



AfroCondomNet, August 2021

Introduction to ISO TC 157
activities

Dr. Sivakumar Kamakshinatha

Introduction to ISO TC 157 activities

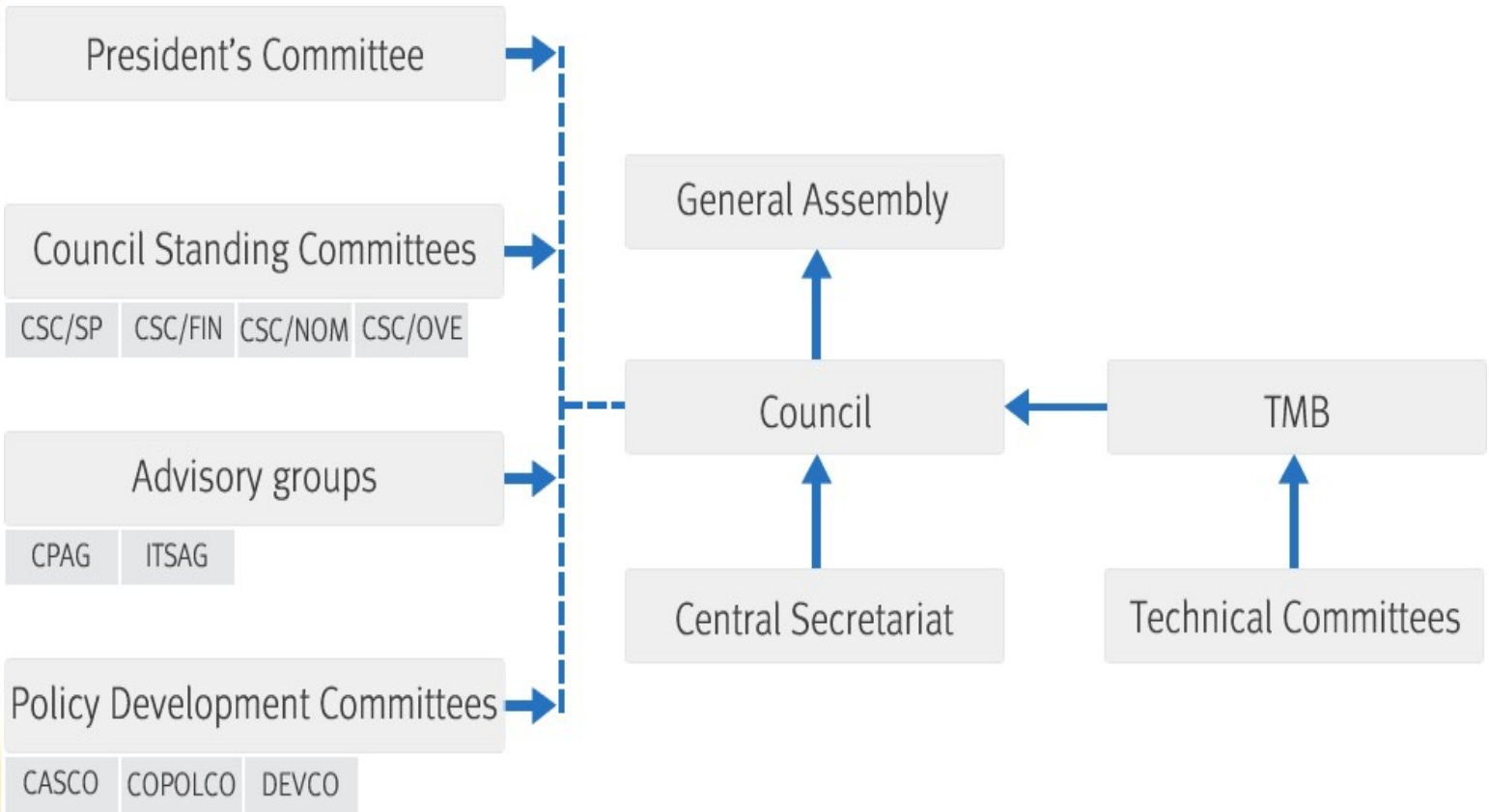
- 1. Introduction**
- 2. ISO TC 157 Scope and Structure**
- 3. Working Groups and Task Groups**
- 4. Development of Standards**
- 5. List of Standards Published by ISO TC 157**
- 6. Projects in progress**
- 7. Meetings and participation**

Introduction – ISO TC 157



- **International Organization of Standardization (ISO)**
- **Independent, non-governmental international organization**
- **Membership of 165 National Standards Bodies (NSB)**
- **Develop and publish International Standards**
- **World Standards cooperation(WSC): ISO, IEC and ITU,**
- **Collaboration with WTO**
- **Central Secretariat in Geneva, Switzerland**
- **Membership: - Full members (Member bodies, ‘P’ members),**
- **- Correspondent members (‘O’ members)**

Introduction – ISO TC 157



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics”

Scope : Standardization of above

- **Standards**
- **Guidance documents**
- **Technical reports**



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics”

Creation date: 1974

SECRETARIAT: DSM, MALAYSIA

Chairperson : Dr. Faridah Hanim Abdul Hanan

Committee Manager: Mr. Feris frederick

23 Participating members (P)

27 Observing members (O)

7 Liaison organizations

Meets usually once every year

Liaison with related ISO TCs and CEN



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics” – Membership (Participating)

Australia	SA
Belgium	NBN
Brazil	ABNT
China	SAC
Egypt	EOS
Germany	DIN
Greece	NQIS ELOT
India	BIS
Indonesia	BSN
Japan	JISC
Korea, Republic of	KATS
Malaysia	DSM

Mauritius	MSB
Mexico	DGN
Saudi Arabia	SASO
South Africa	SABS
Spain	UNE
Sweden	SIS
Switzerland	SNV
Thailand	TISI
Uganda	UNBS
United Kingdom	BSI
United States	ANSI



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics” – Membership (Observing)

Argentina	IRAM	Italy	UNI
Bahrain	BSMD	Kenya	KEBS
Bangladesh	BSTI	Netherlands	NEN
Botswana	BOBS	New Zealand	NZSO
Bulgaria	BDS	Poland	PKN
Cameroon	ANOR	Portugal	IPQ
Cuba	NC	Romania	ASRO
Czech Republic	UNMZ	Russian Federation	GOST R
Finland	SFS	Serbia	ISS
France	AFNOR	Singapore	SSC
Ghana	GSA	Tanzania, United Republic of	TBS
Hungary	MSZT	Turkey	TSE
Iran, Islamic Republic of	INSO	Zimbabwe	SAZ
Ireland	NSAI		



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics” – Membership (Liaison organizations)

CI	Consumers International
DFID	Department for International Development
EC - European Commission	European Commission
IPPF	International Planned Parenthood Federation
PATH	Program for Appropriate Technology in Health
UNFPA	United Nations Population Fund
WHO	World Health Organization



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics” – Structure

ISO/TC 157/CAG	Chairman Advisory Group	Working group
ISO/TC 157/TG 1	Statistical task group	Working group
ISO/TC 157/TG 2	Environmental Information Group	Working group
ISO/TC 157/TG 3	Forward Planning and Financing of ISO/TC 157 Meetings	Working group
ISO/TC 157/TG 5	Procedures for opening condom packages for testing	Working group
ISO/TC 157/TG 6	Provision of labelling and information	Working group
ISO/TC 157/WG 3	Intra-uterine devices	Working group
ISO/TC 157/WG 10	Burst requirements	Working group
ISO/TC 157/WG 11	Packaging integrity	Working group



ISO TC 157 – Scope and Structure

“Non-systemic contraceptives and STI barrier prophylactics” - Structure

ISO/TC 157/WG 13	Stability assessment	Working group
ISO/TC 157/WG 14	Guidance on the use of condom standards	Working group
ISO/TC 157/WG 15	Additional lubricants	Working group
ISO/TC 157/WG 17	Synthetic Male Condoms	Working group
ISO/TC 157/WG 18	Female condoms and diaphragms	Working group
ISO/TC 157/WG 19	Methods for hole detection	Working group
ISO/TC 157/WG 20	Clinical trials	Working group
ISO/TC 157/WG 21	Chemical residues	Working group
ISO/TC 157/WG 23	Natural rubber latex male condoms	Working group



ISO TC 157 – Development of Stanadards

Discussion and consensus building process with balloting.

- Identification of development project
- Registration of new work item – WG/ TG, Convenor, Project Leader
- Collection of relevant technical information
- Circulation of Proposal and balloting
- Working Draft (WD)
- Committee Draft (CD)
- Draft International Standard (DIS)
- Final Draft International Standard (FDIS)
- International Standard



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Standards Published:

- **ISO 4074:2015** - Natural rubber latex male condoms — Requirements and test methods
- **ISO 7439:2015** - Copper-bearing contraceptive intrauterine devices — Requirements and tests
- **ISO 8009:2014** - Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests
- **ISO 11249:2018** - Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Standards Published:

- [ISO 16037:2002](#) - Rubber condoms for clinical trials — Measurement of physical properties
- [ISO 16037:2002/AMD 1:2011](#) - Rubber condoms for clinical trials — Measurement of physical properties — Amendment 1
- [ISO 16038:2017](#) - Male condoms — Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms
- [ISO 19351:2019](#) - Fallopian rings — Requirements and test methods



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Standards Published:

ISO 19671:2018 - Additional lubricants for male natural rubber latex condoms — Effect on condom strength

ISO/TR 19969:2018 - Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom

ISO 23409:2011 - Male condoms — Requirements and test methods for condoms made from synthetic materials



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Standards Published:

- [ISO 25841:2017](#) - Female condoms — Requirements and test methods
- [ISO 25841:2017/AMD 1:2020](#) -Female condoms — Requirements and test methods — Amendment 1
- [ISO 29941:2010](#) - Condoms — Determination of nitrosamines migrating from natural rubber latex condoms
- [ISO 29942:2011](#)- Prophylactic dams — Requirements and test methods



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Standards Published:

- [ISO 29943-1:2017](#) - Condoms — Guidance on clinical studies — Part 1: Male condoms, clinical function studies based on self-reports
- [ISO 29943-2:2017](#) - Condoms — Guidance on clinical studies — Part 2: Female condoms, clinical function studies based on self-reports



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Projects in Progress:

- **ISO CD 7439: Copper-bearing contraceptive intrauterine devices — Requirements and tests**
- **ISO AWI 8009: Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests**
- **ISO AWI TR 22406: Clinical studies on biomarkers for semen exposure — New research tool for condom studies**
- **ISO AWI TR 23148: Compatibility of lubricants with synthetic male condoms**



ISO TC 157 – Work

“Non-systemic contraceptives and STI barrier prophylactics”

Projects in Progress:

- **ISO AWI 23533: Synthetic polyisoprene latex male condoms — Requirements and test methods**
- **ISO AWI TR 23660: Handling used condoms returned to manufacturer or research centre**
- **ISO CD 24484: Female condoms — Guidance on the use of ISO 25841 in the quality management female condoms**



ISO TC 157 – Participation

- **NSB (member bodies) to contact ISO CS and initiate participation**
- **National mirror committees**
- **Access to documents and participation and contribution to development of standards, Participation in WG/TG**
- **Get advance information of developments**
- **Enable preparation for implementation**
- **Harmonization of standards**
- **Implementation**

The United Nations
sexual and reproductive
health agency

Ensuring
rights and choices
for all

UNFPA

