



The SABS was established by the Standards Act, 1945 (Act 24 of 1945)

SABS exists as a public entity under the Standards Act, 2008 (Act 8 of 2008)

The objectives of SABS are as follows:

- Develop, promote and maintain South African National Standards (SANS)
- Promote quality with respect to commodities, products and services
- Render conformity assessment services and matters connected therewith





Our portfolio of services





Our organisational structure

INTERNAL AUDIT Oratile Mothudi

RESEARCH, STRATEGY, REPORTING & MEDIA Nils Flaatten

COMPANY SECRETARY Joseph Leotlela (Acting)

LEGAL SERVICES Joseph Leotlela



Standards Sadhvir Bissoon



Certification Amanda Gcabashe



Laboratory **Services**



Digital Transformation & Innovation

Ian Plaatjes



Stakeholder **Engagement** & Regulatory Compliance

Zingisa Motloba



Human Capital

Lizo Makele



Tina Maharaj

Standards Development

Verification

Laboratory Operations

ICT & Business Intelligence

Stakeholder Engagement **Human Capital** Management

Financial Management

International Relations (ISO, IEC, ARSO)

Consignment Inspection

Local Content

Integration & **Technical Support**

Consulting Services

Sales, Marketing,

& Customer Services

Enterprise Risk Management

Health, Safety & Environment

Accreditation

Procurement Services

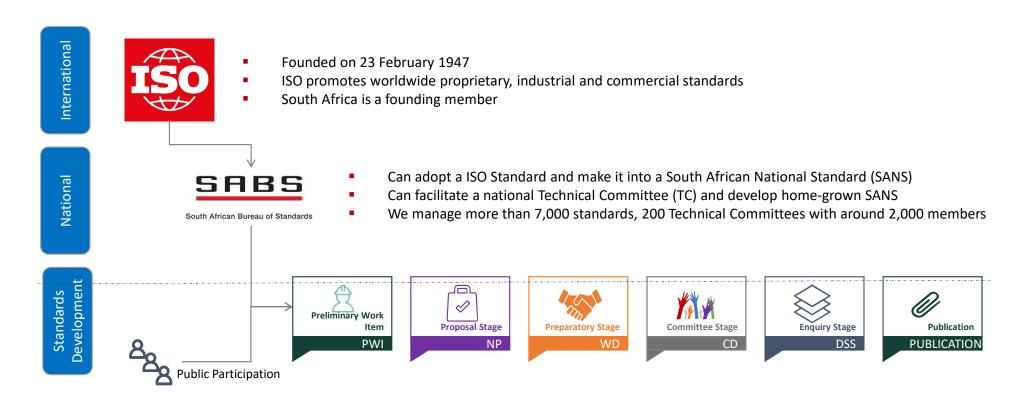
Asset Management

Facilities & **Security Services**

Training Academy

Product & Systems Certification

> Records Management



SABS is the only organisation in South Africa with the mandate to develop, promote and maintain national standards

How the technical committee function



On receipt of a request for the development of a standard, an evaluation is conducted and the project is submitted for authorisation



Public notice of intent to proceed is published and a TC is formed or the project is assigned to an existing TC



A working draft is prepared and a project schedule is established



The TC or SC (facilitated by Standards staff) develops the draft through a process that typically involves a number of committee meetings



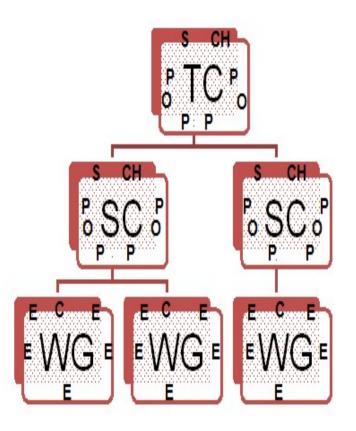
The draft is offered to the public for review and comment, the TC reaches consensus, Standards staff conduct a quality review and a pre-approval edit is completed

The TC approves the technical content by letter ballot or recorded vote



Standards staff conduct a final edit to verify conformity with the applicable editorial and procedural requirements and then publishes and disseminates the standard

- International Principles
- Governance process
- SABS Norm
- Alignment to ISO and IEC programme of work
- Maintenance
 - Reaffirmations
 - Withdrawal
 - Amendments
 - Revisions





- System certification
- Product certification
- Status of certification to SANS 13485 Medical devices:
 - Quality Management Systems –
 - Requirements for regulatory purposes





Over 4 000 system certificates & 2 835 product permits held by customers

Laboratory Services



Our primary products and services include:

- Sampling, testing and analysis (inside the lab)
- Testing and calibration of laboratory and testing equipment
- Environmental monitoring (at client's premises)
- Proficiency testing
- Reference materials



Technical evaluations and surveys:

- Analysis by testing
- Area classifications



Product conformity testing:

- Type testing
- Conformity testing against requirements
- Batch testing
- Non-destructive testing











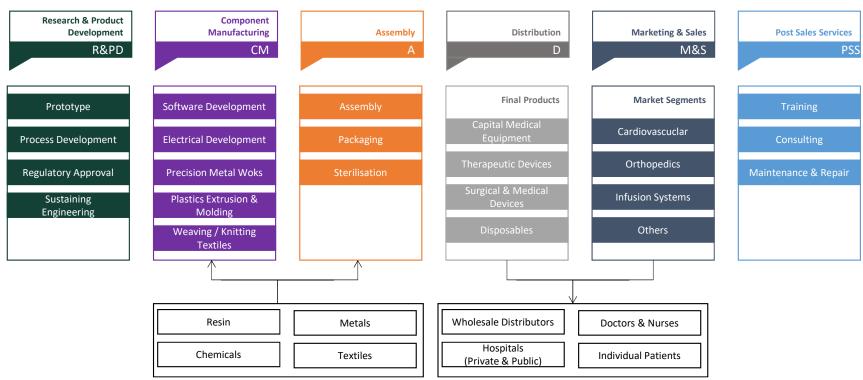


- Failure assessments
- Ionizing radiation monitoring
- Efficacy testing

Calibration services:

- In house and on site calibrations
- Calibration system

Medical devices value chain



Source: Gereffi, 2013

Stakeholders











national regulator for compulsory specifications







INDUSTRY: MANUFACTURERS, DISTRIBUTORS AND WHOLESALERS

Sample Testing is required before being eligible to participate in the NDoH tender processes

The SABS Laboratories have tested the following for customers:

- Condoms tender RT 75 in our Condom Test Laboratory
- Surgical gloves to SANS 11193 and SANS 68 tender RT 76 in our Rubber, Plastics, Paints & Sealant Laboratory
- Medical sundries, bandages, cotton wool and gauze -RT42 to SANS in our Textiles & Leather Laboratory
- Surgical gowns and drapes tender RT 32 to SANS 53795 (CSR testing) in our Textiles and Leather Laboratory
- Diapers (CKS 648), sanitary towels tender RT 32 to SANS 1043 in our Textiles & Leather Laboratory







Examples of medical device tenders (cont)

- Umbilical cord clamps to SANS 312 in our Textiles & Leather Laboratory
- Catheters and Urine bags in tender RT253 to SANS 51616, CKS 463 in our Pharmaceutical Chemistry Laboratory
- Administration sets in tender RT31 to SANS 1775 various parts, 305 Pharmaceutical Chemistry Laboratory Advertised Feb 2019, samples arriving for testing
- Syringes and Needles in tender RT284 to SANS 1116 in our Pharmaceutical Chemistry Laboratory which was advertised Feb 2019 (testing in progress)





- Role of industry in ensuring relevance of tender requirements
- Requirements for laboratory Accreditation
- Where samples are mostly imports, logistics are challenging. e.g. samples rejected and causing delays
- Following sampling requirements of the standards
- Cost of testing and certification
- Some standards are outdated and sometimes there are no national standards
- SAHPRA registered, why test again for tenders?



- Existence of standards, where there is no testing capability
- Maintaining test capability and test capacity while tests are not requested frequently
- Establishing and maintaining accreditation requires regular testing
- Establishing and maintaining certification requires a pool of experts and clients
- Alignment of cost of testing to industry expectations
- Unrealistic timelines from National Treasury on tenders
- Large stakeholder base to engage and agree a way forward



- Regular engagements with NDoH and National Treasury as well other stakeholders.
- Regular structured meetings with SAMED, MDMSA and other industry role players.
- Collaboration with industry for sourcing experts in support of Certifying to SANS 13485.
- Industry participation in the developments and review of standards.
- CSR testing is now fully implemented by the SABS Laboratories.
- Exploring collaboration and PPP opportunities for new tech objectives



Thank you