South African National Accreditation System

MDRC Workshop

Mr Tumelo Ledimo

QUALITY INFRASTRUCTURE

the dtic
Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

CONFORMITY ASSESSMENT BODIES (CABs)
(Inspection, Testing, Verification, Calibration & Certification)

- Accreditation
- Traceability
- Standards
- Regulations

sanas South African National Accreditation System

nmisa National Metrology Institute of South Africa

SABS

NRCS national regulator for compulsory specifications

QUALITY INFRASTRUCTURE

sanas
South African National Accreditation System

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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SABS

SAHPRA
South African Health Products Regulatory Authority

LEGISLATIVE MANDATE

ENABLING ACT	MANDATE
Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 **(Act No. 19 of 2006)**	**SANAS is the Sole National Accreditation Body that provides an internationally recognised and effective accreditation and monitoring system for the Republic of South Africa by doing the following:** a) Accredit or monitor, for good laboratory practice compliance purposes, organisations falling within its scope of activity b) Promote accreditation as a means of facilitating international trade and enhancing South Africa's economic performance and transformation c) Promote the competence and equivalence of accredited bodies d) Promote the competence and equivalence of good laboratory practice-compliant facilities
Additional Roles	**In any legal proceedings SANAS certificates issued is upon its production, evidence of the facts contained therein.** Is the official Good Laboratory Practices GLP Compliance Monitoring Agency for the Organisation for Economic Cooperation and Development (OECD) on behalf of South Africa

QUALITY INFRASTRUCTURE SYSTEM

- **South African National Accreditation System** (SANAS) provides an internationally recognised accreditation infrastructure for formal recognition of the technical competence of conformity assessment service providers in the areas of laboratories (testing and calibration), Certification Bodies (Management Systems, Product, and Personnel), Inspection Bodies, Medical and others.

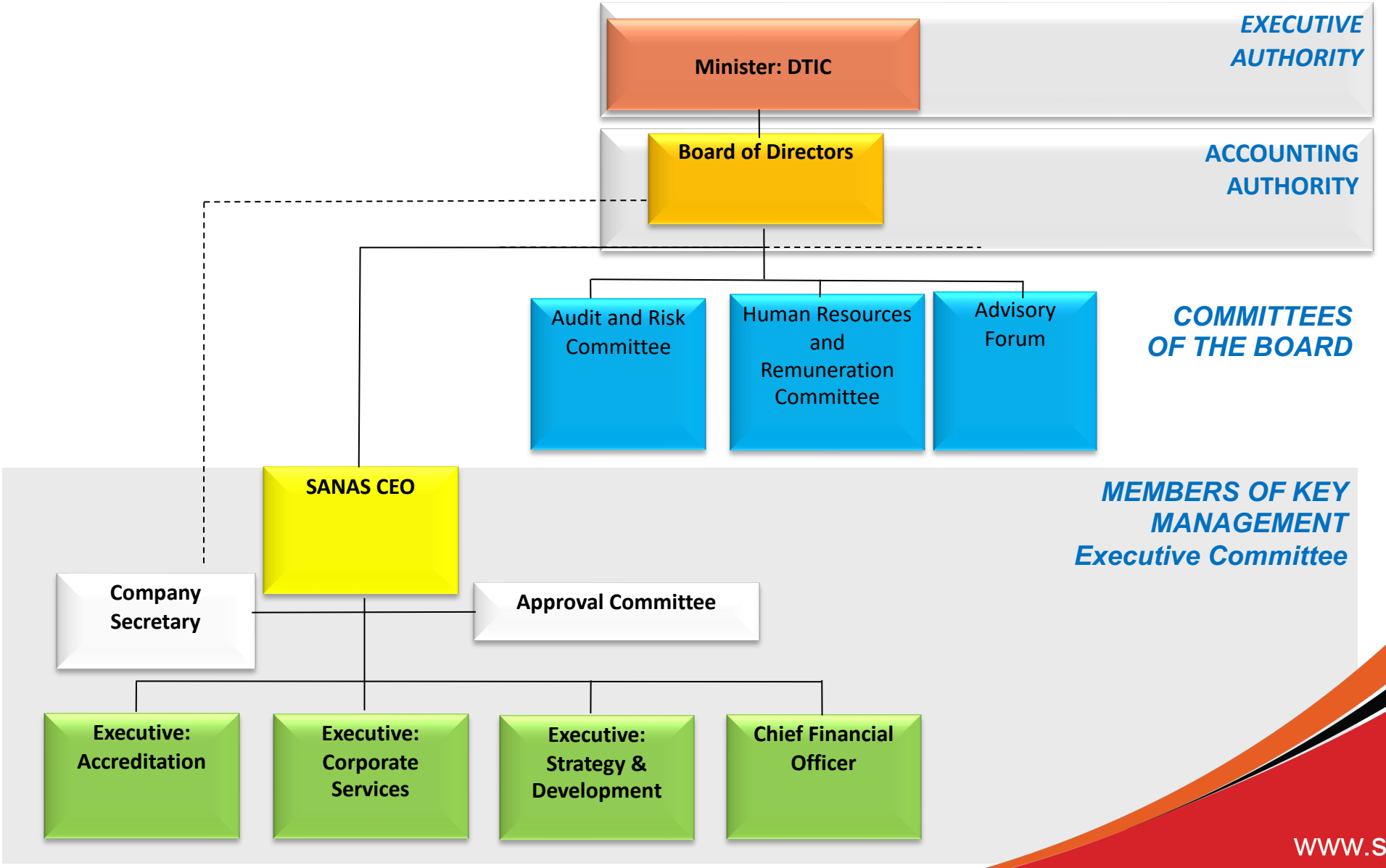
- **National Regulator for Compulsory Specification** (NRCS) provide legal framework for administration and maintenance of compulsory specification in the interest of public safety and health or for environment protection in the Republic. Also, trade fairs in terms of Legal Metrology.

QUALITY INFRASTRUCTURE SYSTEM

- **National Metrology Institute of South Africa** (NMISA) is primarily responsible for the scientific and industrial metrology. It offers measurements capability and traceability of measurements to South African National Measurement Standards and Units and thus provides confidence in the accuracy of results.

- **South African Bureau of Standard** (SABS) mandate is limited to preparing voluntary South African National Standards and conformity assessment activities like Testing, Calibration, Inspection and Certification.

SANAS GOVERNANCE STRUCTURE



SANAS EXECUTIVE COMMITTEE

Acting CEO

Mpho Phaloane

Company Secretary

Dawood Petersen

Executive: Accreditation

Mpho Phaloane

Executive: Strategy and Development

Farhad Osman

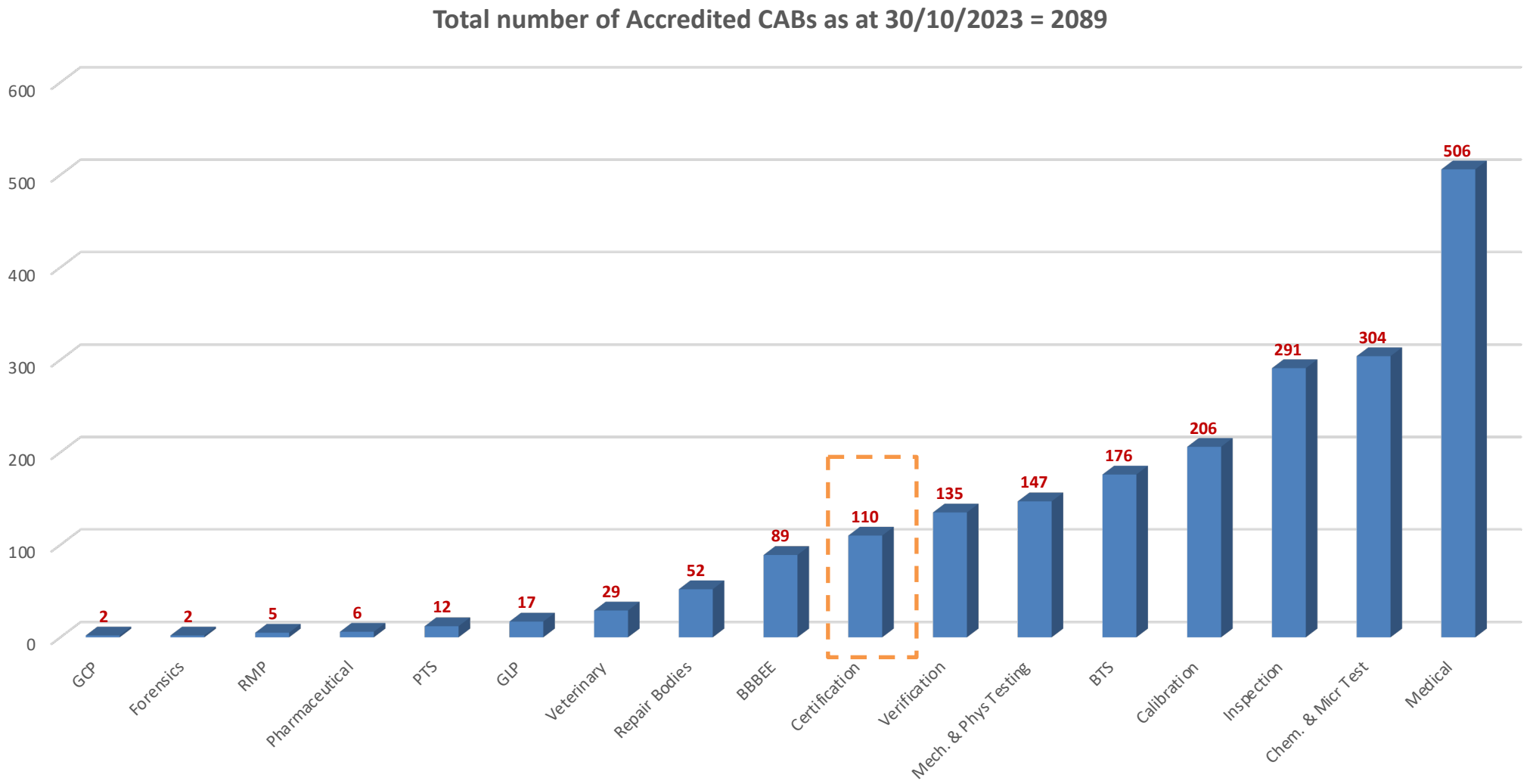
Chief Financial Officer

Jonas Shai

Executive: Corporate Services

Busi Radebe

Accreditation Statistics



ROLES and RESPONSIBILITIES: SAHPRA and SANAS

Responsibilities of Regulator

- Grants approval to CABs to work in the regulatory domain;
- Participates in the SANAS STC;
- Advises SANAS on relevant regulatory matter;
- Deals with complaints and contraventions of the regulatory requirements;
- Notifies SANAS on any changes to approval status of CAB's;
- Meeting with SANAS on a quarterly basis to discuss issues of mutual interest.

Responsibilities of SANAS

- Accredits CABs based on their technical competence;
- Participates in Regulators workshops;
- Deals with accreditation related transgressions;
- Notifies the regulator of any changes in the CAB's accreditation status;
- Maintain a database of accredited CABs.

TYPES OF MUTUAL RECOGNITION AGREEMENT

- The ultimate acceptance of the conformity assessment certificate or attestation is decided by regulatory authority in the **regulatory space**, and by a purchaser/buyer in the **voluntary space**.

Two types of MRAs

Government to Government

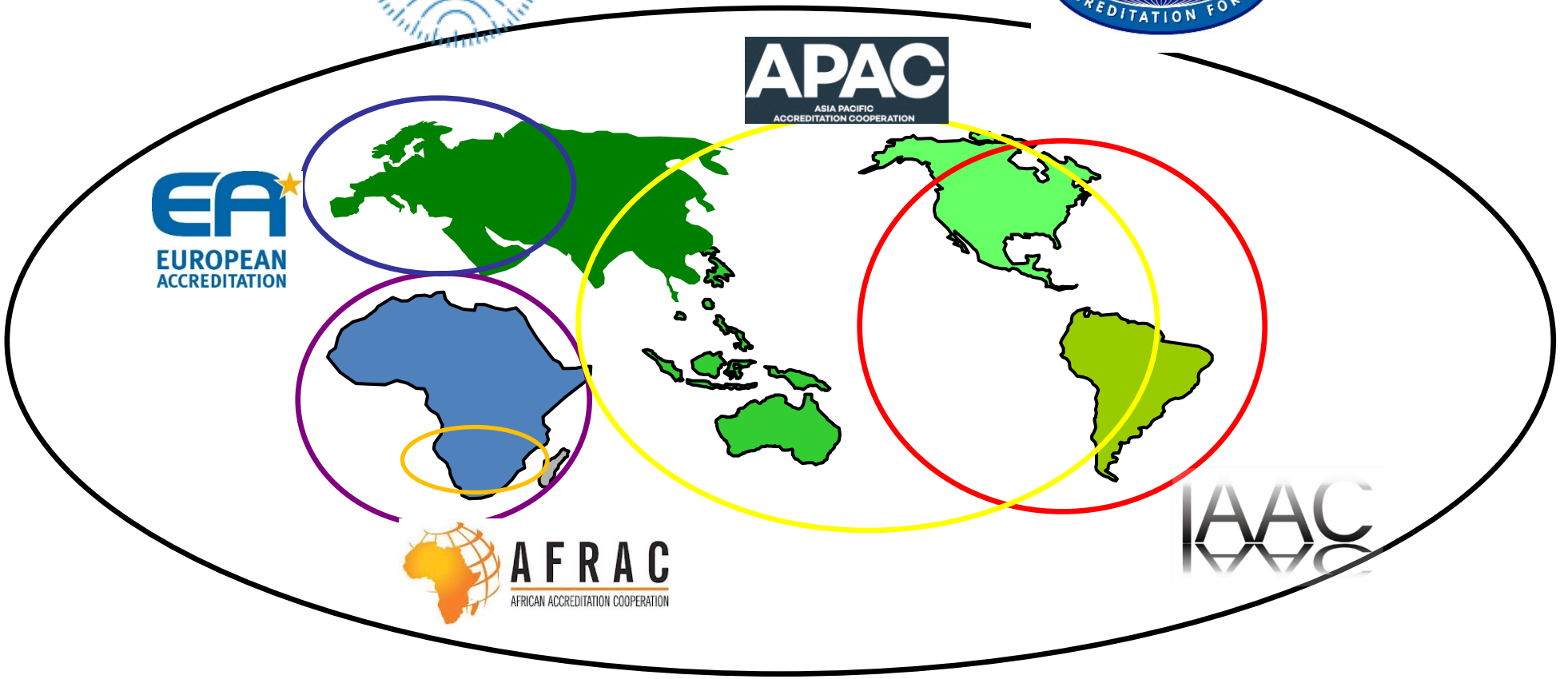
- MRA concluded through trade agreement. (AfCFTA, TFTA, EPA, BRICS, bilateral)

Voluntary MRA

- IAF/ILAC MRA

- The recognition of voluntary Mutual Recognition Arrangement/Agreement in **regulatory space** is done through legislative provision, for sector to sector or commodity by commodity.

ILAC/IAF



EA	European co-operation for Accreditation
APAC	Asia Pacific Accreditation Cooperation Incorporated
IAAC	Inter-American Accreditation Cooperation
AFRAC	African Accreditation Cooperation
SADCA	Southern African Development Cooperation in Accreditation

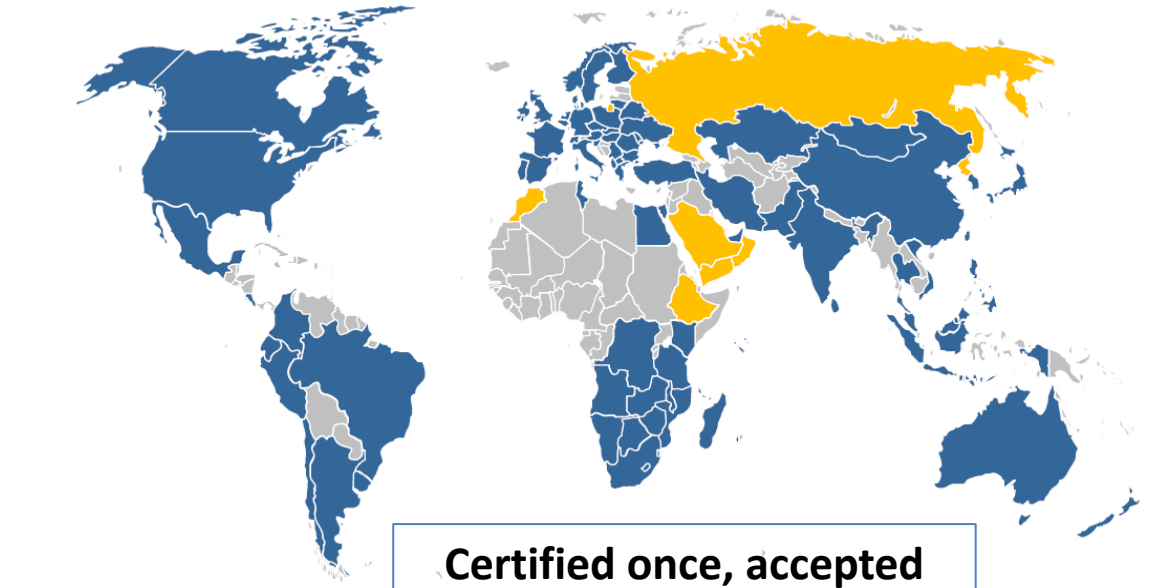
Common Aims of IAF and ILAC

- Support conformity assessment schemes which reduces risk for businesses, regulators and the consumer by ensuring that accredited services can be relied upon

105 Economies; 82 000 labs; 12 200 IB's; 550 PTS signatories;

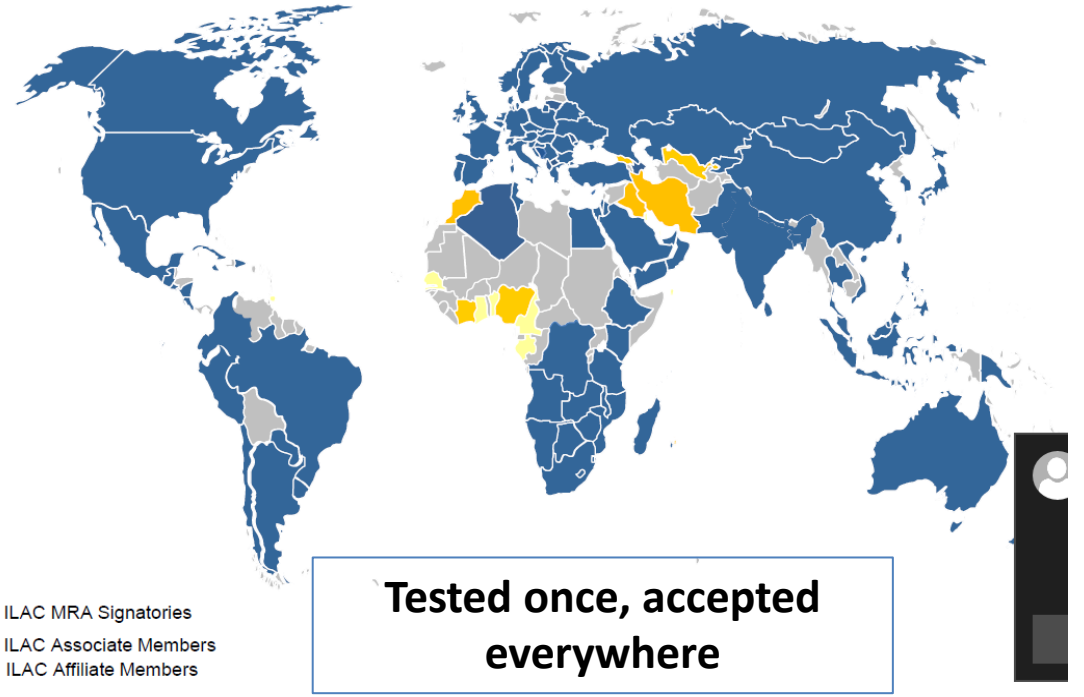
88 Accreditation Bodies; 76 AB MLA

Coverage of the IAF MLA (July 2021)



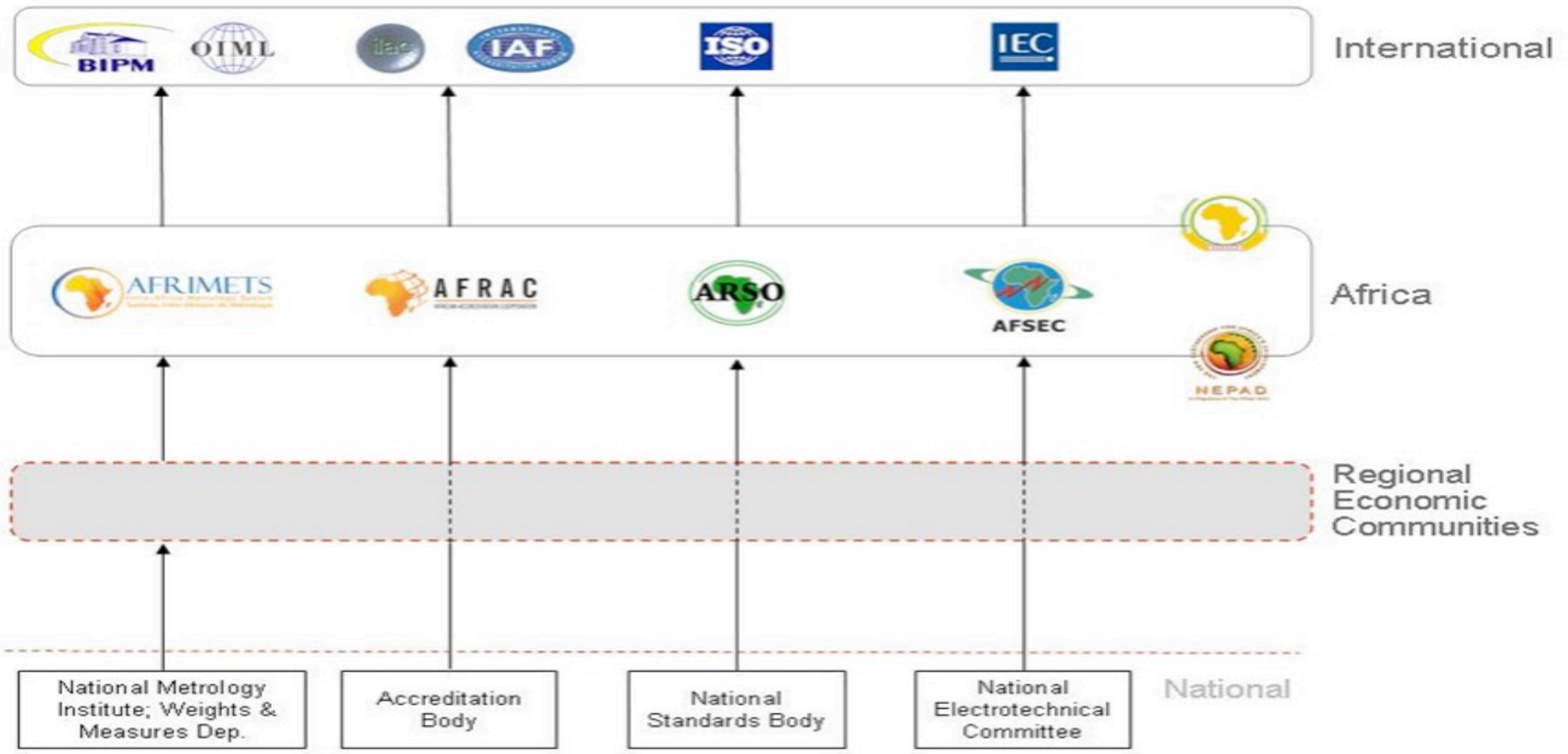
Certified once, accepted everywhere

Coverage of the ILAC MRA (2 March 2021)

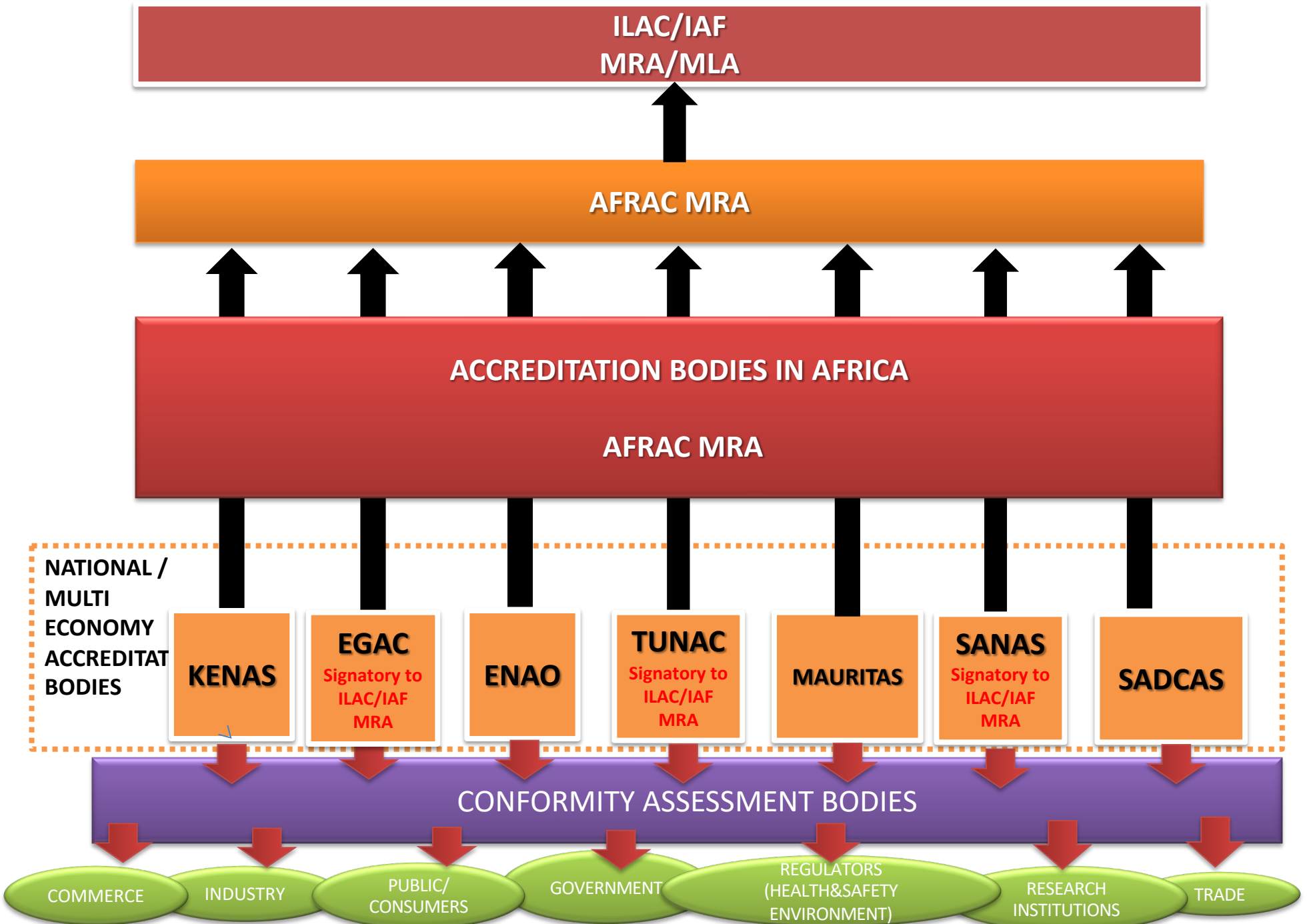


Tested once, accepted everywhere

REGIONAL and INTERNATIONAL LINKAGE



Source: PAQI


ILAC/IAF
MRA/MLA
AFRAC MRA
ACCREDITATION BODIES IN AFRICA
AFRAC MRA
NATIONAL / MULTI ECONOMY ACCREDITAT BODIES
KENAS
EGAC
Signatory to ILAC/IAF MRA
ENAO
TUNAC
Signatory to ILAC/IAF MRA
MAURITAS
SANAS
Signatory to ILAC/IAF MRA
SADCAS
CONFORMITY ASSESSMENT BODIES
COMMERCE
INDUSTRY
PUBLIC/ CONSUMERS
GOVERNMENT
REGULATORS (HEALTH&SAFETY ENVIRONMENT)
RESEARCH INSTITUTIONS
TRADE

IAF MLA STRUCTURE

Structure of the IAF MLA								
Level 1	ISO/IEC 17011							
Level 2	Product Certification	Management Systems Certification					Personnel Certification	Validation and Verification
Level 3	ISO/IEC 17065	ISO/IEC 17021-1					ISO/IEC 17024	ISO/IEC 14065,
Level 4	Global G.A.P, IFA General Regulations	ISO 22003 (FSMS), FSSC 22000	ISO/IEC TS 17021-3 (QMS)	ISO/IEC TS 17021-2 (EMS)	Medical Devices and In-Vitro Diagnostic Regulation	ISO/IEC TS 17021-5 (Asset Management Systems)		ISO/IEC 14066
Level 5	Global G.A.P, Scheme Rules IFA CPCC	ISO 22000; FSSC Rules	ISO 9001	ISO 14001	ISO 13485	ISO 55001	Scheme Rules	ISO/IEC 14064-1 or 14064- 2

TECHNICAL COMPETENCE

Accreditation bodies such as **SANAS** assess factors relevant to an organisation's ability to produce precise, accurate test, calibration and inspection data, including the:

- technical competency of staff;
- validity and appropriateness of methods;
- traceability of measurements to national standards;
- suitability, calibration and maintenance of equipment;
- suitable environmental conditions;
- handling of test / inspection items;
- quality assurance processes.

IAF MANDATORY DOCUMENTS (IAF MD 8)

- The objective of the IAF MD8 document is to enable accreditation bodies to harmonise their application of ISO/IEC 17011 for the accreditation of bodies providing audit and certification to ISO/IEC 13485 by including:

  - Annexure 1: Scopes of accreditation.

  - Annexure 2: Required types of knowledge and skills for personnel involved with the ISO 13485 activities.

IAF MANDATORY DOCUMENT (IAF MD9)

- The objective of the IAF MD9 document is to enable consistence application of ISO/IEC 17021-1 by Conformity Assessment Bodies.

  - Annexure A: Medical Devices Technical Area.
  - Annexure B: Required types of knowledge and skills for personnel involved with the ISO 13485 activities.
  - Annexure C: Auditor qualification, training and experience.
  - Annexure D: Effective number of personnel and auditing duration.

Regulatory framework covers the whole product life cycle

PREMARKET ----------> PLACING ON THE MARKET
QMS, Risk, Performance, Registration, Tech dossier,

. ----------> **POST MARKET ----------> END OF LIFE,**
Adverse Event reporting,
Market Surveillance, MD modification, Disposal

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Thank you

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