Laboratory accreditation
WHO global perspective

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Laboratory Quality and Management Strengthening
IHR coordination department

Eleventh General Programme of Work 2006-2015
A Global Health Agenda

- **WHO core functions**
  1. **Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;**
  2. **Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;**
  3. **Setting norms and standards, and promoting and monitoring their implementation;**
  4. **Articulating ethical and evidence-based policy options;**
  5. **Providing technical support, catalysing change, and building sustainable institutional capacity;**
  6. **Monitoring the health situation and assessing health trends.**

2 strategic approaches towards accreditation

1. WHO accreditation

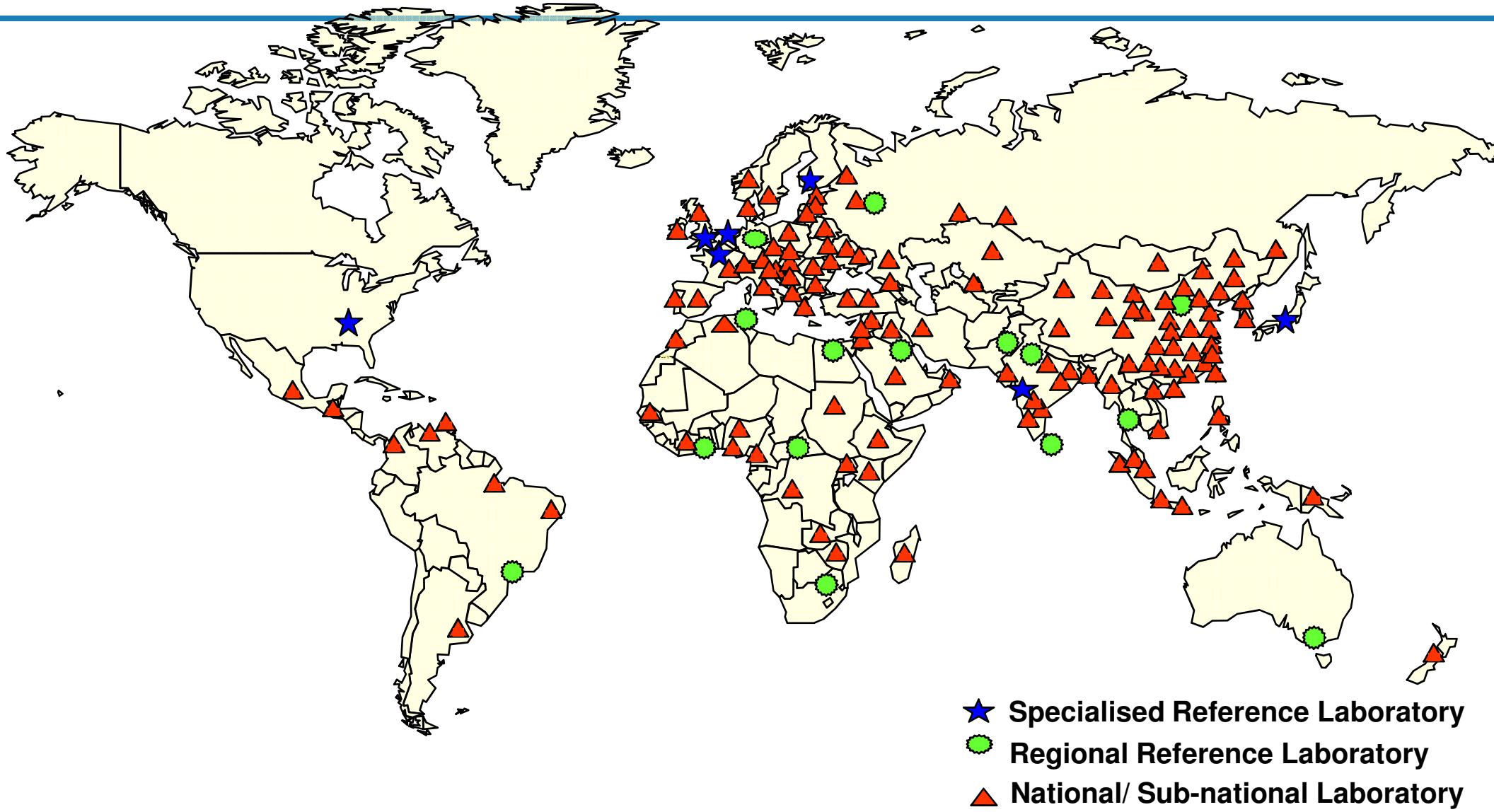
2. WHO support to Quality Management Systems towards accreditation

WHO accreditation

- System in place only for laboratories members of WHO Vaccine-Preventable Diseases networks (polio, measles, rubella, +/- YF and JE) and HIV drug resistance genotyping
- Started before development of ISO 15189
- VPD: WHO short-term need of reliable lab-based surveillance data for disease eradication or elimination
- WHO provides the standard, Proficiency-testing, +/- equipment, reagents and staff costs

Global Lab Network for Polio Eradication

N = 145 laboratories (2005)



International Health Regulations

The designation employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the secretariat of the World Health Organisation concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

World Health Organization

WHO accreditation

- Advantages
  - **For countries:**
    - achievement of a high level of quality at minimal cost
    - international recognition
    - high confidence in laboratory results
    - Accreditation of these few laboratories can highlight the actual lack of quality in many other laboratories (or other units in the same laboratories, such as the bacteriology units vs. virology units) and raise awareness on laboratory quality
  - **For WHO**: high confidence in laboratory results

WHO accreditation

- Challenges:
  - For countries:
    - Quality improvement of a small number of laboratories, usually at central level, and for a limited number of diagnostic tests
    - Problematic sustainability
    - In cases where other donor funding is not available, high financial dependence on WHO
  - For WHO
    - Funding and human resources
    - Absence of formally recognized WHO supranational laboratories or formal networks for many laboratory tests (e.g. biochemistry, malaria, HIV) that could be mobilized to conduct accreditation visits.
    - Credibility as an accreditation body (e.g. WHO is not accredited to ISO 17011, WHO is not signatory of ILAC Mutual Recognition Arrangement)
    - Technical and management requirements of WHO standards and accreditation vis-à-vis existing accreditation schemes using internationally recognized ISO standards (ISO 17025 or ISO 15189).

WHO support to Quality Management Systems towards accreditation

- Advocacy and information sharing
- Technical guidance (guidelines, manuals…)
- Technical assistance (at country and/or institutional level): assessment, training…
- Proficiency-testing
- Quality of reagents (pre-qualification schemes)

WHO support to Quality Management Systems towards accreditation: *advocacy*

SEA-HLM-393
Distribution: General

Establishment of
Quality Systems and Accreditation
in Health Laboratories

Report of an Intercountry Workshop
Thailand, 9-13 October 2006

World Health Organization
Regional Office for South-East Asia
New Delhi

WHO support to Quality Management Systems towards accreditation: *publications*

SEA-HLM-354
Distribution:General

Quality Assurance in Health Laboratory Services: A Status Report

Project No: ICP BCT 001

SEA-HLM-379
Distribution: Limited

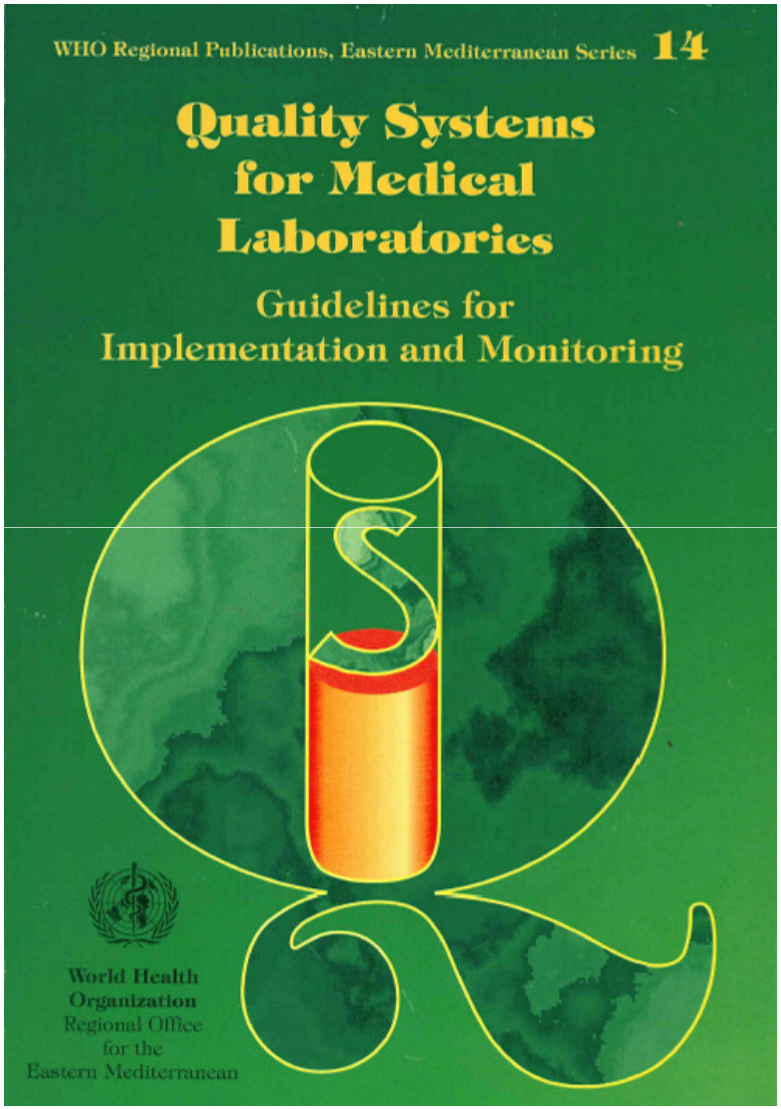
Accreditation of Health Laboratories in the Countries of the SEA Region

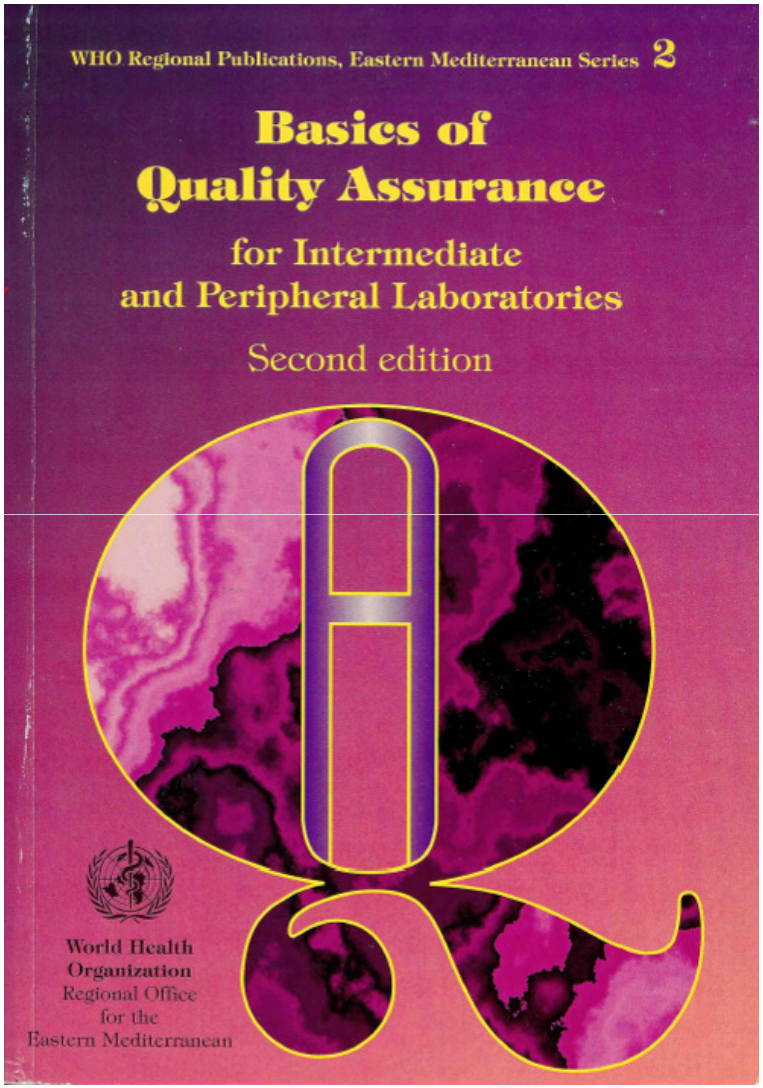
Report of a Regional Consultation
Bangkok, Thailand, 6-10 October 2003

WHO Project: ICP BCT 001

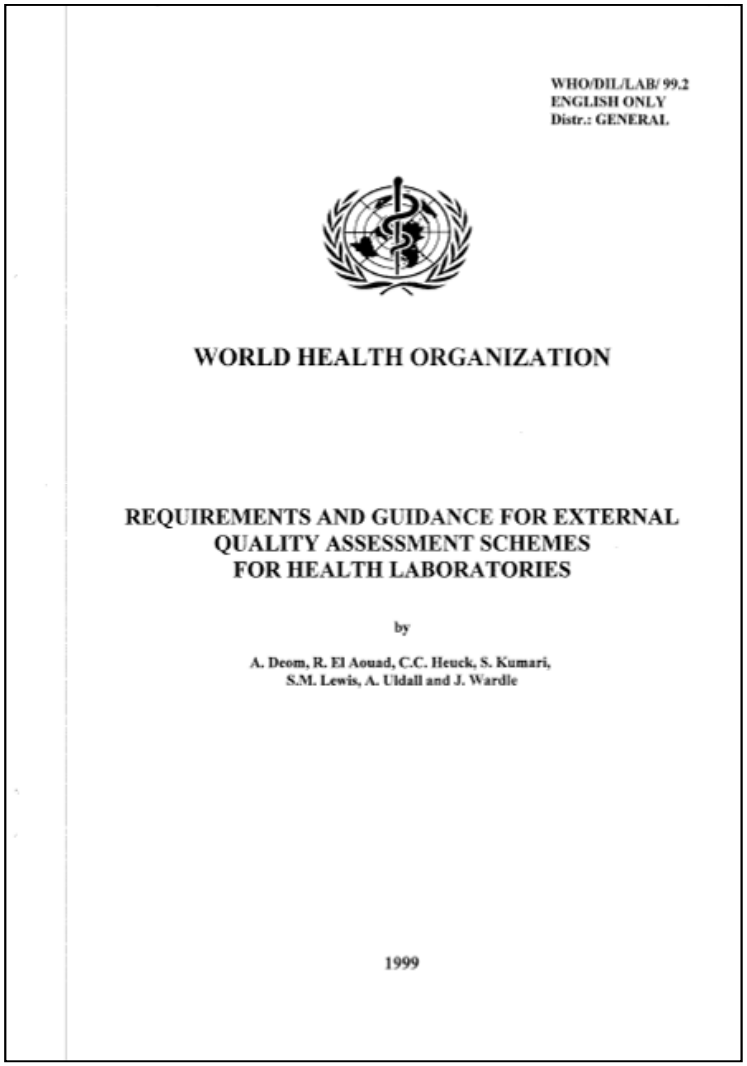
World Health Organization
Regional Office for South-East Asia
New Delhi
February 2004

WHO support to Quality Management Systems towards accreditation: *publications*





WHO support to Quality Management Systems towards accreditation: *publications*



WHO/DIL/LAB/ 99.2
ENGLISH ONLY
Distr.: GENERAL

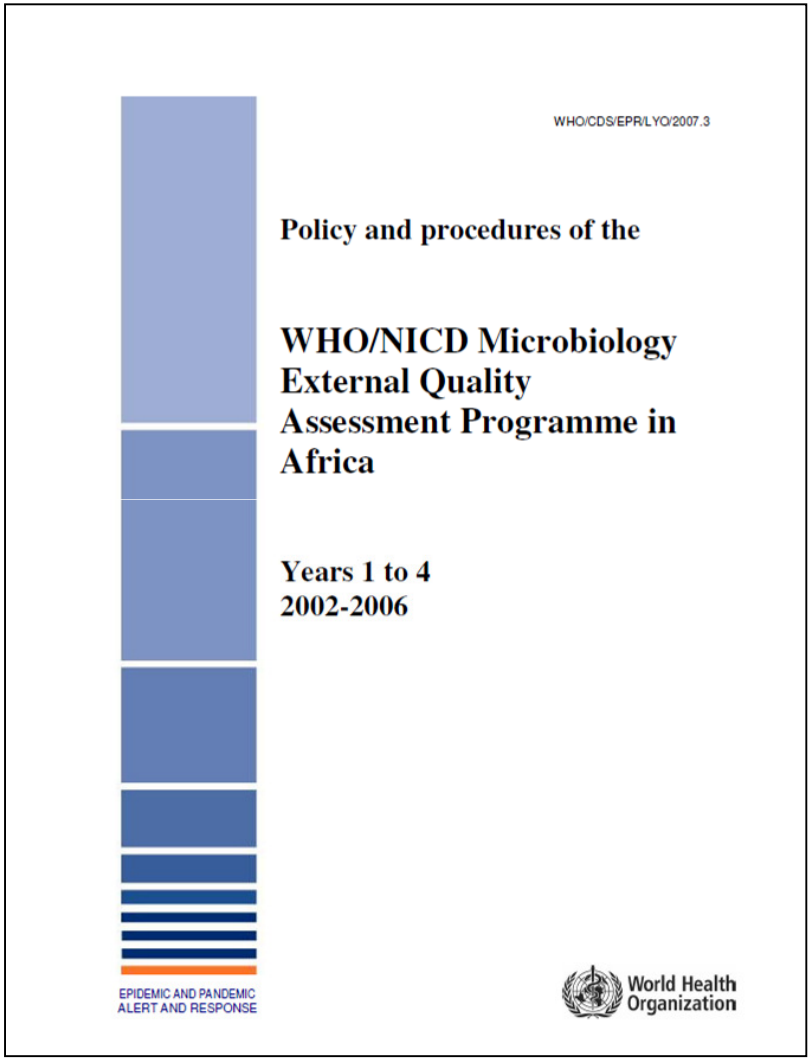
WORLD HEALTH ORGANIZATION

REQUIREMENTS AND GUIDANCE FOR EXTERNAL QUALITY ASSESSMENT SCHEMES FOR HEALTH LABORATORIES

by

A. Deom, R. El Aouad, C.C. Heuck, S. Kumari, S.M. Lewis, A. Uldall and J. Wardle

1999



WHO/CDS/EPR/LYO/2007.3

Policy and procedures of the

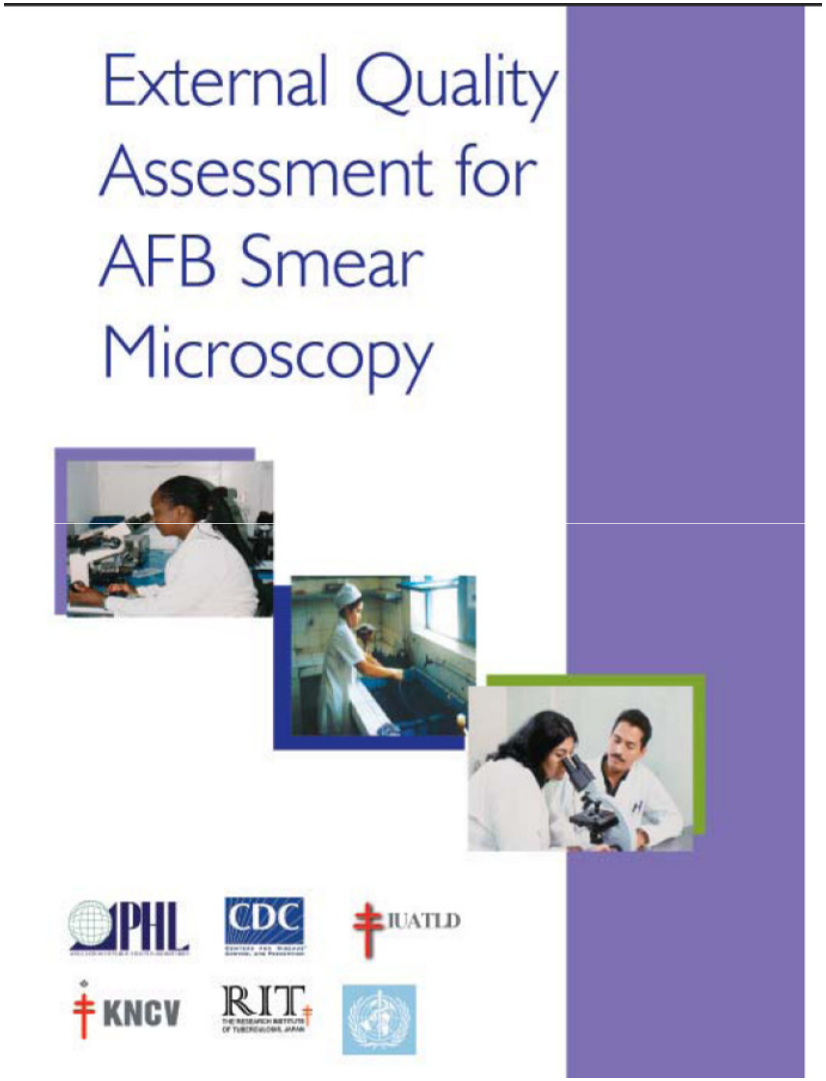
WHO/NICD Microbiology External Quality Assessment Programme in Africa

Years 1 to 4
2002-2006

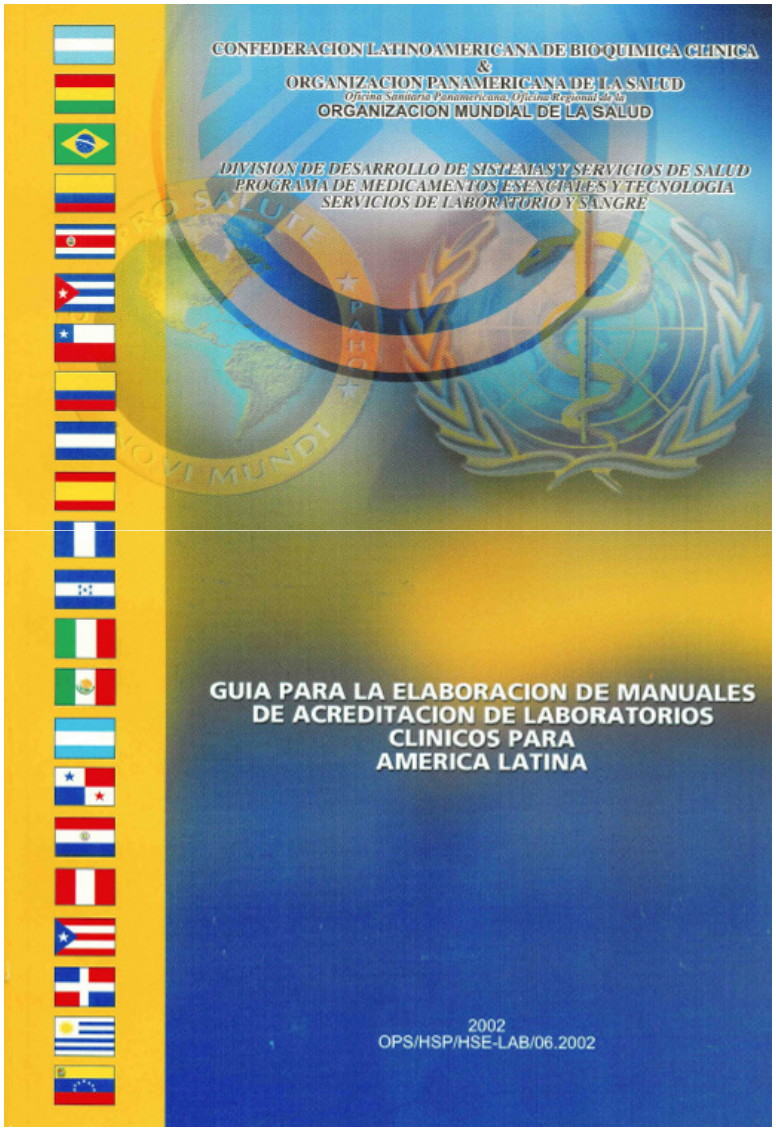
EPIDEMIC AND PANDEMIC ALERT AND RESPONSE

World Health Organization

WHO support to Quality Management Systems towards accreditation: *publications*



WHO support to Quality Management Systems towards accreditation: *publications*



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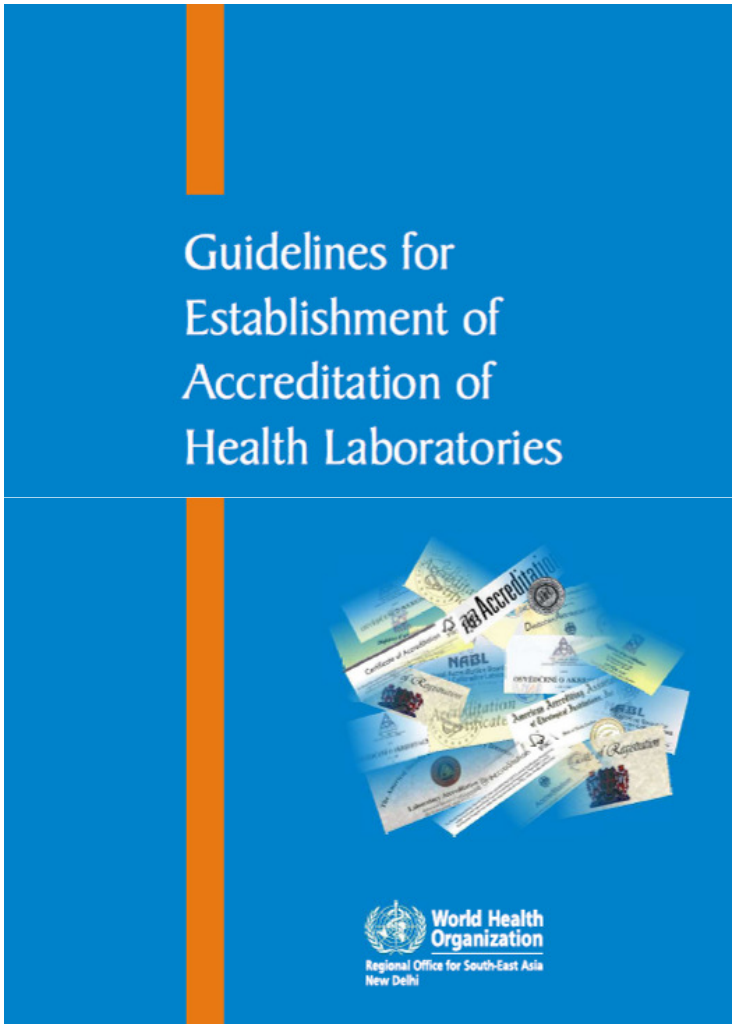
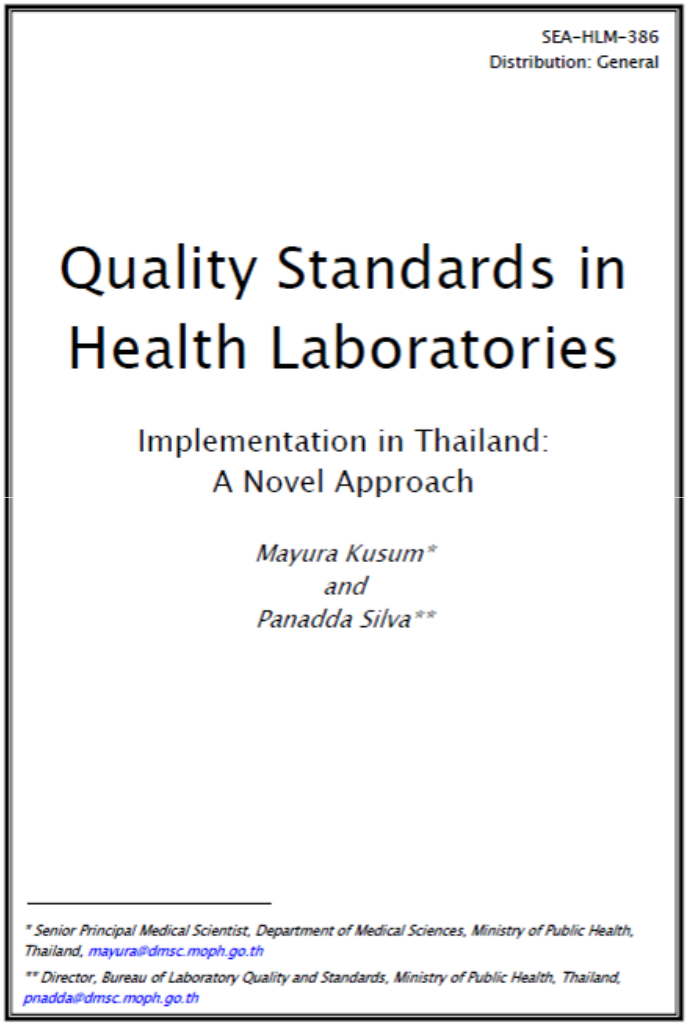




SEA-HLM-386
Distribution: General

Quality Standards in Health Laboratories

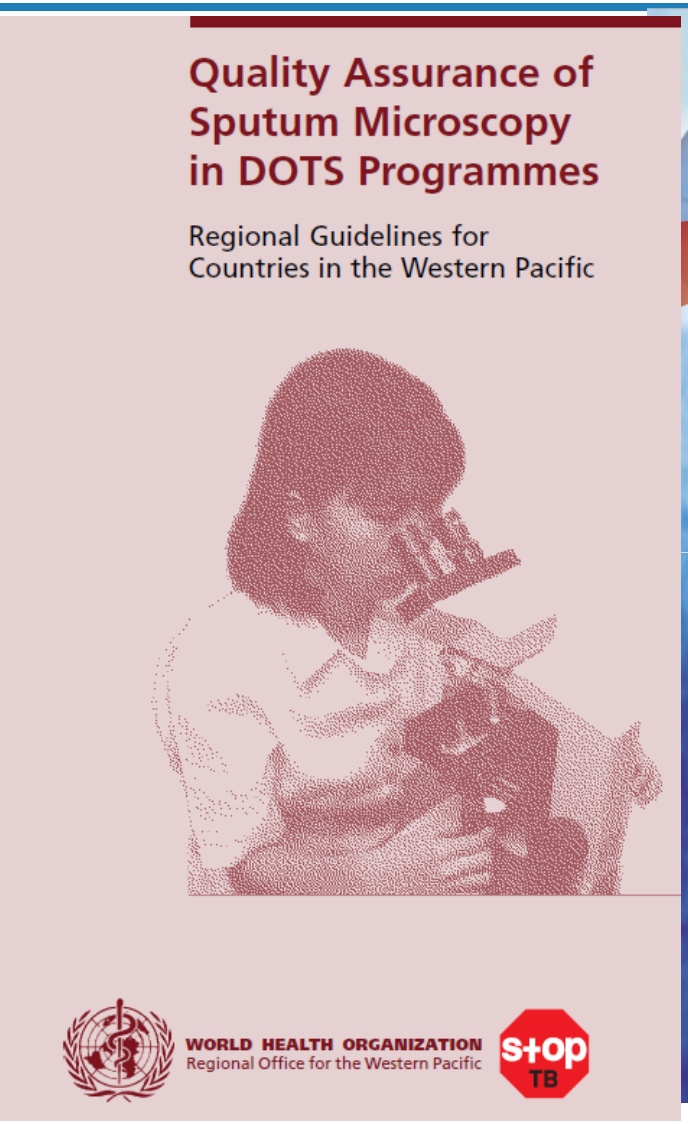
Implementation in Thailand: A Novel Approach

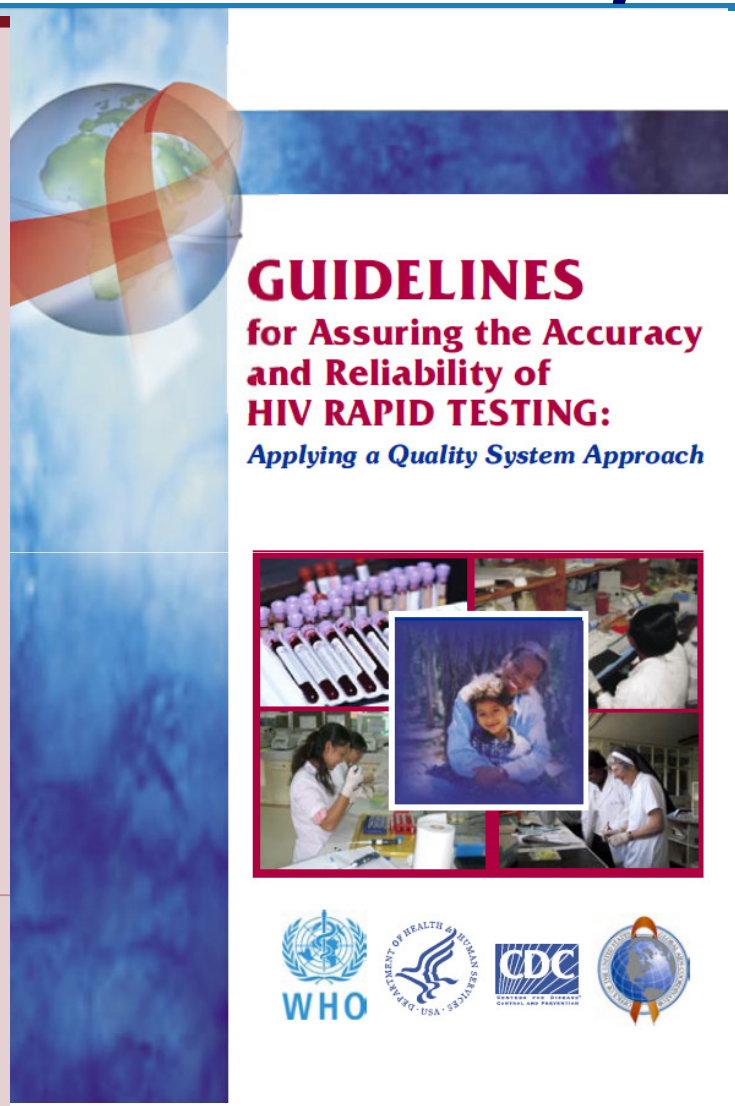
*Mayura Kusum**
and
*Panadda Silva***

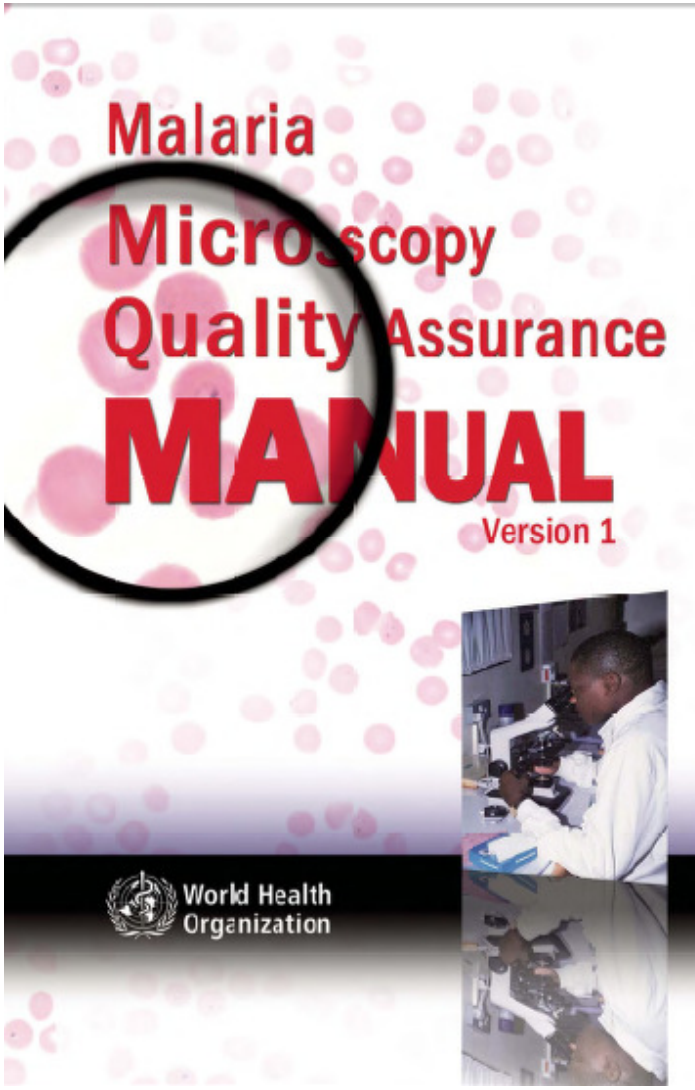
* Senior Principal Medical Scientist, Department of Medical Sciences, Ministry of Public Health, Thailand, mayura@dmsc.moph.go.th

** Director, Bureau of Laboratory Quality and Standards, Ministry of Public Health, Thailand, pnadda@dmsc.moph.go.th

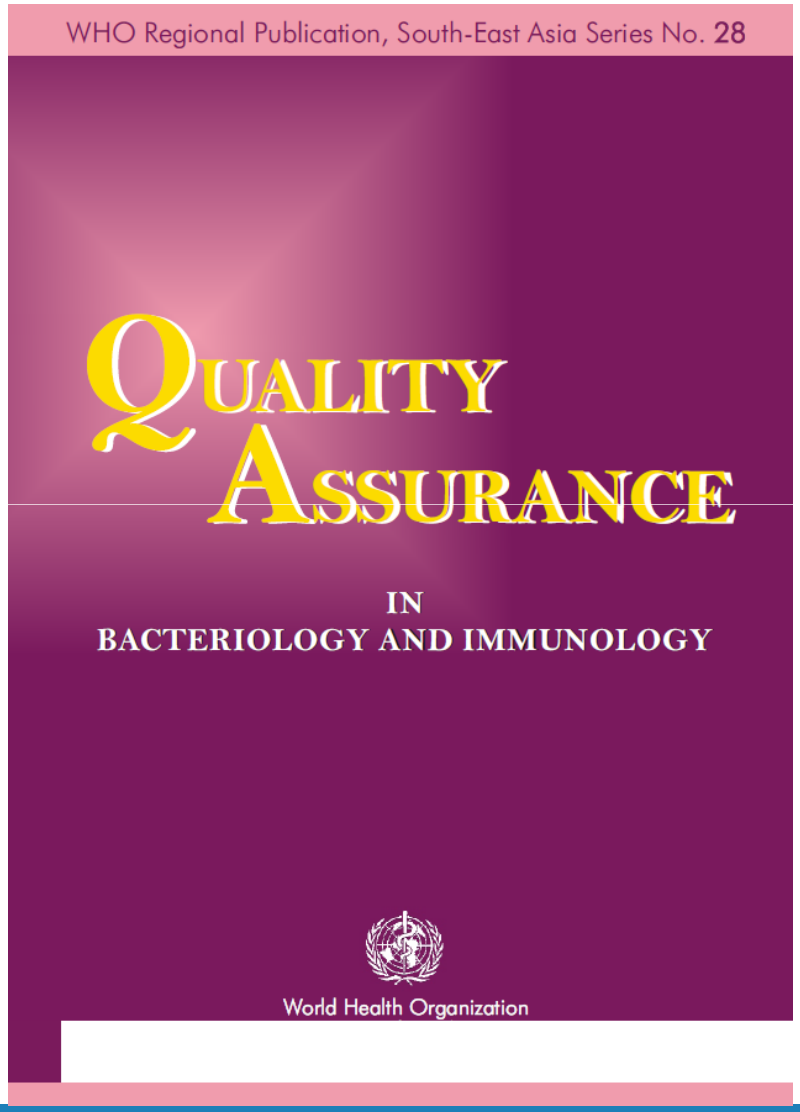
WHO support to Quality Management Systems towards accreditation: *publications*







WHO support to Quality Management Systems towards accreditation: *publications*



WHO support to Quality Management Systems towards accreditation: *advocacy*

2008, 83, 285–292 No. 32

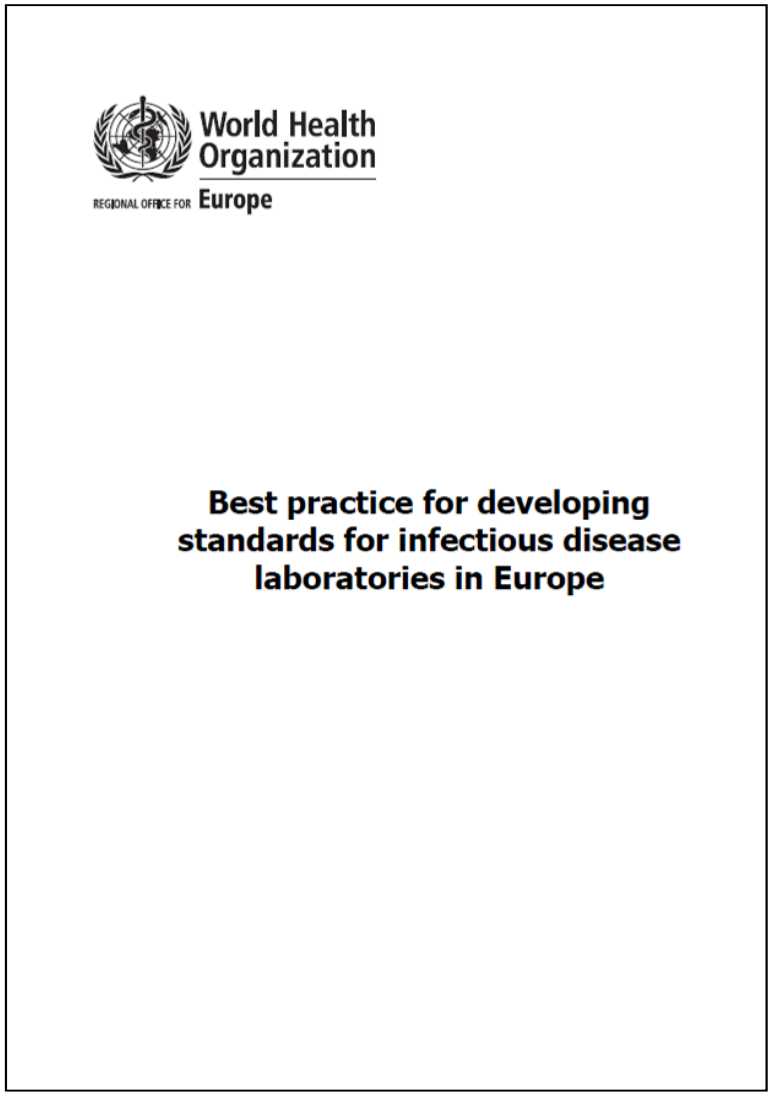
World Health Organization
Organisation mondiale de la Santé

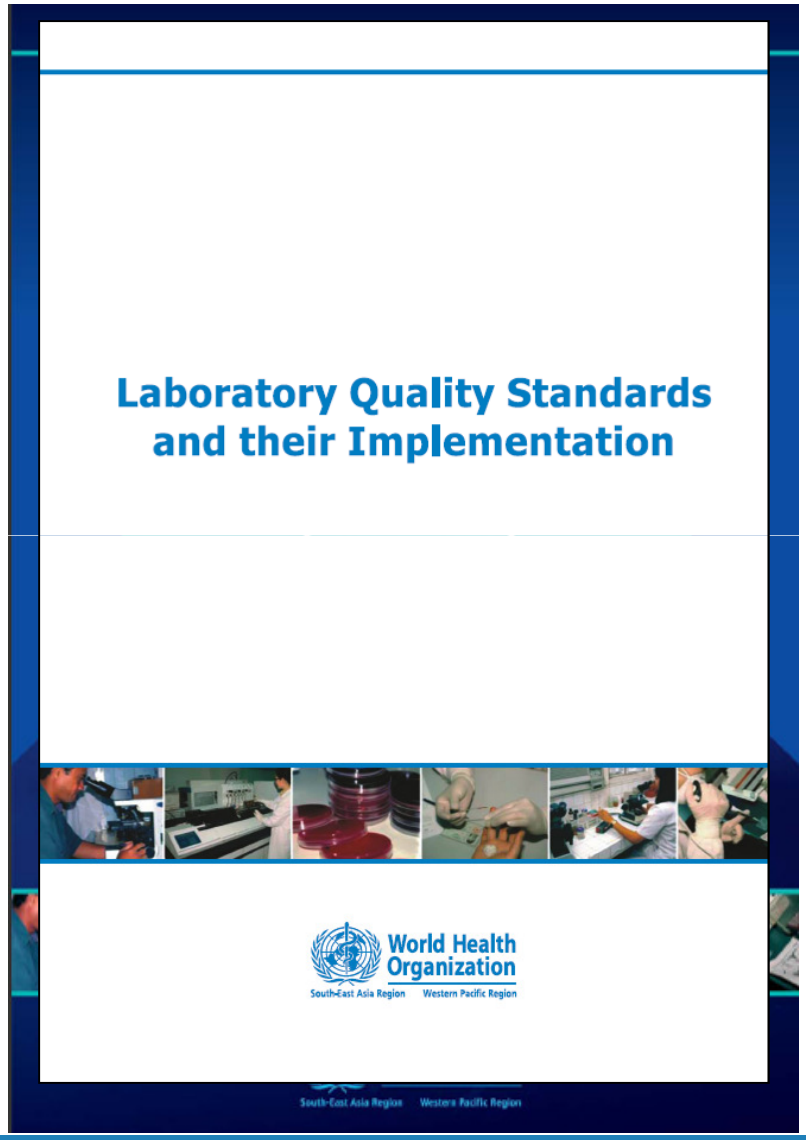
Weekly epidemiological record
Relevé épidémiologique hebdomadaire

8 AUGUST 2008, 83rd YEAR / 8 AOÛT 2008, 83e ANNÉE
No. 32, 2008, 83, 285–292
http://www.who.int/wer

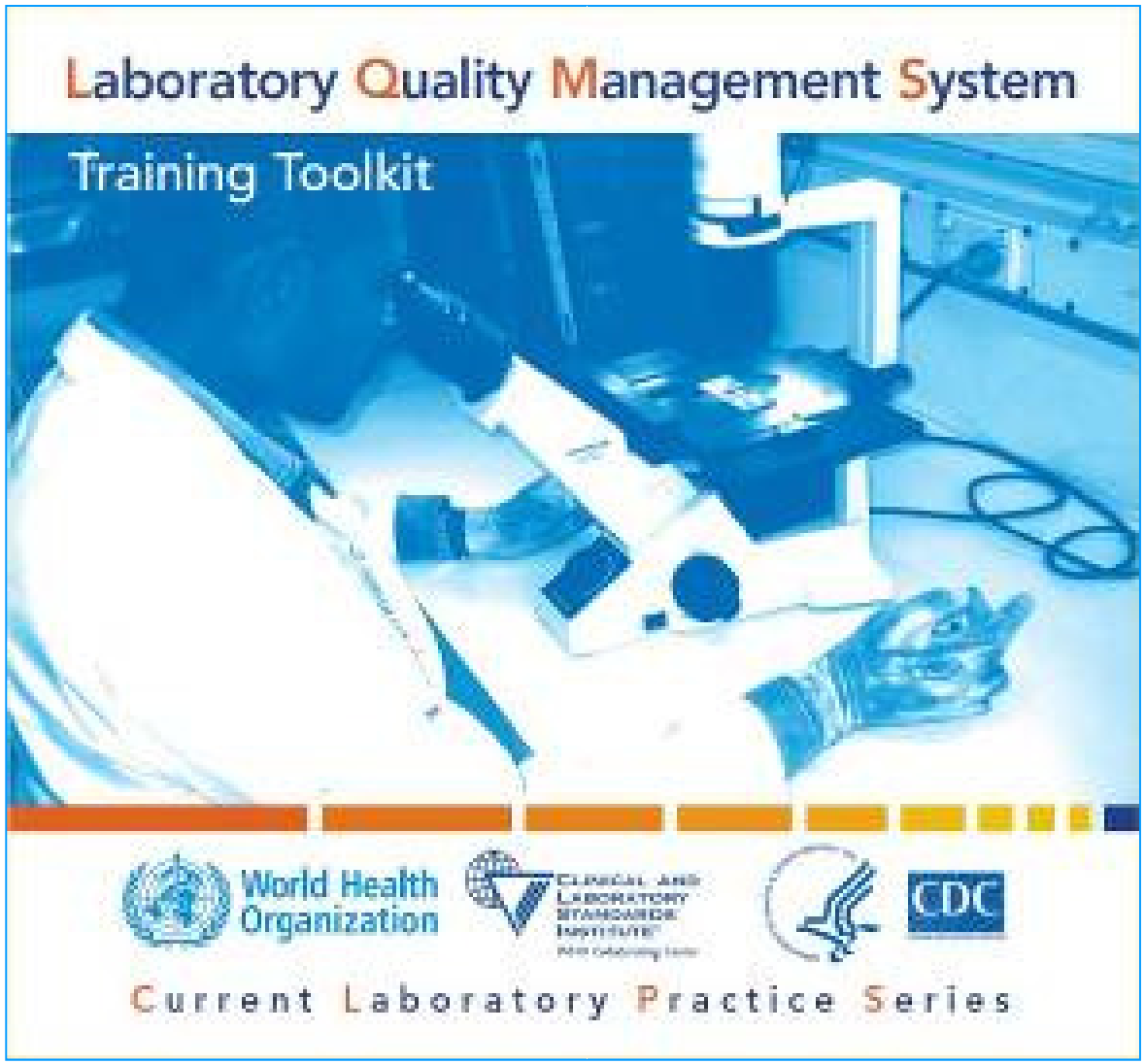
- It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189.

WHO support to Quality Management Systems towards accreditation: *publications*





WHO support to Quality Management Systems towards accreditation: *training*



WHO support to Quality Management Systems towards accreditation: *proficiency-testing*

- Polio PT (RIVM, Nertherlands)
- Measles and rubella PT (VIDRL, Australia)
- HIV, Hep B, Hep C PT(NRL, Australia)
- Global Foodborne Infections Network EQA (National Food Institute, Denmark)
- Tuberculosis DST EQA (Antwerp, Belgium)
- Haematology and Clinical chemistry (UKNEQAS)
- Microbiology EQA scheme for Africa (NICD, South Africa)
- Microbiology EQA scheme for Eastern Mediterranean Region (CPHL, Oman)
- Support to National EQA schemes
- …

WHO support to Quality Management Systems towards accreditation: *pre-qualifications of diagnostics*

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Diagnostics and Laboratory Technology

- Diagnostics and Laboratory Technology
- Contributions to universal access
- Prequalification of diagnostics
- Procurement of diagnostics
- Quality assurance
- Guidance and training
- Country projects

WHO Prequalification of Diagnostics Programme

The WHO prequalification of diagnostics programme aims to increase access to affordable diagnostic technologies of assured quality that are appropriate for use in resource limited settings. The programme provides Member States, UN agencies and other partners with technical information and advice on the quality of currently available HIV/AIDS, malaria and hepatitis B and C test kits and technologies.

Prequalification of diagnostics is a prerequisite for UN procurement ensuring that public monies are spent in a cost effective manner, on quality diagnostics.

Overview of prequalification of diagnostics

Overview document
pdf, 196kb

New

Issue 6 - Q1 2011
pdf, 434kb

WHO support to Quality Management Systems towards accreditation: conclusion

- WHO is not a medical or clinical laboratory accreditation body even if specific WHO laboratory accreditation schemes have been established to serve disease specific surveillance activities
- WHO recognizes ISO 15189 as the gold standard for medical laboratories
- WHO encourages a stepwise implementation of ISO 15189 for advanced/central level laboratories, while national regulations should ensure that basic quality requirements are met in all clinical laboratories

WHO support to Quality Management Systems towards accreditation: conclusion

- WHO works closely with partners and MoHs to support regional or national strategies to improve quality in a stepwise process through:
  - Advocacy and strategic planning activities with MoHs and partners
  - Technical assistance at country level to develop appropriate quality systems through national laboratory policy, regulatory and licensure mechanisms
  - Development of tools (implementation guidelines, assessment checklists…)
  - Workforce development (curricula or training materials development, training sessions organization…)