Topics for discussion...

- Origins and development of ISO 15189
- Role in accreditation and regulation
- Practical application in the laboratory
- Audit/assessment of examination processes

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Topics for discussion...

- Origins and development of ISO 15189
  - Role in accreditation and regulation
  - Practical application in the laboratory
  - Audit/assessment of examination processes
Origins and development of ISO 15189

- Creation of International Standards
- History and development of ISO 15189
- What is the purpose of ISO 15189?
Creation of international Standards

INTERNATIONAL

ISO
International Organization for Standardization

The Vienna Agreement

Mandated by the EC to produce Standards to support Directives

REGIONAL

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

NATIONAL

BSi

PLUS

Standards bodies of 27 other EC members and 3 EFTA countries
History and development of ISO 15189

- ISO/TC 212 – Clinical laboratory testing and \textit{in vitro} diagnostic systems (1995)
  WG1 Quality and competence in the medical laboratory


- ISO/DIS 15189:2011 (a revision focused on improving the presentation of content)
Development of ISO 15189 (1)

- 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
It is a ‘sector specific’ Standard related to ISO 17025 :2005 (the generic Standard for testing and calibration laboratories)

It is to be used for ACCREDITATION not for CERTIFICATION
Sector specific aspects of ISO 15189 (1)

- defines the competences of a laboratory director
- focuses on the patient outcome without downgrading the need for accuracy of measurements
- emphasizes not only the quality of the measurement but of the total service of a medical laboratory (consultation, turn around time, cost effectiveness etc.)
Sector specific aspects of ISO 15189 (2)

• uses a language and terms that are familiar in the profession
• highlights important features of pre and post investigational (examination) issues
• addresses ethics and information needs of the medical laboratory.

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4 Management requirements

4.1 Organisation and management
4.2 Quality management system
4.3 Document control
4.4 Review of contracts
4.5 Examination by referral laboratories
4.6 External services and supplies
4.7 Advisory services
4.8 Resolution of complaints
4.9 Identification and control of nonconformities
4.10 Corrective action
4.11 Preventive action
4.12 Continual improvement
4.13 Quality and technical records
4.14 Internal audits
4.15 Management review

5 Technical requirements

5.1 Personnel
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment
5.4 Pre-examination procedures
5.5 Examination procedures
5.6 Assuring the quality of examination procedures
5.7 Post-examination process
5.8 Reporting of results
The ISO revision process...

- Standards reviewed and revised if necessary every 5 years
- Proposal for revision (2003)
- ISO/WD 15189
- ISO/DIS 15189 .....ISO/FDIS 15189 etc.
- ISO 15189 (3rd Edition) ....late 2012?
Aims of the revision... 3\textsuperscript{rd} Edition

- Improved access* for users
- Obviate the need for guidelines
- Remove unnecessary prescription

...is unequivocally verifiable by assessors

* ‘improved access through clarity of structure and content’
Proposals for revision... 3rd Edition

- 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’

Option 2. was accepted initially but...
4 Management requirements

4.1 Organisation and management responsibility
4.2 Quality management system
4.3 Document control
4.4 Service agreements
4.5 Examination by referral laboratories
4.6 External services and supplies
4.7 Advisory services
4.8 Resolution of complaints
4.9 Identification and control of nonconformities
4.10 Corrective action
4.11 Preventive action
4.12 Continual improvement
4.13 Control of records
4.14 Internal audits
4.15 Management review

5 Technical requirements

5.1 Personnel
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment, reagents and consumables
5.4 Pre-examination processes procedures
5.5 Examination processes procedures
5.6 Ensuring Assuring the quality of examination results procedures
5.7 Post-examination processes procedures
5.8 Reporting of results
5.9 Laboratory information management (formerly Annex B)
‘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
‘Lack of precision in use of terms…’ (1)

ISO 15189 (3rd edition)

‘Laboratory management shall...’

‘The laboratory shall...’

ISO 9001:2008

‘Top management shall...’

‘The organisation shall...’

‘Executive responsibility’

‘Corporate responsibility’
‘Lack of precision in use of terms...’ (2)

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'Documented procedure(s)' (1)

NOTE 1

Where the term 'documented procedure' appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

A single document may address the requirements for more than one procedure or alternately the requirement for a documented procedure may be covered by more than one document.
Documented procedures (2)
ISO 15189 (3rd Edition)

4 Management requirements

4.1 Organisation and management responsibility
4.2 Quality management system
*4.3 Document control (1)
4.4 Service agreements (1)
4.5 Examination by referral laboratories (1)
4.6 External services and supplies (2)
4.7 Advisory services
4.8 Resolution of complaints (1)
*4.9 Identification and control of nonconformities (2)
*4.10 Corrective action (1)
*4.11 Preventive action (1)
4.12 Continual improvement
*4.13 Control of records (1)
*4.14 Internal audits (1)
4.15 Management review

5 Technical requirements

5.1 Personnel (1)
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment, reagents and consumables (3)
5.4 Pre-examination processes (3)
5.5 Examination processes (x)
5.6 Ensuring the quality of examination results (1)
5.7 Post-examination processes (1)
5.8 Reporting of results (2)
5.9 Laboratory information management (1)
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 validated for their intended use and fully documented.

5.5.2 The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation.

The methods and procedures selected for use shall be evaluated and found to give satisfactory 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 Examination processes

5.5.1 Selection, validation and verification of examination procedures

The laboratory shall select examination procedures which meet the needs and requirements of users and are appropriate for the examination being undertaken.

5.5.2 Biological reference intervals

5.5.3 Documentation of examination procedures
5.6 Assuring quality of examination procedures

5.6.1 The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.

5.6.2 The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operator.

5.6.3 A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference. Where none of these are possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

a) participation in a suitable programme of interlaboratory comparisons;

...from the content being in seven untitled sub clauses...
... to the content being contained in titled clauses...

5.6.1 General
5.6.2 Quality control
  5.6.2.1 Quality control materials
  5.6.2.2 Quality control data
5.6.3 Calibration of measuring systems
5.6.4 Inter laboratory comparisons
  5.6.4.1 Participation
  5.6.4.2 Alternative mechanisms
  5.6.4.3 Analysis of external quality assessment samples
  5.6.4.4 Evaluation of laboratory’s performance
  5.6.4.5 Comparability of results
The lost opportunity… ?

- Problems with the fundamental structure of ISO 15189...
- Restructure the Standard into a ‘process and outcome model’
- How – use the synergy that can be created from using ISO 15189 with ISO 9001
What is the purpose of ISO 15189?

- Primarily it is for use by medical laboratories in developing their systems for managing quality and in assessing their competence...

- Secondarily...it may be used by Accreditation Bodies in confirming or recognising the competence of medical laboratories
Topics for discussion...

- Origins and development of ISO 15189
- Role in accreditation and regulation
- Practical application in the laboratory
- Audit/assessment of examination processes
Role in accreditation and regulation

- The overall context
- Why laboratory accreditation?
- ISO 15189 as the standard of choice
- Choosing an accreditation body

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Internationally recognised Standard

(A) Used by a laboratory for SELF ASSESSMENT (and in preparation for assessment by an accreditation body)

MEDICAL LABORATORY

(B) Used by the Accreditation body to make an objective assessment of a laboratory

(C) Accreditation Body assesses the laboratory and grants accreditation if it is in compliance with the chosen standard. VOLUNTARY ACCREDITATION

Internationally recognised Accreditation Body

(D) Government or a designated regulator mandates accreditation to a chosen standard, as part of its regulatory framework for medical laboratories

Regulation by Government

(E) Accreditation Body informs Government or a designated regulator of the accreditation status of the medical laboratory

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Why medical 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.

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ISO 15189 as the standard of choice ...

- ‘IFCC recognises 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...’ [www.ifcc.org]
Choosing an accreditation body (1)

‘If a laboratory seeks accreditation, it should select an accrediting body which operates to appropriate International standards (ISO 17011) and which takes into account the particular requirements of medical laboratories’

ISO 15189:2007 Introduction

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Choosing an accreditation body (2)

- **Is there a choice?** *Probably NOT...*
  EU Regulation 765/08 on Accreditation and Market Surveillance (9 July 2008).

- **HOWEVER** accreditation bodies do have a special responsibility to ‘take into account the particular requirements of medical laboratories’

- **AND** National Accreditation Bodies (NAB’s) in Europe do operate to appropriate international standards (ISO 17011)
Choosing an accreditation body (3)

INTERNATIONAL

REGIONAL

NATIONAL

Mandated by the EC to provide Accreditation services

Accreditation bodies of 34 ‘European’ countries

European co-operation for Accreditation

UKAS

PLUS
Topics for discussion...

- Origins and development of ISO 15189
- Role in accreditation and regulation
- Practical application in the laboratory
- Audit/assessment of examination processes
ISO 15189 – Creating a practical tool...

- Re-ordering ISO 15189 (not a perfect Standard)
- Using the packages of information to examine...
  1. Pre examination, examination and post examination processes
  2. Internal audit of examination processes

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Re-ordering ISO 15189:2007

- As we have seen earlier the requirements are set out in two main clauses
  - 4. Management requirements
  - 5. Technical requirements

- Within each main clause there are sub clauses (15 in Clause 4 and 8 in Clause 5 – 23 in total)

- Each sub clause is a packet of information and to create a practical tool for the medical laboratory....the packages need to be re-ordered in logical manner...
Using the synergy of ISO 9001 to re-order ISO 15189
### 4 Management requirements

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- 5.7 Post-examination processes
- 5.8 Reporting of results
- 5.9 Laboratory information management

From linear lists with no clear interrelationships...
...to a ‘process and outcome model...
‘A medical laboratory’s fulfilment of the requirements of ISO 15189:2007 means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results.

The management system requirements in ISO 15189 (Section 4) are written in a language relevant to a medical laboratories operations and meet the principles of ISO 9001:2008 Quality management systems- Requirements and are aligned with its pertinent requirements’

Joint IAF-ILAC-ISO Communiqué (2009)
Topics for discussion...

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• Audit/assessment of examination processes

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Pre-examination, examination and post-examination processes
4.7 ADVISORY SERVICES
- Interpretation of examination results

4.7 ADVISORY SERVICES
- Advice on choice of examinations

5.4 PRE-EXAMINATION PROCEDURES
- Information for patients and users
- Requests for examinations
- Request form
- Sample collection and handling
- Sample transportation
- Sample reception

5.5 EXAMINATION PROCEDURES
- Choice of validated procedures
- Verification of procedures
- Documentation of procedures

5.6 ASSURING THE QUALITY OF EXAMINATION PROCEDURES
- Internal quality control (IQC)
- Calibration
- External Quality Assessment (EQA)

5.7 POST EXAMINATION PROCEDURES
- Review of results
- Storage and safe disposal of samples

5.8 REPORTING OF RESULTS
- Format of reports
- Procedures for reporting

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5.4 PRE-EXAMINATION PROCEDURES

4.7 ADVISORY SERVICES

5.5 EXAMINATION PROCEDURES

5.6 ASSURING THE QUALITY OF EXAMINATION PROCEDURES

5.7 POST EXAMINATION PROCEDURES

5.8 REPORTING OF RESULTS

4.7 ADVISORY SERVICES

REPORT

4.3 DOCUMENT CONTROL

4.13 QUALITY AND TECHNICAL RECORDS

- Procedure for identification, storage and retrieval e.g. IQC and calibration records

5.1 PERSONNEL

5.2 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

- Adequate space

5.3 LABORATORY EQUIPMENT

- Equipment acceptance

5.6 ASSURING THE QUALITY OF EXAMINATIONS

- Internal quality control records (limits in use)
- Calibration procedures
- Participation in EQA and discussion regarding results
- Measurement uncertainty
- Comparability of results (POCT etc.)

4.6 EXTERNAL SERVICES AND SUPPLIES

- Procedures for selection and purchase of consumables

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