

# QMS Implementation Using a Stepwise Approach

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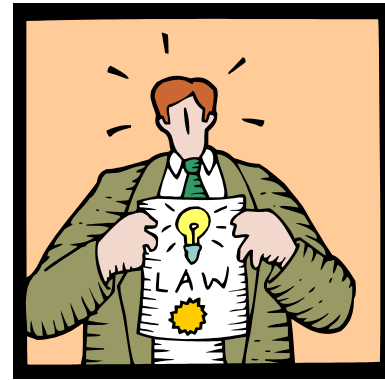
# Overview

- Why a stepwise approach to QMS implementation?
- International Models
- Caribbean Model for Stepwise Approach to QMS Implementation
- Roles and Responsibilities
- Current situation – Tier 1
- Progress to date

# Key Declarations

- **International Health Regulations (2005)** – to be implemented by 2014
  - Require countries to strengthen their existing capacities for public health surveillance and response
  - Quality laboratory services are critical for IHR implementation
- **Joint WHO-CDC Conference on Laboratory Quality Systems, Lyon, France (April 2008): 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.”

# A STARTLING REALITY!



- CARICOM governments have implemented regulations and monitoring systems for:
  - Food establishments and vendors
  - Pharmaceuticals
  - Many professions including health
- 70-80% of critical medical decisions are influenced by laboratory results

# Regional Realities

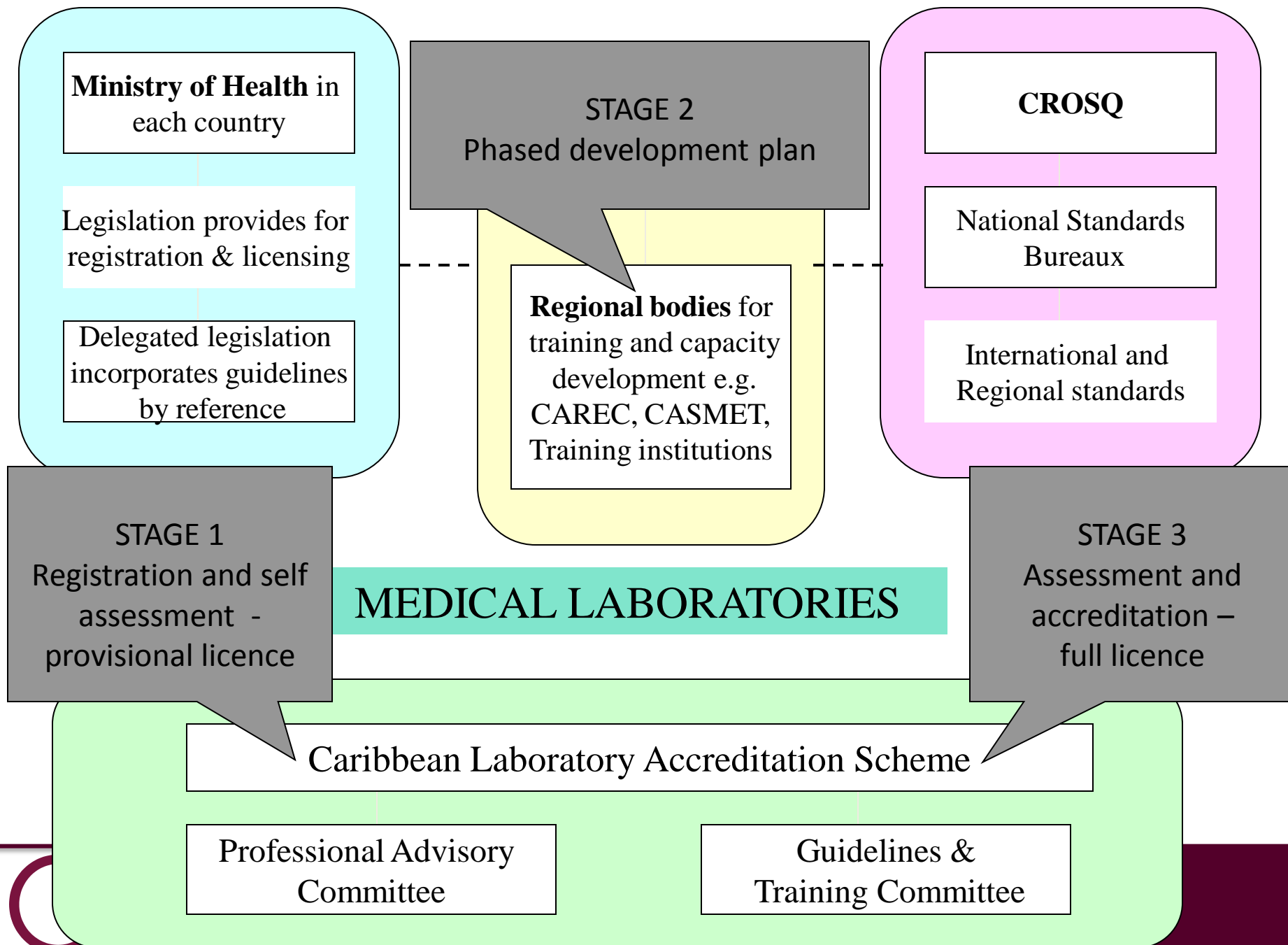
- Few Countries (Barbados, Bahamas, Bermuda, Guyana) have established regulations requiring licensing and monitoring of laboratory services
- Generally partially or not implemented
- Bermuda has implemented legislation requiring accreditation of laboratories for licensing
- Jamaica has introduced legislation but no regulations
- Aruba – no regulations but required for insurance reimbursement



# Accredited Laboratories



- Aruba – 3 of 5 laboratories
- Curacao – Public laboratory department (water)
- Suriname – Private laboratory
- Barbados – 1 public and 1 private laboratory
- Trinidad & Tobago, Jamaica, St. Lucia – one private laboratory
- Bermuda – one private/public laboratory



# Stepwise Models

- Thailand Model for Stepwise Accreditation
- Argentina Stepwise Accreditation Model
- Accreditation Canada Model – silver, gold and diamond accreditation
- CDC-WHO/AFRO Step-wise Accreditation Process



## Phase 1

- Sensitisation of Management and Staff
- Assessment and Plan
- Basic QMS Training
- Documentation of Basic QMS Policies and Procedures

## Phase 2

- Assessment and Plan
- Training for Phase 2 Implementation
- Implementation Evidence Provided by Records

## Phase 3

- Assessment and plan
- Training for Phase 3 Implementation
- Integration into Daily Operations
- Continual Improvement and Monitoring of QMS Indicators

**Accreditation**

# *Partners Initiative on Stepwise approach to QMS*

## Objectives:

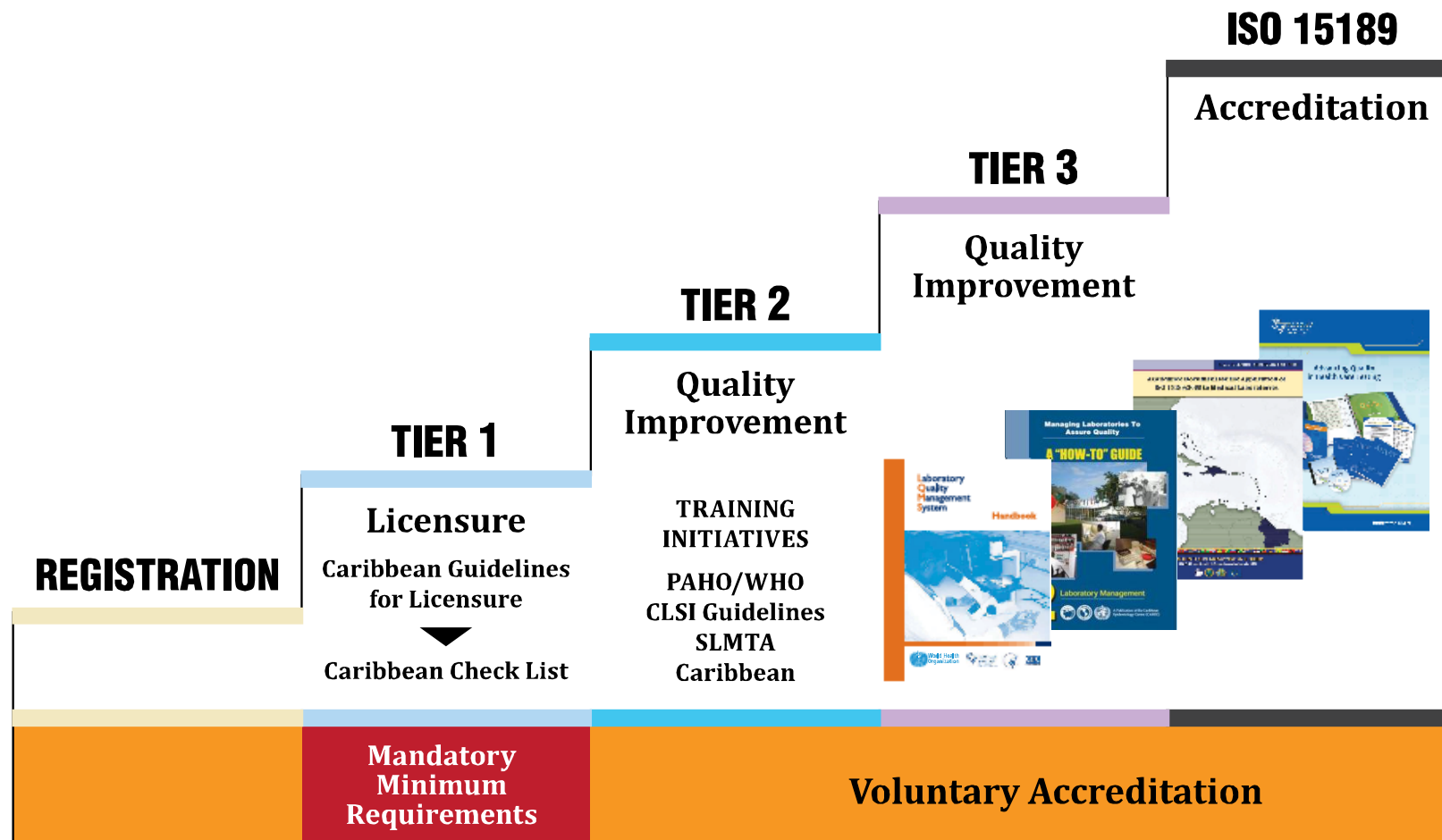
- To explore various step-wise models for implementing quality management systems leading to laboratory accreditation, assess their applicability in the Caribbean region, and develop a strategic framework document for implementation.

# ***Partners Initiative on Stepwise Approach***

- CDC and PAHO co-ordinated to bring together regional experts to develop:
  - Tiers for QMS implementation
  - Review draft model legislation for licensing of medical laboratories to agree on mandatory requirements
  - Recognition mechanisms for labs meeting requirements for Tiers 2 and 3

# IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS

## Stepwise Approach towards Accreditation (PAHO/WHO/CDC)



# Roles and Responsibilities

- **CARICOM Regional Organisation for Standards and Quality (CROSQ):**
  - Assist in strengthening of capacities of National Accreditation Focal Points (NAFPS) and laboratories
  - Develop a marketing and communication strategy and mechanism to support laboratory system development, information sharing and communication
  - Coordinate periodic reviews of the LQMS-SIP with CARPHA and other stakeholders
  - Coordinate evaluations/assessments (impartiality will be insured) of enrolled laboratories and take decisions regarding the “tier” recognition
  - Establish arrangements with NABs and Ministries of Health for conducting evaluations/assessments and issuing “joint” certificates
  - Monitor use of the LQMS-SIP recognition certificate
  - Promote technical guidelines i.e. for tiers of quality management systems implementation, for adoption by countries to facilitate the operation of the system
  - Convene a technical advisory committee to provide guidance on LQMS-SIP

# Roles and Responsibilities

## **CARPHA:**

- 1. Promote implementation of LQMS-SIP within the Region
- 2. Coordinate and promote quality assurance programs for national health laboratories through consultation; training and oversight of implementation
- 3. Provide scientific and managerial leadership in developing national and regional public health laboratory policy by developing, promoting, and integrating public health laboratory science into practice
- 4. Participate in developing standards and regulation guidelines for all health-related laboratories
- 5. Develop material and administer external quality assessment (EQA) schemes
- 6. Collaborate with the review and updates of LQMS-SIP Checklist to keep it aligned with appropriate internationally recognized standards

# Roles and Responsibilities

## Ministries of Health:

- Designate an LQMS-SIP focal point responsible for coordination, information-sand implementation
- Develop and implement a country strategic plan for laboratory quality improvement training with prioritization of potential applicant laboratories. Care should be given to the selection, orientation and performance evaluation of prioritized laboratories
- Allocate financial and human resources
- Oversee the implementation of corrective actions outlined in the assessment/reports
- Grant licenses to laboratories (for countries with licensure requirements)

# Roles and Responsibilities

## ***Bureaux of Standards:***

1. Advocate for the use of the Tier approach (LQMS-SIP as a tool for assessment)
2. Support countries to establish their own set of standards according to country-specific needs and resource constraints, and based on regionally agreed requirements and internationally agreed standards
3. Provide technical assistance to national laboratories for implementation of quality management systems
4. Provide a pool of multi-disciplinary technical experts to serve as assessors
5. Provide laboratories with traceability of measurements



# Roles and Responsibilities

## **Professional Associations and Non-Governmental Organizations:**

1. Advocate and lobby for the enactment of national legislation for regulating laboratory operations based on LQMS-SIP requirements
2. Promote the implementation of QMS using LQMS-SIP
3. Contribute to the development of competencies required for effective and sustainable implementation of LQMS-SIP
4. Mobilize resources specifically for laboratory strengthening efforts in the region
5. Provide technical assistance and mentoring to regional laboratories for implementation of quality management systems
6. Provide training for improvement of laboratory services for laboratory staff and related support services
7. Facilitate linkages between the public and private sector
8. Provide a pool of multi-disciplinary technical experts to become advisors, mentors or assessors (taking appropriate measures to avoid any conflict of interest)

# Roles and Responsibilities

## PAHO/WHO:

1. Normative role in providing guidance for selection and use of appropriate standards and promoting and monitoring implementation of quality management systems.
2. *PAHO Country Offices*
  - Country Representatives: political support and strategic direction at country level
  - Health Services Advisors: technical support to national staff for implementation of laboratory QMS plans.

# Roles and Responsibilities

**US Centers for Disease Control and Prevention (CDC):** Support for:

1. Developing National Laboratories' Policies and Strategic Plans
2. Strengthening a regional referral laboratory and sub-regional hubs, including infrastructure and equipment upgrades
3. Increasing access to point-of-care laboratory services, including expanded HIV rapid testing and Prevention of Mother To Child Transmission (PMTCT) programs
4. Enhancing Laboratory Quality Management System (LQMS) and the accreditation process to include Gap analysis, documentation, and training using the SLMTA package, and embedding laboratory mentors to drive through the accreditation process
5. Supporting training, procurement, supply chain management systems, and Laboratory Management Information System (LMIS)
6. Supporting the expansion of the Digital Proficiency Testing (PT) EQA panels and the Dry Tube Specimen (DTS) HIV EQA technology to testing sites

Further support will be provided to strengthen the CROSQ Secretariat that will coordinate current quality systems strengthening and accreditation efforts.

# Baseline Assessments 2011

<b>Proposed Licensing Requirements (Tier 1) (PAHO/CDC in collaboration with CMLF, Accreditation Bodies)</b>	<b>% Labs Compliant 2011</b>
Quality Improvement Plans	<b>17</b>
Audits	<b>33</b>
Adequate staff, equipment & supplies	<b>25</b>
Quality Management Training	<b>25</b>
Staff competency for QMS implementation	<b>8</b>

# Dec 2012

<b>Proposed Licensing Requirements (Tier 1) (PAHO/CDC in collaboration with CMLF, Accreditation Bodies)</b>	<b>% Compliance 2012</b>
Country A – public - public	<b>88</b> <b>84</b>
Country B – public - public	<b>68</b> <b>54</b>
Country C - public - private	<b>53</b> <b>50</b>
Country D - public	<b>88</b>
Country E - public	<b>49</b>
Country F - private	<b>68</b>

# Progress to Date

LQMS-SIP launched by PAHO in September 2012 – CMOs, PSs, Laboratory Directors/Managers:

## **Acknowledged:**

- The LQMS-SIP as the regionally recognised framework to improve laboratory quality

## **Recommended:**

1. The adoption by CARICOM/COHSOD of the implementation of LQMS-SIP in the CARICOM countries and the development of a recognition mechanism for Tier 2 and 3 of LQMS-SIP
2. That all countries establish and implement national regulations for licensing using minimum mandatory requirements based on Tier 1 in order to facilitate the accomplishment of the IHR laboratory requirements by June 2014.
3. That CARICOM Secretariat coordinate the regional approach for implementation of the LQMS-SIP initiative and in collaboration with partners mobilize resources towards its achievement

# Progress to Date

- Review of Tier 1 requirements undertaken as part of CMLF laboratory network meetings (Barbados, Belize, Dominica, Jamaica, Suriname, St. Lucia, St. Kitts and Nevis, St. Vincent & the Grenadines, Trinidad & Tobago)
- CROSQ has undertaken leadership role – LQMS-SIP Secretariat and Co-ordinator
- September meeting scheduled by PAHO with stakeholders to:
  - Formalise implementation of LQMS-SIP Framework
  - Review and formalise role of CARPHA, CROSQ and other stakeholders
  - Discuss next steps for implementation and progress



A large elephant with prominent tusks is the central focus of the image. It is standing in a savanna environment with tall, dry grass in the foreground and a line of trees and shrubs in the background. The elephant's trunk is curled slightly, and it appears to be looking towards the left. The lighting suggests a bright, sunny day.

**MAJOR OUTSTANDING ISSUE –  
COSTS FOR SUSTAINABILITY?**





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