ISO 15189 : 2012
“E-COURSE ON THE NEW VERSION OF ISO 15189”

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Quality of care and patient safety
INTERNATIONAL STANDARD

ISO 15189

Third edition
2012-11-01

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence
Development of ISO 15189

- Written by medical laboratory professionals (ISO TC 212 : WG1)
- It has its origins in two ISO standards ... ISO 9001 and ISO 17025
- Requirements for quality and competence of medical labs
- It’s a ‘sector specific’ standard related to ISO 17025
- It is to be used for developing a QMS and assessing the competence
Different quality standards

Clinical Pathology Accreditation (UK) Ltd

INTERNATIONAL STANDARD
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Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence
of 9 July 2008
setting out the requirements for accreditation and market surveillance relating to the marketing of
products and repealing Regulation (EEC) No 339/93

CCKL part of RvA since 2008

AB accredited according EN ISO/IEC 17011

**one** recognized accreditation body in **each country** that
assesses laboratories against an international agreed
standard
an association of national accreditation bodies

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LABORATORY ACCREDITATION WITH A SPECIFIC SCOPE

• Why?
  – to follow the procedure of ISO
  – review takes into account the results of a major survey of different stakeholders
  – re-written as a document for the medical laboratories, that can be used by accreditation bodies
  – to keep it up to date and relevant to working practices, including requirements appropriate to genetic & pathology testing

• Example 1 5.9.1 Release of reports

  NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

• Example 2 5.2.6 Facility maintenance and environmental conditions

  The laboratory shall provide a quiet and uninterrupted work environment where it is needed.

  NOTE Examples of a quiet and uninterrupted work area include cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutations results.

- content is 90% the same
- but more “user-friendly”, additional detail included, but in most cases this has **not resulted in a change of intent** to the requirements
- wording has been simplified, sequencing has been made more logical
Example: Finding a topic within the new edition

Section 5.2 “Accommodation and environment conditions” (Same sub heading) then lists sub-sections that were not so identified in the earlier editions

5.2.1 General
5.2.2 Laboratory and office facilities
5.2.3 Storage facilities
5.2.4 Staff facilities
5.2.5 Patient sample collection facilities
5.2.6 Facility maintenance & environmental conditions
Example : more explanation

5.5 Examination processess

5.5.1 Selection, verification and validation of examination procedures
   5.5.1.1 General
   5.5.1.2 Verification of examination procedures
   5.5.1.3 Validation of examination procedures
   5.5.1.4 Measurement uncertainty of measured quantity values

5.5.2 Biological reference intervals or clinical decision values

5.5.3 Documentation of examination procedures
5.5.1.2 Verification of examination procedures

Amended / new

Validated examination procedures used without modification must be subject to independent verification by the laboratory prior to routine use.

Information is to be obtained from the manufacturer regarding the performance characteristics of the procedure.

The verification must confirm that the performance claims for the procedure have been met.

The procedure used for verification must also be documented, with the obtained results recorded. Verification results are to be reviewed by the appropriate staff.

ISO 15189 : 2003

Before: Previously the laboratory was required to ‘evaluate’ methods and procedures selected for use, ensuring that they give satisfactory results before being used for medical examinations.
In house method versus CE-IVD label kit?
5.5.1.4 Measurement uncertainty of measured quantity values

Amended / new

Before: the laboratory was required to determine the uncertainty of results, where relevant and possible.

Now the laboratory must determine uncertainty of measurement (MU) for each measurement procedure in the examination phase used to report measured quantity values on patients’ samples.

The performance requirements for the measurement uncertainty of each procedure must be defined and the MU estimates regularly reviewed.

When interpreting measured quantity values, MU must be considered and the laboratory must make MU estimates available to laboratory users, upon request.

Where examinations include a measurement step but do not report a numerical result, the laboratory should estimate the MU for the measurement step where it can assess the reliability of the examination procedure or has influence on the report result.

• Two **new normative sections** (5.9 and 5.10):
  – Release of results (5.9)
  – Laboratory Information management (5.10) which has been taken from Annex B – this was previously informative
Some examples of changes

Scope:

NOTE International, national or regional regulations or requirements may also apply to specific topics covered in this International Standard.

Personnel:

• Expansion of training requirements (each position, areas, minimum criteria, ...)
• The effectiveness of the training program / continuing educational program must be periodically reviewed.

Pre-examination procedures

• Documentation of deviations should be communicated for all personnel involved in examination & post examination process

Equipment:

• documented procedures for the calibration
• Metrological traceability
5.3.1.4 Equipment calibration and metrological traceability

The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:

a) taking into account conditions of use and the manufacturer’s instructions;

b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;

... 

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.

ISO 15189 : 2012
Some examples of changes

5.6.2.1 Calibration
5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

NOTE 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

ISO 17025 : 2005
5.6 Ensuring quality of examination results

Performance in inter-laboratory comparisons shall be reviewed and discussed with relevant staff.

What about the results?  Evaluation?
- Situation of your lab
- Situation of all participants
- Situation of labs using the same method
- What about IQC?
- Need to do an additional validation?
Progressive reduction in percentage of laboratories making errors on a number of samples

Example CF EQA schemes

% of laboratories with incorrect genotypes
(6 samples)

Dequeker et al., Nature Reviews Genetics, 2001, 2, 717-723
Where can I buy the ISO 15189: 2012?

- ISO store
  http://www.iso.org/iso/home/store.htm

- National Institute for normalization
  eg NBN, NEN, DIN, BSI, ANSI, ...
Conclusion

Plan  Do
Act  Check

Quality Management System
Accreditation
External Quality Assessment

Time → Quality