

***Regional Model Framework:
National Laboratory Policy
TRANSFORMING THE MEDICAL
LABORATORY LANDSCAPE***

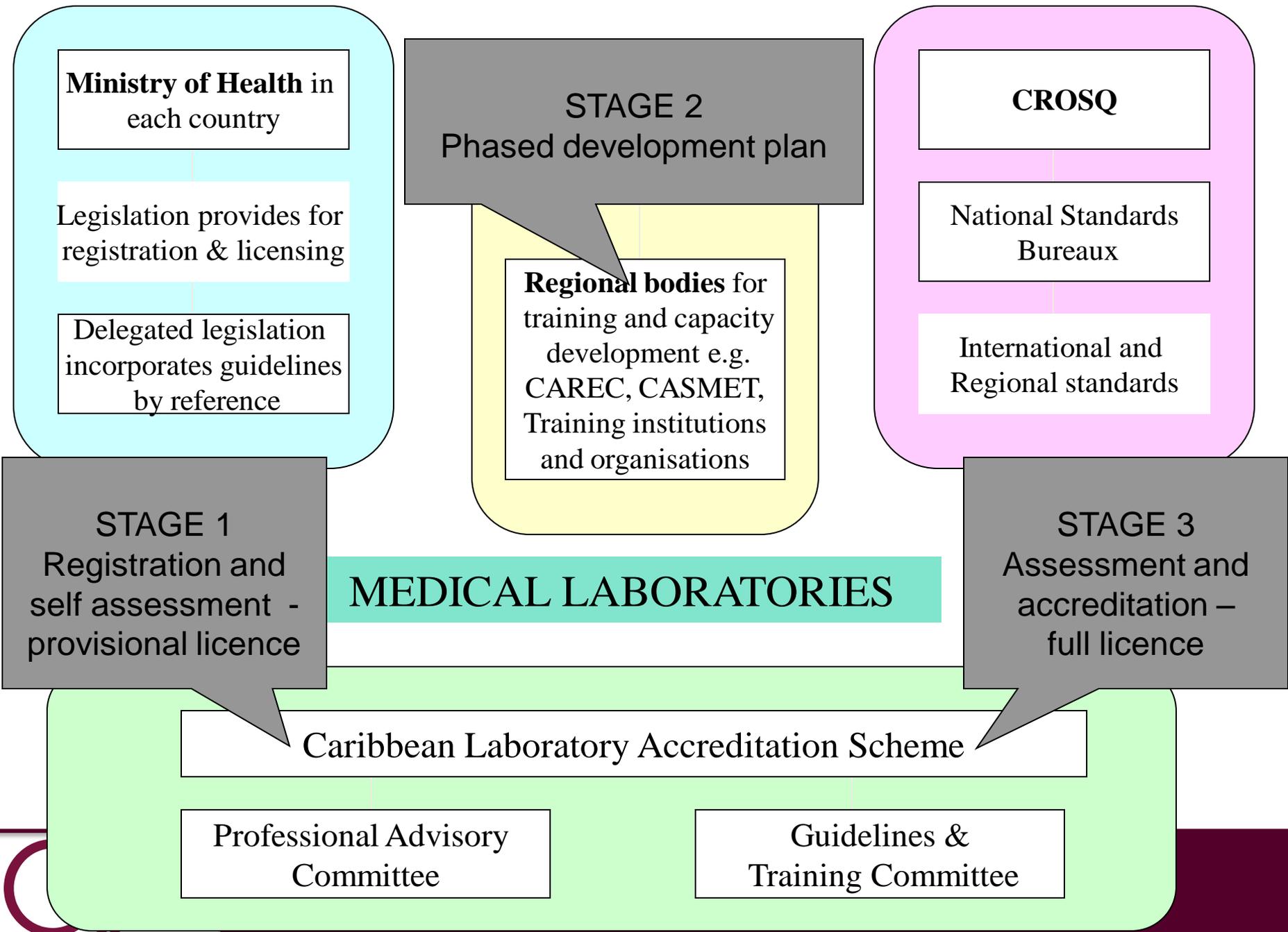
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CHART-CCAS-CMLF Meeting
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Presentation Outline

- Why a regional model framework for National Laboratory Policy?
- Working Group – convened by CMLF (under CARICOM PANCAP GF Round 9)
- Highlights of National Policy Framework
- Pilot implementation
- Next Steps

Rationale for Regional Initiative

- Under EU-funded Medical Laboratory Strengthening project, a phased system for laboratory regulation was identified
- In 2006 – countries provided with model legislation for laboratory regulation under EU-funded Med Labs Project

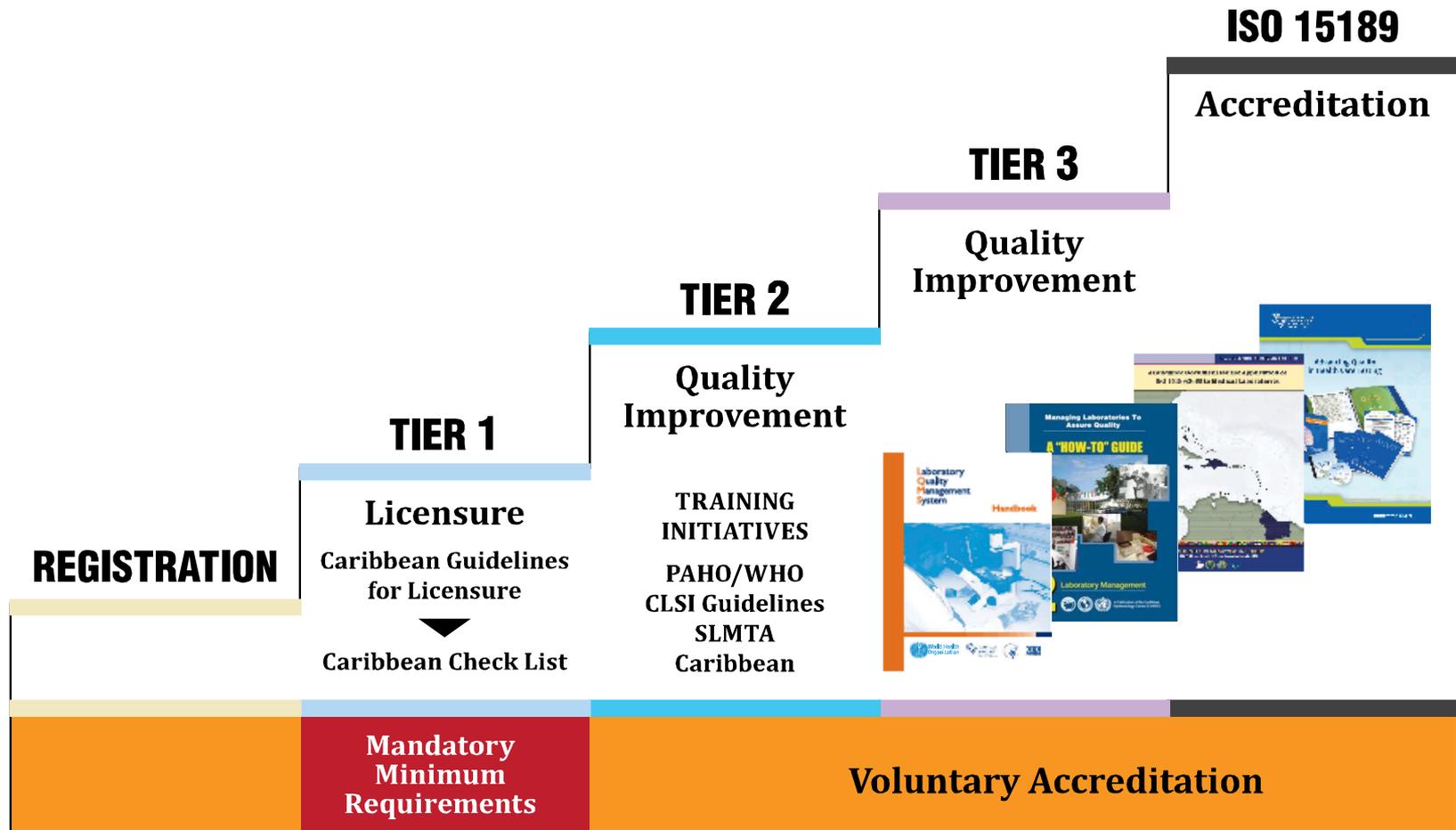


WHO-CDC International Conference Lyon 2008

- i) Each country should establish its own set of standards based on internationally agreed standards;
- ii) National laboratory standards need to take into account local factors (national regulations, organization of laboratory system, resource constraints);
- iii) Countries with limited resources consider taking a staged approach

IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS

Stepwise Approach towards Accreditation (PAHO/WHO/CDC)



Licensing and Accreditation

- Few CARICOM Countries (Barbados, Bahamas, Belize, Guyana) and Curacao have established regulations requiring licensing/monitoring of laboratory services - generally partially or not implemented
- Bermuda has implemented legislation requiring accreditation of laboratories for licensing (hospital lab accredited since 2005 – support for other labs)
- Aruba – no regulations but accreditation required for insurance reimbursement (3 of 5 labs accredited)
- Accredited labs in Bermuda, Aruba as well as:
 - Barbados (2), Trinidad (1), St. Lucia (1), Bahamas (1), Suriname (1), Jamaica (1), Curacao (1)

Decision of 16th COHSOD - 2012

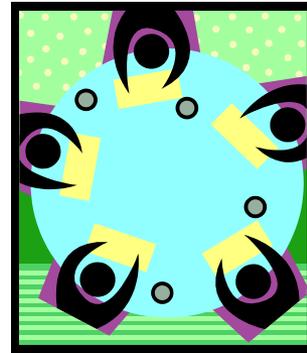
In response to CMLF presentation of information on laboratory issues and CCAS Declaration 2011, the COHSOD agreed to:

- The establishment of the required national regulations and monitoring networks for licensing and management of Laboratories in the region
- Consider key policy issues relative to lab services and support the development of transitional plans to ensure sustainability of laboratory quality interventions through a smooth handover of resource responsibilities from donor to national governments

Recommendation from **CMOs meeting 2013** and discussions with countries – **develop regional model policy framework to guide legislation**

Working Group

- Permanent Secretaries
- Chief Medical Officers
- Directors – Policy and Planning
- Laboratory Directors (public and private)
- CARICOM GF Programme
- OECS HAPU
- Representative – Standards Bureau
- Representative - Training Institutions



Background

- National policy represents government's commitment and support for the organizational and management effectiveness and efficiency:
 - National standards for laboratory operations
 - Active encouragement of evidence-informed decision-making and quality improvement.
- Consistent with WHO Building Blocks and guidance for national laboratory policy as well as regional laboratory strengthening initiatives

Importance of Laboratory Support

- IHR and MDG mandates
- NCDs – key regional and national priority
 - Effectiveness of PH interventions, diagnosis, care and treatment largely dependent on laboratory data
- Communicable diseases - Caribbean economies - very fragile and easily impacted negatively by “breaking news” of disease outbreaks
 - Critical role of laboratory is identification of disease outbreaks in order to facilitate rapid and effective public health action.
 - Critical to protecting the region’s tourism market and maintaining national GDPs.

80% of medical decisions are influenced by laboratory results



The Future

- Historical view of labs as “factories” of test results has to change
- Caribbean is straining under the burdens of severe economic and fiscal challenges, prevalent health risks and disorders
- New thinking is needed to forge and sustain excellence in health care services - maximizing user satisfaction and minimizing healthcare costs - **reliability, effectiveness and efficiency.**
- Requires:
 - adequate and predictable financing;
 - well-trained and motivated staff;
 - well-stocked inventory of equipment and reagents;
 - a robust electronic architecture of data and information processing, reporting and networking;
 - appropriate test algorithms and general laboratory procedures;
 - expert management;
 - competent governance oversight.



National Laboratory Policy Components

- Situation Analysis
- Mission and Vision
- Essential elements of the national laboratory policy should include :
 - **Laboratory Governance and Network Structure**
 - **Quality Management Systems**
 - **Laboratory Support Systems**
 - **Information and Data Management**

Mission

Example:

- ***“The National Laboratory Network will support essential public health functions through delivery of relevant, equitable and client-focused services of uncompromising quality”***

Laboratory Governance and Network Structure

POLICY STATEMENT

There shall be a National Laboratory Network (NLN) that operates on a well-defined structure - good governance, sustainable financing and efficient use of the resources, of which monitoring and evaluation is a key component.

Addresses the following components:

- A National Health Policy & Strategy
- Legislation & Regulation
- National Structure
- Financing
- Human Resource
- Partnerships & Networking
- Monitoring & Evaluation
- Sustainability

Quality Management Systems

POLICY STATEMENT

There shall be a national laboratory quality management framework supported by legislation and regulations to ensure that laboratories maintain quality management systems in accordance with a national standard and in keeping with the Ministry of Health's overall quality policy.

The national laboratory standard at a minimum shall align with the regional LQMS-SIP (derived from ISO 15189) for medical laboratories and with the accepted regional standard (ISO 17025) for non-medical laboratories.

A quality-managed laboratory service addresses the following components:

- A Regulatory System
- A Network Quality Monitoring and Evaluation System
- Training and Continuing Education
- Community & Customer Service
- Research & Development

Laboratory Support Systems

POLICY STATEMENT

There shall be a system (legislation and management) to ensure that laboratory operations are cost effective, environmentally friendly and safe.

A national laboratory support system should address the following components:

- Procurement & Inventory Management
- Equipment Management
- Safety and Biosafety

Information and Data Management

POLICY STATEMENT

There shall be a national information management framework that includes industry-established standards and guidelines.

The national health information management framework shall ensure that the laboratories and testing sites have information management systems - bearing in mind that laboratory information management systems (LIMS) are distinct from but are an integral part of health information systems.

Laboratories shall be supported in their effort to optimise the impact of their data in the context the national health information management framework.

A national laboratory support system should address the following components:

- Laboratory Information Management Structures
- Provision of Appropriate Data
- Public Communication

Piloting of Framework for National Laboratory Policy

- Framework utilised in collaboration with PAHO HIV Caribbean Office (PHCO) to facilitate in-country stakeholder consultations to develop National Laboratory Policy in OCTs:
 - Anguilla
 - Cayman Islands
 - St. Eustatius
 - St. Maarten
 - St. Eustatius
 - Stakeholders highly engaged
 - Framework facilitated focused discussion and well developed outcome of consultation
 - Defined process for adoption at national level

Next Steps

- Countries are required to have National Laboratory Policies to meet IHR requirements (deadline extended to 2016)
- Regional Framework – provides guide for facilitated national discussion and development of policy
- Under GF R9, CMLF facilitating in-country consultations and development of National Laboratory Policy (Dec 2015)



Thank-you