



Overview of the SABS, Testing Laboratories and the Role of Testing in the Medical Devices Value Chain

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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

International Membership

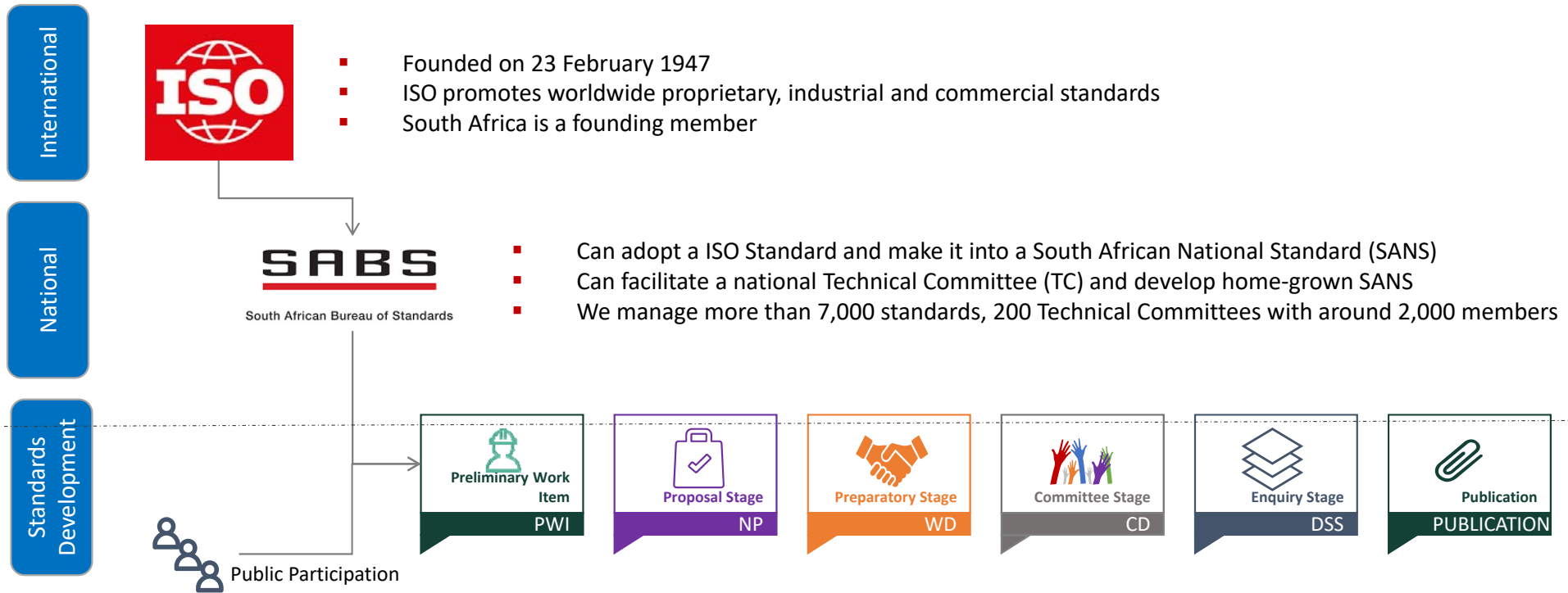


Accreditation of SABS

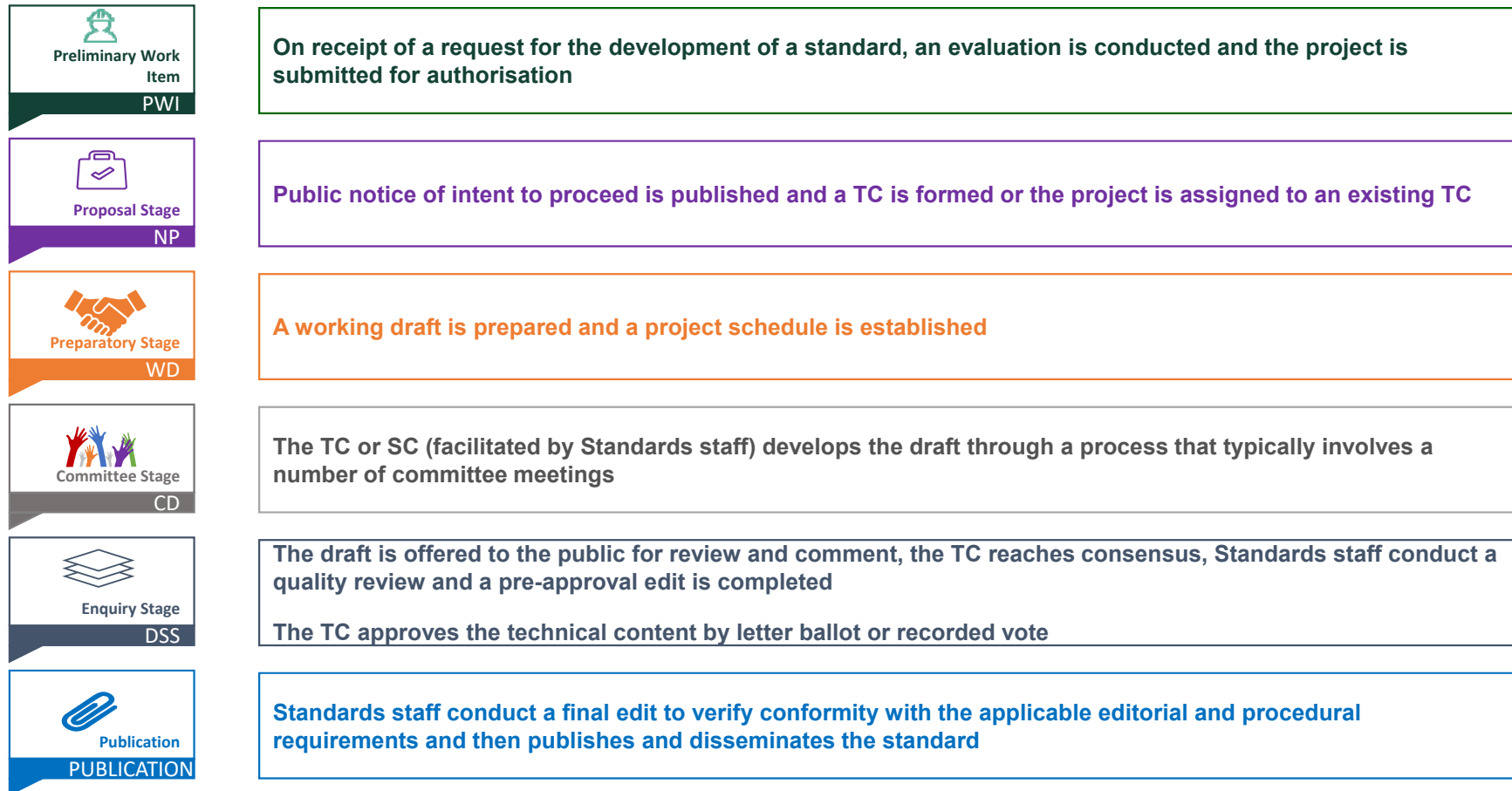




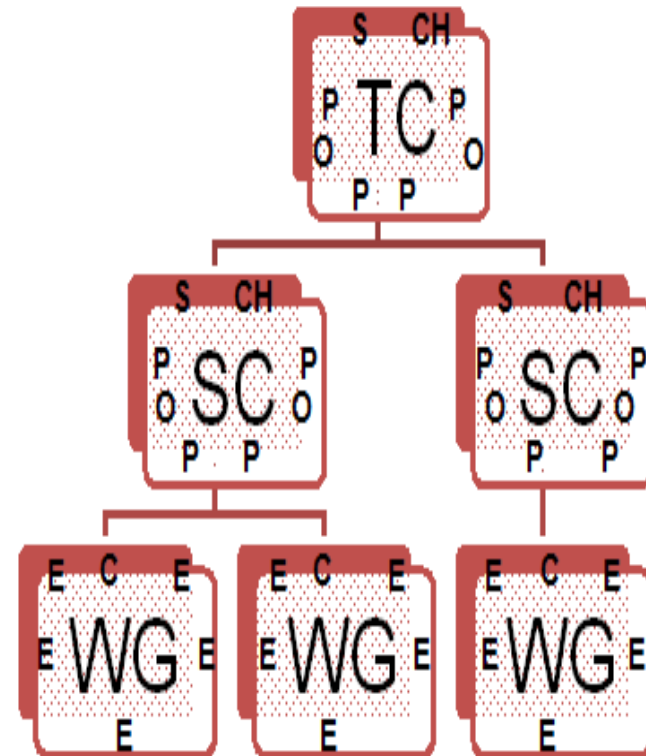


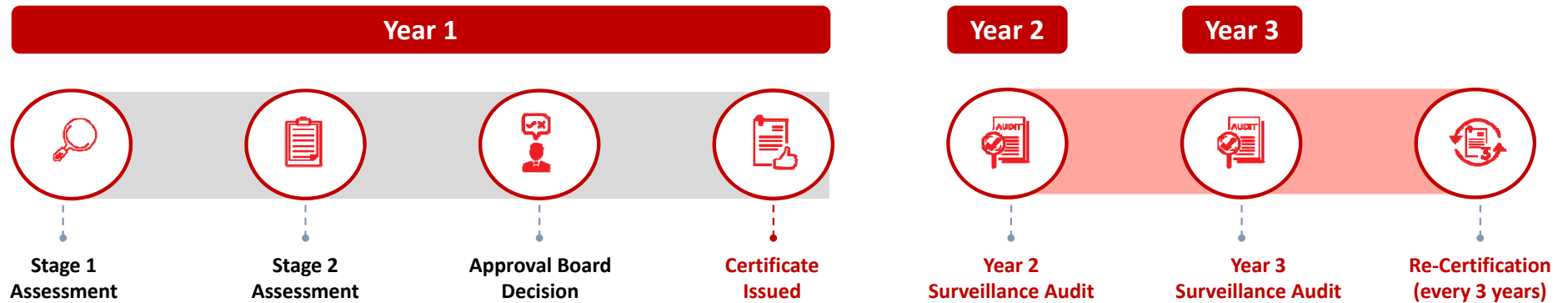


SABS is the only organisation in South Africa with the mandate to develop, promote and maintain national standards



- 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



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



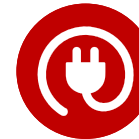
Technical evaluations and surveys:

- Analysis by testing
- Area classifications
- Failure assessments
- Ionizing radiation monitoring
- Efficacy testing



Product conformity testing:

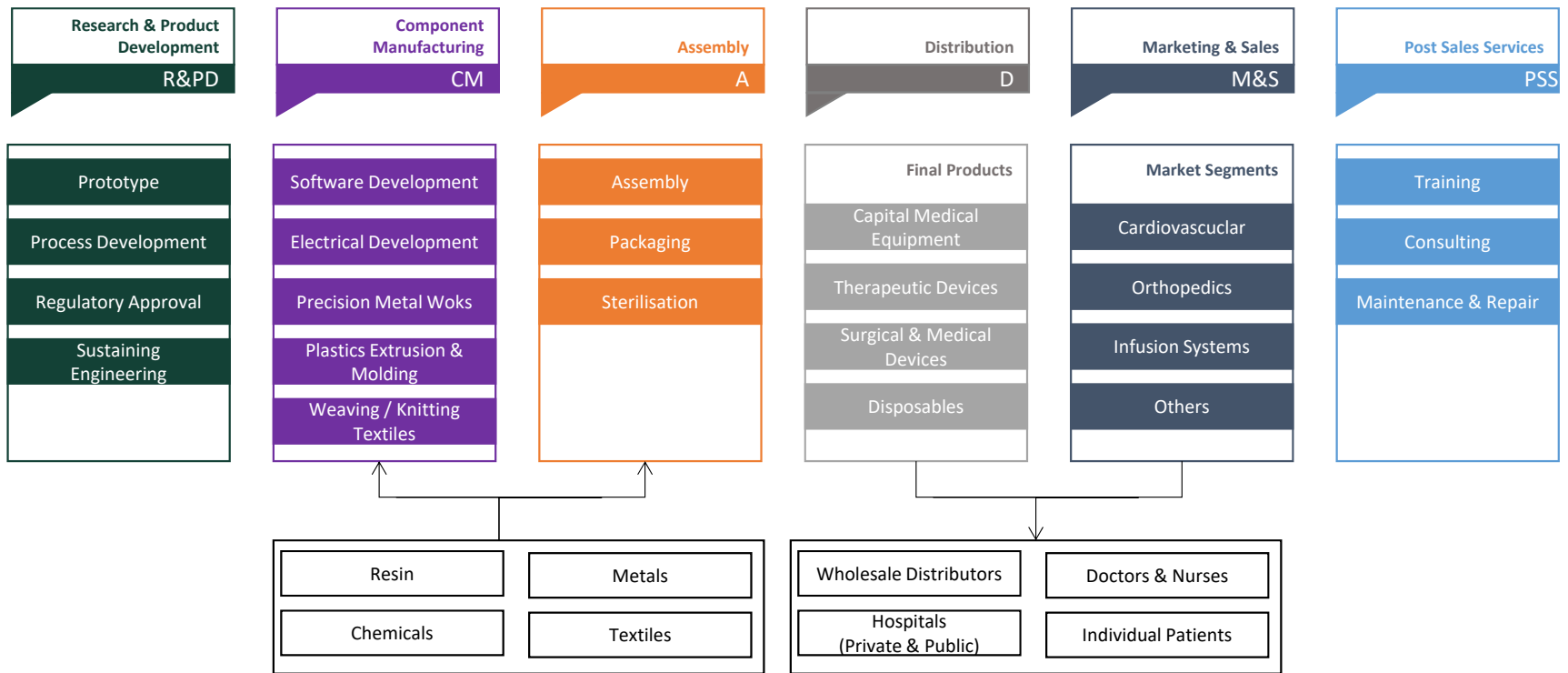
- Type testing
- Conformity testing against requirements
- Batch testing
- Non-destructive testing



Calibration services:

- In house and on site calibrations
- Calibration system





Source: Gereffi, 2013



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



- 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