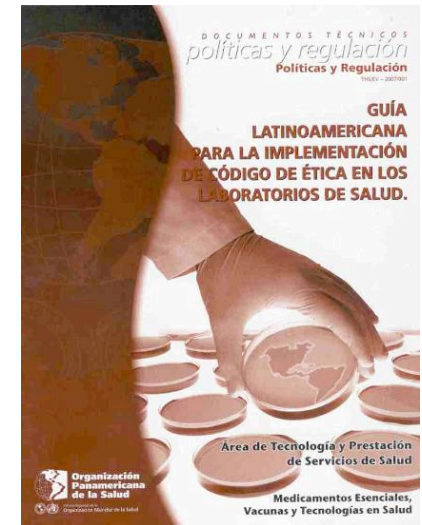
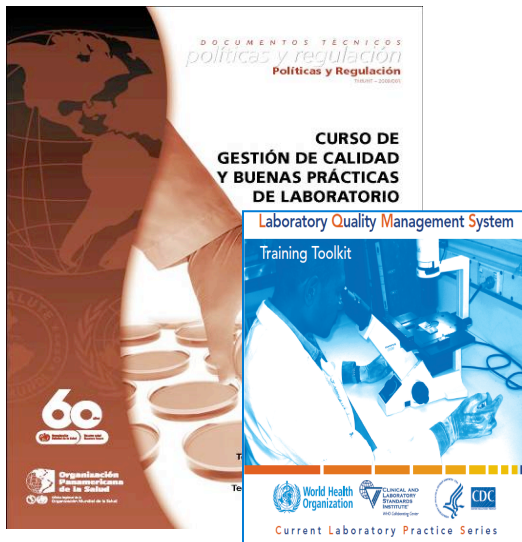


HSD/IR/LAB PUBLIC HEALTH LABORATORY SERVICES

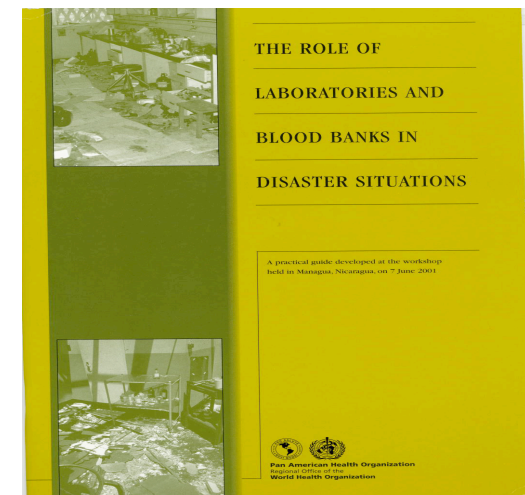
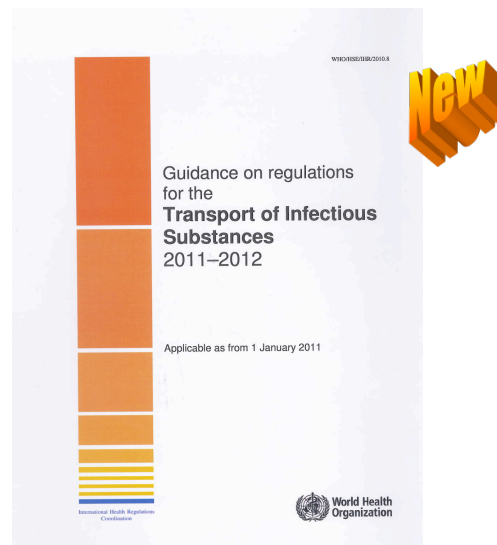
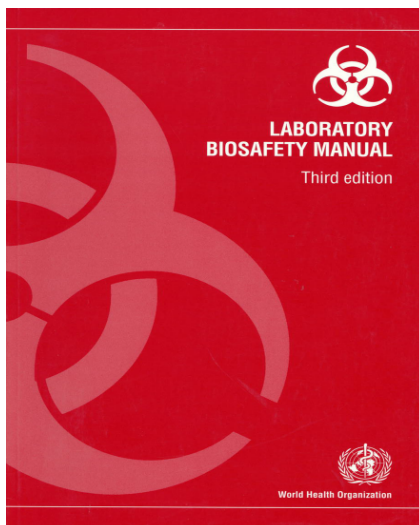


Sustainable Laboratory QMS for Strengthening the Quality of Care and Surveillance in the CARIBBEAN

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LABORATORY SERVICES PAHO/WHO

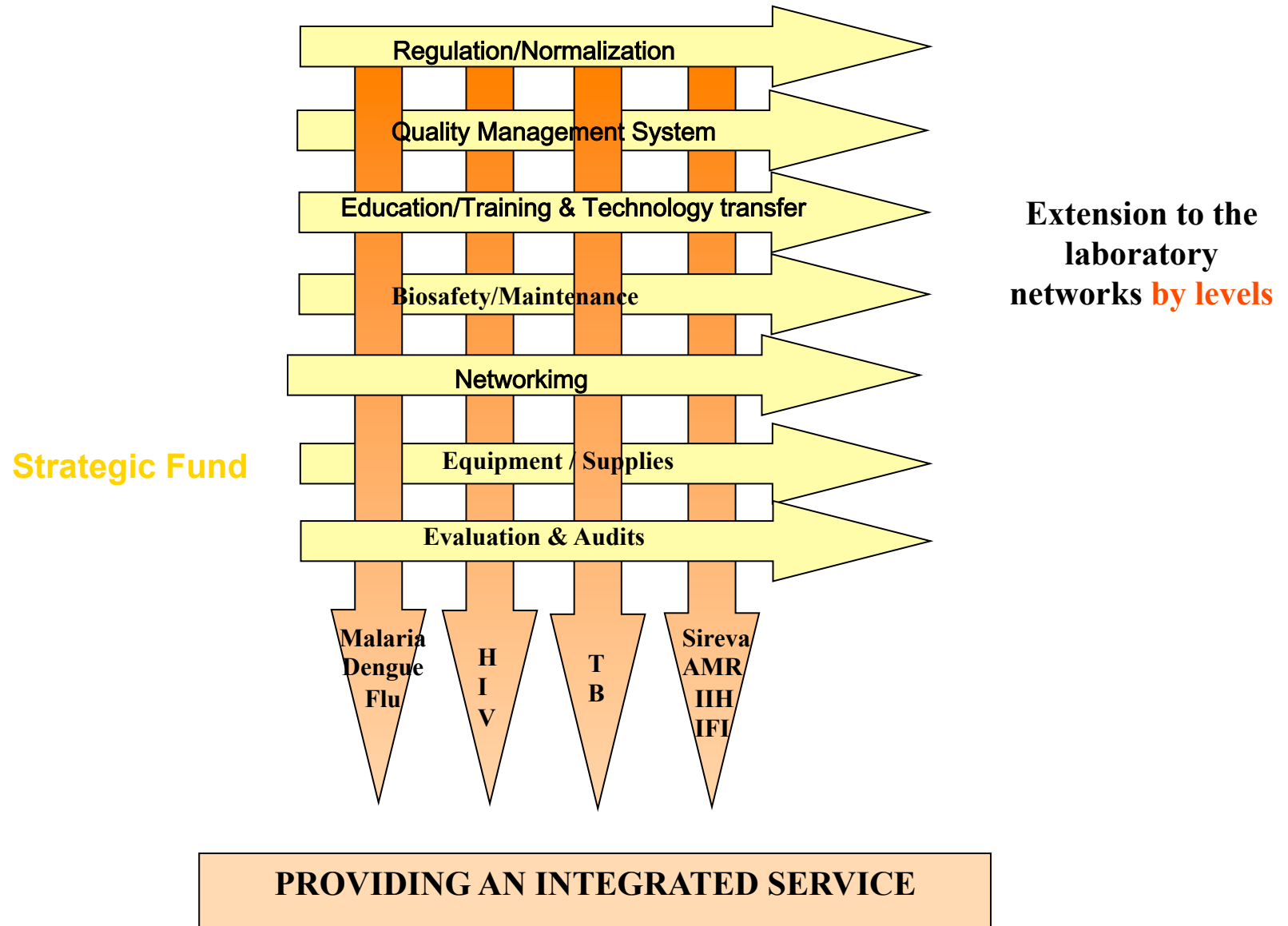


Safe Laboratory, 2010

PAHO LABORATORY SERVICES MANDATE

- To Implement and sustain **Quality Management Systems** in Laboratory Networks for the Strengthening of Patient Care and Surveillance.

CROSS CUTTING INTERVENTIONS



PUBLIC HEALTH LABORATORY

Core Functions

1. Reference and Referral for specialized testing;
2. Disease prevention, control, and surveillance;
3. Integrated data management;
4. Environmental health and protection;
5. Food safety;
6. Laboratory improvement and regulation;
7. Policy development;
8. Emergency response;
9. Public health-related research;
10. Training and education; and
11. Partnerships and communication.

APHL/CDC

1. Reference and Referral for specialized testing;
2. Strengthening Surveillance
 - Disease prevention, control, and surveillance
 - [Disaster and Emergency response](#)
 - Water and Food Safety
 - Environment Health
3. Integrated data management;
4. Policy development, Laboratory improvement and Regulations;
5. Training and education
6. Public health-related research;
7. Partnerships and communication.

PAHO/WHO

HSD/IR PUBLIC HEALTH LABORATORY SERVICES

- One Denominator: **Quality**
- One Target: **Patient**
 - Community
 - Vulnerable population
 - High risk groups
 - Vulnerable areas
 - » Borders
 - » Emergencies (IHR) & Disasters
- One Need: **Evidence**
- One strategy: **Networking**

Health
Services



Surveillance

PATIENT EXPECTATIONS

- Accessibility, Availability, Equity
- Accuracy, Timeliness of the Results
 - Competent and Qualified Human Resources
 - Certified Equipment
 - Validated Technology
 - Registered Reagents
 - Sensitivity, Specificity
 - Predictive Values
 - Good Laboratory Practices: Traceability
 - QA/QC
 - Proficiency Testing
 - Inspection/Audit
- Safety, Biosafety, Biosecurity, Infrastructure
- Cost: cost/effectiveness
- Transparency, Confidence
- Ethics



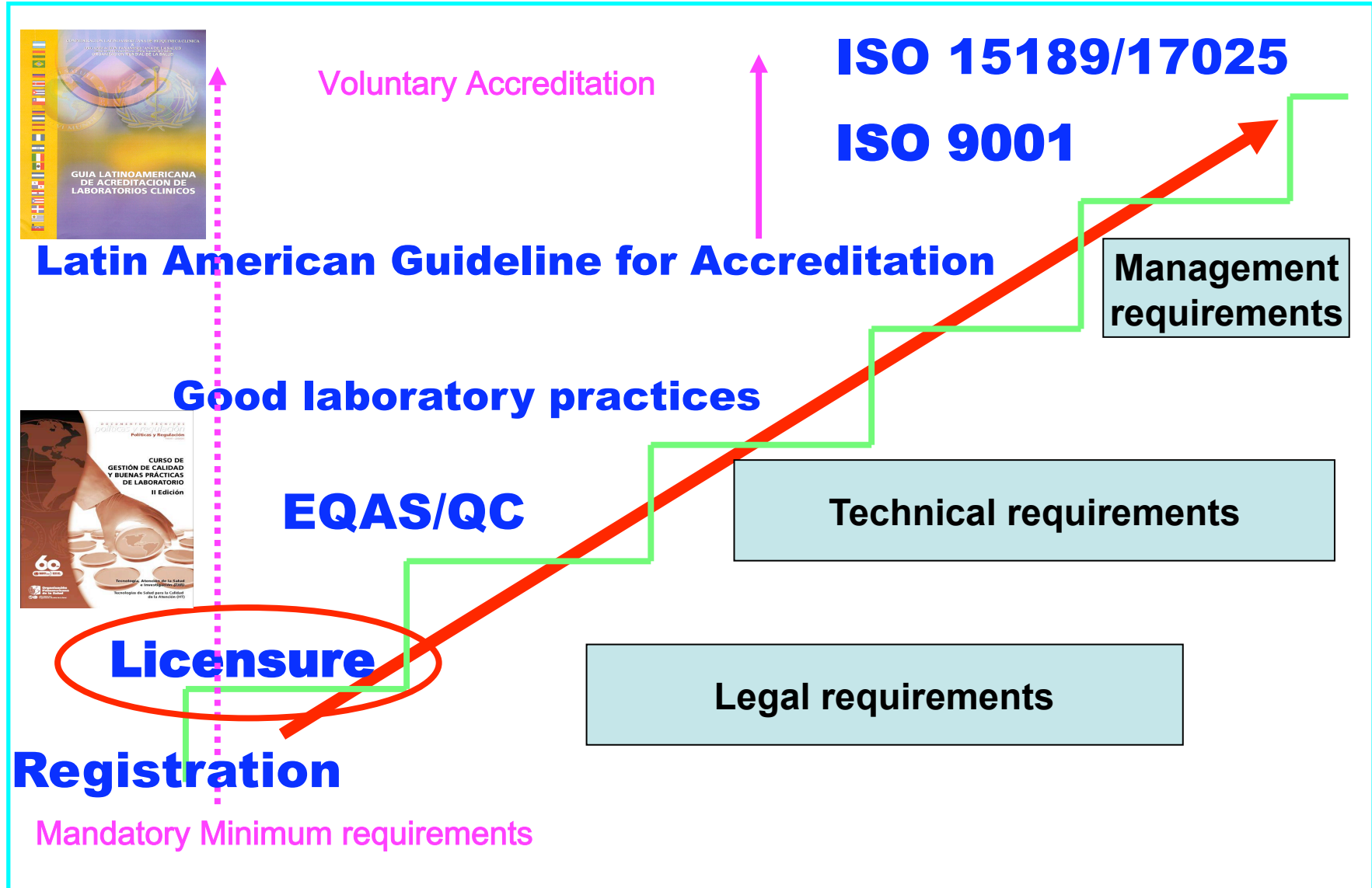
Quality
Based on
Evidence

Joint WHO-CDC Statement Lyon Conference, 2008

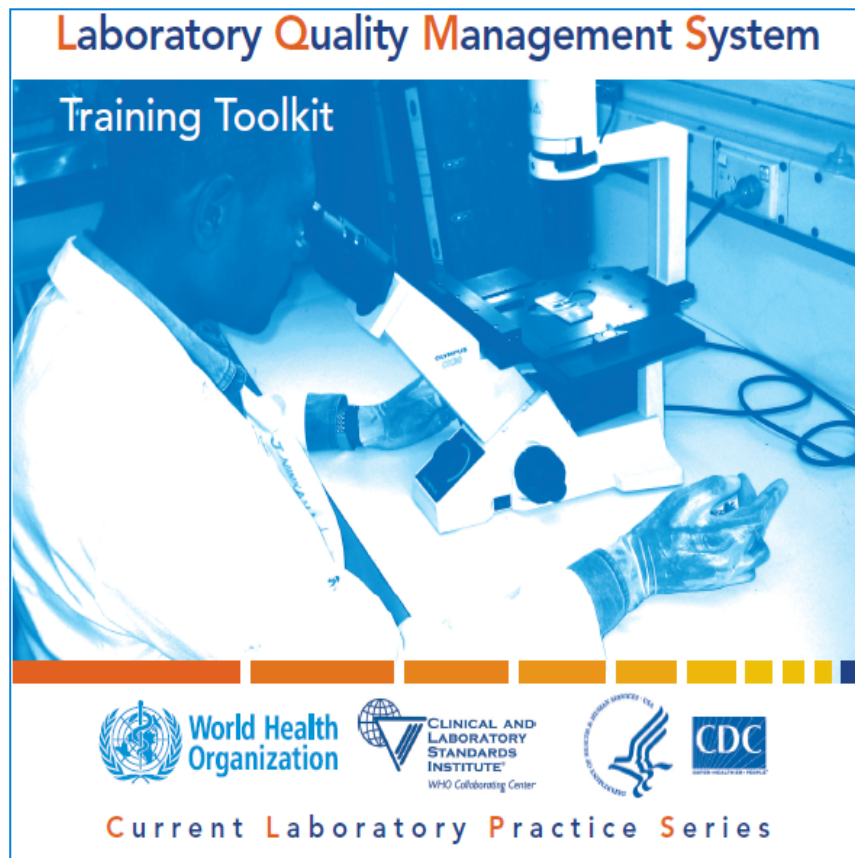
- Each country should establish its own set of standards according to country-specific needs based on internationally agreed standards
- National laboratory standards need to take into account local factors, including any pertinent regulations, organization of the country's laboratory systems and resource constraints
- 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

QUALITY MANAGEMENT SYSTEMS

Continuous improvement



QUALITY MANAGEMENT & GOOD LABORATORY PRACTICES



CONTENT

1. General Overview
2. QMS Planning
3. Documentation
4. Human Resource Management
5. Provider's Management
6. Equipment and Supplies
7. Process Management and Control
8. Management of non Conformities
9. Cost of the Quality
10. Customer Satisfaction
11. Biosafety Management



+ CD

+ SLIDES

+ Check List

+ Distance learning material

MODULE CONTENT

- General objective
- Objectives of the training
- Definitions
- Theoretical course
- Breaks for the reflexion
- Exercises
- Work plan
- Check list



CHECK LIST

Mod. 7 – Process Management and Control

No.	Preguntas	ISO 9001	ISO 17025	ISO 15189	Evaluation criteria	Y/N	Evidences & observations
7.21	¿Mantiene el laboratorio sistemas de control de calidad interno que verifiquen la calidad de los resultados?	5.6.1	5.9.1	8.2.3	Verificar que los sistemas de control y sus registros provean al personal de información clara y comprensible para sustentar sus decisiones técnicas y clínicas y tomar medidas correctivas apropiadas.		
7.22	¿Mantiene el laboratorio un programa de calibración de sus sistemas de medición?	5.6.3	5.6.2 5.9.1	7.6	Verificar que el programa de calibración esté documentado, que se tomaron medidas correctivas y que se mantienen actualizados los registros correspondientes		
7.23	¿Participa el laboratorio de comparaciones inter laboratorio o programas de evaluación externa del desempeño?	5.6.4	5.9.1	No se contempla	Verificar que la participación es programada y periódica. Registros y certificados de participación.		
7.24	¿Evalúa la Dirección del laboratorio los resultados de la evaluación externa implementando medidas correctivas cuando sea necesario ?	5.6.4	5.9.2	No se contempla	Registros de resultados de la evaluación externa del desempeño. Registros de las acciones correctivas.		

CHALLENGES IN THE CARIBBEAN

- Sustainable Implementation of QMS
- Develop a Regional framework for minimum mandatory requirements (licensure)
- National Legislations revisited
- Advocacy for a Step-wise approach toward Accreditation
- Training trainers on QMS and BRM
 - National Public Health Laboratories
 - Medical laboratories
 - Accreditation bodies

**PAHO-CDC Joint Strategic Framework
Document for Implementation of Quality
Management Systems
in a Step wise Approach Toward Accreditation
for Laboratories in the Caribbean**

**Advocacy – Policy – Capacity Building
for a sustainable QMS**

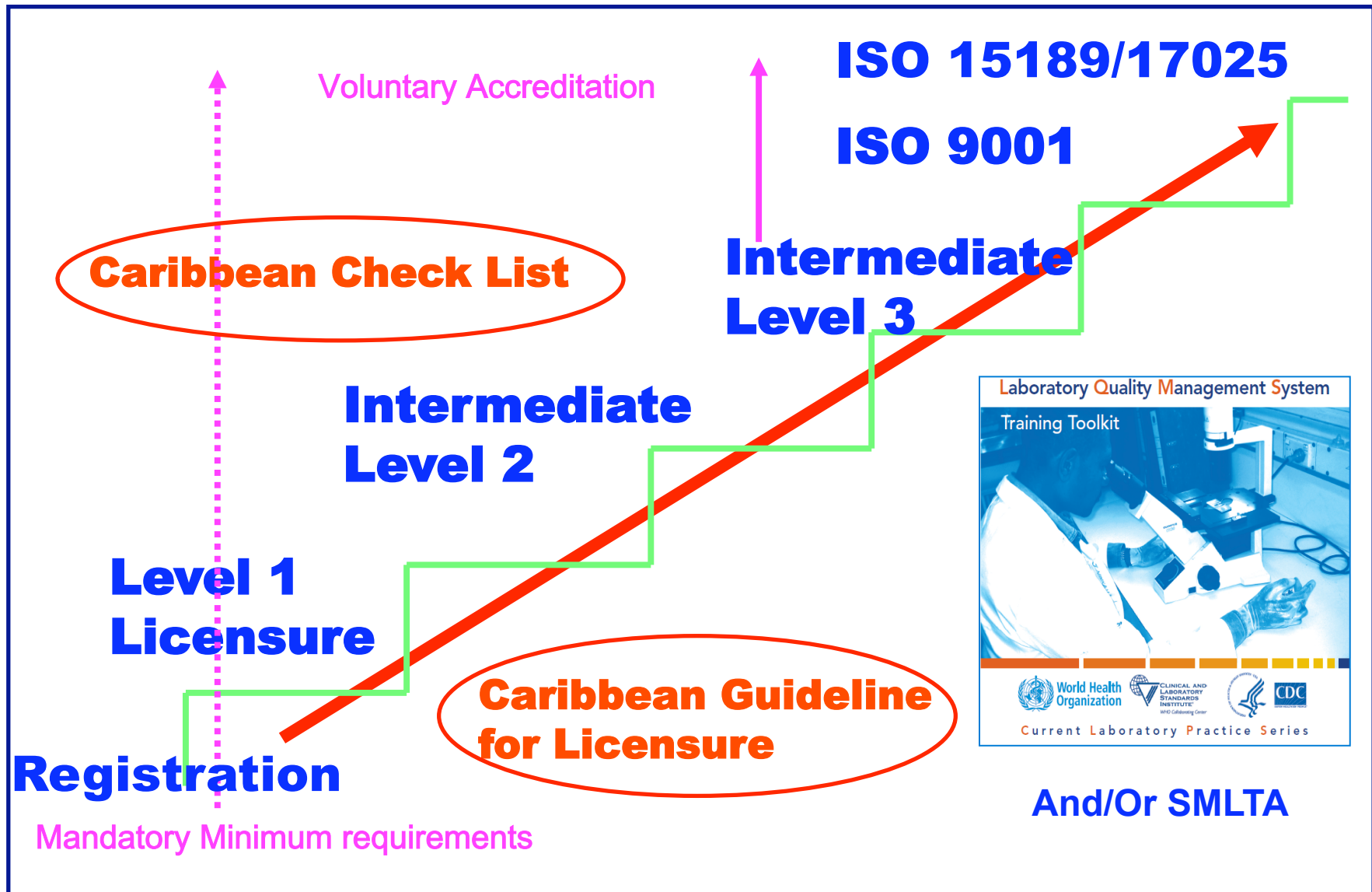
1. Census of medical laboratories and national regulations
2. Cost/benefit of accreditation for laboratories
3. Develop check list for each tier pilot document
4. Regional Consultation for the implementation of QMS in a step-wise approach and Pilot document endorsement

➤ **PAHO/WHO is not an accreditation body**

➤ **PAHO/WHO will facilitate a process**

QUALITY MANAGEMENT SYSTEMS

Step Wise approach toward Accreditation



ACTIVITIES PLANNED IN 2011

- Year 1 of the QMS implementation in a step-wise approach toward accreditation
- Publication of the first laboratory regulations in SUR
- Conduct a gap analysis for International Standards in GUY
- Maintain Caribbean participation in UK-EQAS
- NPHL construction and CAREC Re-location within CARPHA Transition
- Smooth transition to CARPHA
 - CAREC Lab Core functions
 - Services and list of analysis
 - Caribbean Laboratory Network TORs establishment
 - QMS implementation at CAREC

Relationship of CLSI QSEs Between CLSI Documents HS1 and GP26 to ISO Standards 15189 and 9001

CLSI QSEs	CLSI HS1: A Quality Management System Model for Health Care	CLSI GP26: Application of a Quality Management System Model for Laboratory Services	ISO 15189: Medical laboratories— Particular requirements for quality and competence	ISO 9001: Quality management systems —Requirements
Organization	5.2	6.2	4.1 Organization and management 4.2 Quality management system	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 6.1 Provision of resources
Personnel	5.3.1, 5.3.2 5.3.3, 5.3.4 5.3.5, 5.3.6 Appendix F Appendix G	6.3.1	5.1 Personnel	6.2 Human resources
Equipment	5.4.1, 5.4.2 5.4.3, 5.4.4 5.4.5	6.4	5.3 Laboratory equipment Annex B.1 General Annex B.7 Hardware and software Annex B.8 System maintenance	7.6 Control of measuring and monitoring devices
Documents and records	5.1	6.1	4.3 Document control 4.13 Quality and technical records	4.2 Documentation requirements
Purchasing and inventory	5.5	6.5	4.4 Review of contracts 4.5 Examination by referral lab 4.6 External services and supplies	7.4 Purchasing
Customer service	5.11	6.11	4.7 Advisory services 4.8 Resolution of complaints	5.2 Customer focus

Remember that your Quality
Objectives must be
SMART !!!

Specific, **M**easurable,
Achievable, **R**ealistic and
Time-based

Thank you very much !