WTO/TBT MRA Thematic Session

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QUALITY INFRASTRUCTURE

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Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

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

- Accreditation
- Metrology
- Standards
- Regulations

sanas South African National Accreditation System

nmisa National Metrology Institute of South Africa

SABS

NRCS national regulator for compulsory specifications

SAHPRA South African Health Products Regulatory Authority

ICASA INDEPENDENT COMMUNICATIONS AUTHORITY OF SOUTH AFRICA

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 (Bilateral or Multilateral), e.g. AfCFTA, SADC, TFTA, EPA, BRICS.

Voluntary MRA

- IAF/ILAC MRA; CAB MRA

- The recognition of voluntary MRA in **regulatory space** is done through legislative provision.
- .**Accredited once, accepted everywhere**.
- Gives national authority confidence in the accredited CABs.

MRA recognition and importance in trade agreements

AfCFTA Article 4 and 8

- Promote mutual recognition of results of conformity assessment.
- Promote mutual acceptance of conformity assessment results of conformity assessment bodies which have been recognised under appropriate multilateral agreement between their respective accreditation bodies and the relevant mutual recognition arrangement of AFRAC, ILAC and IAF.

SADC Trade Protocol article 17

- SADCA shall create an environment for the conclusion of Mutual Recognition Agreements (MRAs) between qualifying institutions in Member States within the framework of and consistent with global MRAs being prepared by various international organisations in these fields.

EPA SADC Article 56

- Identifying and implementing appropriate mechanisms for particular issues or sectors, i.e. alignment with international standards, reliance on the supplier's declaration of conformity, **the use of internationally recognised accreditation to qualify conformity assessment bodies** and the use of international product testing and certification schemes.
- Undertaking to consider, in due course, negotiating mutual recognition agreements in sectors of mutual

Challenges for successfully negotiating MRA

- Different national quality infrastructure developmental stage, adequacy maturity stage.
- Technical capacity and capability to implement the necessary oversight on application of conformity assessment procedures.
- Limitation in fulfilling certain conformity assessment procedures.
- Disparities in the control mechanism (i.e. Designations, Notification or Approvals).
- Different approaches in implementation technical regulations, conformity assessment procedures and market surveillance.

Accreditation as basis for MRA

"Conformity Assessment Body" means a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body recognized by Council, according to a standard as determined by the Council, as competent to carry out the assessment, verification and certification of medical devices or IVDs before they are placed on the market by manufacturers;

"conformity assessment certificate" means the certificate used to demonstrate that a manufacturer has been assessed and has the appropriate systems in place to manufacture the device;

South African Health Products Regulatory Authority

Approval and duties of approved inspection authority

7. (1) Only an organisation holding an approval certificate from the chief inspector shall perform the duties of an approved inspection authority within the scope of accreditation.

(2) An application for approval in terms of subregulation (1) shall include the applicant's proof of accreditation prescribed by paragraph (a) or (b) of subregulation (3), including full contact details and address.

(3) The chief inspector's approval –

(a) of inspection bodies operating in the Republic shall be subject to the submission of an accreditation certificate issued by the accreditation authority in accordance with the requirements of SANS/ISO 17020 and SANS 10227: Provided that the chief inspector may set additional requirements before granting approval; or

(b) of foreign inspection bodies shall be subject to the submission of an accreditation certificate issued by an International Laboratory Accreditation Cooperation (ILAC) or an International Accreditation Forum (IAF), Mutual Recognition Arrangement signatory in accordance with the requirements of ISO/IEC 17020: Provided that –

Pressure Vessel Regulation

Accreditation as basis for MRA

National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008)

4 Definitions/Abbreviations

NRCS means the National Regulator for Compulsory Specifications

5 General rules

5.1 Conformity assessment bodies shall demonstrate appropriate technical and proficiency skills for the assessment of the conformity of commodities or products with the requirements of compulsory specifications, and meet any additional specific requirements that the Regulator may prescribe.

5.2 In addition the body shall meet with one of the following requirements in respect of competency to determine the conformity of commodities or products, with the requirements of a compulsory specification:

a) Accreditation to ISO/IEC 17025, ISO/IEC 17020 and/or ISO Guide 65, SANS 10378 as applicable, by SANAS or an ILAC or IAF affiliated organization; or

b) Successful peer review/mutual acceptance against the above requirements, acceptable to the Regulator; or

c) In the absence of evidence of appropriate accreditation, or successful independent peer review/mutual acceptance, the conformity assessment body shall provide satisfactory evidence of compliance with the requirements of ISO/IEC 17025 or ISO/IEC 17020, as applicable, that satisfies the Regulator.

5.3 The Regulator will only use conformity assessment bodies that meet with the competency criteria in 5.2.

sanas
South African National Accreditation System

Thank you

