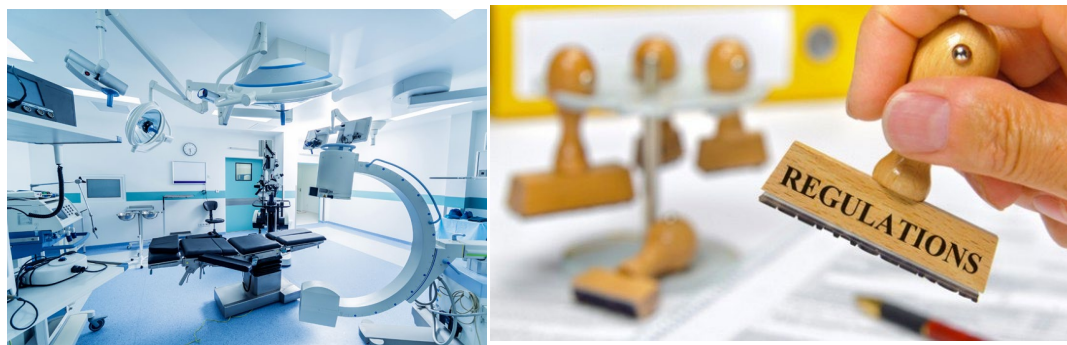


SNI for Medical Devices

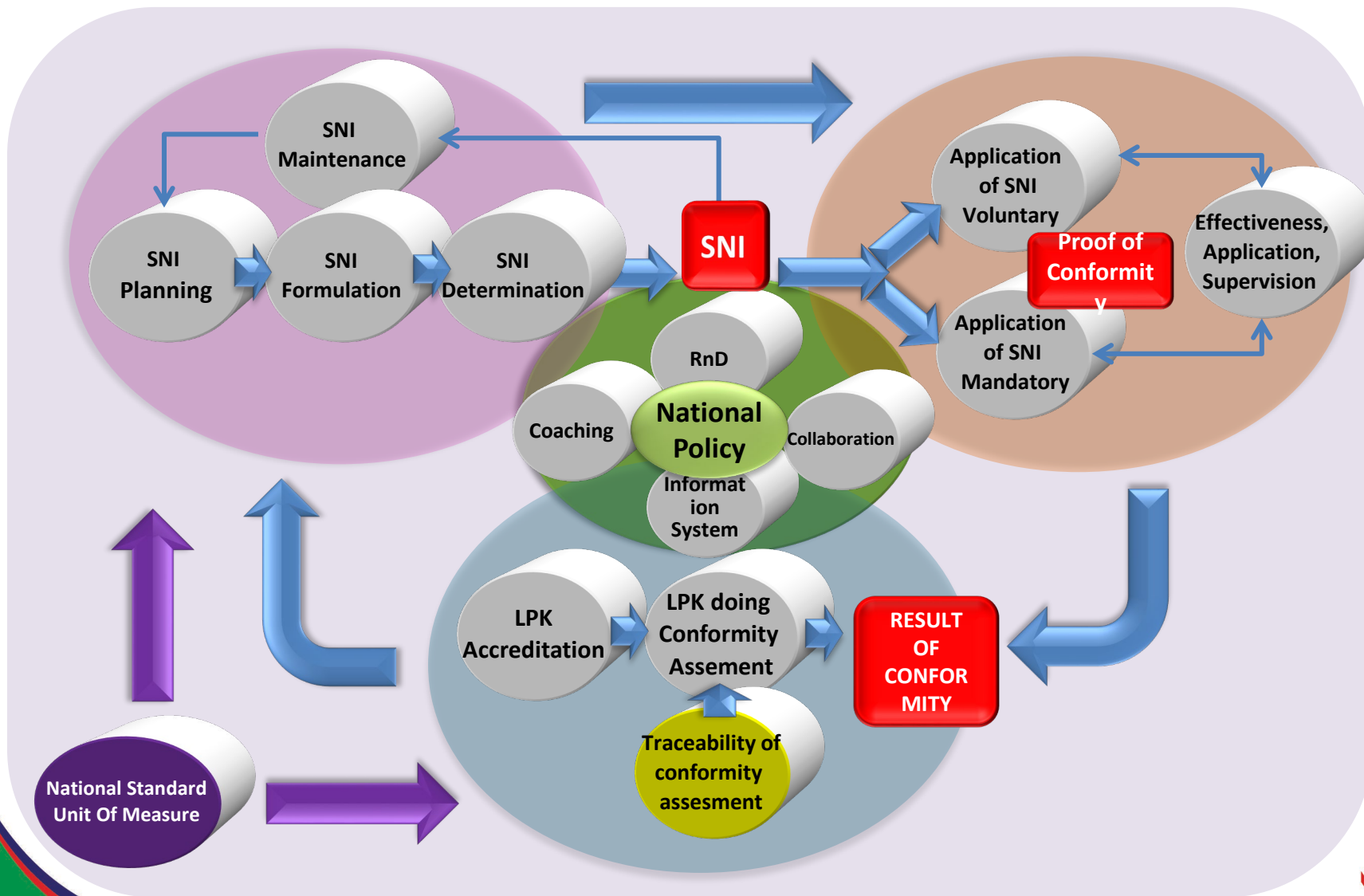


HERU SUSENO

Director of Standards Development for Agro, Chemical, Health and Halal
The National Standardization Agency of Indonesia (BSN)

Jakarta, 27 July 2022

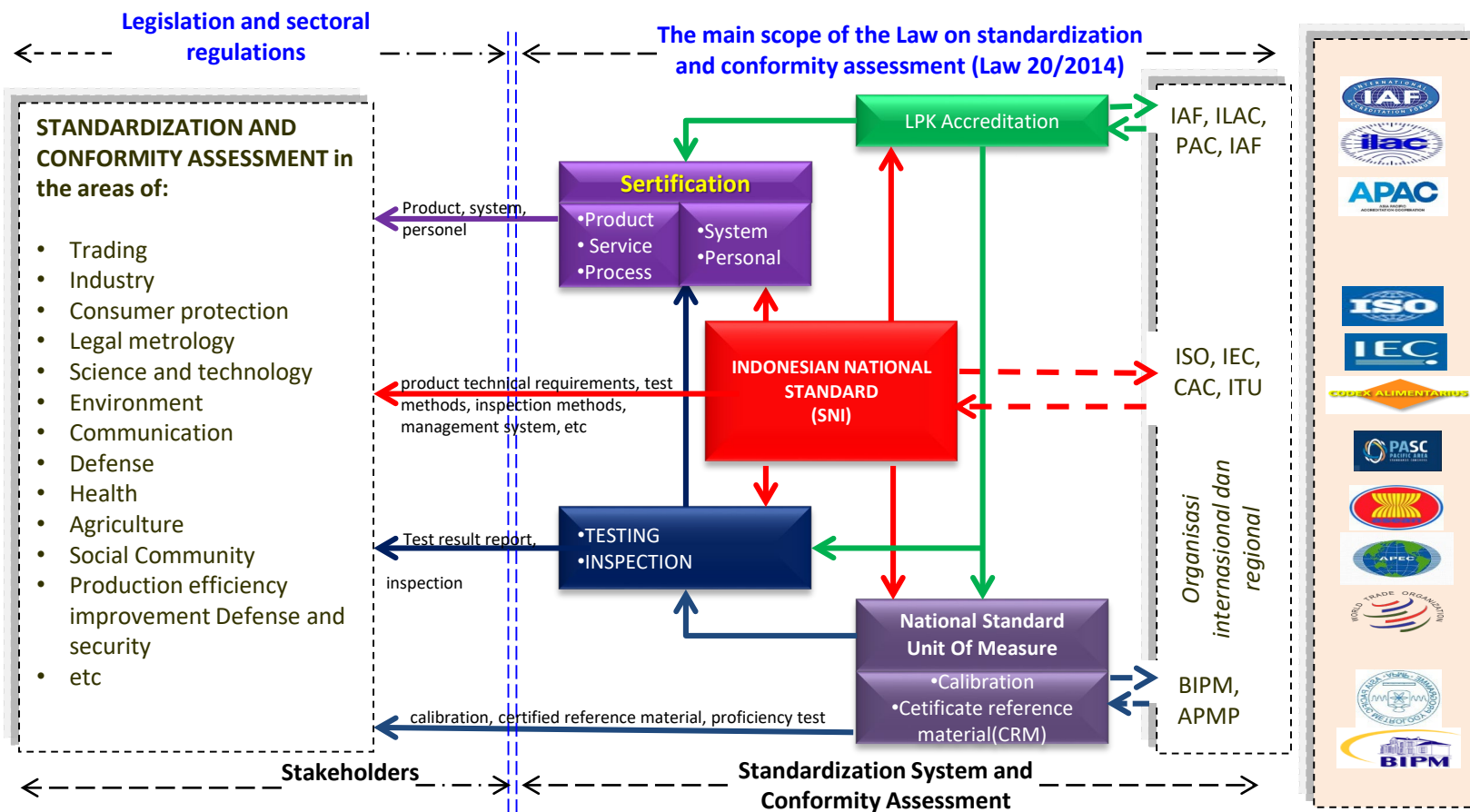
Standardisation and Conformity Assessment System In Indonesia



WHY A STANDARDIZATION APPROACH AND CONFORMITY ASSESSMENT IS NEEDED?

There is synergy and collaboration between stakeholders

SPK for sectoral regulation implementation

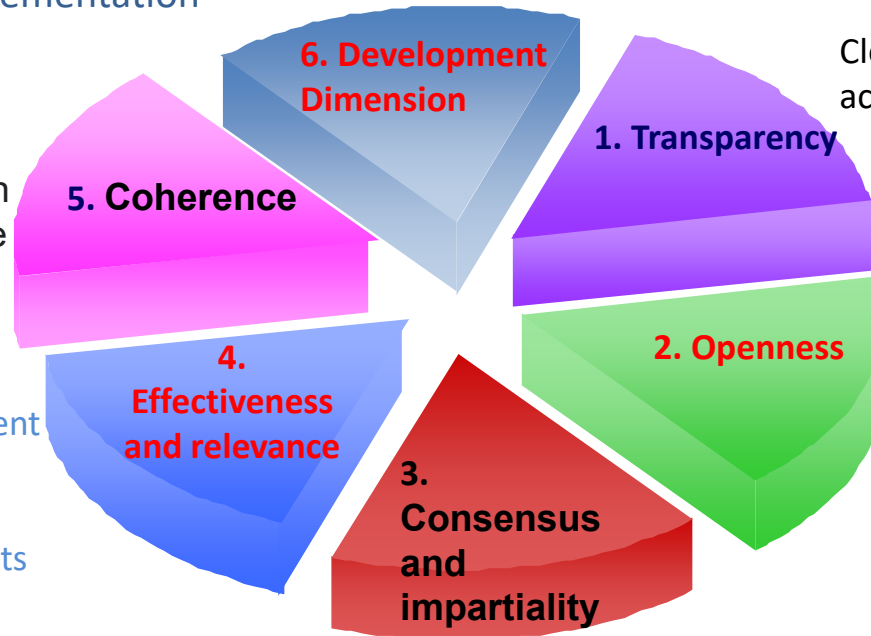


Basic Principles of Formulation of SNI

Involving all stakeholders, including considering the ability of SMEs in its implementation

Referring to relevant international standards and avoiding duplication between Komteks in the formulation of SNI

Considering the development of science and technology, able to meet market needs and regulatory requirements



Clear rules and procedures, accessible to all parties

Each stage of the formulation can be followed by all stakeholders according to the rules and procedures

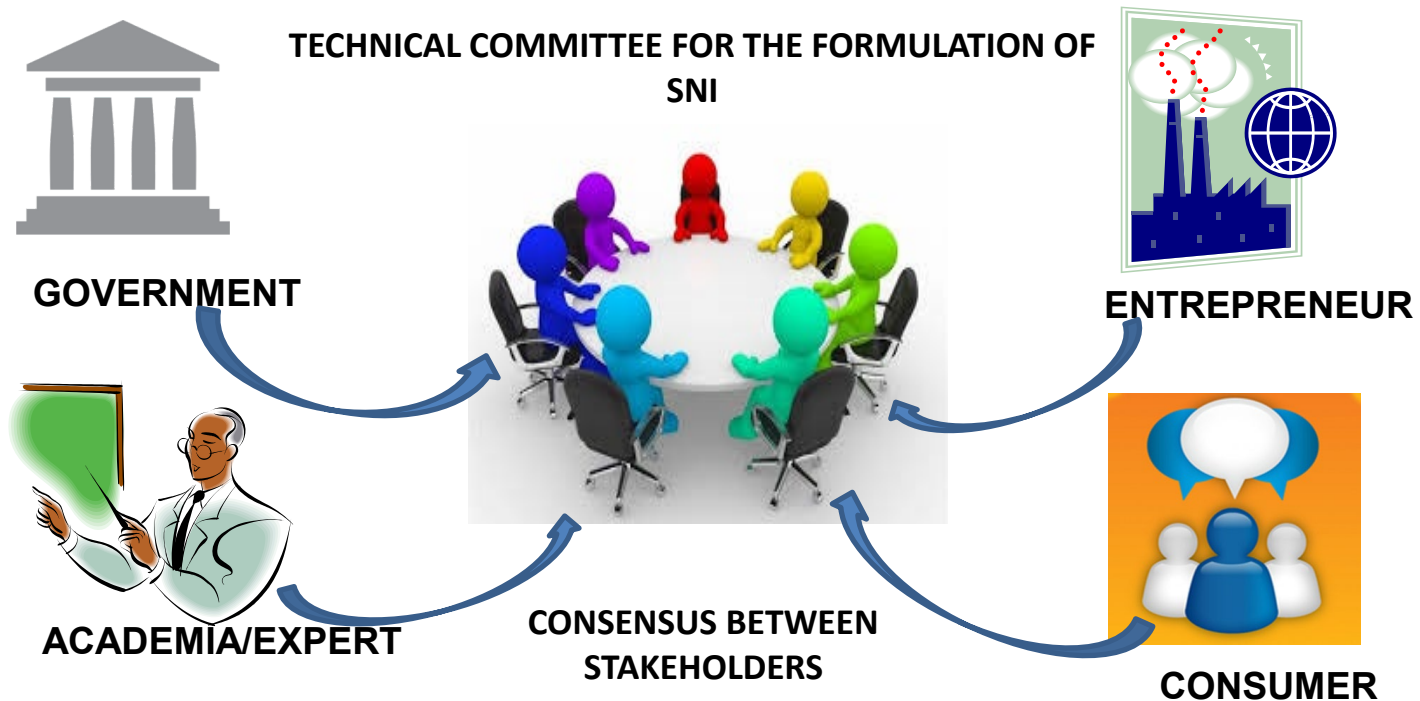
Taking into account the views of all parties, decision making is based on consensus

Note:

- Principles 1 to 6 refer to the decisions of the TBT Committee on the principles of developing international standards
- Referring to ISO Publication on Good Standardization Practices:

- Stakeholder engagement
- Legal process
- Implementation at the national level

REPRESENTATION OF STAKEHOLDERS IN STANDARDS DEVELOPMENT



NOTES:

PBSN 04/2018 concerning the Management of the SNI Formulation Committee:

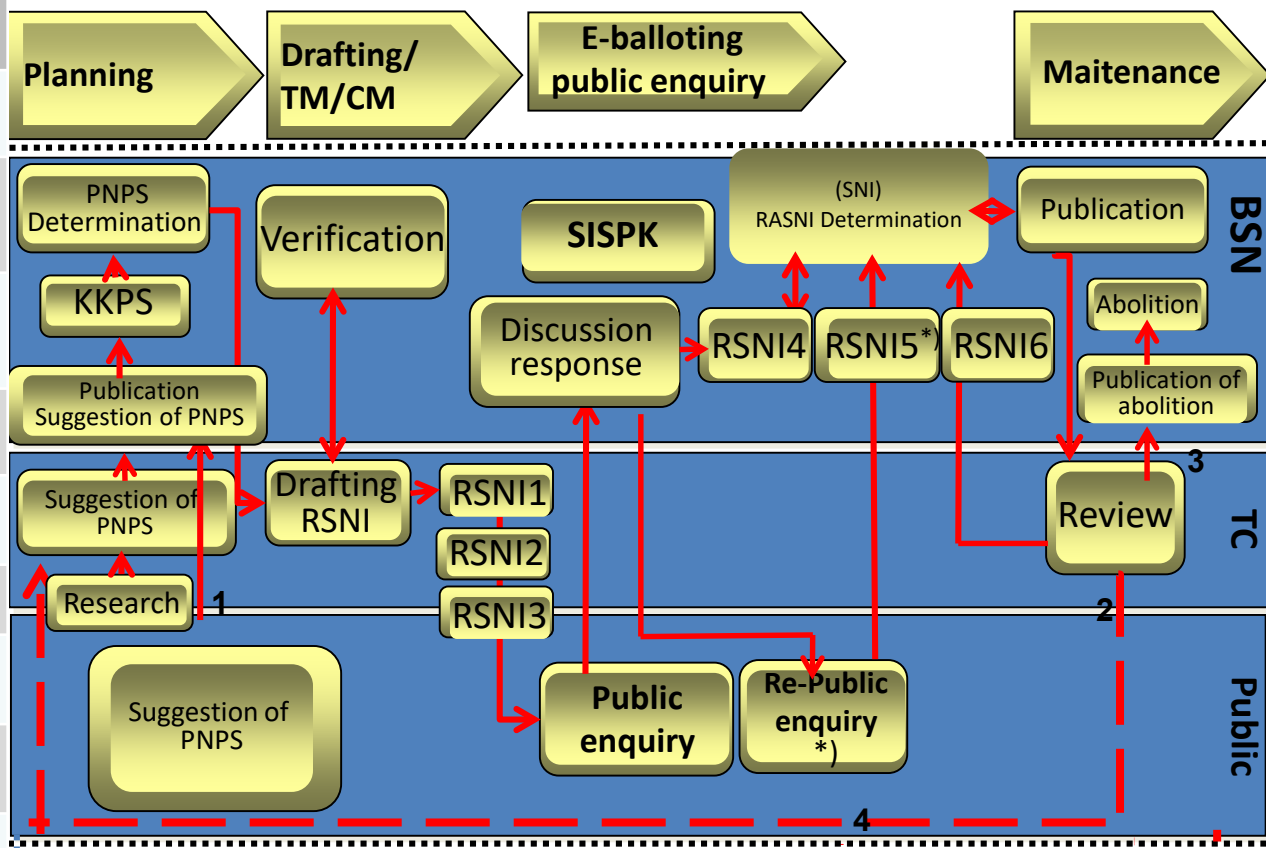
- The number of Komite membership is a minimum of **9 people** and a maximum of **15 people (odd)**
- The number of one stakeholder element should **not exceed 50%**

METHODS OF SNI DEVELOPMENT

- Adoption of international standards identically to the republication-reprint method;
- Adoption of international standards identically to translation methods;
- Adoption of modified international standards with translation methods;
- Formulation of SNI with own development method.

STANDARD FORMULATION STAGE

Activities	PIC	Participant	Output
Drafting	TC or Conseptor	Conseptor	RSNI1
Technical meeting (TM) ¹⁾	TC	Conseptor , TC, Stakeholder, and TPMS ²⁾	RSNI2
Consensus Meeting (CM)	TC	Conseptor , TC, Stakeholder, and TPMS	RSNI3
Public enquiry (JP) ³⁾	BSN	Stakeholder ⁴⁾	public response data
Discussion RSNI3, (Results of JP) ⁵⁾	BSN	Conseptor , TC, Stakeholder, and TPMS	RSNI4
Re- Public enquiry	BSN	Stakeholder	public response data
Discussion RSNI3, (Results of JP)	BSN	Conseptor , TC, Stakeholder, and TPMS	RSNI5 ⁶⁾
Discussion of RSNI review result ⁷⁾	TC	TC, BSN, Stakeholder	RSNI6
Finishing RSNI4/5/6 for determination	BSN	BSN	RASNI
SNI SNI Determinatuib	BSN	BSN	SNI



SNI in Health Sector (2021)

TC 13-12 : Personal Protective Equipment
and Work Protective Equipment

TC 13-09: Biosafety and Biosecurity

TC 13-01: Occupational Health and Safety

TC 11-14: Aids for Persons with Disabilities

TC 11-13: Sterilization of Healthcare Products

TC 11-12 : Dentistry

TC 11-11 :Household Hygiene Products

TC 11-10: Medical Equipment
Management System

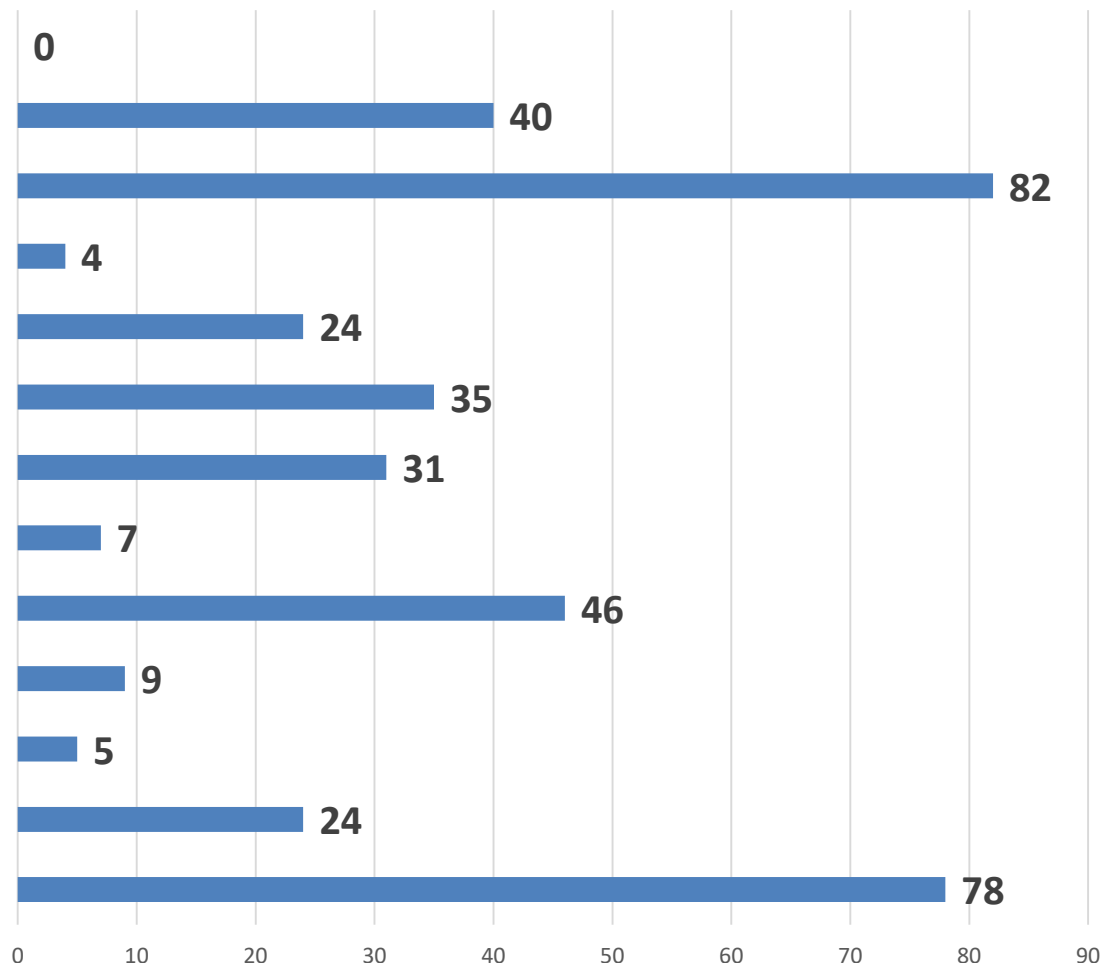
TC 11-09: Non-Electromedical
Medical Devices

TC 11-07: Optical and Photonic
Products for Health

TC 11-06: Contraception

TC 11-04: In Vitro Diagnostic Test System

TC 11-03:Electromedical medical device

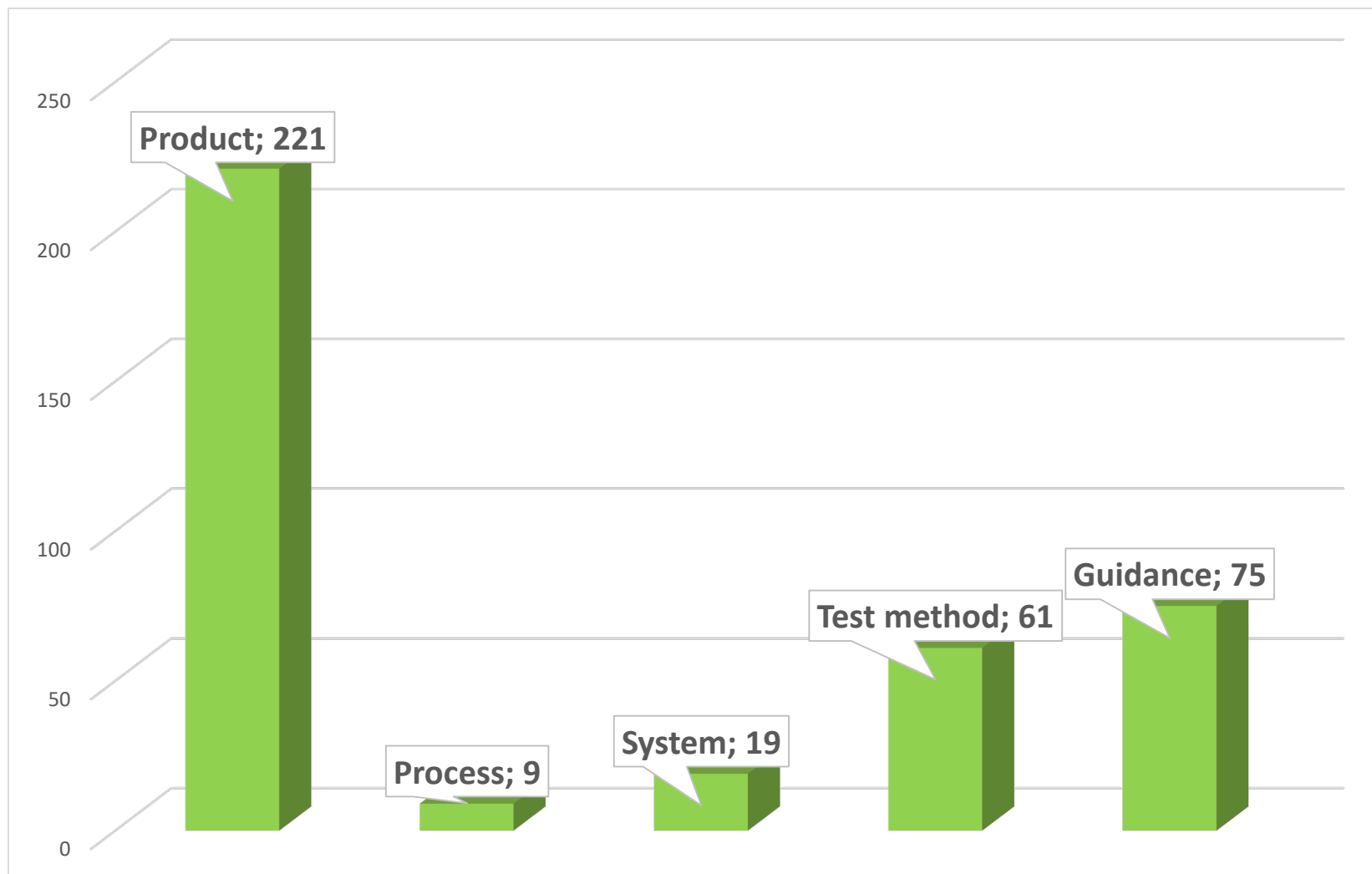


TOTAL: 385 SNI

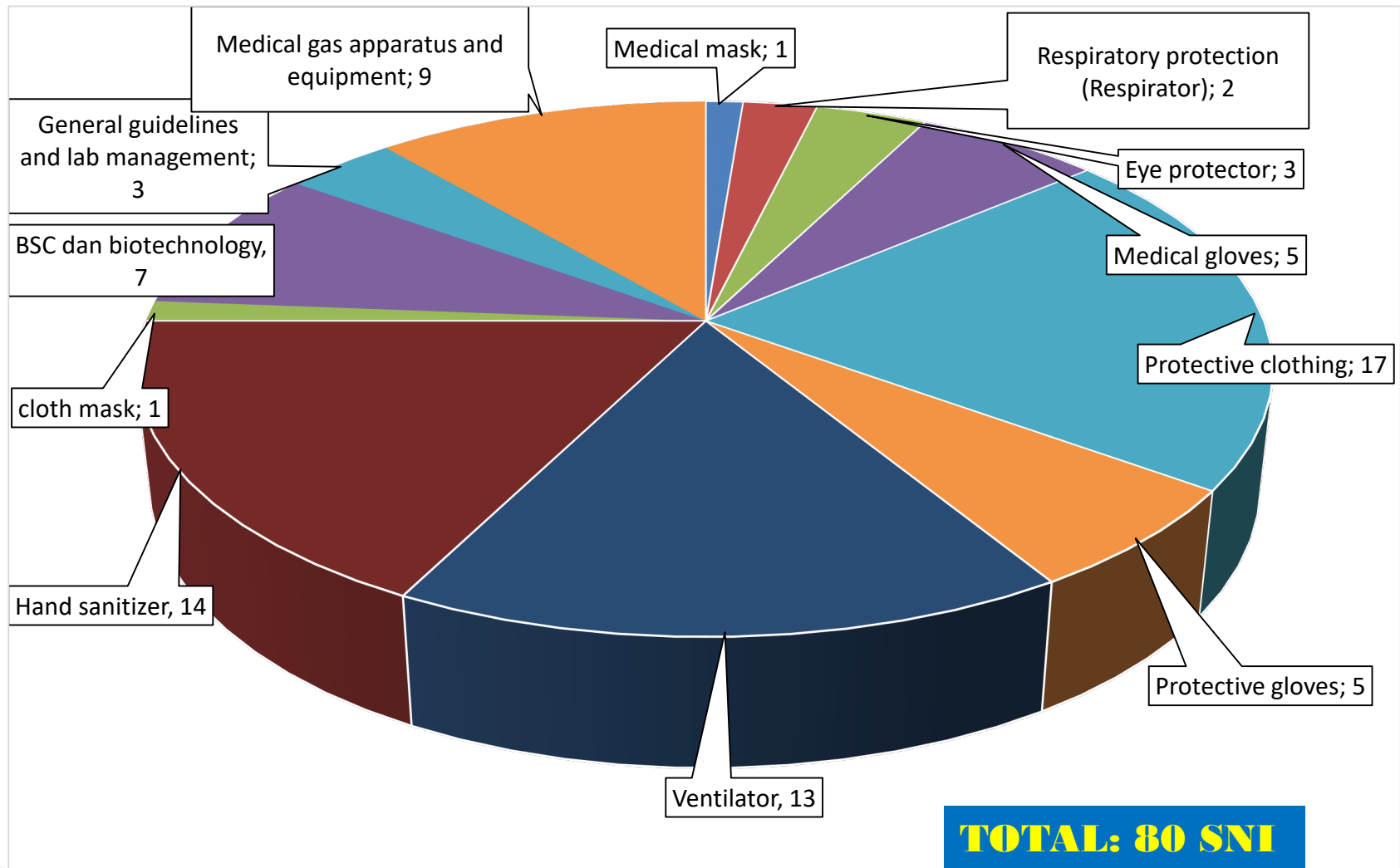
Komtek – MC TC (ISO/IEC)

Komite teknis		Mirroring TC/SC ISO atau IEC	Jumlah SNI adopsi
11-03	Alat Kesehatan Elektromedik	IEC/TC/SC 62A Common aspects of electrical equipment used in medical practice, IEC /TC/ SC 62D Electromedical equipment dan ISO /TC 121 Anaesthetic and respiratory equipment yang meliputi ISO/TC 121/SC1 Breathing attachments and anaesthetic machines, ISO/TC 121/SC2 Airways and related equipment, ISO/TC 121/SC3 Respiratory devices and related equipment used for patient care, ISO /TC 121/SC4 Vocabulary and semantics, dan ISO /TC 121 / SC8 Suction devices.	80
11-04	Invitro Diagnostic Test System	ISO/TC 194 Biological and clinical evaluation of medical devices ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test system	25
11-06	Kontrasepsi	ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics	3
11-07	Produk optik dan Fotonik untuk Kesehatan	ISO/TC 172/SC 7 Ophthalmic optics and instruments	11
11-09	Alat Kesehatan non Elektromedik	ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, ISO/TC 84 Devices for administration of medicinal products and catheters, ISO/TC 150 Implants for surgery, ISO/TC 170 Surgical instruments	21
11-10	Sistem Manajemen Peralatan Kesehatan	ISO/TC 210 Quality management and corresponding general aspects for medical devices	6
11-11	Produk Higiene Perbekalan Kesehatan Rumah Tangga	Ruang lingkup meliputi produk perawatan bayi dan ibu, antiseptik, desinfektan, pestisida rumah tangga, kapas, tisu dan produk tisu lainnya	0
11-12	Kedokteran Gigi	ISO/TC 106 Dentistry.	36
11-13	Sterilisasi Produk Pelayanan Kesehatan	ISO/TC 198 Sterilization of health care products	8
11-14	Alat Bantu Penyandang Disabilitas	ISO/TC 173 Assistive product yang juga meliputi, ISO/TC 173/SC 1 Wheelchairs, ISO/TC 173/SC 2 Classification and terminology, ISO/TC 173/SC 3 Aids for ostomy and incontinence, ISO/TC 173/SC 4 Assistive products for persons with impaired sensory functions	25
13-01	Keselamatan dan Kesehatan Kerja	ISO/TC 283 Occupational health and safety management	0
13-09	Biosafety and Biosecurity	Ruang lingkup meliputi sistem keamanan dan keselamatan di laboratorium atau instansi terkait bahan biologi berbahaya	38
13-12	Alat Pelindung Diri dan Alat Pelindung Kerja	- ISO/TC 94/SC 1 Head Protection, - ISO/TC 94/SC 3 Foot protection, - ISO/TC 94/SC 4 Personal Equipment for Protection Against Falls, - ISO/TC 94/SC 6 Eye and Face Protection, - ISO/TC 94/SC 13 Protective clothing, - ISO/TC 94/SC 15 Respiratory protective devices.	0

SNI for Health by Types (2021)



SNI for the Handling of COVID-19 Pandemics



TERIMA KASIH THANK YOU



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