

SABS

STANDARDS DIVISION

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- Standard Act 8 of 2008

To provide for:

- develop, promote and maintain South African National Standards (SANS)
- promote quality in connection with commodities, products and services
- rendering of related conformity assessment services

- SABS is the only national standardisation body in South Africa
- Section 4(2) (c) mandates SABS to obtain membership in international and foreign bodies having any similar objectives or scope of work



SECTION 4(2) (C) OF THE STDS ACT

International

- 165 member countries
- 761 TCs/SCs
- >22500 ISO standards



- 164 member countries
- 134 TCs/SCs
- >9000 IEC standards

Regional



The African Electrotechnical
Standardization Commission
Commission
Electrotechnique Africaine
de Normalisation



	Objective
1	Develop and maintain relevant national standards that address market needs, support and enable socio-economic and environmental objectives, industrial policy, innovative and competitive industries
2	Maintain a credible, inclusive and efficient national standards development system and processes underpinned by international standardisation principles and digital enablement
3	Acquire, develop and retain skills to drive strategic and thought leadership, achieve stakeholder diversity amongst the pool of professional standardisers and meet the changing needs of society
4	Promote the widespread use of SANS through enhancing the public understanding of the value of SANS and related conformity assessments and demonstrate the benefits and positive impacts to the public and private sector
5	Strategic collaboration and leadership in regional and international standardisation forums; active participation in the harmonisation of standards and conformity assessment tools to support the implementation of the AfCFTA
6	Enhance the access, distribution and uptake of national standards by all stakeholders

Impartiality And Consensus

Impartiality

- Decisions that are based on objective criteria rather than on the basis of bias, prejudice, or conferring the benefit to one organization over another for whatever reasons

Consensus

- general agreement
- seeking to take into account views of all parties concerned and reconcile conflict



Openness

- Collaboration that enriches the process to develop better content
- An open system in which participation is expanded to include a wide and relevant audience
- Indiscrimination of participants at every stage of the standards development process



STAKEHOLDER ENGAGEMENT

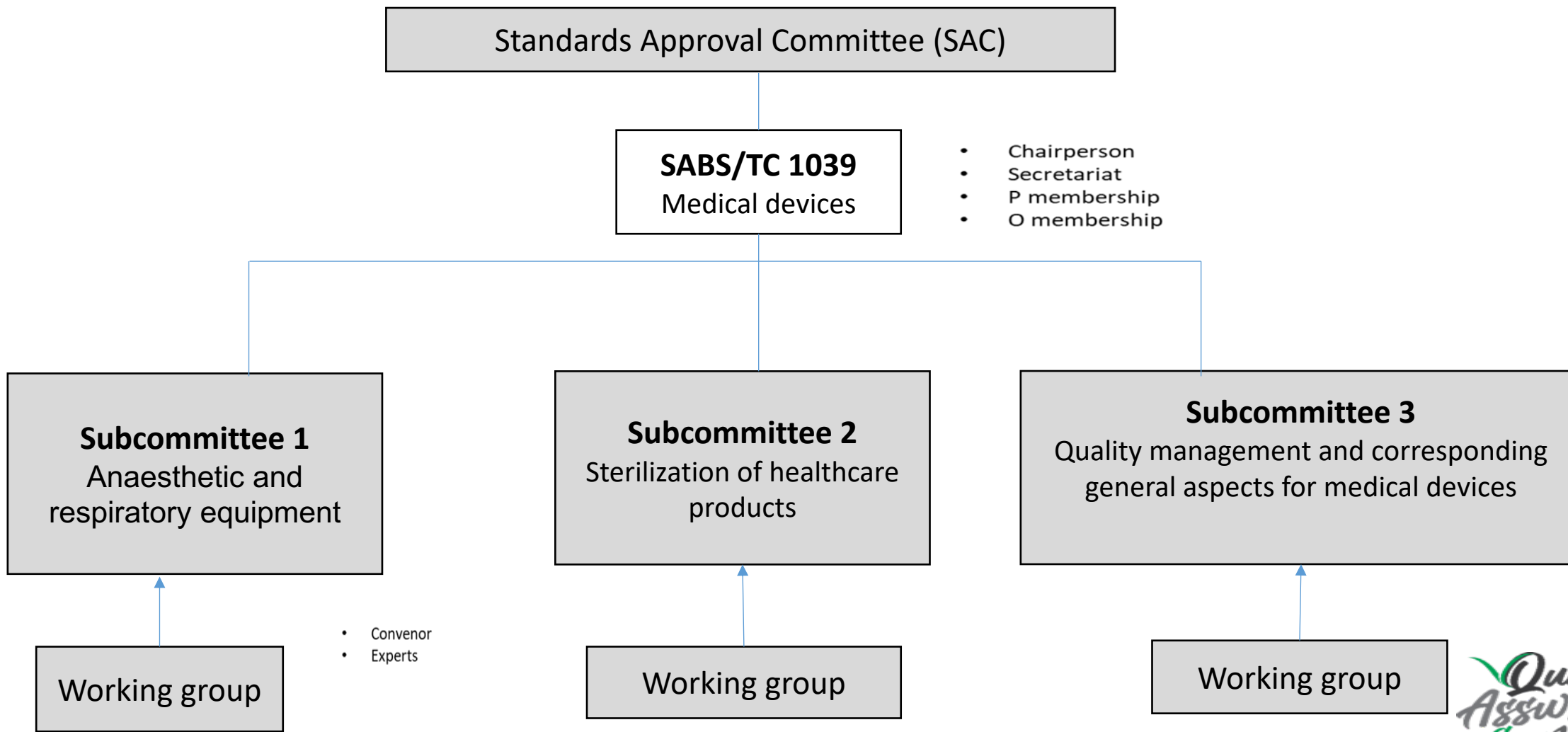
- Necessity to involve players that may be materially affected by the standard's implementation *i.e., Industry, government, consumers, NGOs*
- Role of members complemented by 'direct' engagement of relevant stakeholders



SABS services

- Standard Development
- Conformity assessment Services
- Certification (system certification and product certification)
- Training





Standards development process flow is based on international best practice principles



- Revision i.e., changes in the scope or technical changes on requirements for conformity
- Amendment i.e., partial alteration of a provision of a standard
- Reaffirmation



68 published standards in total

- SANS/ISO 13485 Quality management systems- Requirements for regulatory purposes
- SANS/ISO 14971 Medical devices- Application of risk management
- SANS/ISO 13408 series Aseptic processing of health care products
- SANS/ISO 11137 parts 1 Radiation Requirements for development validation and routine control



Involvement in harmonization of standards projects

- P-Member of ARSO/TC 78 - *Medical devices*
- P-Member in ARSO/TC 80 - *Pharmaceutical and medicinal products*



Quality
Assurance
Since 1945

- P-member of ISO/TC 198 - *Sterilization of healthcare products*
- O-member in ISO/TC 121 - *Anaesthetic and respiratory equipment*
- P-member in ISO/TC 210 - *Quality management and corresponding general aspects for medical devices*



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Thank You, SABS Team

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