Accreditation according to ISO15189 in Europe

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Chair Quality and Regulations EFLM
Teheran, iqc 18 april 2014
The medical laboratory…. and the service it provides?

- 3.9
- medical laboratory
- clinical laboratory
- laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examinations for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

- ISO 15189:2007
Aspects needed for the medical laboratory

- It provides information for diagnosis, prevention, and treatment of diseases.

- It does not only deliver correct data, but as well consultant advisory service.

- It includes all aspects, including collecting the samples and further investigation.
Aspects needed for the medical laboratory

- Pre-examination aspects
  - advice on relevant tests
  - guidelines for sampling
  - transportation
- Examination aspects
  - internal and external quality assessment
  - traceability
- Post-examination aspects
  - short turn around time
  - reporting with adequate reference ranges
  - advice about the meaning of the outcome
Aspects needed for the medical laboratory

- Specific demands concerning staff
  - For instance registered clinical biochemists
- Specific demands on results (state of the art)
  - For instance: traceability to international standards
  - See: joint Committee on Traceability on Laboratory Medicine

- General requirements for the competence of testing and calibration laboratories and Quality Management Systems–Requirements
Needed for the medical laboratory

ISO 15189 – 2012
Medical laboratories – Particular requirements for quality and competence

This third edition has some changes in comparison with the first from 2003 and the second from 2007 (These were in essence the same)
Medical laboratories — Particular requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières concernant la qualité et la compétence

- Written by medical laboratory professionals
- Responsibility of ISO/TC212 WG1
- Requirements for quality and competence
- It has its origins in two ISO Standards ...ISO 9001 and ISO 17025
ISO/TC 212 and ISO 15189

ISO/TC 212– Clinical laboratory testing and in vitro diagnostic systems– established by CLSI (1995)


(Responsible for many other standards on medical laboratory testing, for instance POCT)
Aims of the revision

- Improved access through clarity of structure and content for users
- Obviate the need for guidelines
- Remove unnecessary prescription
- Is unequivocally verifiable by assessors
Proposals for revision

- Option 1 Content of the standard
  Content
  Titled paragraphs
- Option 2 Structure of the standard
  Content
  Titled paragraphs
  Major restructuring to a process and outcome model
The intended restructuring is shown next, but eventually it was not permitted
CONTINUOUS IMPROVEMENT OF THE 4 Quality management system

5 Management responsibility

6 Resource management

7 Product realization

8 Measurement, analysis and improvement

Satisfaction

KEY
Value-adding activities

Information flow
…into the ‘process based model’ of ISO 9000:2000
Content of the Standard

- **Lack of precision in the use of terms**
  - Laboratory management or the laboratory
  - Policies, processes and procedures
  - Measurement uncertainty, uncertainty of results
  - Traceability of measurement or traceability of sample

- **Unnecessary prescription**
  - ‘the primary collection manual shall include’

- **Untitled paragraphs**
  - Assuring the quality of examination results
  - Examination processes – validation and verification
From ISO 15189:2007 – Untitled clauses…
‘5.5 Examination procedures’

5.5 Examination procedures

NOTE Some of the following might not be applicable to all disciplines in the scope of laboratory medicine.

5.5.1 The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately documented.

5.5.2 The laboratory shall use examination procedures that are suitable for the specific examinations to be performed and that have been appropriately validated.

The method or procedure selected for the examination shall be validated to give laboratory results before being used for medical examinations. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals. Such a review is normally carried out annually. These reviews shall be documented.

5.5.3 All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory.

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.
To ISO 15189 (3rd Edition)
‘5.5 Examination processes’

5.5 Examination processes

5.5.1 Selection, validation and verification of examination procedures

The laboratory shall select examination procedures appropriate for the examination being performed.

The specified requirements (performance characteristics) are intended to be met by the examination.

NOTE Preferred procedures are described in nationally or internationally recognized texts or journals, or in international standards.

5.5.1.1 Validation of examination procedures

The laboratory shall only use examination procedures which have been validated.

The laboratory shall validate examination procedures:

a) non standard methods;

5.5.2 Biological reference intervals

5.5.3 Documentation of examination procedures

... to the content being contained in titled clauses...
Some clarifications

Validation versus verification

- Validation intended for “newly developed tests”, modified tests, or tests used in other type of samples; this shall be done sufficient extensively; it is in the draft IVD Regulation demanded.

- Verification intended for tests bought from manufacturers (CE marked); it is sufficient to show the tests are functioning as reported by the manufacturer.

- In any case the specifications of the test have to be as required for the intended purpose.
Removal of appendices

Both Appendices concerning ICT and Ethics are removed

- An appendix is just a suggestion, not a requirement, as a note in the standard
- The essential elements are now part of the standard themselves
Requirements not specified, related to purpose

- The laboratory shall select examination procedures which have been validated for their intended use.

- The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of examination.

- The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.
4.7 Advisory services

- Ways to inform the requestor
- Choice of examinations
- Required type of sample
- Repeat frequency
- Interpretation of results
- Advising on individual clinical cases
- Majority of errors in the pre-examination trajectory
- Discuss ways and tools to reduce errors and faults f.i. with nurses who take the samples
- Regular feedback with clinicians
- Scheduled meetings and pathological conferences
What is ISO?

- ISO is a network of the national standards institutes of 161 countries, one member per country, with the Central Secretariat in Geneva.
- ISO standards are developed by technical committees, composed of experts that participate as national delegations, chosen by the ISO national member body for the country concerned.
National standard bodies relation to ISO

World

ISO

Vienna Agreement

Region

European Committee for Standardization
Comité Européan de Normalisation
Europäisches Komitee für Normung

Mandated by EC to produce standards

National

NEN

PLUS

Standard bodies of 27 other EC members
ISO/Technical Committee 212
Clinical laboratory testing and in vitro diagnostic systems (1995)
ISO/TC 212
Clinical laboratory testing and in vitro diagnostic systems

‘Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.’
ISO/Technical Committee 212

Dr. Donald M. Powers (USA)

WG 1. Quality management in the clinical laboratory
Mr. John L. James (UK)

WG 2. Reference systems
Dr Neil Greenberg (USA)

WG 3. In vitro diagnostic products
Mr Claude Giroud (Fr)

WG 4 Antimicrobial susceptibility testing
WG 1 of ISOTC212

- Edited ISO15189 in 2012
- Worked on revision of ISO22870 (POCT), now halted, but will continue
- Works on revision of ISO TS22367 (Continual improvement and risk management)
- Works on a new TR/TS in relation with pre-examination aspects
- Works together with WG2 on a TS on Measurement Uncertainty (will resemble the Australian approach)
Continual Improvement

- Get input from customers and personnel
- Learn from your mistakes (A corrective action includes: Cause analysis, extensiveness analysis, solution of root cause, and check that solution was right to solve the problem)
- Prevent mistakes by using risk analysis
- Audit your system
- Use management Review for making your system better
- Use these elements of ISO15189 and do not consider them as administrative burden
WG2 ISO TC212

- Work on Measurement Uncertainty
- Work on reference methods
- Work on reference laboratories
- Work in relation with Proficiency testing
WG3 of ISO TC212

- Specifically related to diagnostic testing
- Examples are glucosemeters
WG4 of ISO TC212

- Proposal to change its scope to specific aspects of laboratory medicine
- Original focus on microbiology
- New focus on DNA/RNA testing
Structure of EFLM
Quality and Regulations Committee

- Supports the establishment of effective accreditation schemes and quality management systems in all European countries
- **WG Accreditation and ISO/CEN**, represents EFCC in EA, ISO TC212 and CEN TC140. The WG focuses on influencing ISO/CEN standards and harmonisation of accreditation by international surveys, education and training of assessors related to specific professional standards of ISO 15189 and on setting European procedures for accreditation according to the flexible scope.
- **WG IVD**, provides guidance for the application of the Directive in laboratory practice and during accreditation of laboratories.
European Communities
Confederation of Clinical Chemistry (EC4)

Working Group on harmonisation
of Quality Systems and Accreditation (WG)

EC4-WG
Essential Criteria for Quality Systems of Medical Laboratories

Eur J Clin Chem Clin Biochem
1997; 25:123–132

Rob T.P. Jansen, Vic Blaton, David Burnett, Wim Huisman, Jose M. Queralto, Simone Zerah and Brian Allman
Additional Essential Criteria for Quality Systems of Medical Laboratories

Clin Chem Lab Med
1998;36:249–252

Rob T.P. Jansen, Vic Blaton, David Burnett, Wim Huisman, Jose M. Queralto, Simone Zerah and Brian Allman
Decided to support ISO 15189 since 1999
Worked together with colleagues in TC212
Decided to influence the way accreditation of medical laboratories was performed
Decided to work on guidelines
Activities in ISO TC 212 and CEN TC140 Committee

Activities in TC212–WG1
- Worked on ISO15189 and now standards on POCT, Risk management, and Pre-examination guideline

Important further items:
- Discussion about Measurement Uncertainties
- Specific standards related to specific specialalities (microbiology, molecular biology) and specifications for manufacturers
What is laboratory accreditation?

‘a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks’

ISO 15189:2007 definition

3.1

…it is not ‘certification’
Accreditation is confirmation of five essential points...

1. Competence and experience of staff
2. Integrity and traceability of equipment and materials
3. Technical validity of methods
4. Validity and suitability of results
5. Compliance with ISO management system standards
Why laboratory accreditation...

- 'It is in the interests of patients, of society, and of governments that clinical laboratories operate at high standards of professional and technical competence...

- It is in the interests of competent laboratories that their competence is verified through a process of inspection, comparison against appropriate standards, as a confirmation of their good standing.
Accreditation bodies of the 34 ‘European’ countries
Accreditation Bodies in Europe

By law:

- Only one accreditation body allowed per country a laboratory has to approach their NAB

Cooperation: National Accreditation bodies work together in EA (European cooperation for Accreditation)

- NAB have an MLA (Mutual Lateral Agreement) for mutual recognition
European cooperation for Accreditation

Health Care Committee installed around 2000 as WG within Laboratory Committee of EA Members,

- National Accreditation Bodies
- EDMA (industry)
- Professionals – WG on Accreditation EC4 et al.
EA Health Care Committee

Original discussions in HC committee EA

- Is a specific standard needed for medical laboratories
- Scope of accreditation
Scope of accreditation

- According to ISO 17025
  - A specific test is accredited

- According to the original intention ISO 15189
  - a specific service for the customer is accredited
WG Accreditation

Summarized

- Accreditation on the base of the test is in contrast to the reason ISO 15189 was developed
- Accreditation just based on the test is more in line with ISO 17025
- Accreditation should be done for the complete workload of a medical service
- The extensiveness of such a medical laboratory service should be in line with the extensiveness of the medical service in general
Points of view of EFCC:

Article

Accreditation of medical laboratories in the European Union

Wim Huisman, Rita Horvath, David Burnett et al
CCLM 2007,45:268–275
EA Position

EA–4/17–2008

Position Paper on the description of scopes of accreditation of medical laboratories
IFCC Position

IFCC Statement on the use of ISO 15189 in the accreditation of Medical laboratories

IFCC/EMD Committee on Clinical Laboratory medicine, June 2007

- ‘IFCC recognizes that this Standard (ISO 15189) encompasses all the assessment criteria specified in the policy statement and as such should form the basis for accreditation of laboratories’

- ‘To comply with the IFCC/WASP policy statement, the accreditation of medical laboratories by Accreditation bodies have to follow some key principles…’
Present situation related to “old items”

- ISO 15189 accepted
- Much discussion about flexible scope within EA

For specific tests (for instance molecular biology) accreditation for a test warranted. For general laboratory tests: whole range needed.
Activities in Health Care Committee

Competence and composition of assessment teams
  ◦ Specific selection of assessment teams
  ◦ Time spent on assessment

POCT standard can only be used in connection with ISO 15189

Flexible scope – ungoing

Pre-analytical aspects

Specific items
  ◦ Uncertainty
  ◦ Retention time
Activities Health Care Committee

POCT
Assessment of laboratories against ISO 22870: 2006 “Point-Of-Care Testing (POCT): Requirements for quality and competence”
  - Connection with ISO 15189
Items under discussion

- Recent report on specific items under discussion within EA
- POCT
- Flexible scope
- Pre-examination
- Training assessors

Wim Huisman CCLM 2012; 50: 1147–1152
“European medical laboratory accreditation. Present situation and steps to harmonisation”
Accreditation in European countries

- ISO15189 the preferred standard
- Gradual increase in number (differences between countries)
- Results of different questionnaires by EFLM and EA shown
- WG EFLM 2009
- WG EA HC 2011
- WG EA HC 2013
% of medical laboratories accredited in 2009

<table>
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<tr>
<th>Percentage</th>
<th>Countries</th>
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<tr>
<td>0%</td>
<td>MK, MT, RO, SI</td>
</tr>
<tr>
<td>0.1-5%</td>
<td>AT, CH, DE, ES, FR, HU, IT, LV, RS</td>
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<tr>
<td>6-15%</td>
<td>CZ, LT</td>
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<tr>
<td>16-30%</td>
<td>BE, EE</td>
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<tr>
<td>31-50%</td>
<td>-</td>
</tr>
<tr>
<td>51-75%</td>
<td>NL, UK, SE</td>
</tr>
</tbody>
</table>

Counts:
- MK, MT, RO, SI: 4
- AT, CH, DE, ES, FR, HU, IT, LV, RS: 9
- CZ, LT: 2
- BE, EE: 2
- NL, UK, SE: 3
Accredited & in the process Medlabs in 2011

GERMANY (DAKKS) 500
FRANCE (COFRAC) 160
SWITZERLAND (SAS) 118
CZECH REPUBLIC (CAI) 107
IRELAND (INAB) 50
NORWAY (NA) 33
SPAIN (ENAC) 32
GREECE (ESYD) 32
FINLAND (FINAS) 27
DENMARK (DANAK) 23
PORTUGAL (IPAC) 17
SERBIA (ATC) 16
CYPRUS (CYS-CYSAB) 14
ESTONIA (EAK) 9
LATVIA (LATAK) 9
NETHERLANDS (RVA) 8
REPUBLIC OF CROATIA (HAA) 5
TURKEY (TURKAK) 1
MALTA (NAB-MALTA) 0

number of Medlab
number of MedLab in process
Experience accreditation HC(2013)

<table>
<thead>
<tr>
<th>Country</th>
<th>Start</th>
<th>Accreditations</th>
<th>Assessors (LA  TA  TE)</th>
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<tr>
<td>Austria</td>
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<td>3</td>
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<td>Czech R</td>
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<td>12  70  26</td>
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<tr>
<td>France</td>
<td>1997/2004</td>
<td>187</td>
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<tr>
<td>Cyprus</td>
<td>2006</td>
<td>16</td>
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<tr>
<td>Estonia</td>
<td>1999/2004</td>
<td>10</td>
<td>1  12  2</td>
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<tr>
<td>Spain</td>
<td>2005</td>
<td>37</td>
<td>9  1(7) 30</td>
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<tr>
<td>Greece</td>
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<td>3  4  8</td>
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<tr>
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<td>118</td>
<td>11  0  50</td>
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<td>1992</td>
<td>75</td>
<td>6  55  4</td>
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<tr>
<td>Serbia</td>
<td>2002/2009</td>
<td>22</td>
<td>6/2  8  19</td>
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## Experience accreditation HC(2013)

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<th>Country</th>
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<th>Assessors (LA TA TE)</th>
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<td>22</td>
<td>5 42</td>
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<tr>
<td>Norway</td>
<td>1995/2006</td>
<td>31</td>
<td>6 34</td>
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<tr>
<td>Denmark</td>
<td>1981/2001</td>
<td>25</td>
<td>3 23</td>
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<tr>
<td>Germany</td>
<td>1995</td>
<td>490</td>
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<tr>
<td>Turkey</td>
<td>2010</td>
<td>10</td>
<td>6 6 10</td>
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<tr>
<td>Belgium</td>
<td>1994/2003</td>
<td>67</td>
<td>10 50</td>
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<tr>
<td>Netherlands</td>
<td>1995/2004</td>
<td>262</td>
<td>60 250</td>
</tr>
</tbody>
</table>
Present situation: Accreditation mandatory

Some countries restricted specific areas

ROMANIA: Payment depended on Accreditation
BELGIUM: Molecular genetics.
GERMANY: newborn
SWISS: Human genetics
Need for making accreditation mandatory?

- In some countries majority accredited without legal or money driven demand
- Correct implementation of ISO15189 is made public for user at web site AB
- Makes playing field equal for laboratories
- But strong input needed for correct application
Involvement of laboratory professionals needed

- Work in ISO and CEN
  - TC 212 and TC140
- Work on guidance documents
- Work in National Standard Bodies
  - Voting is by standard bodies
- Work with your accreditation body
  - as technical auditor
  - in the committees
Involvement of laboratory professionals in audits

- Accreditation = competence = role of professional
  - Calibration
  - Quality circle not just inspection
Accreditation according ISO15189 can really improve quality of all medical laboratories for patient and doctor.