a management system. The laboratory shall implement a management system in accordance with Option A or Option B.



- Emphasis on risk management (aligned with the principles of ISO 22367 Medical laboratories – Application of risk management to medical laboratories) and evaluation of effectiveness of processes
- The requirements for laboratory safety are aligned with the principles of ISO 15190 Medical laboratories – Requirements for Safety.

Implementation of POCT requirements - additional requirements for Point of Care Testing (POCT) - Annex C (normative)

We cannot forget that the most critical parameter for improving the quality of labs is educational activities inside and outside the labs, which are the key points in accreditation and quality management systems.

Accreditation is mandatory in some countries or will be mandatory in the future (e.g. France, Hungary, Lithuania) or some specific parameters should be accredited (e.g. Germany, Belgium, Czech Republic, Serbia, Greece – molecular biology, newborn screening, blood transfusion, etc.) or accredited labs have better reimbursement or contract with health insurance companies (e.g. Sweden, Belgium, Czech Republic).

The accreditation of labs improves laboratory medicine and all processes in laboratories, which include – reduction of errors in the pre-analytical, analytical and post analytical processes, facilitation of accurate and rapid diagnostics, participation in acceleration and efficiency of treatment, facilitation of personalised medicine development, and stimulates continuous improvement.

Accreditation is more an instrument than the aim that increases the quality of services for clients – patients, physicians. Accreditation is not about who the best is, but who has a system of standard procedures. Improvement of quality system in labs is ambitious and never ending story. Don't forget that quality system is about people, with people and for people.

References

1. Zima T. Accreditation in clinical laboratories. *Biochemical Medical* 2010; 20/2: 215-220.
2. EN ISO 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories.
3. EN ISO 15189:2012 - Medical laboratories – Requirements for quality and competence.
4. EN ISO 15189:2022 - Medical laboratories – Requirements for quality and competence.

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