Accreditation Bodies in other WHO Regions
Overview

- ILAC
- Accreditation
- International Standards vs Guidance
- Auditing (NATA)
- EQAS/Proficiency Testing
- Take home message
International Laboratory Accreditation Cooperation (ILAC)

- Developing and harmonizing laboratory and inspection accreditation practices
- Promoting laboratory and inspection accreditation to industry, governments, regulators and consumers
- Assisting and supporting developing accreditation systems
- Global recognition of laboratories and inspection facilities via the ILAC Arrangement, thus facilitating acceptance of test, inspection and calibration data accompanying goods across national borders
International Laboratory Accreditation Cooperation (ILAC)

• Established for 30 years
• The ILAC network consists of 135 bodies representing 88 different economies
• Worldwide there are almost 35,000 laboratories accredited by an ILAC signatory
• There are over 6000 accredited inspection bodies
• Accreditation bodies have been evaluated by peers as competent
• Africa, Asia, South America under represented
Accreditation using standards from the International Organization for Standardization (ISO)

ISO 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing
Accreditation using standards from the International Organization for Standardization (ISO)

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

Two areas of expertise
1. QMS (common to many areas)
2. Subject matter expert

Auditor?
- qualifications/training of auditor
- CV/experience
- supervision
- 'registered' 'certified'
- personal attributes

(the NATA model)
Standards

Standards?

• Biological standards

• Standards – documented consensus

ISO 17025 – General laboratory
ISO 15189 – Medical laboratory
ISO 17043 – Proficiency programme
'Guidance' towards obtaining internationally recognized accreditation

AFRO/WHO/CDC
GLI
CLSI
etc

Note: Laboratories often perform a variety of tests.
Clinical and Laboratory Standards Institute (CLSI)

'Guidance'
CLSI -
Quality Management System: A Model for Laboratory Services; Approved Guideline – Fourth Edition (June 2011) 160 pages

• QMS model
• Quality System Essentials
• Path of Workflow Concept
• Phases of Implementation of QMS
• Ethics
• References
• Appendices (forms for auditing, validation of processes, quality manual etc)
External Quality Assurance Schemes (EQAS)

Participation is a requirement for accreditation (if EQAS is available).
(If EQAS not available, lab is expected to 'improvise')

Why?
• Check test is OK - secondary gain (cut off values etc) (peer compared – e.g. in 'real time via internet)
• Check lab and lab personnel can perform, interpret and report results
  – primary purpose.
QAP Molecular Diagnostics
Take Home Messages

- EQAS / Proficiency Testing – essential for accreditation, primarily tests laboratory
- Auditors – skilled at auditing, QMS and technical
- International Standards (used to accredit) vs Guidance towards accreditation
**Take Home Messages**

- Accreditation – creates an expectation of a recognized standard of 'best practice'
- ILAC – International 'best practice' for accrediting laboratories – expanding influence and membership

*WHO role?*
WHO and Accreditation

Questions?