Transition to the new ISO 15189:2022 Standards

What does it mean in practice?

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ISO 15189 over the years

- **2007**
  - ISO 15189:2007
  - Previously

- **2012**
  - ISO 15189:2012
  - Now
  - Improved layout
  - More sub-clauses (e.g. Ethics,...)
  - Addition of 5.9 & 5.10

- **2016**
  - ISO 22870:2016
  - Now
  - Specific for POCT

- **2022**
  - ISO 15189:2022
  - Replaced by
  - 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

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

Layout of ISO 15189:2022 Standards
Application of the new standard

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

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

→ e.g the full tuberculosis diagnostic cascade (lab + imaging) can be accredited.
How will the transition happen?
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:
  o Risk assessment and patient care
  o EQA
  o Customer feed back
  o Process control
  o Equipment
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

- 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

6 months to a year
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
  o National Bureau of Standards and Licensing office to revise and update the national standards, guidelines and regulations in line with ISO 15189:2022
  o Professional councils
  o Clinical care stakeholder (POCT)
  o 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