ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Lab CoP

Transition to the new ISO 15189:2022 Standards

What does it mean in practice?

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ISO 15189 over the years

2007

Previously

ISO 15189:2007

2012

Now

ISO 15189:2012

- Improved layout
- More sub-clauses (e.g Ethics,…)
- Addition of 5.9 & 5.10

2016

Now

ISO 22870:2016

- Specific for POCT

2022

Replaced by

ISO 15189:2022

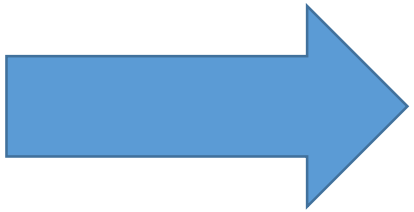
- Alignment with ISO/IEC 17025:2017
- Requirements for point-of-care testing (POCT), previously in ISO 22870, are incorporated
- Increased emphasis on risk management and patient care.

Changes in ISO15189:2022

ISO 15189:2012

1. Scope
2. Normative references
3. Terms and definitions
4. **Managerial Requirements**
5. **Technical Requirements**

Layout of ISO 15189:2022 Standards



ISO 15189:2022

1. Scope
2. Normative references
3. Terms and definitions
4. **General Requirements**
5. **Structural and governance requirements**
6. **Resource requirements**
7. **Process requirements**
8. **Management system requirements**

Application of the new standard

- Beyond medical laboratories to other healthcare services, such as;
  - diagnostic imaging,
  - respiratory therapy,
  - physiological sciences,
  - blood banks and transfusion services

- The use of this standard will help to
  - Facilitate cooperation between medical laboratories and other healthcare services
  - Assist in the exchange of information, and
  - Harmonization of methods and procedures

    → **e.g the full tuberculosis diagnostic cascade (lab + imaging) can be accredited.**

How will the transition happen?

International Laboratory Accreditation Cooperation (ILAC)

https://ilac.org/latest_ilac_news/iso-151892022-for-medical-labs-published/

ILAC Resolution GA 26.08

The resolution was endorsed to allow a 3-year implementation period from the date of publication of ISO 15189:2022 standards **(complete transition by December 2025)**

- Laboratories will have 3 years to comply to the new standard.

Where to get the new ISO 15189:2022

- The ISO 15189 standard is under copyright
- Each laboratory seeking accreditation is required to possess a copy (soft or hard)
- The copy comes with the name of the laboratory/person
- A laboratory **cannot share** the copy with other facilities
- Unit price is 200 USD (approximate!)

Obtaining a copy of the standard

- The ISO online store at https://www.iso.org/standard/76677.html

- National Bureau of Standards in countries that have adopted the ISO standard

- Clinical and Laboratory Standards Institute (CLSI), American National Standards Institute and other standard agencies

What should laboratory facilities do?

If laboratory is already accredited (1)

- Conduct a gap analysis to assess whether their current system (laboratory policies, processes, procedures, and management system) aligns to the new requirements of ISO 15189:2022

  → **To be done as part of the internal audit process by the quality manager or internal auditors at facility level**

  → **New areas to be addressed:**
    - Risk assessment and patient care
    - EQA
    - Customer feed back
    - Process control
    - Equipment

If laboratory is already accredited (2)

- Once the gaps are identified, an in-house action plan developed to align the processes to the new standards

  → **done by the quality and laboratory managers**

- The plan will include:
  - Training of laboratory staff on the new standard **with emphasis on risk assessment & patient care** (ASLM, CLSI, …)
  - Revise quality documents to align to the new requirements
  - Train people on the newly revised quality documents
  - Authorize and adopt the documents with clear effective date
  - Monitor the implementation as part of the Continuous Quality Improvement (CQI)
  - Liaise with the accrediting body for a re-assessment

At least 12 months!!

For laboratories preparing for their first accreditation (1)

- Designate a focal person that will lead the process
  → The quality manager and the laboratory Director
- Management and staff trained on the new standard
  → This can take a longer time

6 months
to a year

- Review and revise the existing quality documents and identify gaps
- Ensure that the training and other QMS implementation tool (SLMTA , SLIPTA, LQSI, others) are aligned to the new ISO standard
  → connect with WHO, ASLM, US CDC and other agencies to get the revised packages
- Establish a system to manage risks and opportunities for improvement
  → Laboratory director assigns roles and responsibilities across the board

For laboratories preparing for their first accreditation (2)

- Identify and select an accreditation body
  → Based on geographic region (language)
  → Practicing in accordance with ISO/IEC 17011 (list is available at AFRAC/ILAC)
    - https://www.intra-afrac.com/Pages/Home.aspx
    - https://ilac.org/
  → Price

- Plan and prepare for the first assessment

What does MoH have to do?

What does MoH need to do (1)?

- Communicate to the national and regional accrediting bodies to identify the potential changes and transition plan
- Incorporate the requirements of ISO 15189:2022 into relevant laboratory documents:
    - National Laboratory Policy (NLP), National Laboratory Strategic Plan (NLSP), national laboratory quality manual template, medical laboratory guidelines, site supervision checklist, and training and mentorship curricula.
    - Do not forget POCT guidance

      → **Done by the directorate of laboratory services supported by the national laboratory TWG**

What does MoH need to do (2)?

- Enforce the adoption of change by all stakeholders, including
  - National Bureau of Standards and Licensing office to revise and update the national standards, guidelines and regulations in line with ISO 15189:2022
  - Professional councils
  - Clinical care stakeholder (POCT)
  - Manufacturers (Equipment)

    → **Through MoH mandated oversight and follow up**
- Train laboratory staffs, mentors and assessors,
- Re-visit the mentorship program for effective and efficient TA support

  → **TWG coordinates national and international partners (agencies)**

What do quality in-charge persons have to do?

QMS assessors and auditors

- Assessors and auditors should seek for training as soon as possible
  →Through packages offered by accrediting bodies ($$$)
  →Online trainings as part of continuing education (ASLM, CLSI, etc).
  CLSI = 15 CPD

- Competencies of all assessors will have to be re-assessed
  →by third party

Question??

Comment??