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BUREAU OF INDIAN STANDARDS

AGENDA

Technical Textiles for Medtech Applications Sectional Committee, TXD 36 **24th Meeting**

Date	Time	Venue
07 November 2023 (Tuesday)	1030 h	Video Conference through CISCO Webex

CHAIRMAN: **Dr. Prakash Vasudevan, Director**
The South India Textile Research Association, Coimbatore

MEMBER SECRETARY: **Shri Dharmbeer, Scientist D/Joint Director, 'Textiles'**
Bureau of Indian Standards, New Delhi

Item 0 WELCOME & INTRODUCTORY REMARKS

Item 1 CONFIRMATION OF THE MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 23rd meeting of the TXD 36 committee held on 04-08-2023 through CISCO Webex Videoconferencing were circulated vide our reference TXD 36/A 2.23 email dated 30 August 2023.

No comments were received.

1.1.1. The Committee may **APPROVE** the minutes as circulated.

Item 2 SCOPE AND COMPOSITION OF TXD 36

2.1 The present scope and composition of the committee is given in **Annex 1 (Pages 6-8).**

2.1.1 The Committee may **REVIEW**.

2.2 It has been informed by Shri Rakesh Sahni that due to global restructuring plan of Johnson & Johnson, the Consumer Health Business of Johnson and Johnson Private Limited in India has demerged and transferred to a new legal entity under the name of **JNTL Consumer Health (India) Private Limited** (JNTL) through a Demerger Scheme with effect from 2nd January 2023 itself. **Johnson and Johnson Private Limited** (J&J) continues to operate and retain its Pharmaceutical and Medical Devices divisions in India.

JNTL and J&J wishes to seek modification of the membership with Sectional Committee for Technical Textiles for Medtech Applications TXD36.

Johnson & Johnson Pvt. Ltd will continue to be your committee member as per their existing and current membership and will be responsible for sutures, meshes etc. Mr. Mehul Tyagi and Mr. Aaditya Vats would continue to represent J&J. JNTL will be representing the technical committee for the Sanitary Napkins and other Mensuration health products. Ms. Roocha Khedkar, Dr. Milind Deore and myself will represent on behalf of JNTL.

2.2.1 The Committee may **DECIDE.**

2.3 Shri Madhan R has requested for membership of TXD 36. He has done Diploma (Handloom Technology), B,Tech (Textiles Technology), MBA (International Business), and is working as an ASSISTANT QUALITY MANAGER in Manjushree Spntek Pvt Ltd, Bangalore since 06th July 2022. He has 18 years' experience in Quality Management Systems as per ISO 9001, ISO/IEC 17025, Medical & Hygiene conversion industries, Physical & Chemical testing of Textile materials.

2.3.1 The Committee may **DECIDE.**

2.4 Dr Michael Rodrigues, CareNow Medical Pvt. Ltd., Coimbatore has requested for membership of TXD 36. He has done B.Tech, M.Tech, Ph D in Textiles and have 23 years of experience in the Production and research of advanced wound care products, Implantable meshes, Sutures and artificial Tendon, Ligaments and Drug delivery products.

2.4.1 The Committee may **DECIDE.**

2.5 Smt. Komal Sharma, Regulatory Affairs- Product Manager, Kimberly Clark Pvt. Ltd., Mumbai has requested to become member from industry in TXD 36. She has completed Master in pharmacy (Quality Assurances) and have 9+ years' experience in regulatory affairs for diaper and sanitary pads.

2.5.1 The Committee may **DECIDE.**

2.6 Shri Ashish Naik, Swara Baby Products Pvt. Ltd. and Shri Kavinder Kumar, Solis Hygiene Pvt. Ltd. have requested to become member from industry in TXD 36. They have 18 years' experience in baby diaper Industry.

2.6.1 The Committee may **DECIDE.**

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETING OF TXD 36

3.1 Summary of actions taken on the various decisions of the 23rd meeting is given in **Annex 2 (Pages 9-11).**

3.1.1 The Committee may **NOTE**.

Item 4 DRAFT AMENDMENTS FOR FINALIZATION

4.1 As decided by the committee in last meeting, the following draft standard was issued in wide circulation for two months for eliciting comments from stake holders vide our letter reference no. TXD 36/22466 dated 12-07-2023: -

i) Doc: TXD 36 (22466), Guidelines for Reprocessing of Multiple Use Healthcare Textiles

The last date for comments was 10 September 2023.

The draft standard as issued under wide circulation is given at **Annex 3 (Pages 12-38).**

The comments were received from Dr. Gurjeet Singh, Maharishi Markandeshwar Institute of Medical Sciences and Research, Ambala and Hospital Planning Sectional Committee MHD 14. The comments are given at **Annex 4 (Page 39).**

4.1.1 The Committee may **DECIDE.**

Item 5 RESEARCH AND DEVELOPMENT PROJECT

5.1 New Subject - Surgical Sutures (Absorbable and Non-Absorbable)

The subject of surgical suture was identified in the Standards National Action Plan 2022-27 for the formulation of a Indian standard. It is proposed that this subject may be taken up as an R&D project. The proposed ToR has been prepared and given in **Annex 5 (Pages 40-43).**

The guidelines for research & development projects for formulation of new standard and review of standards is given in **Annex 6 (Pages 44-61).**

5.1.1 The Committee may **DECIDE.**

Item 6 COMMENTS ON PUBLISHED STANDARDS

6.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

In the last meeting of TXD 36, the committee decided to constitute a panel under Convenorship of Ms. Shradha Dongre, SASMIRA, Mumbai (Convenor) to review the comments received on IS 5405 and IS 17514. The committee requested panel to discuss the following comments/parameters/aspects on IS 5405 and IS 17514 and provide its recommendation: -

i) Comments received from Shri D. Veera Subramanium, SITRA, Shri Abhisek Saini, Lending Hand Foundation, New Delhi and Ms. Roocha Kedkar, Johnson & Johnson Ltd. (Kvenue), Mumbai.
ii) The disclosure of material and chemical ingredient used in the sanitary pad.
iii) The chemical compound/substances, frequency and requirement of Volatile Organic Compound test.
iv) Any other technical information/suggestion

The panel meeting was convened on 29th September, 2023. The agenda and minutes of panel meeting are given **Annex 7 (Pages 62-73).**

The comments were also received from JNTL Consumer Health (India) Pvt Ltd, Mumbai; and Procter & Gamble, Mumbai which are given **Annex 8 (Pages 74-106).**

6.1.1 The Committee may **DECIDE.**

6.2 IS 758 : 2023, Medical Textiles — Absorbent Cotton Gauze — Specification (Fifth Revision)

The comments received from CMD-2 of BIS on above standard are provided as follows :-

'For the optional test of sterility, the requirement specified is "complies with test" and the method given is IS 10150. IS 10150 is revised as IS/ISO 11737-1:2018 but this standard is only a guide for on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product and does not specify any bioburden level or objective criteria for establishing conformity to this requirement.

Bioburden level or objective criteria for establishing conformity to this requirement may be specified'

6.2.1 The Committee may **DECIDE.**

6.3 IS 17508 : 2020, Disposable Adult Incontinence Diaper - Specification

The proposed amendment 1 to IS 17508 (similar to IS 17509 Baby diaper, IS 5405 Sanitary Pad) after including the phthalate test has been prepared and given in **Annex 9 (Page 107).**

6.3.1 The Committee may **DECIDE.**

Item 7 INTERNATIONAL ACTIVITIES

7.1 CIB (Committee Internal Ballot), N59 - Draft ISO TC 338 Strategic Business Plan for comments

ISO/TC 338 secretariat issued a Committee Internal Ballot (CIB) for comments of member countries. The document was circulated to committee member/expert vide email dated 25 October 2023 for their comments and views. The last date of comments was 31 October 2023. The comments are yet to be received.

The document is given at **Annex 10 (Pages 108-135).**

7.1.1 The Committee may **DECIDE.**

7.2 The panel meeting of working group WG 1 'general requirement' and Adhoc Group for terminology under ISO/TC 338 were held on 06-07 September 2023 and 27th September/30th October 2023 through virtual mode.

The minutes of the panel meeting for WG 1 'general requirement' and Adhoc Group for terminology are given at **Annex 11 (Pages 136-152).**

7.2.1 The Committee may **NOTE.**

7.3 3rd plenary meeting of ISO/TC 338 'Menstrual Product' has been scheduled on 08th December 2023 through virtual mode. The meeting notice and agenda has been given in **Annex 12 (Pages 153-156).**

The committee may decide the participation of delegation and India point of view on relevant agenda item.

7.3.1 The Committee may **NOTE.**

Item 8 DATE AND PLACE OF NEXT MEETING

Item 9 ANY OTHER BUSINESS

ANNEX 1
(Item 2.1)

Scope and Composition of Technical Textiles for Medtech Applications, TXD 36

Scope: To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.

Meeting(s) held	**Date & Place**
21st Meeting	27 March 2023 (Through VC)
22nd Meeting	09 June 2023 (Through VC)
23rd Meeting	04 August 2023 (Through VC)

SL NO.	ORGANIZATION REPRESENTED	NAME OF THE REPERESENTATIVE PRINCIPAL/(ALTERNATE)	ATTENDANCE
1.	**Director, SITRA**	**Dr. Prakash Vasudevan** (Chairman)	3/3
2.	3 M India Limited New Delhi	Shri Kulveen Singh Bali (Smt. Prabha Hegde)	1/3
3.	Alpha Foam Ltd., Pune	Shri Rajiv Ranka (Shri Apurva Ranka)	3/3
4.	Association of Indian Medical Device Industry (AiMeD), New Delhi	Shri Amit Kumar (Smt. Rama Venugopal)	1/3
5.	All Indian Institute of Medical Sciences, New Delhi	Dr. Vijaydeep Siddharth (Dr. Anoop Daga)	1/3
6.	Business Coordination House New Delhi	Shri Kanav Gupta Smt. Ritika Gupta	3/3
7.	Cologenesis Healthcare Pvt. Ltd, Salem	Shri R Krishana Kumar Shri K. Ramprasad	1/3
8.	Defence Research & Development Establishment (DRDE), Gwalior	Dr. Vikas B. Thakre (Shri Suraj Bharati)	2/3
9.	DGAFMS, Ministry of Defence, New Delhi	Surg Capt S.S Dalawayi (Surg Lt Cdr Kotian V. Gopal)	2/3

10.	DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar (Shri Arnab Das)	3/3
11.	Dima Products, Mumbai	Shri Nirav Mehta	3/3
12.	Director General of Health Services, New Delhi	Dr. Naresh Panchal (Dr. B. S. Charan)	3/3
13.	Dispoline India Private Limited, Bangalore	Shri Sumit Marwah	3/3
14.	DMSRDE, Kanpur	Dr. Mukesh Kumar Sinha	1/3
15.	Dr. Sabharwals Manufacturing Labs Pvt Ltd Panchkula	Shri Manish Sabharwal (Shri Dhruv Sabharwal)	3/3
16.	Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr. Sanjiiv Rehlan (Ms Tulsi)	3/3
17.	Ginni Filaments Limited NOIDA	Shri Pramod Sharma	3/3
18.	Govt. Medical College & ESI Hospital, Coimbatore	Dr. N. Tamilselven (Dr. K. Kulendaivelu)	0/3
19.	Indian Council of Medical Research, New Delhi	Dr. Sadhana Srivastav	1/3
20.	Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal (Prof Bipin Kumar)	2/3
21.	Indian Technical Textile Association	Dr. Anup Rakshit (Shri Mahesh Kudav)	2/3
22.	Johnson & Johnson Ltd. Mumbai	Ms. Roocha Khedkar	3/3
23.	KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade (Shri T. Balaji)	3/3
24.	Kovai Medical Center and Hospital, (KMCH), Coimbatore	Dr J. Jayalakshmi	1/3
25.	Livinguard Technologies Pvt. Ltd., Mumbai	Ms. Shivani Swamy (Shri Virendra Madiyar)	3/3
26.	Maulana Azad Medical College, New Delhi	Dr. Pawanindra Lal (Dr. Kirti Nath)	1/3
27.	Medline Healthcare Industries Pvt. Ltd, Pune	Mr. Anothony D' Costa (Shri Dhaval Ghuge)	3/3

28.	Ministry of Textiles (NTTM), New Delhi	Nomination awaited	0/3
29.	National Physical Laboratory, New Delhi	Dr. Suraj Khanna	3/3
30.	Nobel Hygiene, Mumbai	Shri Joy Devassy (Smt. Sneha Gupta)	2/3
31.	Office of the Drug Controller (CDSCO), Delhi	Dr. Ravikant Sharma (Mr. Arvind Hiwale)	1/3
32.	Office of the Textile Commissioner, Mumbai	Shri Sivakumar S. (Shri Narottam Kumar)	1/3
33.	PGIMER, Chandigarh	Dr. Pankaj Arora (Dr. Vijay Tadia)	3/3
34.	Procter and Gamble Co., Mumbai	Shri Prashant Jadhav (Shri Girish Parhate)	1/3
35.	South India Textile Research Association, Coimbatore — 641014	Shri S. Sivakumar (Dr. E. Santhini)	3/3
36.	Surya Textech, Chandigarh	Shri Khalil Khan (Shri Yogesh Yadav)	3/3
37.	Textiles Committee Mumbai	Shri Kartikeyan Dhanda (Dr. P. Ravichandran)	3/3
38.	The Bombay Textile Research Association, Mumbai — 400086	Mrs Aruna Apte	2/3
39.	The Pad Project (NGO), India	Smt. Tanya Mahajan	1/3
40.	The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur (Mrs. S. S. Dongre)	3/3

ANNEX 2
(Item 3.1)

SUMMARY OF ACTIONS TAKEN ON THE MINUTES OF 23rd MEETING OF TXD 36

Item No.	Decision	Action taken
2.1	Certain modifications were suggested in the composition of the committee.	Updated composition is given in **Annex 1**
4.1	**DRAFT AMENDMENTS FOR FINALIZATION** **4.1** 1) Amendment No. 3 to IS 5405 : 2019, Sanitary napkins — Specification (second revision) [Doc: TXD 36 (22464)] 2) 2) Amendment No. 3 to IS 17514 : 2021, Reusable Sanitary Pad/Sanitary Napkin/ Period panties — Specification [Doc: TXD 36 (22465)] The committee decided that the above draft amendments as given in agenda are FINALIZED for publication as amendments to Indian Standards. The committee decided to constitute a panel under Convenorship of Ms. Shradha Dongre, SASMIRA, Mumbai in IS 5405 and IS 17514.	Under Publication Coming up for discussion under agenda item **6.1.**
5.1	**DRAFT AMENDMENT FOR WIDE CIRCULATION**	

	Amendment 1 to IS 17354 : 2020, Medical Textiles — Dental Bib / Napkins — Specification The committee decided that the draft amendment shall be issued in wide circulation for 2 months for eliciting technical comments.	Under preparation
6.1	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** IV Dressings (Film/Non-Woven), Synthetic Orthopaedic Cast Bandage, Synthetic Orthopaedic Cast Splint, Burn Sheet, Medical Wipes The committee requested the following committee members to share the additional inputs on scope, raw material/fabric, workmanship and finish, performance requirement, sampling, packing and marking on the above subjects: - 1) Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi 2) Dr. Prabha Hegde, 3 M India, Bengaluru 3) Shri Khalil Khan, Surya Textech, Chandigarh 4) Shri T. Balaji, KOB Medical Textiles 5) Dr. Michael Rodrigues, Healthium Medtech, Coimbatore 6) Shri Gurmeet Singh, Ginni Filament, Noida	The inputs are yet to be received.
6.2	**NEW SUBJECTS FOR FORMULATION OF INDIAN STANDARD** Sterilization wrap, scrub suits, Sutures and Other Subjects	Suture is coming for discussion under **agenda item 5.1.** The technical inputs on the other subjects are yet to be received.
7.1	**COMMENTS ON PUBLISHED STANDARDS** **IS 17334 : 2019, Medical Textiles — Surgical Gowns and Surgical Drapes — Specification** The committee decided that the draft revision of above standards shall be issued in wide circulation for a period of two months for eliciting technical comments	Under preparation

7.2	**COMMENTS ON PUBLISHED STANDARDS** **IS 17351 : 2020, Medical textiles – Dressing, shell compressed – Specification** The committee decided that the requirement as per defence standard on compressed dressing cell shall be incorporated in the existing standard in consultation with Dr. Dr. Manish Sabharwal, Dr. Sabharwal Wound Care, Baddi and Directorate of Standardization (DoS), Ministry of Defence	The inputs are yet to be received.
8.1	**INTERNATIONAL ACTIVITIES** **Committee Internal Ballot (CIB) - ISO TC 338 N 38 Menstrual Products — Terminology** The committee decided that the above Ballot shall be approved for voting.	Ballot Approved
8.2	**INTERNATIONAL ACTIVITIES** **ISO/NP 20384, Surgical clothing and drapes — Requirements and test methods** The committee approved the nomination of the following experts for active participation in development of Project/International Standard on ISO/NP 20384, Surgical clothing and drapes — Requirements and test methods: - a) Shri Sumit Marwah, Dispoline India Private Limited, Bengaluru b) Dr. Sanjiiv Rehlan, Representing FICCI, New Delhi c) Head (Textiles) and/or Member Secretary, TXD 36, BIS New Delhi	Ballot Approved and experts nominated.
9.1	**REVIEW OF PUBLISHED STANDARDS** Standards due for review and pre-2000 standards	Standards Reaffirmed. Draft revision under preparation.

ANNEX 3
(Item 4.*1*)

DRAFT STANDARD FOR FINALIZATION

Doc: TXD 36 (22466)

Draft Indian Standard

Guidelines for Reprocessing of Multiple Use Healthcare Textiles

FOREWORD

(Formal clause will be added later)

With the rise in the demand of reusable (multiple use) healthcare textiles, it is more imperative than ever that these products are to be processed according to the highest standards of infection prevention, quality, and safety.

Concern is rising about the risk of spreading infections from reusable healthcare textiles/linen used in healthcare setting (bed sheets, blankets, towels, personal clothing, patient apparel, uniforms, scrub suits, gowns, and drapes etc.) to patient, healthcare personnel, staff and the public, if not washed under a monitored environment. Reusable textiles used in healthcare settings can be a component in the chain of infection transmission.

The risk is greater in such cases because contaminated garments have to be handled properly. Such garments can be a source of microbes, if the laundry process fails to eliminate contamination, it can spread to the other items in the laundry load. For example, if laundry is left damp, this encourages microbial survival and residual microorganisms could grow. A healthcare facility can avert this risk by having these garments professionally laundered by a hygienically clean healthcare certified linen & uniform service. Thus, laundering is a very necessary process in the life cycle of reusable textiles.

However, this process consumes large amounts of water and consequently produces the same amount of wastewater. And, even if the resulting wastewater is fully treated and recycled to reducedetrimental effects to the environment, there is still the problem of energy consumption during thelaundry operation. From a material life cycle perspective, however, reusable textiles (woven or knitted) have the advantage of a longer lifetime, capable of surviving up to 50 or more hospital laundry cycles and thereby offering an additional saving to users and the environment.

This recommended practice is intended to provide guidelines that will help material managers, laundry managers, central service managers, and other health care professionals implementeffective quality assurance systems for the processing of reusable healthcare textiles. The guidelines provided may also be useful to hospitals/users in evaluating the capabilities of facilities being considered for the processing of reusable healthcare textiles.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*).'

1 SCOPE

1.1 This standard provides the general guidelines for re-processing of reusable healthcare textiles under hospital laundry whether in-house or outsourced laundry services. The re-processing guidelines are applicable to hospital laundry in the following areas:

i) Hospitals – private, public and any extended healthcare facilities
ii) Clinics
iii) Dental Services
iv) Nursing homes
v) Mental health institutions
vi) General healthcare centres etc.

1.2 This standard generally covers reusable healthcare textiles for general ward linens and operating theatre textiles such as

i) General purpose linen — Patient care like curtains, drapes, table clothes and similar itemscommonly used in all parts of the hospital.
ii) Patient linen — Patient clothing such as pyjamas, shirts, gowns, coats etc. worn by patients.
iii) Bed linen — Bed clothing such as bed sheets, pillow covers, blankets used by the patient.
iv) Operation theatre (OT), labour room, procedure room linen —Items such as pyjamas, kurtas, gowns, coats, shirts, surgical gowns, caps, masks etc. worn by healthcare personneland also trolley covers, towels required in operation theatre, labour room and procedure room.

1.3 This standard does not cover the following: -

i) Design, specification or construction criteria for machine and equipment used to processing of reusable healthcare textiles;
ii) Criteria for staff qualification who handles the re-processing of healthcare textiles.
iii) The application of any sterilization technology or sterility assurance practices;
iv) Selection of reusable healthcare textiles;
v) Performance standards for reusable healthcare textiles

vi) Other laundry service purpose like commercial, hotel, industrial and institutional laundry,etc.

2 REFERENCES

The standards listed below contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

LIST OF REFERRED INDIAN STANDARDS

IS/Other Publication	*Title*
IS 201 : 2022	Quality tolerances for water for textile industry (*third revision*)
IS 1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of pH of aqueous extract (*third revision*)
IS/ISO 10993-7 : 2008	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
IS/ISO 11137-1: 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
IS/ISO 11137-2: 2013	Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose
IS/ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 11607-1: 2006	Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems
IS/ISO 11607-2: 2006	Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes

ISO 11138-7: 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 17665-1 : 2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions shall apply:

3.1 Barrier Properties — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms, blood, and OPIM.

3.2 Bio-hazardous bags — Bags used to collect, compile, pack, and dispose the harmful and infectious wastes that are generated by the clinical laboratories, healthcare facilities, and pharmacy industries.

3.3 Bleaching — Use of an oxidizing agent (usually sodium hypochlorite or hydrogen peroxide)within a laundry formula to decompose some types of stains and/or disinfect contaminated textiles

3.4 Blood-borne Pathogen — Infectious microorganisms including virus carried in blood or otherbody fluids.

3.5 Body Fluids — Any liquid produced (secreted/ excreted) by body.

3.6 Calendaring – Calendaring is a finishing process used on cloth in which fabric is passed between rollers at high temperatures and pressures.

3.7 Centrifuging — Excess water from the washed clothes are spin-out of fabric which facilitates faster drying.

3.8 Cleaning — The process to physically remove contamination by foreign material, e.g. dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a healthcare textiles for disinfection or sterilization.

3.9Cleanliness–microbial — Freedom from population of viable microorganism on a product and/ or a package.

3.10 Cleanliness–particulate Matter — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.11 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.12 Contaminated — State of having been actually or potentially in contact with microorganisms.

3.13 Contamination — The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

3.14 Decontamination — The use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

3.15 Detergent — A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. Detergents are needed to allow effective cleaning to take place.

3.16Disinfection — Process that kills pathogenic and other microorganisms by physical or chemical means.

3.17 Doffing — Removal or take off of protective materials such as gloves, aprons, and so on.

3.18 Effluent – Effluent is wastewater from sewers or industrial outfalls that flows directly into surface waters either untreated or after being treated at a facility.

3.19 EPA – Environmental Protection Agency.

3.20 Extraction — Use of physical forces (usually centrifugal or strike/impact) to remove excesswater from a wash load prior to drying.

3.21 Germicide — a substance or other agent which destroys harmful microorganisms.

3.22 Health Care Facility — means a place where diagnosis, treatment or immunization of human beings is provided irrespective of type and size of health treatment system, and research activity pertaining thereto. Health care facilities includes District Hospitals, Sub Divisional Hospitals, Community Health Centres, Primary Health Centres and Sub centres.

3.23 Healthcare Personnel (HCP) — Refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (for example blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminatedair. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (for example clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient carebut potentially exposed to infectious agents that can be transmitted among from HCP and patients.

3.24 Healthcare Textiles —Healthcare textiles materials are mainly used for protection from infections in hospital environment. They are used either in the operation theatre or in the hospitalwards for safety of healthcare personnel/staff, doctor and patients. For example, bed sheets, blankets, towels, patient apparel, uniforms, scrub suits, coverall, mask, cap, gowns, and drapes etc.

3.25 Hospital Acquired Infection (HAI) – A hospital-acquired infection (HAI) is an infection whose development is favoured by a hospital environment, such as one acquired by a patient during a hospital

visit.

3.26 Hospital Linen — Refers to all textiles used in the hospital including mattress, pillow covers, blankets, bed sheets, towels, screens, curtains, doctors' coats, theatre cloth and table cloths etc.

3.27 Hydro-extraction – It is a process of extracting water from the textiles usually done after laundry.

3.28 Infected textiles — Textiles which holds pathogenic disease-causing bacteria or virus.

3.29 Infective Agent — Microorganism that has been shown to potentially cause infections.

3.30 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa.

3.31 Laundry Processes — Activities that encompass the handling, washing, and drying of soiled textiles.

3.32 Liquid Penetration — Migration of liquid(s) through the material.

3.33 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.34 Microbial Penetration — Migration of microorganisms, from one side of the material through the other.

3.35 Microorganism — Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

3.36 OT – Operation Theatre.

3.37 Other Potentially Infectious Materials (OPIM) — Any materials, other than blood or body fluids, containing blood-borne pathogens or materials that have been linked with the potential transmission of infectious disease.

3.38 Personal Protective Equipment — Commonly referred to as "PPE", is specialized clothing or equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological,physical, electrical, mechanical, or other workplace hazards.

3.39 pH – A measure of how acidic or basic a substance or solution is.

3.40 Processing Area — Area of the laundry containing the processing equipment used to decontaminate and clean soiled textiles.

3.41 Protective Textiles — Used to prevent or minimize exposure to hazards biological hazards.

3.42 Reprocessing — All steps that are necessary to make a contaminated reusable healthcare textile ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilization.

3.43 Reusable/Multiple Use Product — Product intended by the manufacturer to be reprocessed and reused.

3.44 Rinsing — An operation designed to remove all suspended soils, soaps, detergents and bleachfrom the textiles being laundered.

3.45 Scrub suits — Loose-fitting, usually two-piece garment, worn by surgeons and assisting personnel in an operating room.

3.46 Single-use /Disposable Product — Product intended by the manufacturer to be used only once.

3.47 Sluicing – It is the process of freeing potentially harmful or infectious substances from laundry and flushing it away prior to the main washing cycle.

3.48 Soiled (Contaminated) Textiles- Textiles that have had potential contact with blood, body fluids, or OPIM.

3.49 Soil-Sort Area — Area of a laundry facility designated for receiving, retention, handling, and sorting of soiled textiles.

3.50 Soil Sorting — Process of sorting soiled items into defined or established categories so thatthey can be laundered together.

3.51 Sterile Field — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.52 Sterilization – Sterilization is defined as a process of complete elimination or destruction of all forms of microbial life (i.e., both vegetative and spore forms), which is carried out by various physical and chemical methods.

3.53 Surgical Gown — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

3.54 Surgical Drape — A covering for the patient for the prevention of transfer of infective agents,such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

3.55 Validation — Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize instruments and other medical devices.

4 GENERAL REQUIREMENT FOR LAUNDRY SERVICES MANAGMENT

4.1 Laundry service in a hospital is one of the major components which directly affects the patient and hospital staff's health and hygiene. It is accountable for supplying clean and adequate linen to the hospital. It includes collecting, sorting, storage and transportation of dirty linen from hospital and washing, disinfection, extracting, drying, ironing, folding, transportation of clean linen from laundry service; back to the hospital and storage of clean linen in the hospital.

4.2 The laundry service shall establish, document, implement and maintain a quality policy for laundry infection control which includes risk management and maintain its effectiveness. The purpose of this policy is the prevention of infection or injury in service users and laundry staff involved in the use, handling or laundering of healthcare textiles. Policies and procedures shall be framed to provide a clear framework for ensuring that all individuals involved in the handling, processing, and transportof used/ soiled healthcare textiles understand their roles and responsibilities forpreventing contamination.

4.3 The supervisors/managers and laundry staff shall be fully trained about the laundry procedure, handing of equipment, machine operation etc. Regular training shall be provided to supervisor and laundry staff about potential infectious hazards and techniques to prevent the spread of micro-organisms in the environment to finished healthcare textiles/linen. The role and responsibility of the supervisors/managers and laundry staff shall be defined by the laundry service provider.

5 LAUNDRY LAYOUT AND DESIGN – GENERAL REQUIREMENT

5.1 The laundry facility in a health-care setting shall be designed for efficiency in providing hygienically clean textiles, fabrics, and apparel for healthcare personnel and patient. The laundry facility shall comply with all the relevant regulatory requirements (amended from time to time) by Govt. of India for facilities and equipment. Maintaining hygiene and clean environment at laundry facility is essential for ensuring products that are appropriate for consumers use. Following are recommended guidelines for ensuring adequate infrastructure, hygiene and clean environment at laundry facilities:

i) Location of laundry facility should be free from objectionable odours, smoke, dust and other contaminants.
ii) The building shall be of adequate size to hold the required equipment, services and systems,and afford comfort to and protection of staff, equipment and goods.
iii) The laundry facility shall be designed to have a physical barrier or functional separation between areas in which soiled textiles are received and processed and areas in which clean textiles are handled and stored for distribution to the pack assembly area. This is done to prevent cross-contamination and maintain hygiene standards.
iv) A laundry facility is usually partitioned into two separate areas - a "dirty" area for receiving and handling

the soiled laundry and a "clean" area for processing the washed items.

v) If healthcare textiles are processed outside the building (off site laundry), provisions shall be made for a service entrance, protected from inclement weather, for loading and unloading of healthcare textiles; an area for pick-up and receiving.

vi) Machine, equipment and systems shall be designed to reduce the risk of injury to operators/staff and to provide safe working conditions particularly with respect to odours, noise, lighting, heating, cooling, standing, sitting, stretching, bending and lifting.

vii) Work area design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas.

viii) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors,walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.

ix) Appropriate lighting and proper ventilation of the facility shall be ensured.

x) Separate areas shall be demarcated for sorting/collection, handling, segregation of soiled and cleaned products. Dedicated areas for washing, disinfection, sterilization and packing of cleaned healthcare textiles shall be provided.

xi) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.

xii) All personnel involved in the collection, transport, sorting, and washing of soiled linen shall be adequately trained and wear appropriate personnel protective equipment (PPE).

xiii) The standard operating procedures (SOPs) should be developed and implemented to ensure that all the employees/staff shall follow the same procedures for handling contaminated materials and minimizing exposure to bloodborne pathogens.

xiv) To minimize the potential for re-contaminating cleaned laundry with aerosolized contaminated lint, areas receiving contaminated textiles should be at negative air pressure relative to the clean areas.

xv) Toilet and hand-washing station shall be provisioned away from cleaning and storage area.

xvi) There should be an eyewash station located near the equipment(s) where staff/workers are handling chemicals or other hazardous materials.

xvii) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility. Hand hygiene shall be practiced before packing of cleaned products.

xviii) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility,machine, equipment, toilets, washing areas, waste receptacles and for cleaning/ disinfection of the equipment.

xix) Regular pest control measures and fly screen shall be put in place.

xx) Drain outlets carrying effluent from washing machines should be sealed (close piped) into the disposal system. If a washing machine drains into an open sump, this should, where practicable, be covered to prevent the spread of organisms by aerosol when the water is dumped from the machine and also to minimize the potential chemical hazardfrom splashing.

xxi) The humidity should not exceed 65 percent and the temperature should be in a controlled condition from 20°C to 27°C. If the laundry facility is in the basement, adequate ventilation will be provided through proper installation and management of heating, ventilation, and air

conditioning (HVAC), fresh air blowers and exhaust lines.

xxii) The environment should be made as comfortable as possible, which can generally be accomplished by proper ventilation in the work area.

xxiii) The exhaust in the laundry section should be provided with the necessary filters to capture the dust and lint.

5.2 The laundry service layout and process flow are given in FIG 1 and FIG 2 for guidance only.

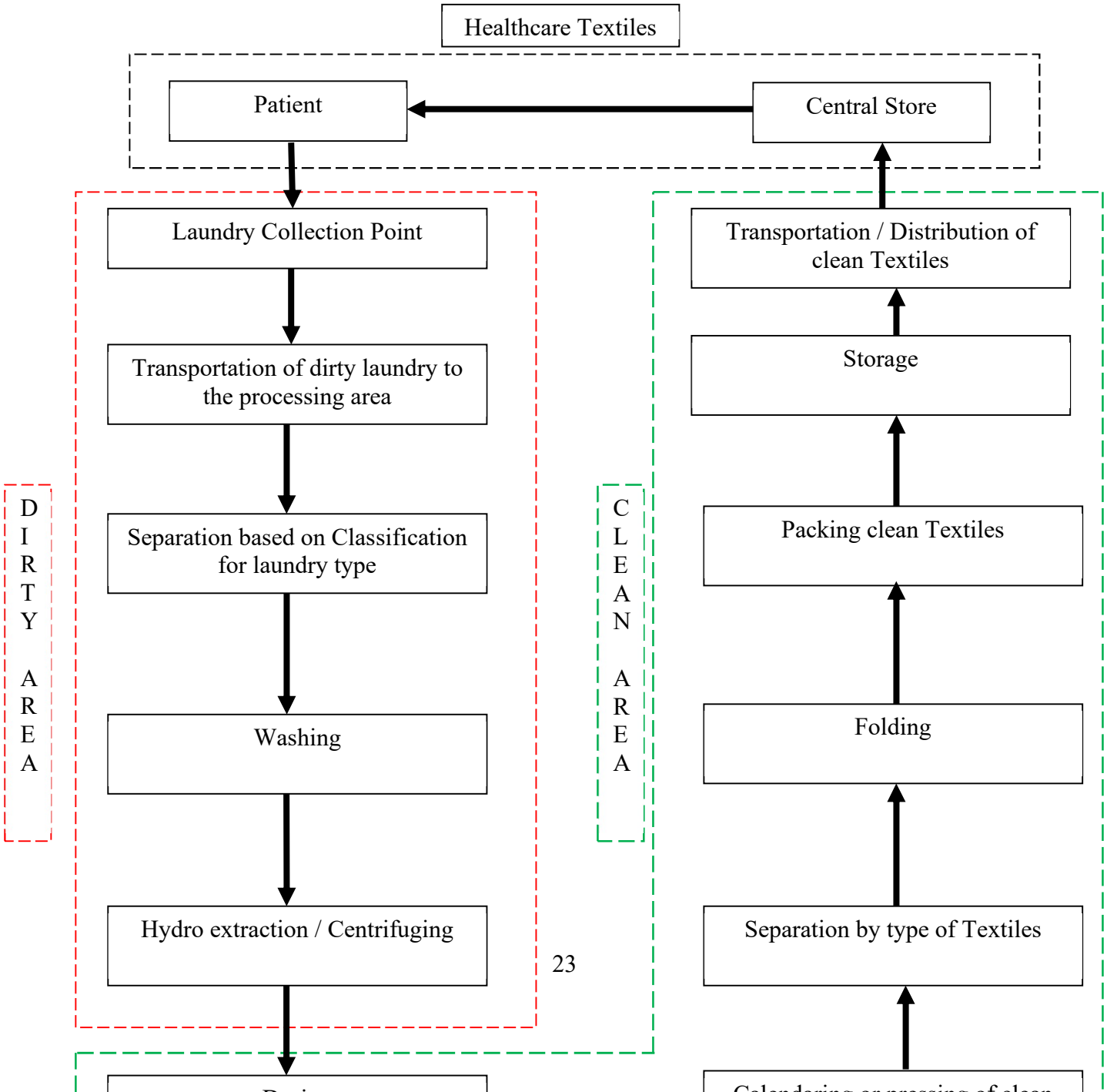

FIG 1 LAUNDRY LAYOUT

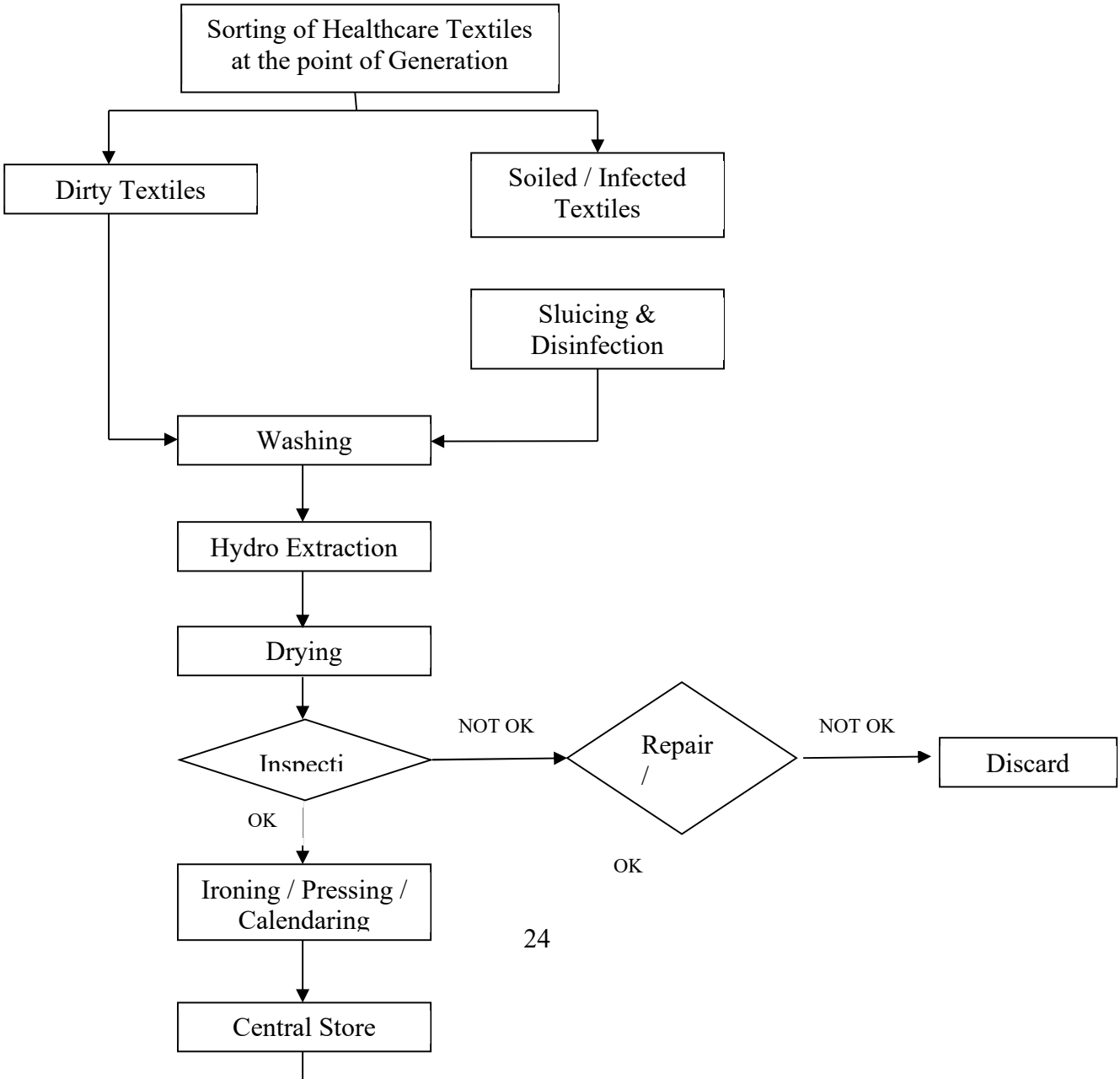

FIG 2 LAUNDRY PROCESS FLOW

6 COLLECTION AND SEGREGATION OF SOILED MATERIAL

6.1 The soiled/contaminated healthcare textiles are collected from the patient wards, patient-care areas, surgical areas, operation theatres and clinical laboratories in bio-hazardous bags. The soiled healthcare textiles may be sorted out in two ways - pre-sort systems and post-sort systems. Pre-sort systems involve sorting soiled healthcare textiles at the point of use, before they are transported to the laundry soil-sort area. Post-sort systems involve sorting soiled healthcare textiles in the laundry soil-sort area, after they have been transported from the point of use.

6.2 Sorting must be performed carefully as the textiles from operating room or other procedure areas may often contain sharps (suture needles, razor blades, scalpel blades etc.) and the bedding from patient's rooms may contain soiled dressings or bloodstains, as well as other body fluids. Such materials should be handled cautiously by wearing gloves, goggles, apron of high protection and disposed after sorting.

6.3 Disposable gloves and personnel protective equipment shall be used during collection and the person should not touch his/her personnel before doffing. The bags and gloves should be leak proof and possess for optimum tensile strength and high thickness. The contamination levels of the collected healthcare textiles are identified by the colour codes or labelling the bags.

6.4 The textiles with soil stain and dirt to be segregated in one cluster and the material with blood stains and infected textiles from operation theatre are to be grouped separately based on the hazardous rate, nature and depth of the stain. Segregation reduces the exposure of laundry workers to the infected material. It protects the textile and processing machinery from hard objects such as needles, syringe and sharp objects from patients.

6.5 The soiled textile materials are removed carefully by folding and rolling to avoid unnecessary agitation and directly placed into the appropriate bags. Separate areas should be used for the processing of soiled textiles from those used for folding clean healthcare textile, patient wards and food preparation areas. The areas for clean and soiled healthcare textiles should be adequately ventilated and separated by physical hindrance.

6.6 The following instruction and information should also be monitored at collection and segregation area in laundry service in healthcare facility: -

i) Hospital should have organize a daily schedule for the collection of healthcare textiles.

ii) Extra care should be taken before collection to ensure that there is no non-textile items namely syringes, needles etc. are presented.

iii) Reusable healthcare textiles from operation theatre, procedure areas and patient wards should be changed on daily basis and the healthcare material of hospital staffs should be replaced weekly.

iv) Whenever any reusable healthcare textile material is visibly dirty or soiled in the hospital,it should be changed.

v) Hand hygiene should be followed strictly before and after handling of the healthcare textiles. In case of any skin lesions, it should be covered properly.

vi) Infected textiles must be collected only in bags and should not be placed in any other surfaces. It should be stored only in the designated area.

vii) Different colour codes or labels should be followed for distinguishing the textiles collected from different areas.

viii) The supervisor/in-charge of the area should update the daily records every time when the soiled or infected textile is collected from the area. It includes the type and number of items collected from the particular area. The record of soiled/infected healthcare textiles should be maintained for different areas for the same.

7 TRANSPORT OF CONTAMINATED HEALTHCARE MATERIALS TO RECEIVING AREA OF LAUNDRY

7.1 Soiled healthcare textiles collected from various areas of the hospital should be transported in different trolleys, bins, bags or other transport means. Transportation of soiled healthcare textiles is an important aspect of the overall process of handling these materials. Proper transportation procedures help to minimize the risk of infection transmission and ensure that textiles are effectively cleanedand disinfected.

7.2 Healthcare textiles collected through chutes should have proper design, and maintained periodically as the piston-like action of a laundry bag traveling in the chute can propel airborne microbial contaminants throughout the facility. It should be maintained in negative air pressure to avoid the transmission of microbes from floor to floor. Laundry personnel who receives the reusable healthcare textiles must enter the details in the receiving and distribution register which includes the type and quantity of item received, department that receives the material, date and time of receiving.

7.3 The following the key steps involved during transportation of contaminated healthcare textiles to receiving area of laundry service: -

i) Soiled materials should be transported in separate trolleys, bins, bags or other transport means.

ii) The containers for transportation shall be selected based on their ability to contain the materials being transported, as well as their durability and ability to prevent leaks or spills.

iii) Dedicated trolley/container should be used for transportation and the trolleys used for any other purposes should not be used.

iv) While transportation, it is to be ensured that that the collection bags are leak-proof and tied firmly.

v) In case of any leakage of infected textile materials during transport, it needs to be placed securely in the trolley and the spilled surface should be cleaned as per the spill management protocol of the hospital.

vi) Loose and contaminated pieces of healthcare textiles should not be placed in transport media to prevent the contents from falling out.

vii) The hospital must keep records for laundry management of healthcare textiles to ensure quality.

8 PRE-TREATMENT/DISINFECTION BEFORE WASHING

8.1 Heavily soiled textiles may sometime require additional pre-treatment, such as soaking in chemical/disinfectant/spot cleaning, before laundering to ensure that all soil is removed. Healthcare textiles used during radiotherapy also require special handling and washing to ensure they are properly disinfected and free of any radioactive particles.

8.2 The laundry service in healthcare facility shall decide the suitable and effective reprocessing and disinfection method depending upon fibre content of fabric, manufacturing process, design, level of contamination, anticipated risk, type of coating etc. The most common method used for disinfection of soiled healthcare textiles is by using sodium hypochlorite solution. Hydrogen peroxide is also used as disinfectant for soiled healthcare textiles.

8.3 Disinfecting the contaminated textile material is the first step for processing. Soiled healthcare textiles should be stripped from the bed with care taken not to shake the textiles during this action. It should be soaked in 1:50 hypochlorite solution for 30 min for white textiles and the coloured materials to be processed as per hospital policy where a suitable high-level disinfectant to be used.

8.4 It is then rinsed in water until the residual bleach is removed and handed over for washing. If the laundry services are outsourced, it is the responsibility of the hospital to disinfect and sluice the soiled textile material within the facility itself before handing over the same to the outsourced agency or personnel for further processing.

9 WASHING

9.1 The laundry service in healthcare facility should follow the instruction of manufacturer of the finished healthcare textile product before deciding the washing and drying procedures to be followed. The laundry service shall have ongoing programs that record and monitor all key laundry processes. The programs shall include clear procedures for-

i) Achieving and maintaining effective washing, disinfection, drying, finishing as well as appropriate product life; and
ii) Preventative maintenance systems that ensure correct and safe operation of all plant and equipment including appropriate calibration of all key equipment such as water level controls, agitation level, temperature controls and other process timer controls that ensures compliance and process stability.
iii) The effectiveness of the washing/laundering process depends on many factors like time and temperature, mechanical action, water quality (pH, hardness), volume of the load, extent of soiling, model/availability of commercial washers and dryers.
iv) Bleach/detergent acts as a chemical germicide to kill the microbes present in the contaminated textiles. Chlorine bleach is safer and provide colour safety and better anti-microbial activity. Oxygen-based bleach or detergent registered under Environmental Protection Agency (EPA) or concerned regulatory authority authorities may also be used as an alternative for chlorine bleach.

9.2 Textiles contaminated with blood and body fluids collected in a leak-proof bag should be immersed in compatible disinfectant. Washing of the contaminated textile material should be performed immediately after the removal. During washing soiled healthcare textiles, the washing person should be given PPE.

9.3 The soiled healthcare textiles may be re-processed with hand wash or machine wash at laundry facility as per the agreement between the user and laundry service provider.

9.3.1 Hand Wash

Heavily soiled or contaminated healthcare textiles should be separated from the non-soiled material. The whole material is washed in water with liquid soap to remove the dirt, soil and spillages. The material is pre-soaked only for the soiled or infected textiles. The usage of warm water for washing is preferred based on availability. Add 30 – 60 ml of a 5% chlorine solution (bleach) for cleaning the soiled material and to assist the microbial removal. Add sour (mild acid) for neutralizing and to avoid textile materials from yellowing. Evaluate the final material for its cleanliness (wash again if it is dirty) Rinse the item with clean water.

9.3.1Machine Wash

Soiled textile material is separated from non-soiled and washed heavily. When the wash cycle is complete, check the material for cleanliness. Rewash if it is dirty or stained. (Heavily soiled may require two wash cycles). Dirty healthcare textile is to be washed in the first batch, with plain water and detergent. The commercial hospital laundry detergent as agreed between the buyer and seller may be used. Infected healthcare textiles is derived from known infectious patients, including those withHIV,

Hepatitis B, C and other infectious agents. After sluicing, the infected textile is treated with hot water and detergent.

9.4 Process Parameter

The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean/decontaminate soiled textiles. These individual processes can be adjusted in one washing machines to optimize the productivity of the operation and the performance and durability of the textiles being processed. The parameter for guidance are provided as follows: -

i) The water used for washing should meet the requirement specified in IS 201.

ii) Hot water with temperature > 71°C is recommended.

iii) Bleaching should be performed at 22°C to 25°C for heat sensitive fabrics.

iv) 50 mg/L to 150mg/L of chlorine bleach should be used in rinsing cycles after disinfection.

v) Wash cycle – 30 min.

9.5 Hydro-Extraction and Drying

Washed and clean healthcare textiles should be put in the mechanized hydro-extractor for extraction of water from the processed textiles. If the hospital does not have hydro extracting facility then the healthcare textiles can be air dried in a direct sunlight. During the process of drying of the healthcare textiles it is to be ensured that the material is kept off the ground and away from dust exposure.

9.6 Repair

All the healthcare textile material is checked for any damage, wear and tear. In case of any damage like minor hole or tear observed, it should be sent for repair and mending. The reusable healthcare textiles with crack, hole, tears and stains that cannot be removed should be incinerated. If the textile material is severely damaged and cannot be repaired, the same can be discarded or condemned as per the hospital condemnation policy, by the laundry supervisor.

9.7 Calendaring and Iron

Hospital should have a provision for a calendaring machine for calendaring the heavy reusable textile materials. If the hospital does not have the facility of calendaring machines, the textile material needs to be ironed using flat work iron and should be folded properly.

10 STERILIZATION AND PACKING

10.1 Need of Sterilization

Critical area of healthcare textiles are needed to be sterilized after every wash. Most of the textiles at healthcare facilities which includes surgical drapes and reusable gowns must be sterilized before use and therefore require steam autoclaving after laundering.

10.2 Sterilization Methods

Healthcare textiles that have contact with sterile body tissues or fluids are considered critical items.These items should be sterile when used because any microbial contamination could result in disease transmission. If healthcare textiles are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. However, reprocessing of healthcare textiles which are heat- and moisture-sensitive requires use of a low- temperature sterilization technology like ethylene oxide. The other type of sterilization process may also be used if agreed between the user and laundry service provider.

10.3 Validation of sterilization

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed. Sterilization and validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

10.3 Packing

The sterile healthcare textiles shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. The details of the packing shall be legibly made to provide necessary information for usage including sterilization date, identification, lot details, list of pack contents, etc. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life. For packaging of the products, requirements as per IS/ISO 11607-1 and 2 should be followed.

11 SPECIAL LAUNDRY/OTHER RE-PROCESS CONSIDERATIONS

For reprocessing and disinfection, the manufacturer of the healthcare textiles is required to select and recommend a suitable method/technology for their product. One of the following methods or their combinations as suggested by the manufacturer (complete and detailed protocol for reprocessing, disinfection

and quality control has to be prepared by manufacturer) based on the scientific experimentations, specific to their product and agreed by the user may be used:

1) Washing with detergent;
2) Sodium hypochlorite and/or soap solution;
3) Ultraviolet (UV) irradiation;
4) Gamma and electron beam irradiation;
5) Ethylene oxide sterilization;
6) Vapourised hydrogen peroxide or hydrogen peroxide or gas plasma sterilization; and
7) Steam (autoclaving).

12 STORAGE AND DELIVERY

12.1 General Guidelines

The processed textile is transported in clean covered trolley to the central store. It is to be ensured that the storage of clean healthcare textiles before distribution is separate from dirty material. From the central store the clean textiles is issued to respective departments based on the indent generated from the departments. The clean and hygiene healthcare textile materials is supplied from the central store to respective departments in the clean and closed trolleys. Record of issued healthcare textiles needs to be updated in the central store room while therespective departments need to update the transaction register with the details of textile material received in the department.

12.2 The following instruction shall be followed for storage area in laundry service at healthcare facility: -

i) The trolleys used for transporting clean textiles should be washed routinely. It should be washed in a washing station after use and clean trolleys should be separated.

ii) Good ventilation systems to prevent the accumulation of soil, dirt and micro dusts.

iii) Sewage apertures or water pipers should not be present near the storage area.

iv) The shelves for storage placed should be 15-20 cm above the floor, 2.5-5 cm away from the walls and 25 cm below ceiling.

v) The storage shelves should be used only for storing clean reusable healthcare textile materials and the door of the storage shelf should be always closed.

vi) The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60%) in all works areas except sterile storage,where the relative humidity should not exceed 70%.

vii) The floors and walls should be constructed of materials capable of withstanding chemical agents

used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

13 RESPONSIBILITIES OF PERSONNEL IN HOSPITAL LAUNDRY SERVICE

13.1 Nursing In-charge

i) Manage the process of collecting and transporting used textiles from the health care facilities.
ii) Ensure that the central laundry documentation reflects infection control requirements.
iii) Observe and monitoring the infection control requirements in the outsourced laundry servicewith a documented book.
iv) Engaging and assisting in the renovation of the laundry department.
v) Infection control basics should be taught annually and prior to starting any new contracts.

13.2 Laundry supervisor

i) Ensure these guidelines are implemented, monitored and supervised.
ii) Establish an open communication channel between the laundry department and the users.
iii) Provide training on these guidelines to all employees in the laundry.
iv) Inspect linen for correct and safe handling.
v) Maintenance and calibration of laundry equipment.

13.3 Laundry Workers

i) Collecting used linen from wards or operation theatre and transporting it to laundry facilities.
ii) The used linen must be sorted, handled by wearing impermeable aprons, gloves and using standard measures.
iii) The safe transportation of clean textiles to departments using closed carts.

Table 1 Responsibilities of Personnel in Hospital Laundry Service

(*Clause* 13)

Sl No. (1)	Steps Involved (2)	Personnel Responsible (3)
i)	Change of linen	Staff nurse/ward attendant
ii)	Sorting and storing of used linen	Ward attendant/housekeeping staff
iii	Disinfection of soiled/infected linen	Housekeeping/laundry staff
iv)	Collection of used/soiled linen	Laundry staff
v)	Counting of collected linen	Laundry staff/nursing in-charge
vi)	Transporting dirty linen	Laundry staff
vii)	Washing, drying and ironing	Laundry staff
viii)	Receipt of washed linen in departments	Nursing in-charge
ix)	Storage and issue of washed linen	Nursing in-charge

14 QUALITY INSPECTION

There are inspection methods which can be done on laundered healthcare textiles to indicate the effectiveness of laundry process performance. Such process performance measures include the results of visual inspection pH tests, residual chlorine spot tests, and cleanliness / microbial load on cleaned healthcare textiles. The user may randomly check the performance requirement of a specific healthcare textiles product as per the Indian Standard published by Bureau of Indian Standard.

14.1 Visual Inspection

14.1.1 Before each reuse, all healthcare textile products should be visually inspected against written quality standards. These standards should be developed by individuals responsible for product inspection, in consultation with end users, and should be based on the functional requirements and the identified important related attributes, which may vary depending on product classification, design, construction, and intended end use. After each laundering, the critical zones of healthcare textiles like gowns, drapes, table covers, and sterilization wraps should be visually inspected with the assistance of a light table to determine if

i) Stain or residue removal is necessary;
ii) Physical defects, such as holes and missing components, need to be repaired;
iii) Chemical or thermal damage needs to be repaired;
iv) Foreign debris (e.g., lint, hair) needs to be removed;
v) Appropriate labels are in place; and
vi) The tracking system is intact.

14.1.2 The written quality standards should define the acceptance and rejection criteria for each product type and explain how rejected items should be handled. Depending on the functional requirements, there may be different limitations for different items or even for different areas within the same item.

14.1.3 The results of quality control inspections can provide valuable feedback regarding the performance of the process. Increased levels of lint, colour loss or transfer, ineffective removal of tape, and the development of holes can provide an indication that the process can be improved upon or is out of alignment. Colour transfer on healthcare textiles occurs when hospital greens, blues, and whites are laundered together (i.e., textile classifications have been incorrectly combined in laundering). Colours transfer from coloured to white fabrics, tinting the white fabrics. This tinting is permanent because polyester does not release colour. Although dyed polyester fibres are fast to laundering, the migration of loose dye contained in new fabrics is sufficient to produce this tinting effect.

14.2 Acceptable Stains/Damages/Defects

The acceptability of healthcare textile products for use in surgery may be influenced by their appearance and the user's perception of cleanliness. Discolorations that do not interfere with the functional performance of a textile are acceptable, and every effort should be made to allow for their continued use. However, discolorations caused by certain types of residual soils might have to be removed before the item can continue in service, because they could affect the functional performance of the product, potentially introduce particulate matter into the surgical site, and potentially prevent effective sterilization.

Table 2 An Example of Inspection Criteria for Stains

(*Clause* 12.2)

Sl No. (1)	Stain (2)	Accept (3)	Reject (4)
i)	Dye transfer from product identification labels	×	
ii)	Medicinal stains (e.g., iodine, scarlet red, methyl blue)[1]	×	

iii)	Colour lift/change from closure tape (e.g., autoclave tape onwrappers)	×	
iv)	Dark brown or rust-coloured stains resembling blood		×
v)	Light or dull discoloration	×	
vi)	Bright or dark discoloration covering a total area that is smaller thana 6-inch square (36 square inches), with the exception of medicinal stains (e.g., iodine, scarlet red, methyl blue) caused by the user/customer[2])	×	
vii)	Tactile stain (e.g., sticky residue, foreign matter)		×
viii)	Residue; raised (e.g., tape, casting material)[3]		×
ix)	Elastic band marks (on wrappers)	×	
x)	Colourless oil stain[4]		×
xi)	Dye/colour fade because of repeated laundering	×	
xii)	Yellow tie-dyed effect on wrappers, mayos, table covers	×	
xiii)	Scorched, burned, or melted fabric		×
xiv)	Ink or marker stains[5]	×	
xv)	Heavy ends (thick threads or additional threads in the fill)	×	
xvi)	Slubs (knots or nubs)	×	

NOTE -

1) Medicinal stains typically do not affect the performance of healthcare textiles; however, they may present an aesthetic issue for some users. Continued use of products with such stains should be discussed with and agreed to by the end user.

2) Continued use of healthcare textiles with bright or dark discoloration in primaryareas should be discussed with and agreed to by the end user.

3) ltems with raised residues may be acceptable for an alternative use, such as a decontamination gown. If acceptable for an alternative use, the items should be appropriately marked to ensure that they are not used inadvertently in clinical applications.

4) An item with a colourless oil stain may continue to be used if it can be demonstrated that the oil does not affect the performance of the item.

5) Legible writing should be rendered illegible to prevent potential misinterpretation in subsequent uses.

14.3 Tests to Ensure the Effectiveness and Safety of Clean Laundered Materials

14.3.1 The functional properties of all the healthcare textiles are expected to meet the quality compliance as per manufacturer's declaration. However, to ensure the effectiveness of the laundering process and to have an evidence that the laundry

process has not left the healthcare textiles harm to use after chemical exposures, the following two tests at the healthcare settings are recommended after every batch laundering on sampling basis. To ensure the effectiveness and safety of clean laundered materials, the following test may be carried out :

i) pH test - 6 to 8 when tested as per IS 1390
ii) Chlorine spot test – absent when tested as per clause **14.3.1.2**.
iii) Microbial load / cleanliness ≤ 300 CFU/ 100cm^2 when tested as per ISO 11737 (Part 1)

14.3.1.1 pH Spot Test

The pH of a finished product can indicate whether it has been appropriately rinsed and soured. Depending on the product type and end use of the product, the final pH of the finished product can vary. However, all textiles should be soured to a pH in the range of 6.0 to 8.0 to be compatible with human skin and to maximize their durability. The pH of a finished product can be measured by means of a "universal" or "sour" tester. In these qualitative tests, a pH indicator is dropped on the product and gives a visual indication of the product's pH by the resulting colour change of the indicator. The indicator is usually placed on a white portion of the textile after extraction but before drying.

14.3.1.2 *Spot Chlorine Test*

The presence or absence of residual chlorine indicates whether chlorine was appropriately used in the laundry process and rinsed from the product. Residual chlorine can reduce the life expectancy of textiles and is also a potential skin irritant. The presence of residual chlorine can be detected by means of orthotolidine, which turns yellow in the presence of chlorine; the darker the yellow, the more chlorine is present.

14.3.1.2 Cleanliness / Microbial Load on the Laundered Material

Healthcare textile products should be clean and possess an inherent bio burden low enough to allow for safe handling and effective sterilization. Commercially available test methods can be used to assess bio burden levels during process qualification, process validation, or ongoing process monitoring. ISO 11737-1 provides guidance on the selection and use of these methods; this standard should be referenced for all bio burden assessments for industrial or other commercial applications. Typically, these methods involve extraction of the item and then enumeration of aerobic and spore- forming organisms, reported ascolony-forming units (CFU).

15 Maintenance of Records:

The following record of files and registers should be maintained for reprocessing of healthcare textiles management in the hospital: -

i) Linen stock register at the central store

ii) Area wise daily transaction register

iii) Laundry and linen receiving register and distribution register at the laundry

iv) Any other record as per the policy and procedure of hospital or laundry service provider.

16 GENERAL GUIDELINES FOR ENVIRONMENT PROTECTION

16.1 Laundry service in hospitals have critical roles in society and their operations have major social and environmental risk. The factors including high consumption of water, high energy consumption, smoke emission by boilers, generation of bio medical waste and liquid waste, and processing and disposal of water with chemicals used in decontamination and sterilization processes will lead to environmental risks. It is imperative to be that the hospitals or laundry service provider should be concerned about the environmental risks of the laundry process. The laundry facility for healthcare textiles shall follow the applicable requirement of the concerned State/Central Pollution Control Board as per the provisions of Water (Prevention and Control of Pollution) Act, 1974 and Air (Preventions and Control of Pollution) Act, 1981 under the Environment (Products) Act, 1986 and the rules made thereunder.

16.2 Treatment, Disposal and Re-use of Waste Water:

The following steps should be taken for treatment and disposal of waste water to minimize or avoid those environmental risks due to reprocessing of healthcare textiles: -

i) Chemical disinfection is to be performed by 1-2% hypochlorite solution or equivalent disinfectant like aldehydes, lime, ammonium salts, phenolic compounds etc. Chemical disinfection performed must meet the standard of chemical disinfection as listed in Schedule II of Bio Medical Waste Management (BMWM) Rules, 2016 or other rules/regulation issued by the concerned regularity authority.

ii) Effluent Treatment Plant (ETP) shall be necessary if discharge from laundry service in Health Care Facility (HCF) is connected with city's/town's public sewerage network not having any terminal sewage treatment plant or if the HCF is not connected to public sewerage network. Treated wastewater from healthcare facility should conform to the

standards of liquid waste as listed in Schedule II of BMW Rules, 2016.

iii) Wastewater generated from the laundry service in healthcare facilities is treated in the ETP and shall be disposed into drain /sewer or may be reused in: flushing, horticulture, and scrubber. The effluent from the laundry facility, after treatment in an ETP shall meet the general standards for discharge of environmental pollutant and common effluent treatment plants emission as stipulated in The Environment (Protection) Rules, 1986 (as amended from time to time).

ANNEX 4
(Item 4.*1*)

DRAFT STANDARD FOR FINALIZATION

Comments received on Doc: TXD 36 (22466), Guidelines for Reprocessing of Multiple Use Healthcare Textiles

a) Dr Gurjeet Singh, Professor, Department of Microbiology Maharishi Markandeshwar Institute of Medical Sciences and Research, Ambala.

The draft is written in very good format, the only correction i have found in 3.25 Hospital Acquired Infection (HAI)

Please considered below definition for Health care associated infections

3.25 Hospital Acquired Infections (HAI) – The hospital-acquired infection (HAI) also referred to as healthcare-associated infections or nosocomial infections is defined as the infections that develops in patient within 48 to 72 hours of admission to a hospital for treatment, these infections were neither present nor in incubation period at the time of admission.

b) Hospital Planning Sectional Committee, MHD 14 comments

1) "Guidelines for Processing of Multiple-use Healthcare Textiles" and the word reprocessing may be changed to ‘processing; at all places.
2) Including the Diagnostics sector into the scope of Healthcare facilities
3) Elaborating the references of reusable textiles
4) Separate mention about protocol for highly infectious material
5) Elaboration of sterilization protocols or refereeing it to industry requirements
6) Refining the Wash cycle requirements, definition
7) Storage conditions and Shelf life of the processed material
8) Defining the role of Infection Control Committee
9) Modification of flowcharts ix. References to latest CPCB, BMW rules

ANNEX 5
(Item 5.*1*)

RESEARCH AND DEVELOPMENT PROJECT

New Subject - Surgical Sutures (Absorbable and Non-Absorbable)

Medical Textiles — Surgical Sutures (Absorbable and Non-Absorbable) — Specification

1) **Title of the project:** — Preparation of draft standard on Medical Textiles — Surgical Sutures (Absorbable and Non-Absorbable) — Specification

2) **Background:-**

i) **Technical Committee:** TXD 36 Technical Textiles for Medtech Applications sectional committee under Textile Division council.

ii) Technical Textiles for Medtech Applications TXD 36 of BIS has identified the subject of Surgical Sutures (Absorbable and Non-Absorbable). In order to take holistic view on the subject and to formulate an indigenous Indian Standard, a detailed study of Surgical Sutures (Absorbable and Non-Absorbable) on raw material and performance parameter is required.

iii) Briefly explain the rationale for the commissioning of the project.

In India, a wide variety of surgical sutures, including absorbable, non-absorbable, and barbed sutures, are used across different medical specialties such as orthopaedic, cardiovascular, alimentary, ophthalmic, laparoscopic, and other surgical procedures. In recent years, suturing techniques have gained increasing significance in minimal access surgeries (MAS) due to their potential to reduce post-operative discomfort, shorten hospital stays, and expedite patient recovery. As a result, the demand for surgical sutures is steadily rising in India. The domestic

surgical sutures market is projected to experience a compound annual growth rate of approximately 4.55%, ultimately reaching an estimated value of $220.0 million by 2028, according to Mordor Intelligence.

Given this growing demand, and diverse applications, it becomes essential to formulate standards that describes the material (such as polypropylene, nylon, polyamide, linen, silk), structure (monofilament or multifilament), length, diameter, knot strength/breaking load, needle attachment, extractable color, sterility, and other safety and performance requirements for various types of sutures. These specifications not only assist manufacturers in producing high-quality sutures and provide patients with a reliable product but also contribute to elevating the quality of locally manufactured surgical sutures to meet international standards.

3) Scope: -

The project aims to bring out a draft standard for surgical sutures with specific reference to absorbable and non-absorbable sutures supported by technical information, scientific data, inhouse test report/third party report/International Practice.

The project involves generation and collection of technical data for raw material, general requirement, specific requirement/value and test method for performance parameters like length, diameter, tensile strength, needle attachment strength, breaking strength retention test, biocompatibility evaluation, extractable colour etc. Given the priority to SDGs which also encompasses responsible consumption, it is desired to ensure that all the inputs are fit for the draft standard. The resultant draft document should also specify requirements or provide guidance from the perspective of SDGs also.

4) Expected Deliverables: -

i) Detailed information for sutures used in India, their manufacturers and contact details, availability of testing facility and testing laboratories with contact details, List of users/stakeholders and their contact details
ii) Relevant supportive technical documents, test reports, technical and research

paper, International Standards, Govt. Technical Regulation, Applicable guidelines as per medical device rules.

iii) To provide the data for the technical and performance requirements of absorbable, non-absorbable surgical sutures.

iv) To prepare a draft standard after incorporating the scope, raw material, manufacture, general requirement, performance requirement, method of test, sampling, packing and marking.

v) Any other important requirement for surgical suture may also be incorporated in the draft standard if required.

5) Research Methodology:-

i) To collect the available data for the requirements of surgical sutures through desktop study, books, magazines, national and international standards information available with manufactures, laboratories, academia or any other source. Identifying the stakeholders, including manufacturer, Laboratories, etc. for surgical sutures to understand the manufacturing process and collect data.

ii) To purchase/collect the sample of each variety of surgical sutures and carry out tests from BIS recognized Lab/NABL Accredited lab or industry facilities equipped with the necessary capabilities for the performance requirement(s) either using Indian Standard/ISO International standards or those specified by the manufacturer on the product labelling. These results are to be tabulated and examined to determine the final values which has to be incorporated in the standard.

iii) Visiting of surgical sutures industries (Large, Medium and small scale) and testing labs to collect information, regarding raw materials, varieties, performance parameters, manufacturing and packaging practices, sampling and testing methods or any other important requirement of surgical sutures (if required).

iv) Visiting/Consulting or Taking feedback from the users/hospitals/doctors/healthcare professional regarding the issues faced related to quality of sutures and including the specific requirement and characteristics in the draft standard.

v) Develop and formulate the specification standard (as per IS 12) based on the collected data, ensuring that they align with international quality benchmarks, meet user expectation and industry norms.

6) Requirement for the CVs:-

Graduate in Textile Technology/Textile Engineering with minimum 5 years of experience in testing or manufacturing of sutures.

7) **Timeline and Method of progress Review:-** 5-6 Months

Time line	Method of progress
0 to 45 days	Literature review/Desktop Study Collecting the references (books/magazines/ national and international standards) and studying these standards to execute the project with appropriate knowledge on the subject. To purchase/collect the sample of each variety of surgical sutures
45 to 90 days	Carry out tests from BIS recognized Lab/NABL Accredited lab or industry facilities Visiting of surgical sutures industries (Large, Medium and small scale) and testing labs to collect information
90 to 135 days	Visiting/Consulting or Taking feedback from the users/hospitals Examining the results of samples tested, Analysing Data collected through visit and literature survey/Desktop Study
135 to 180 days	Consolidation of data , Submission of draft Indian standard of the project.

8) **Support BIS will Provide:-**

All the relevant Indian Standards/ISO Standards or any other standards required during the project will be provided by BIS.

ANNEX 6
(Item 5.*1*)

RESEARCH AND DEVELOPMENT PROJECT

GUIDELINES FOR RESEARCH & DEVELOPMENT PROJECTS FOR FORMULATION AND REVIEW OF STANDARDS

1 INTRODUCTION

Bureau of Indian Standards (BIS), as the National Standards Body of India is responsible for formulating Indian Standards for products, processes and services. In the pursuit of this endeavour, it has so far developed more than 22000 Indian Standards. Action Research and Research & Development Projects have always been part of the standardization process. However, there has been a growing realisation in the context of the increasing diversification, innovation and complexities in the manufacturing sector and evolution of services and also due to the fast pace of changes in the manufacturing and services landscapes, research & development projects have to be made an integral part of the standardization process. The idea is that in principle no standard should be developed without intensive and insightful research work, which is not confined only to the review of the existing literature and focus group discussions on the subject chosen for standardization, but also covers the detailed field level study of the existing processes and practices in product manufacturing and service delivery. This requires a large network of domain area experts to carry out the research & development work. The existing network encompasses only a small segment of experts, who are either associated with technical committees as members or belong to some R&D organizations. The Memorandum of Understanding with the premier educational institutions imparting technical and professional education opens the window to the opportunities to expand this network substantially by utilizing the intellectual capital that resides with the faculty and the research scholars in these institutions. This association is conceived not only as a way to promote research & development work necessary for standards formulation but also to enrich the research ecosystem in these educational institutions.

2 OBJECTIVES

Objectives of this Scheme are to:

2.1 support and commission research & development projects to generate knowledge, empirical data and insights that would help in formulating new standards and updating & upgrading the existing Indian standards;

2.2 expand the network of domain area experts to carryout research & development projects in the areas related to standardization and conformity assessment; and

2.3 enrich the research ecosystem in the educational institutions imparting technical and professional education.

3 RESEARCH & DEVELOPMENT PROJECTS

3.1 Research & development projects under these guidelines are described as follows:

A project aimed at comprehensive, in depth and incisive study of a product, process or service or all taken together in respect of a subject under standardization, encompassing literature review, analysis of the data from secondary sources, collection and analysis of data from primary sources and stakeholder consultations.

3.2 The duration of a project shall not exceed six months counted from the date of the award of the project to acceptance of the final report by the Sectional Committee concerned, provided that the Sectional Committee must not take more than one month to give its decision on the final report. Further provided that the time taken by the Sectional Committee for giving its decision shall not be counted. The Sectional Committee may extend the duration but for not more than 2 months in special circumstances, the reasons for which shall be recorded in the minutes of meeting of the Sectional Committee.

3.3 The upper limit for expenditure for a project shall be Rs 10 lakhs (including taxes) only.

3.4 BIS will publish a list of research & development projects along with Terms of Reference (ToR) on Standardization portal or any other suitable digital platform.

3.5 If any organization or an expert on behalf of an institute wants to propose a research & development project on any new and emerging area in which they have expertise, they can do so through the same platform for the consideration of the Sectional Committee.

4 TERMS OF REFERENCE (ToR)

4.1 The ToR of Research& development project shall be prepared by the Sectional Committee concerned, and shall contain:

a) Title, background and objectives of the study;
b) Expected research methodology (brief information, for example, survey, testing, industry visits, etc.);
c) Scope of study;
d) Outline of the tasks and final deliverables expected from the Proposers;
e) Methods of review, schedule for submitting the 1st draft report and project completion report;
f) Any support or inputs to be provided to the Proposer; and
g) Maximum duration of project and timelines for submission of proposal

4.2 While preparing the Terms of Reference (ToR) the sectional committee may consider the following points as a research & development project may include one or mix of the following:

a) Secondary research based on internet or published information including authentic data sources;
b) Survey based research (including industry visits) to ascertain prevailing market conditions and practices, standards in use, industry and consumer preferences,

availability of infrastructure, technical capabilities, comparative trends, economic trends;

c) Ascertaining compliance to existing and proposed standards through testing, review of past test reports, other validation and verification checks; and
d) Basic and innovative research to establish normative criteria. Criteria may include performance, health, safety, environmental impact.

5 APPROVAL OF COMISSIONING OF THE RESEARCH AND DEVELOPMENT PROJECTS

5.1 There shall be a Review Committee for approving the projects recommended by the Sectional Committee. The composition of Review Committee shall be as follows:

DDG (SCMD)	: Chairperson
DDG (Standardization) concerned	: Member
DDG (Certification)	: Member
DDG (Labs)	: Member
Officer in-charge for research works in SCMD	: Member Secretary

5.2 The Head of Technical Department concerned and Member Secretary of the Sectional Committee shall apprise the review committee about the project and explain the rationale behind the proposed research & development project.

6 ELIGIBILITY CRITERIA

6.1 The following shall be eligible for carrying out research & development projects under the Scheme:

a) Academic institutions & universities having MoU with BIS and faculties and research scholars thereof;
b) Member(s) of Technical Committees of BIS.

6.2 Faculties and research scholars shall submit proposals through their institute. Members of technical committees belonging to any association/organization shall submit the proposals through their association/organization. Members of technical committees in personal capacity can submit their proposals directly to BIS, however if carrying out a research & development project requires collaboration with any institution/organization, concurrence of the same shall also be submitted

7 PROCEDURE FOR APPLICATION

7.1 Submission of Proposal

7.1.1 Applications for undertaking research & development projects shall be submitted in the manner prescribed by the Bureau and within the prescribed timelines,

7.1.2 Proposer(s) shall submit their proposal in a "single stage - two envelope bid system" consisting of separately sealed "Technical and Financial proposals". The Technical Proposal shall be submitted as per format prescribed in **Annex A** and the Financial Proposal shall be submitted in the format prescribed as per **Annex B**, clearly specifying expected expenditure against each element such as manpower, equipment (shall not

include computer hardware and software), travelling, testing, consumables, stationery, overheads, etc.

7.1.3 There shall be maximum one proposal from one institute on a given subject.

7.1.4 No contractual obligation whatsoever shall arise until a formal agreement is signed and executed between the Bureau and the Proposer.

7.2 The proposals shall inter-alia consist of the following:

7.2.1 In respect of the research & development projects put up by the Bureau:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the project and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the research as proposed.
c) A write up on the understanding of the scope and objectives of the project.
d) Methodology (sampling size, if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Stage wise timelines for completion of the project.

7.2.2 In respect of research & development projects proposed by any expert/organization:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the study as proposed.
c) Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable;
d) Methodology (sampling size if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Details of infrastructure facilities available for the project, in the institution and additional facilities required (if any) for carrying out research.
f) Stage wise timelines for the completion of the project.

7.3 The Head of the concerned institution while forwarding the application and nominating the project leader shall certify that:

a) the core facilities (land, buildings, laboratory, manpower and other infrastructure etc.) are available and will be provided to the Project Leader to work on the proposed project,
b) the organization will discharge all its obligations, particularly in respect of management of the financial assistance given, and
c) no other funding is being received/sought for the project proposed to be sanctioned by BIS.

8 PROCEDURE FOR APPROVAL WITHIN BIS

8.1 There shall be a Research Evaluation Committee (REC) to evaluate the proposals received, the composition of which shall be as follows:

DDG (PRT)	: Chairperson
Head (CMD) concerned	: Member
Head (LPPD)	: Member
Head of the Technical Department concerned	: Member
Director Finance	: Member
Two Experts from the Sectional Committee concerned	: Members
Head (SCMD)	: Member Secretary

*The experts shall be nominated by the Sectional Committee and the nominated members shall give a declaration to the effect that there is no conflict of interest with respect to the project.

8.2 The evaluation and selection will be as per Quality and Cost Based Selection (QCBS) method (Rule 192, GFR 2017) which is explained in **Annex C**.

8.3 The criteria for evaluation of technical proposal shall be as under:

Sl No.	**Criteria**	**Max. Marks**	**Score by REC**
1	Profile of key individual/individuals to be associated with the research project	**10**	
2	Experience of the individual/organisation in conducting research projects in the relevant discipline	**20**	
3	Understanding of Scope, Objectives and deliverables	**15**	
4	Methodology	**30**	
5	Work plan/Execution strategy	**15**	
6	Chapterisation, contents and lay out of the proposed report	**10**	
TOTAL		**100**	

Note: REC may call for a presentation by the proposers if deemed necessary.

8.4 The minimum qualifying marks shall be 70. All the proposals with marks below 70 shall be considered rejected.

8.5 REC may refer back, advise changes for reconsideration or reject any proposal.

8.6 REC shall open the financial proposals (bids) within 7 days from completion of technical evaluation.

8.7 A final score sheet of all the proposers shall be made as detailed in Annex C and the proposer getting the highest combined score shall be selected for awarding the project.

8.8 The member secretary (REC) shall send the selected proposals to DG/DDG Standardization concerned, as per their delegated powers, for consideration and approval for sanction of the project.

8.9 After the approval of project, the member secretary (REC) shall inform the concerned technical department and the proposer regarding the decision.

8.10 After the sanction of fund is approved, the draft agreement (prepared in line with model agreement given at **Annex D**, to be modified on case-to-case basis) shall also be prepared by the Member Secretary (Sectional Committee), clearly highlighting the payment term. The Head (Technical Department) shall sign the agreement on behalf of BIS in all cases.

8.11 In case the proposer to whom the project is awarded declines to take up the project, the Research project shall be awarded to the proposer getting the next highest combined score among the qualified proposers.

9 SIGNING OF AGREEMENT AND ISSUING OF SANCTION LETTER

9.1 After receipt of duly signed agreement from the proposer and after the receipt of the approval of competent authority, a sanction letter shall be issued by the concerned Head (Technical Department) to the organization/individual member. The project would be considered to have commenced from the date the sanction letter is issued.

10 FUNDING

10.1 The mode of payment for Research & development projects shall be as follows:

a) First instalment up to a maximum of 30 percent of the total approved project cost would be released after approval of the project.
b) Second instalment to the extent of 50 percent of the approved estimated cost would be released on the submission of progress report along with the report on utilization of the 75 percent of the fund and acceptance of the same by the Sectional Committee.
c) The balance amount shall be released after submission of the final project report along with utilization certificate for the fund released and its acceptance by the Sectional Committee.

10.2 Release of each instalment is subject to satisfactory progress, required stage - wise deliverables and submission of the Utilization Certificate (UC) as per Form GFR12-A of GFR 2017 along with the statement of expenditure (SoE) issued by the Competent Authority.

11 PROGRESS REPORT AND MONITORING OF PROJECT

11.1 The relevant Sectional Committees of BIS will monitor the progress of project to ensure that the project is progressing as per the planned arrangement. However, member secretary of the concerned Sectional Committee under overall coordination of HoD would be the controlling/link officer for Research & Development projects and would constantly monitor the progress of the project every 30-45 days. Any delay in implementation of project should be duly justified by the Project leader and shall be put up to Research Evaluation Committee (REC) for approval.

11.2 The Sectional Committee shall review and give its acceptance of the progress reports submitted, within 3 weeks.

12 SUBMISSION OF FINAL PROJECT REPORT (FPR)

12.1 The FPR must be detailed and should include information about:

a) the original objective(s) of the project,
b) how far these objective(s) have been achieved, and
c) how the results will benefit the development of the national standard(s) and
d) a copy of final working draft of the concerned standard(s) (wherever applicable)
e) include clear inferences, recommendations regarding their use in the proposed standards,
f) all references used, raw data of surveys, sampling, testing and experiments,
g) undertaking that all the information presented is authentic.

12.2 FPR received in BIS would be put up to the concerned Sectional Committee, which will take necessary action for preparation/revision of standard appropriately. The Project leader shall assist in the disposal of comments received on the research project, draft standard and for the preparation of the finalized draft, as may be desired by the Sectional Committee.

12.3 The proposer shall submit the Project Completion Report (PCR), within one month of completion of project along with the Utilization Certificate of the fund released as per Form GFR 12-A of GFR 2017 and the statement of expenditure (issued by the Competent Authority -in case of Govt. organization / Charted Accountant in case of private organization).

13 RESULTS OF RESEARCH & DEVELOPMENT

13.1 Project Leader(s) would be encouraged to publish the results of research & development. While doing so, acknowledgement to the effect that financial assistance was received from BIS should be made in the research paper(s) published. BIS should be acknowledged in similar type of other published work/press reports.

13.2 One re-print of each research paper(s) published as a result of the work done under the BIS funds shall be sent to BIS as and when published.

14 INTELLECTUAL PROPERTY RIGHTS

14.1 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by Proposer shall be vested with that Party.

14.2 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by the Bureau shall be vested with that Party.

14.3 The Intellectual Property arising out as an outcome of research project undertaken under these guidelines shall be vested with Bureau.

15 OPERATION OF FUNDS

15.1 The utilization certificate of the funds received in previous instalment (if any) to BIS should be annexed with the Statement of all equipment, books, etc purchased out of the funds certified by the Head of the organization. The name, description of the equipment, cost in rupees, date of purchase, and the name of the supplier to be given in the list. The main purpose/function of the equipment may also be mentioned against each item.

15.2 Any unspent balance lying with the organization should be refunded to BIS after the finalization of the draft immediately, by means of demand draft or online transfer.

15.3 The Head of the concerned standardization department of BIS shall ensure that the project leader submits the utilization certificate in the manner prescribed in Form GFR 12-A of GFR 2017.

15.4 Head of the Standardization department shall also ensure that the operation of funds is monitored strictly as specified in **Annex E**. Further the Project Leader is also fully aware and shall adhere to the obligations of his/her as given in this procedure.

16 OTHER REQUIREMENTS

16.1 Organizations receiving financial assistance for research & development projects from BIS would have to maintain separate accounts for each research project.

16.2 In the event of a Project Leader's absence from his normal place of duty for two months at a stretch, the Head of the organization would need to immediately nominate an Alternate Project Leader(s) to supervise the implementation of the project and such a name has to be approved in advance by BIS. In any event, a Project Leader shall give prior notice to BIS of his intention to stay away from the project.

16.3 Items of equipment, etc should be purchased on the basis of the established rules and procedures of the entity/organization.

16.4 Stock register of all equipment, books, etc purchased out of the funds shall be maintained.

16.5 Any capital-intensive equipment/devices purchased using financial assistance from BIS for research & development projects shall be allowed to be retained by the proposer for their research activity etc.

16.6 The organization shall have to ensure that expenditure with respect to TA/DA are made only as per their own norms but under no circumstances the executive/business class air travel or stay in a five-star hotel is made. The overhead expenses should not be more than 20 percent of the cost of the project.

16.7 The Project Leader must ensure that the concerned organization's newsletter would carry information on the activities and accomplishments of the various projects funded by the BIS.

17 TERMINATION OF PROJECT:

The research & development project can be terminated in case of any of the following:

a) the approval of research & development project may be treated as withdrawn, if the sanctioned research & development project does not commence within one month from the date of receipt of the sanction letter, unless otherwise authorized by BIS;
b) A Proposer may request for the withdrawal of a research & development project even after commencement of the project. In such case the entire fund given till that date shall be refunded to the Bureau; and
c) if the Proposer fails to submit Progress report/Completed Project report within the prescribed timelines.

The REC shall take decision on all cases of termination.

18 RESOLUTION OF DISPUTES

Dispute Resolution: In case of any dispute that cannot be resolved amicably, it shall be referred to Sole Arbitrator appointed by the Director General of the Bureau of Indian standards, whose decision shall be final and binding upon both the parties. The provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time, shall be applicable.

ANNEX A

TECHNICAL PROPOSAL

1. Name of the Proposer and Organization	
2. Project title	

3. Project leader

a) Title: Prof/Dr/Mr/Ms b) Name:	Sex M/F
c) Full official address	
Mobile/Telephone Fax E-mail	
d) Designation	
e) Date of birth	
f) Academic qualifications along with year of completion	
g) Experience	

4. Other members of the research team (give name, address, experience and academic qualifications for each member)

1. Name	Designation: Address: Experience: Academic Qualifications:
1. Name	Designation: Address: Experience: Academic Qualifications:

5. Research support availed/being availed/applied for by the Project leader from different sources, including BIS, during the last 5 years:

Funding agency	Title of the project and reference number	Duration (from mm/yyyy to mm/yyyy)	Percentage of time devoted /being devoted/to be devoted, in man months	Amount in lakh Rs.

6. Details of facilities available with the institute/organization w.r.t. the research & development project

Facilities	Relevance to project
1.	

7. Aims and significance of the project
(Include the current status of work in area, both in India and abroad, with appropriate reference list at the end; identify lacunae, define question to be investigated; list briefly specific objectives of investigation. ethical clearance be enclosed where necessary).

8. The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project leader and expert/expert(s) to undertake the study as proposed.

9. Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable.

10. Methodology (sampling size if applicable) to be adopted for the proposed study.
11. Road map (Stage wise timelines for the completion of the project) and time table for completion of the project
12. Plan of work, methods and techniques to be used.
13. List of awards and honours conferred on the Project leader with dates.
14. Deliverables
15. Declaration and attestation:

I certify that all the details declared here are correct and complete. Signature of Project leader	Date:

12. Certificate of the institution:

This is to certify that a) we have read the terms and conditions of the BIS Research & Development Guidelines necessary for the compliance of the same. b) the necessary institutional facilities are available and will be provided for the implementation of this research proposal being submitted to the BIS for funding. c) Full account of expenditure will be rendered by the institution.
Name of the head: of the institution Signature with date: Seal:

ANNEX B
FINANCIAL PROPOSAL FORMAT
[To be submitted on letterhead wherever applicable]

To:
Bureau of Indian Standards
Manak Bhavan, 9 Bahadur Shah Zafar Marg
New Delhi – 110002, India

Sub: Financial Proposal for Research & development Project on (Title: _____)
for Bureau of Indian Standards (Research guidelines document no._____dated: ___-___-2023).

Dear Sir,

We are pleased to submit our Financial Proposal for Research & Development Project on (Title:
_____) for Bureau of Indian Standards as per the terms and conditions of the Research & Development guidelines document (Ref No.: _____ dated: ___-___-2023).

1. We hereby declare that our financial proposal is unconditional in all respects.
2. Our financial proposal is as follows:

3. Cost of the Project:

Sl no.	Budget items	Amount
1	Manpower cost	
2	Consumables	

	[Chemicals, samples, testing glassware, stationery, books etc, information search (from databases)]	
3	Equipment	
4	Travel	
5	Any other/Overhead expenses	
Total project cost		

*Please write NA in case any item is not applicable

a) The prices should be quoted in Indian Rupees above by the proposer.

b) The quoted price should be inclusive of all applicable taxes and charges.

c) Fund shall be released after deducting TDS as per applicable provisions of GST and income tax.

d) Justification of cost (for each item of equipment, consumables and travel. Quotation(s) for equipment should also be enclosed).

Yours faithfully,

Date: (Signature of the Project leader)

Place: (Name and Designation of the proposer)

Name and Signature of the head of the institution

(Rubber seal of the proposer/institution/organization, as applicable)

ANNEX C

Stage 1: Evaluation of Technical Proposal:

a) The proposal will be evaluated against the criteria defined at clause 8 in these Guidelines. The proposer may be required to provide additional details as deemed necessary by the REC.

b) Upon technical evaluation of each proposal, "Technical marks" out of 100 marks will be assigned to every proposal.

c) The proposals with score 70 or more marks in technical evaluation, will qualify for the evaluation of the financial proposal.

d) The proposer with the highest marks in technical proposal will be awarded 100 "Technical Score" and subsequently other proposers will also be awarded "Technical Score" relative to the highest technical marks for the final composite score calculation purpose e.g., if the highest technical marks is 90 then "Technical Score" is (90/90) × 100 = 100, hence the proposer with highest technical marks will score 100 "Technical Score". Similarly, another proposer who scored 80 marks,

will get (80/90) × 100 = 88.88 "Technical Score". Following formula will be used for the "Technical Score" (TS) calculation:

$$\text{Technical Score (TS)} = \frac{Proposer's\ Technica\ \ Marks}{Highest\ Technical\ Marks} \times 100$$

e) The details of technical evaluation parameters are provided at clause 9.

Stage-2 Evaluation of Financial Proposal

a) The evaluation will be carried out if financial proposals are complete and computationally correct.
b) Upon financial evaluation of each proposal, the lowest financial proposal will be awarded 100 "Financial score". The "Financial Score" of other proposer(s) will be computed by measuring the financial proposal against the lowest financial proposal. Following formula will be used for calculating "Financial Score":

$$\text{Financial Score (FS)} = \frac{Lowest\ Financial\ proposal}{Proposer's\ Financial\ Proposal} \times 100$$

Stage-3 Computation of Combined Score

The "Combines Score" is a weighted average of the Technical and Financial Scores. The ratio of Technical and Financial Scores is 70:30 respectively. The Combined Score will be derived using the following formula:

$$\text{Combined Score} = [(TS \times 0.70) + (FS \times 0.30)]$$

The responsive proposers(s) will be ranked in descending order according to the Combined Score, which is calculated based on the above formula. The highest-ranking proposer asper the Combined Score will be selected for award of Research Project.

ANNEX D

MODEL AGREEMENT

(To be modified on case-to-case basis)

This Deed of Agreement made this day of (Month & Year) between Bureau of Indian Standards having Head Office at Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi – 110 002 (hereinafter called 'BIS', which expression shall, wherever the context so admits, includes its successors and assigns) on one part and (name of the

organization/expert) (hereinafter called which expression shall, wherever the context so admits, include their heirs, executors, administrators, legal representative and assigns) of the other part, witness as follows:

1. Whereas (name of the organization/expert) through (name of the Project Leader) has submitted a proposal to BIS pertaining to Research & development project titled for consideration and BIS has accepted the proposal.

2. That duration of the Research & development project shall be months with periodic and final reviews. The total cost of the project shall be Rs /- (Rupees in words) for the complete project. No further expenditure shall be borne by BIS on any account of this project including escalation of time.

3. The fund would be utilised for the specific project/assignment as approved by BIS and shall be spent within the specified time. Any portion of the fund which is ultimately not required for expenditure for the approved purpose shall be duly surrendered to BIS.

4. (Name of the organization/expert) shall not entrust the implementation of the project/assignment approved by BIS for which fund has been received to any other institution/expert or to divert the fund received from BIS as assistance to any other institution/expert/proposer.

5. (Name of the organization/expert) indemnifies BIS from any legal and/or financial encumbrance arising out of any infringement of IPR/licensing of IPR/technology transfer/commercialization.

6. (Name of the organization/expert) shall maintain an audited record in the form of a register for permanent, semi-permanent assets acquired solely or mainly out of BIS fund. Once the Research & development project is completed satisfactorily, the organization taking up the Research project may retain the equipment/devices for their Research & development activities, etc. The equipment procured through BIS fund should bear a label "BIS Funded".

7. BIS shall release the funds for the project as follows:

a) First instalment up to a maximum of 30 percent of the total approved project cost would be released after approval of the project.
b) Second instalment to the extent of 50 percent of the approved estimated cost would be released on the submission of progress report along with the report on utilization of the 75 percent of the fund and acceptance of the same by the Sectional Committee.

c) The balance amount shall be released after submission of the final project report along with utilization certificate for the fund released and its acceptance by the Sectional Committee.

8. The completion of the Research & development project shall remain the responsibility of (name of the organization/expert) even if the project leader is not available due to any reason whatsoever. After completion of the project, a Project Completion Report giving details (objective(s) achieved, raw data of surveys, sampling, testing and experiments) of shall be submitted by the Project leader the original objective(s) of the project,

9. (Name of the organization/expert) shall ensure the completion of the project under the guidance and supervision of any other faculty/researcher, if the nominated project leader would not be available due to any reason. Such a faculty member/researcher can only be nominated with the approval of BIS.

10. In case (name of the organization/expert) is unable to complete the project to the satisfaction of BIS in stipulated time or extended time and leads to termination of the research project, BIS shall be entitled to claim the refund of fund so sanctioned with interest @ 10 percent thereon from (name of the organization/expert).

11. The authority to extend the duration of the project shall rest with BIS.

12. BIS shall have the right to formulate monitoring methodology of the Research & development project.

13. Dispute Resolution: In case of any dispute that cannot be resolved amicably, it shall be referred to Sole Arbitrator appointed by the Director General of the Bureau of Indian standards, whose decision shall be final and binding upon both the parties. The provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time, shall be applicable.

14. Undertaking given by project leader, if any, shall be part of the agreement.

15. (Name of the organization/expert) shall be responsible for discharge of all its obligations of the project through the nominated project leader or any other expert/expert(s) in case of necessity particularly in respect of management of financial assistance given to them. (Name of the organization/expert) shall refund any excess/unutilized amount of the fund to BIS.

16. Release of subsequent instalments is subject to satisfactory progress, required stage - wise deliverables and submission of the Utilization Certificate (UC) as per Form GFR12-A of GFR 2017 along with the statement of expenditure (SoE) issued by the Competent Authority.

17. (Name of the organization/expert) shall ensure that Project leader shall give presentation on the progress of project to BIS as and when directed by BIS for continuation of the project, and shall assist in the disposal of comments received related to the Research & development Project.

18. The project shall be deemed to have been commenced from the date of release of sanction letter.

19. (Name of the organization/expert) shall ensure that while publishing the results of research & development, acknowledgement to the effect that financial assistance so received from BIS be made in the research papers published/ other published work/ press reports.

20. Procedure for screening/evaluation, selecting, monitoring Research & development projects prescribed in "Guidelines for Research & Development Projects for Formulation and Review of Standards' shall be part of the agreement.

ANNEX E

OPERATION OF FUNDS AND PROGRESS REPORT

1. Title of the Project:	Project number:
2. Name & Address of Project leader:	Date of Commencement: dd/mm/yyyy

3. Details of Equipment Purchased (if any):

Name of equipment	Cost	Supplier	Date of purchase/ placing order for each item of equipment
NOTE - The equipment fund once fixed cannot be enhanced. Project leaders are advised to give authenticated estimates of the cost of equipment. Equipment should invariably be purchased within 1 month from the date of receipt of the fund and/or sanction letter.			

4. Fund received

.

5. Expenditure made in Rupees: (Please provide the details)

Expenditure	Amount	Taxes (as applicable)	Total

Manpower cost			
Consumables			
Equipment			
Travel			
Others			
Grand Total			

6. Amount saved (if any) from the last instalment: Rs .

7. Date on which scheme will complete its normal tenure of months .

8. Whether extension beyond normal tenure has been requested. Yes /No.

If yes, justification for extension and programme of work to be completed. Also mention as to why the work could not be completed as per the original plan.

{Extension beyond normal tenure should be requested at the Project Monitoring Session before end of tenure (as given in ToR)}.

9. Constraints (if any) faced in the progress of work and suggestions to overcome them.

10. Any deviation from original plan with its nature and cause.

11. List of publication giving full bibliographic details accrued from this project (copies of the paper (s) should be enclosed).

12. Summary of work done (200 words).

13. Proposed programme of work for the next month (1000 words).

14. Detailed Progress Report enlisting the objectives in beginning briefly (up to five pages maximum).

Signature of Project leader

Date:

Note: No column should be left blank; write not applicable (NA), wherever applicable.

TEMPLATE FOR THE TERMS OF REFERENCE FOR THE R&D PROJECTS
(*Refer to the Guidelines on R&D Projects issued vide note SCMD/R&D dated xx-09-23*)

1. **Title of the Project:** Mention the title of the project.

2. **Background:**

a) Mention the Technical Committee and Division Council the project is related to;
b) Mention the standard / document no. for the standard under development or review to which the project is related to;
c) Briefly explain the rationale for the commissioning of the project.

3. **Scope**: Mention the scope of the project.

4. **Expected Deliverables**: Mention the outcome of the project.

5. **Research Methodology**:
Mention the essential components of the methodology like mid-term review, focus group discussions, visits to the manufacturing units and/or laboratories, collection and testing of samples etc. with the details of the sample size for them as applicable.

6. **Requirement for the CVs:**

Mention the requirement for the CVs of the persons to be engaged for the project.

7. **Timeline and Method of Progress Review:**

Suggest the stagewise timelines including that for the submission of the first draft, final draft and the report and the mechanism for the review of the progress.

8. **Support BIS will Provide:**
Indicate the support BIS may provide in terms of the standards, other publications, information regarding manufacturers and labs etc.

ANNEX 7
(Item 6.*1*)

COMMENTS ON PUBLISHED STANDARDS

Agenda and Minutes of panel meeting held on 29 September, 2023

For BIS Use Only

BUREAU OF INDIAN STANDARDS

AGENDA

Panel meeting for to discuss presence of volatile organic compounds and other comments on IS 5405 and IS 17514 under TXD 36

Date	Time	Venue
29 September, 2023 (Friday)	1430 h	Video Conference through CISCO Webex

CONVENOR: Smt. Shradha Dongre, SASMIRA, Mumbai

MEMBER SECRETARY, TXD 36 : Shri Dharmbeer, Scientist D/Joint Director, Textiles, BIS New Delhi

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The link and password for Video Conferencing meeting is as follows:
Link: https://bismanak.webex.com/bismanak/j.php?MTID=m49f452733282deb347c7dea48d0f78dc
Meeting number (access code): 2518 181 8900
Password: UYkYbmBc883

Item 0 WELCOME AND INTRODUCTORY REMARKS
Item 1 COMMENTS ON PUBLISHED STANDARDS
1.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

In the last meeting of TXD 36 held on 04 August, 2023, the committee decided to constituted a panel to discuss to discuss presence of volatile organic compounds and other comments on IS 5405 and IS 17514 for necessary amendment. The composition of the panel is provided as follows : -

i) Ms. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)

ii) Dr. Sadhana Srivastava, ICMR New Delhi
iii) Dr. E. Santhini, SITRA, Coimbatore
iv) Shri Nirav Mehta, M/s Dima Products (ITTA), Mumbai
v) Shri Prashant Jadhav, P & G, Mumbai
vi) Ms. Roocha Khedkar/ Dr. Milind Deore, Johnson and Johnson, Mumbai
vii) Shri Rajesh Shah, President, Feminine and Infant Hygiene Association
viii) Shri Vijay Choudhary, Unicharm Gurgaon
ix) Shri Karthik, Real Relief India Pvt. Ltd., Tamilnadu
x) Ms. Shivani Swamy, Livinguard Technology Pvt. Ltd., Mumbai
xi) Smt. Tanya Mahajan, The Pad Products (NGO), India
xii) Smt. Meenakshi Gupta, Goonj, New Delhi
xiii) Smt. Lakshmi Murthy, Jatan Sansthan, Rajasthan
xiv) Prof. Bipin Kumar, IIT New Delhi
xv) Shri Kanav Gupta, BCH, New Delhi
xvi) The convenor/panel may invite users/experts/manufacturers as required.
xvii) Member Secretary, TXD 36

The committee requested panel to discuss the following comments/parameters/aspects on IS 5405 and IS 17514 and provide its recommendation within 30 days: -

i) Comments received from Shri D. Veera Subramanium, SITRA, Shri Abhisek Saini, Lending Hand Foundation, New Delhi and Ms. Roocha Kedkar, Johnson & Johnson Ltd. (Kvenue), Mumbai.
ii) The disclosure of material and chemical ingredient used in the sanitary pad.
iii) The chemical compound/substances, frequency and requirement of Volatile Organic Compound test.
iv) Any other technical information/suggestion.

The Comments received from Shri D. Veera Subramanium, SITRA, Shri Abhisek Saini, Lending Hand Foundation, New Delhi and Ms. Roocha Kedkar, Johnson & Johnson Ltd. (Kvenue), Mumbai are given at **Annex 1 (Pages 1 to 11).**
The comments received from M/s Lending hand foundation, New Delhi vide letter dated 06 September, 2023 has been attached in Annex 2.

1.1.1 The Panel may **DELIBERATE** and **DECIDE.**

ANNEX 1
(Item *1.1*)
COMMENTS ON PUBLISHED STANDARDS

COMMENTS RECEIVED ON IS 5405 :2019 AND IS 17514 : 2021

a) Shri Veera D Subramanian, SITRA, Coimbatore

NAME OF THE COMMENTATOR/ORGANIZATION:

The South India Textile Research Association, Coimbatore

DOCUMENT NO: TXD 36 (22464)

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
IS 5405 Clause 7.1 pH Value	Testing portion taken for pH test	The existing statement "The pH of the absorbent material" needs to be amended as "The *p*H of the absorbent core material"	-	It helps to provide more clarity on the material taken for pH test from the product
IS 5405 Clause 7.1 pH value : Test method adopted to evaluate the pH test	Kindly remove the term "cold method"	IS 1390 may be given in the method.	Current version of the standard does not have different methods (cold and hot, as it was in earlier version) for testing pH.	IS 1390 standard
IS 5405 Clause 7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization	Cytotoxicity testing requirement Existing standard requirement for cytotoxicity is "None"	It may be changed to non-cytotoxic.	Though the standard has got different methods for studying the cytotoxicity of a sample, the performance requirement as given in the standard is non-cytotoxic.	IS/ISO 10993-5 Clause 8.5
IS 5405 Annex-B	Dimension of standard weight (1 Kg) may be given in the standard.	150 mm X 50 mm (Tolerance ± 0.1 mm)	Dimension of standard weight is required to obtain uniform test results	1) FDKS 2925:2021 Textiles – Reusable Sanitary Towels – Specification 2) US 1782:2017

				Reusable sanitary towels - Specification

b) Shri Abhishek Saini, Lending Hands Foundation, New Delhi

Subject: Representation imploring implementation of guidelines, benchmarks or standards in regard to minimum incidence to toxic and harmful substances in female hygiene products, in public interest.

Respected Sir,

I, Abhishek Saini, am the authorized representative of Lending Hands Foundation, which its registered office at 3rd Floor 3391, Arya Pura, Subzi Mandi, Delhi-110007. Please find herein under our representation to your esteemed office:

1. Lending Hands Foundation is a not for profit organization. working towards various social causes plaguing our society, throughout the country.

2. Using a hygienic method of menstrual protection is important for women's health and personal hygiene. Recognizing the importance of menstrual products and menstrual hygiene, various schemes and programs have been initiated in our country to increase awareness and access of menstrual products.

3. Women using female hygiene products are extremely susceptible to toxic and harmful substances present in such products as the mucous membranes in the vagina and vulva absorb chemicals without metabolizing them.

4. However, there is an absence of mandatory guidelines, benchmarks or standards for

    (i.) Minimum incidence of toxic and harmful substances in female hygiene products;

    (ii.) Labeling requirements for manufacturers of female hygiene products to disclose ingredients used and substances present in the final product; and

(iii.) Testing and certification of female hygiene products for safe-use.

5. In the absence of above-mentioned mandatory guidelines, benchmarks or standards, menstruaters in our country are unknowingly exposed to harmful substances, including plasticizers such as phthalates and Volatile Organic Compounds, such as Benzene. pesticides residue and dioxin. These substances are potential carcinogens, repro-toxic and mutagenic and cause harmful effects to human body.

6. Continued long-term exposure to such substances can have severe and disastrous health related consequences on an individual. This is also detrimental to the overall social and economic wellbeing of the country.

7. Due to known toxicity of the abovementioned chemicals and compounds, their presence is regulated by the government in many consumer products, children toys and teethers, and plastic packaging. Moreover, Draft Chemicals (Management & Safety) Rules, 20xx has also listed certain phthalates under Schedule —II list of priority substances.

8. This need for mandatory guidelines, benchmarks or standards for female hygiene products has been recognized internationally, including in many states in the USA, the European Union and Japan.

9. The Bureau of Indian Standards vide IS 5405:1980 laid down standards for Sanitary Napkins in 1969, which were subsequently revised in 1980, which however, were confined only to the physical attributes of the sanitary napkins, such as texture, without any specifications regarding the toxicity of the ingredients. The 1980 standards failed to specify the permissible limits of chemicals used in the manufacturing process.

10. The BIS standard (IS 5405: 2019) was notified in 2019, which, apart from the requirements pertaining to physical attributes of the sanitary napkins, also added biocompatibility of the material, which is to be detected by evaluating the cytotoxicity, irritation and skin sensitization tests.

11. Furthermore, vide Amendment No. 1 dated January 2022 to IS 5405:2019 Sanitary Napkins-Specification (Second Revision), the requirement for Biocompatibility Evaluation- Cytotoxicity, Irritation and Skin sensitization was made optional.

12. The Amendment No. 2 dated October 2022 to IS 5405:2019 Sanitary Napkins-Specification (Second Revision) inserted the marking requirement on the consumer pack indicating information whether the material of the product is biocompatible,

that is, whether it meets the requirement of the standard for biocompatibility evaluation-cytotoxicity, irritation and skin sensitization (if applicable).

13. However, meeting the said BIS standards and the use of the standard mark is voluntary for manufactures and has not been directed as mandatory for manufactures by the central government under section 16 of the Bureau of Indian Standards Act, 2016, As a result, none of the manufacturers of the most widely used Sanitary Pads are obligated to meet the said requirements.

14. Female Hygiene Products were also sought to be regulated as Medical Devices as per the Draft Medical Device Risk Classification released on 03.09.2020, however, the final list of the classification of the Medical Devices pertaining to Obstetrical and Gynecological, released on 03.06.2022 by CDSCO left out sanitary pads and tampons from the classification. Resultantly, the products are not regulated under the Medical Devices Rules, 2017. Pertinently, menstrual cups were retained and placed in Category-B, without specifying the parameters followed, for retaining menstrual cups, but omitting sanitary pads and tampons.

15. A recent study conducted by an NGO Taxies Link, which published its findings in a report titled "Wrapped in Secrecy- Toxic Chemicals in Menstrual Products" on 21.11.2022 demonstrated the presence of harmful substances in samples of the most popular and widely used Sanitary Napkins.

16. A Public Interest Litigation titled *Ayyaa Vs. Govt. of India & Ors. [WP (MD) No. 9162 of 2021]*- filed before the Madurai Bench of Madras High Court sought directions upon the appropriate authorities, including Ministry Of Health & Family Welfare, to make BIS Certification mandatory for manufacturers of Female Hygiene Products as well as Baby diapers, and ensure mandatory disclosure all ingredients used for producing sanitary napkins on the packaging. On 01/06/2021, the Hon"ble High Court was pleased to issue notice to the respondents, and directed the authorities to submit Counter. However, as on date no steps have been taken by the respondents.

17. Given the widespread concerns regarding the possibility of emission of toxic chemicals from Female Hygiene Products, naturally certain queries have risen, regarding the existence of any benchmarks/ permissible limits to regulate the presence of toxic substances and chemicals in Female Hygiene Products. The concerns are particularly valid. in the face of the Amendment No. 1 dated January 2022 to IS 5405:2019, making the requirement for Biocompatibility Evaluation-Cytotoxicity, Irritation and Skin sensitization optional. It seems that the Government is lacking in addressing this issue with the importance that it deserves.

The issue at hand is grave, considering that vast proportion of the population is being exposed to life threatening toxins every month during the menstrual cycle. Also, in the absence of any statutory requirement to disclose ingredients, and clear standards applicable to such

products, the consumers are denied vital information necessary to make informed decisions about our health. In light of these grave concerns, it is pertinent that this important issue of Public Health is addressed timely.

I thank you for your time and assistance.

c) **Roocha Khedkar R&D Johnson & Johnson Pvt. Ltd. (Kenvue**)

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	**Comments**	**Specific Proposal (Draft clause to be add/amended)**	**Remarks**	**Technical References and justification on which (2), (3), (4) are based**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
7.1 pH Value The pH of the absorbent material shall be from 5.5 to 8.0 when tested by the method given in IS 1390 (cold method).	The test method is updated to 1390:2022. pH is co-logarithm of the hydrogen ion concentration in an aqueous extract. In actual situation of use a sanitary napkin is not in form of aqueous extract when worn and therefor pH is not relevant indicator of good condition of intimate area. Available technical literature	It is proposed to remove the pH testing of the absorbent material		An investigator blinded cross-over study to characterize the cutaneous effect and suitability of modern sanitary pads for menstrual protection for women residing in the USA, TSUTOMU FUJIMURA, NORIKO SATO, YUTAKA TAKAGI, ATSUSHI OHUCHI, HIRONORI KAWASAKI, TAKASHI KITAHARA, YOSHINORI TAKEMA & RONALD L. RIZER Evaluation of vaginal and perineal area during the use of external sanitary protection throughout the menstrual cycle

	supports the fact the sanitary pad does not change the pH of intimate area.			PETRA HANKE-BAIER', JOSEF JOHANNIGMANN*, ROY J. LEVIN3 AND GORM WAGNER4
7.2 Ability to Withstand Pressure after Absorption The sanitary napkin shall absorb 30 ml of coloured distilled water and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.		Testing frequency proposed as verification of absorbency and to be done once when a new product is launched or whenever there is a change in the raw material or its supplier.		
7.3.1 Bacterial and Fungal Bioburden		Test method needs to specify - 1. Sampling Quantity 2. IS 5405 does not elaborate procedure for sample preparation and extraction. 3. Dilution factor is not given in the IS. 4. Incubation Condition for test of Staphylococcus aureus i.e., there is no tolerance to 37° C. A tolerance of +/1 to be included 5.Revise the frequency for Hygiene Testing from quarterly to annual basis.		

7.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization	This is optional as per amendment 1 The amendment copy is not available along with BIS copy when purchased.			
8.2 Number of Tests and Criteria for Conformity **8.1 Lot All the sanitary napkin of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.**		It is proposed that manufacturer shall define a lot to enable to trace back to records		
8.2 Number of Tests and Criteria for Conformity **8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.**		Each lot shall be checked for workmanship and finish as defined by the manufacturer		
8.2 Number of Tests and Criteria for Conformity **8.2.1 All sanitary napkins to be selected as per column 3 of Table 1 shall be examined for workmanship and finish.**		Proposal is to adopt to legal metrology guideline for packaged commodity as per prescribed in the fifth schedule		

8.2.4 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.		Perform Hygiene requirement shall be proposed annually.		

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BUREAU OF INDIAN STANDARDS

MINUTES

Panel meeting - Presence of harmful chemicals in Sanitary Napkins (phthalates and Volatile Organic Compounds) - IS 5405 and IS 17514 under TXD 36

Date	Time	Venue
29 September, 2023 (Friday)	1430 h	Video Conference through CISCO Webex

Convenor: Smt. Shradha Dongre, SASMIRA, Mumbai

Member Secretary, TXD 36: Shri Dharmbeer, Scientist D/Joint Director, Textiles, BIS New Delhi

ATTENDEES:

1) Smt. Shradha Dongre, SASMIRA, Mumbai (**Convenor**)
2) Shri S. Sivakumar, SITRA, Coimbatore
3) Dr. Sadhana Srivastava, ICMR New Delhi
4) Prof Bipin Kumar, IIT New Delhi
5) Shri Prashant Jadhav, P & G, Mumbai
6) Shri Girish Parhate, P & G, Mumbai

7) Shri Vijay Chaudhary, Unicharm Gurgaon
8) Ms. Roocha Khedkar, Johnson and Johnson (Kenvue), Mumbai
9) Ms. Gultash Guron, Lending Hands Foundation, New Delhi
10) Ms. Aditi Sharma, Goonj New Delhi
11) Shri Dharmbeer, Member Secretary, TXD 36

Item 0 WELCOME AND INTRODUCTORY REMARKS

Smt. Shradha Dongre, SASMIRA, Mumbai (Convenor) extended a hearty welcome to the members of panel. She emphasized for active participation from the members and requested for the precise inputs so as to arrive at consensus.

Member secretary has also welcomed the Convenor and all other members.

Item 1 COMMENTS ON PUBLISHED STANDARDS

1.1 IS 5405 : 2019, Sanitary Napkins — Specification (Second Revision) and IS 17514 : 2021, Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification

The panel considered the technical input/suggestion received from Shri D. Veera Subramanium, SITRA, Shri Abhisek Saini, Lending Hand Foundation, New Delhi and Ms. Roocha Kedkar, Johnson & Johnson Ltd. (Kvenue), Mumbai. as given in **Annex 1** and **Annex 2** of the agenda.

After deliberations, the panel recommended the following: -

i) IS 5405 : 2019, Page 2, clause 7.1, second line, Delete 'cold method.'
ii) The requirement of cytotoxicity shall be changed from 'None' to 'non-cytotoxic' in IS 5405 : 2019 and IS 17514 : 2021.
iii) The panel requested **Ms. Roocha Khedkar** to share the technical data and test report to justify to change in the requirement of pH in sanitary pad. The technical data shall include the testing of adequate samples from different lots from BIS recognised lab/NABL Approved lab, Inhouse Lab, International Standards on sanitary pad which do not have pH test/have lower pH range, established technical and scientific paper/article supporting lower pH.
iv) It was recommended that the manufacturer shall declare the material of top sheet, middle layer and bottom sheet of the product along with chemical ingredient on the label if agreed between the buyer and seller.
v) It was informed that the amendment no. 3 to IS 5405 : 2019 and IS 17514 : 2021 incorporating the requirement of phthalate test has been finalized by TXD 36 and under publication.
vi) It was informed that test method of Volatile organic compounds for textiles products is under development in Chemical Methods of Tests Sectional Committee TXD 05.

vii) The panel has suggested that the volatile organic compound test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product.

viii) The panel also recommended that the manufacturer of final product shall also do the volatile organic compound test once in a year.

ix) Once the test method is finalized, the panel may suggest the requirement/value of volatile organic compounds based on International Practice or after testing of sanitary pad samples available in market or from manufacturers.

1.2 There being no other business, the meeting ended with a hearty vote of thanks to the *Convenor and members.*

ANNEX 8
(Item 6.*1*)

COMMENTS ON PUBLISHED STANDARDS

COMMENTS RECEIVED ON IS 5405 :2019 AND IS 17514 : 2021

a) **Smt. Roocha Khedkar,** JNTL consumer Health pVt ltd **(Kenvue**)

1.	Clause – 7 Subclause – 7.1	pH Value	Technical	We hereby make our detailed submission and request to revise the pH specification range to 3.5 - 8.0, as against the existing range of 5.5 - 8.0, before the said standard is made mandatory. Our subject request is based on the following factors: 1) International practices on regulating sanitary protection. 2) Key scientific considerations related to use of sanitary napkins (product safety and efficacy) 3) Wood Pulp Technology and Standard Consideration 4) Sanitary Protection access, affordability, and impact on sustainability goals in India **1. International Practices on Regulating Sanitary Protection:** Being a Global organization, having offices and manufacturing units across the globe, we are happy to share with you that, we have looked into various Regulations on Sanitary Protection in developed markets as well as few emerging markets. It is interesting to note that pH is either not a specified	Request to revise the pH specification range from 5.5 - 8.0 to **3.5 - 8.0**

				parameter as part of the relevant standard set or it is a case that pH is a specified parameter, but the relevant standard itself in most of the countries is voluntary. At the same time, it may be noted that wherever pH as a parameter of a standard is mandatory, to our understanding it is a parameter of quality rather than a parameter of efficacy. To confirm on the various regulatory market specific requirements, please refer to **Annexure I** for detailed information. **2. Key scientific considerations related to use of sanitary napkins (product safety and efficacy):** We acknowledge that products designed for feminine hygiene should be effective, provide comfort, care and should also be safe to use. Sanitary pads are worn closer to the Vulva (the outer part of the female reproductive system). The vulva includes the opening of the vagina (sometimes called the vestibule), the labia majora (outer lips), the labia minora (inner lips), and the clitoris. Physiological pH for vulva is about 3.5 - 4.7 and that of vagina is around 3.8 to 4.4 in reproductive age. During menstruation, the pH continues to be in the acidic range between 3.8 - 4.2 for vulva. An acidic environment helps support the microbial flora. The products that are	

				closer to the physiological pH of the intimate area facilitates growth of the commensal bacteria, lactobacilli, which limits the colonization of pathogenic bacteria. Further, being category leaders, we have Post Marketing Safety Data (PMSD) to confirm that no safety signals related to our sanitary protection products under the brand name Stayfree® & Carefree® in India have been identified. Our products in scope continue to have a favorable safety profile for the intended use in India. We will continue routine monitoring of AEs associated with the use of Stayfree® and Carefree® branded sanitary protection products. We have documented evidence to prove that acidic pH supports the intimate health during the menstrual journey. Please refer to **Annexure II**, for details on the physiological aspect as well as the PMSD information. **3. IS Standard and Wood Pulp Technology Consideration** If we refer to IS 5405: 2019 standard (Second revision), it is evident that the standard describes two types of pads, (i) Thick Pads & (ii) Thin Pads. It states that thick pad consists of fluff pulp and thin pads consists of compressed sheet of absorbent material (combinations of pulp and super absorbent polymer).	

				During the manufacturing of the Sanitary Napkins, the Absorbent core (which the majority is of the wood fluff pulp, for absorption of menstrual fluid, holding it under pressure and maintaining the durability of the product) forms the maximum percentage of the product. It is also known that pads made with pure wood pulp would always be more towards the acidic side, since the property of wood pulp itself is acidic in nature. The acidic wood pulp is beneficial, since it leads to denser and longer fibers, which helps in providing better absorbing capacity. Please refer to **Annexure III**, where we would like to highlight technical attributes on the standard as well as the wood pulp processing technology references, which would demonstrate that Thick sanitary pads should have a pH range of 3.5 - 8.0 **4. Sanitary Protection access, affordability, and impact on sustainability goals in India** Central and State Governments has increasingly focused on menstrual health. The Menstrual Hygiene Scheme under the National Health Mission and promotion of menstrual hygiene amongst adolescent was launched to increase awareness of and access to sanitary pads. The programs and initiatives by the central and state government are a	

				necessary medial to promote menstrual health in India. The implementation of the standard with the prescribed pH requirements, will require modification of the composition of Thick Napkins, from a biodegradable wood pulp absorbent core to a non-sustainable combination of pulp and polymer (non-biodegradable and not possible to segregate). This would have a negative impact to the environment and the sustainability goals of the Governments. In the attached **Annexure IV**, we have collated and highlighted that implementation of a standard especially on Thick pads, which would have specific concerns on access, affordability and impact on sustainability. Based on the scientific facts, explanation and the rationale provided hereinabove along with the respective Annexures, we humbly request revision of the pH specification range from 5.5 - 8.0 **to 3.5 – 8.0** under IS 5405: 2019 Sanitary Napkins - Specifications (Second Revision), before the said standard is made mandatory. This would be in the interest of public at large and sustainability goals of the country.	

				 Annexure III.pdf  Annexure II.pdf  Annexure I.pdf  Annexure IV.pdf	

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clause/sub clause/table/fig etc. be started on a fresh box. Information in column 3 should include reasons for the comments and suggestions for modified working of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

Please e-mail your comments to textiles.bis@gmail.com or txd@bis.gov.in or faxed on 011-23231282.
NAME OF THE COMMENTATOR/ORGANIZATION: JNTL consumer Health pVt ltd **(Kenvue)**

DOCUMENT NO: IS 5405: 2019, Sanitary Napkins – Specification and PM/ IS 5405/1 Sept 2020

Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)	Comments	Specific Proposal (Draft clause to be add/amended)	Remarks	Technical References and justification on which (2), (3), (4) are based
(1)	(2)	(3)	(4)	(5)
5. Sizes Class Recommended sizes Pad length (mm) (absorbent core only) Regular ≤ 210mm, Large 211 to 240mm, Extra-large 241 to 280mm, XXL ≥ 281mm, Pad width (mm) (absorbent core only) min 55 mm	If we want to launch longer length product what will be maximum limit for XXL?	**N/A**	Longer length product is an unmet need of consumer	**N/A**
7.1 pH Value	1. As per the procedure, limit of pH is for absorbent material, hence what should be taken for testing - cover + absorbent core + barrier OR cover + absorbent core OR only absorbent core. 2. As per IS1390:2022, deionized or distilled water is mentioned. Can potable water be used as reagent for pH testing	**N/A**	**N/A**	**N/A**

7.2 Ability to Withstand Pressure after Absorption	Can potable water be used to prepare reagent.	**N/A**	**N/A**	**N/A**
7.3 Hygiene Testing Requirement	1. If there is no change in Good Manufacturing Practice, can the test be performed annually for monitoring 2. For testing media, can it be mentioned as plate count agar (PCA) or equivalent media for bacterial bioburden and Sabouraud chloramphenicol agar (SCA) or equivalent media.	**N/A**	**N/A**	**N/A**
7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement	Need clarification on a) "Location should be free from objectionable odours, smoke, dust and other contaminants". **How can be this checked? Can we say Obnoxious odor?**	**N/A**	**N/A**	**N/A**

	f) Appropriate lighting and proper ventilation of the facility shall be ensured. **How would this be checked?** **What is the definition of Prepackage** in the statement Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants			
7. 4 Biocompatibility Evaluation Cytotoxicity, Irritation and Skin Sensitization Amendment 1 "If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use.'	**Confirmation required.** Based on its known toxicological characteristics No testing is not required to be done for raw material and finished product?	**N/A**	**N/A**	**N/A**

8.0 Sampling and criteria for conformity 8.1 Lot All the sanitary napkin of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot. 8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.	Can Manufacturer define the lot to enable to be traced back from records? Example: Can all sanitary napkin of same material can be considered as one lot? What is the justification of lot, where there is no specific difference in the manufacture of 2 different lots? **Can this be excluded?** The manufacturer shall decide the necessary sampling & testing frequencies to ensure compliance with BIS requirements as monitoring of product.	**N/A**	**N/A**	**N/A**
8.2 Number of Tests and Criteria for Conformity	The parameters to check workmanship & finish shall be defined by manufacturer. Ensure testing of requirements in accordance	**N/A**	**N/A**	**N/A**

	with IS 5405 through own or NABL accredited or BIS certified labs at the time of registration and there after at least once in six months. For test of pH and absorbency, Can composite / representative sample be tested			
9. MARKING	**N/A**	N/A	N/A	N/A
9.2 BIS Certification Marking	If there is change in raw material or alternate material is qualified for supply issue what will happen to the license and marking? In case of External Manufacturing site who will take the license and what will appear on the pack? Are Repacker/ copacker (not manufacturer of product) also included in the	N/A	N/A	N/A

	scope? Are they required to take license?			
10 Packing	N/A	N/A	N/A	N/A
Amendment 3 (new) Phthalates	N/A	N/A	N/A	N/A
PM/ IS 5405/1 Sept 2020				
6. Scope of the License	What is Procedure for BIS registration, Licensing & timelines?			
TABLE-1 LEVELS OF CONTROL 3.1 Cover/ top sheet No. of sample- one sample Frequency – each consignment	Can the manufacturers refer supplier certificate of analysis for conformity of raw material?			
TABLE-1 LEVELS OF CONTROL 3.2 Absorbent Core No. of sample- one sample Frequency – each consignment	Can the manufacturers refer supplier certificate of analysis for conformity of raw material?			

TABLE-1 LEVELS OF CONTROL 3.3 Barrier or Bottom Sheet No. of sample- one sample Frequency – each consignment	Can the manufacturers refer supplier certificate of analysis for conformity of raw material?			
SCHEME OF INSPECTION AND TESTING 1. LABORATORY- A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.	The defined scheme of inspection and testing is not practical for operations of sanitary napkins. If the manufacturer having own laboratory is approved by BIS, the inhouse lab can be considered as approved and samples from other EM sites can be allowed for testing at this lab. During application for tenders, reports from approved BIS certified BO can be considered acceptable.		As per food product standard, FBO shall decide themselves the necessary sampling and testing frequency to ensure compliance with the specified requirement. Can we ensure compliance to BIS requirements through testing at own/ NABL accredited/ BIS certified labs at least once in six months. This is proven practice food industry	

b) Dr. Sonal Shidhore, Director-Regulatory Affairs, JNTL Consumer Health (India) Pvt Ltd.

Subject: Request to revise the pH specification range to 3.5 – 8.0 in the IS 5405 : 2019 Sanitary Napkins – Specifications (Second Revision) (with the IS 1390 : 2022 Textiles – Determination of pH of Aqueous Extract, third revision), given the impending implementation of Quality Control Order (QCO) {S.O. 4247(E) dated 27th September 2023}.

Respected Sir,
At the outset, we are pleased to inform that we were the first to develop and produce a commercially available disposable Sanitary napkin in the year 1896 (Lister's Towels).

We are really indebted to your good self for granting us a patient hearing during our visit at Manak Bhavan on 18th Oct, 2023, over our request for revising the IS 5405 : 2019 standard pH requirement to 3.5 – 8.0 (Testing of the Sanitary pads in accordance with IS 1390 : 2022 Textiles – Determination of pH of Aqueous Extract, Third revision).

Further to our discussion, we hereby make our detailed submission and request to revise the pH specification range to 3.5 – 8.0, as against the existing range of 5.5 – 8.0, before the said standard is made mandatory. Our subject request is based on the following factors:

1. International practices on regulating sanitary protection.
2. Key scientific considerations related to use of sanitary napkins (product safety and efficacy)
3. Wood Pulp Technology and Standard Consideration
4. Sanitary Protection access, affordability, and impact on sustainability goals in India

1. 1. International Practices on Regulating Sanitary Protection:
Being a Global organization, having offices and manufacturing units across the globe, we are happy to share with you that, we have looked into various Regulations on Sanitary Protection in developed markets as well as few emerging markets.

It is interesting to note that pH is either not a specified parameter as part of the relevant standard set or it is a case that pH is a specified parameter, but the relevant standard itself in most of the countries is voluntary. At the same time, it may be noted that wherever pH as a parameter of a standard is mandatory, to our understanding it is a parameter of quality rather than a parameter of efficacy or safety.

To confirm on the various regulatory market specific requirements, please refer to **Annexure I** for detailed information.

2. **Key scientific considerations related to use of sanitary napkins (product safety and efficacy):**

We acknowledge that products designed for feminine hygiene should be effective, provide comfort, care and should also be safe to use.

Sanitary pads are worn closer to the Vulva (the outer part of the female reproductive system).
The vulva includes the opening of the vagina (sometimes called the vestibule), the labia majora (outer lips), the labia minora (inner lips), and the clitoris.
Physiological pH for vulva is about 3.5 – 4.7 and that of vagina is around 3.8 to 4.4 in reproductive age. During menstruation, the pH continues to be in the acidic range between 3.8 – 4.2 for vulva. An acidic environment helps support the microbial flora. The products that are closer to the

physiological pH of the intimate area facilitates growth of the commensal bacteria, lactobacilli, which limits the colonization of pathogenic bacteria.

Further, being category leaders, we have Post Marketing Safety Data (PMSD) to confirm that no safety signals related to our sanitary protection products under the brand name Stayfree® & Carefree® in India have been identified. Our products in scope continue to have a favorable safety profile for the intended use in India. We will continue routine monitoring of AEs associated with the use of Stayfree® and Carefree® branded sanitary protection products.

We have documented evidence to prove that acidic pH supports the intimate health during the menstrual journey. Please refer to **Annexure II**, for details on the physiological aspect as well as the PMSD information.

3. 3. IS Standard and Wood Pulp Technology Consideration

If we refer to IS 5405: 2019 standard (Second revision), it is evident that the standard describes two types of pads, (i) Thick Pads & (ii) Thin Pads. It states that thick pad consists of fluff pulp and thin pads consists of compressed sheet of absorbent material (combinations of pulp and super absorbent polymer).
During the manufacturing of the Sanitary Napkins, the Absorbent core (which the majority is of the wood fluff pulp, for absorption of menstrual fluid, holding it under pressure and maintaining the durability of the product) forms the maximum percentage of the product. It is also known that pads made with pure wood pulp would always be more towards the acidic side, since the property of wood pulp itself is acidic in nature.

The acidic wood pulp is beneficial, since it leads to denser and longer fibers, which helps in providing better absorbing capacity.

Please refer to **Annexure III**, where we would like to highlight technical attributes on the standard as well as the wood pulp processing technology references, which would demonstrate that Thick sanitary pads should have a pH range of 3.5 – 8.0

4. 4. Sanitary Protection access, affordability, and impact on sustainability goals in India

Central and State Governments has increasingly focused on menstrual health. The Menstrual Hygiene Scheme under the National Health Mission and promotion of menstrual hygiene amongst adolescent was launched to increase awareness of and access to sanitary pads. The programs and initiatives by the central and state government are a necessary medial to promote menstrual health in India.
The implementation of the standard with the prescribed pH requirements, will require modification of the composition of Thick Napkins, from a biodegradable wood pulp absorbent core to a non-sustainable combination of pulp and polymer (non-biodegradable and not possible to segregate). This would have a negative impact to the environment and the sustainability goals of the Governments.

In the attached **Annexure IV**, we have collated and highlighted that implementation of a standard especially on Thick pads, which would have specific concerns on access, affordability and impact on sustainability.

PRAYER:

Based on the scientific facts, explanation and rationale provided hereinabove along with the respective Annexures, we humbly request revision of the pH specification range from 5.5 – 8.0 **to 3.5 – 8.0** under IS 5405: 2019 Sanitary Napkins – Specifications (Second Revision), before the said

standard is made mandatory. This would be in the interest of public at large and sustainability goals of the country.

Thanks for your kind consideration for taking this up at the committee meeting to be held on 7th November 2023, and we look forward to for a positive confirmation over the same.

Annexure I: International Practices on Regulating Sanitary Protection

Table 1

Market	Mandatory pH requirement	Tests	Document
North America			
United States of America	No specific pH requirement is mentioned in the guideline	None	 US Menstrual-Tampons-a (Page no. 14 of the document)
Canada	No specific guideline on pH requirement	None	Not Applicable
Europe			
Austria Belgium Croatia Denmark France Germany Greece Italy Netherland Norway Poland Portugal Spain Sweden Switzerland	pH requirement for SAP material is mentioned.	The document is related to thin and ultra-thin sanitary pads which have the top sheet and the absorbent core. The absorbent core is composed of a cellulose cover and Superabsorbent polymers (SAP). There is pH range given on page no. for "properties of SAPs" which is in the range of 5.5 to 7.5.	 EU - Absorbent Hygiene Products_Dra (Page no. 67 to 74 of the document)

United Kingdom	REACH Regulation - No specific guideline on Sanitary Napkins, only some reference of 'Cellulose pulp' related information has been mentioned which is enclosed here.	'Cellulose Pulp' is exempted under Annexure IV Exemptions from The Obligation to Register in Accordance with Article 2(7)(A), which mentions " *substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties"*	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217 (Page no. 154 & 155 of the document)
Asia and Pacific			
Australia	No specific guideline on pH requirement	None	Not Applicable
China	pH requirement given in the guideline. It is industry recommended voluntary guideline.	pH Range – 4.0 to 9.0	 GBT 8939-2018.docx  China - GBT - 8939 2018 English Translat (Page no. 3 of the document)
Indonesia	No specific guideline on pH requirement	None	Not Applicable
Malaysia	No specific guideline on pH requirement	None	Not Applicable
Philippines	No specific guideline on pH requirement	None	Not Applicable
Singapore	No specific guideline on pH requirement	None	Not Applicable
South Korea	Acidity & alkalinity test is mentioned but no specific pH range is mentioned in the standard.	Acidity & alkalinity	
Thailand	pH requirement is given in the guideline	pH Range – 5.0 to 8.5	 Thailand Document.PDF  Thailand Document English.PDF (Page no. 3 of the document)

Japan	Acidity & alkalinity test is mentioned but no specific pH range is mentioned in the standard.	Acidity & alkalinity	Japanese PFSB No. 0325-17 Standards fo (Page no. 3 of the document)
LATAM			
Argentina	No specific guideline on pH requirement	None	Not Available
Bolivia	No specific guideline on pH requirement	None	Not Available
Brazil	No specific guideline on pH requirement	None	Not Available
Chile	No specific guideline on pH requirement	None	Not Available
Colombia	No specific guideline on pH requirement	None	Not Available
Costa Rica	No specific guideline on pH requirement	None	Not Available
Republic of Dominica	No specific guideline on pH requirement	None	Not Available
Ecuador	No specific guideline on pH requirement	None	Not Available
El Salvador	No specific guideline on pH requirement	None	Not Available
Guatemala	No specific guideline on pH requirement	None	Not Available
Honduras	No specific guideline on pH requirement	None	Not Available
Mexico	No specific guideline on pH requirement	None	Not Available
Nicaragua	No specific guideline on pH requirement	None	Not Available

Panama	No specific guideline on pH requirement	None	Not Available
Paraguay	No specific guideline on pH requirement	None	Not Available
Peru	No specific guideline on pH requirement	None	Not Available
Uruguay	No specific guideline on pH requirement	None	Not Available
Venezuela	No specific guideline on pH requirement	None	Not Available
Africa			
Kenya	pH requirement given in the draft standard for Disposable Maternity Pads. Further, type of absorbent filler is not clarified (i.e. wood pulp or SAP or combination)	pH value 5.5 – 8 for Disposable Maternity Pads	 Maternity pad kenya standard.pdf (Page no. 7 of the document)
East African Standard (Tanzania)	pH requirement mentioned in the voluntary standard for Sanitary Towels. Further, type of absorbent filler is not clarified (i.e. wood pulp or SAP or combination)	pH value 5.5 – 8.5 for Sanitary Towels	 East African Standard (Tanzania).pdf (Page no. 7 of the document)
Ethiopia	pH requirement in the voluntary standard for Disposable Maternity Pads. Further, type of absorbent filler is not clarified (i.e. wood pulp or	pH value 6 – 8.5 for Disposable Maternity pads	 Ethiopian Standard 6345- 2018 Disposabl (Page no. 5 of the document)

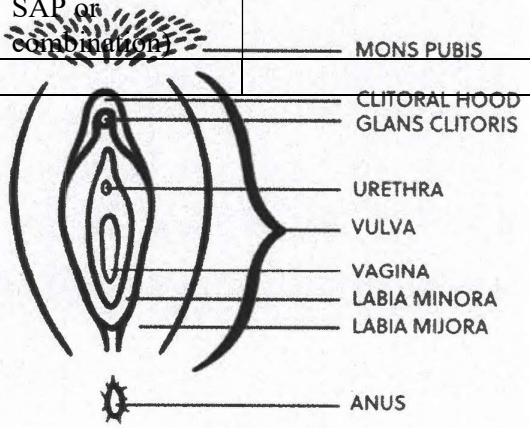
Annexure II

Characteristics of the Female genital tract and Sanitary pads usage

Sanitary napkins are a necessary product used by women during menstruation. The pads are closely applied to genital mucosa, vulvar skin and perinium. [1]

a. Anatomy of the Female Genital Tract

Sanitary pads are worn closer to the Vulva (the outer part of the female reproductive system). The vulva includes the opening of the vagina (sometimes called the vestibule), the labia majora (outer lips), the labia minora (inner lips) and the clitoris.[2]



b. Physiological pH of the Female Genital tract

Table 1. Physiological characteristics of the vulvar and vaginal area.

	Vulva	Vagina
Tissue structure	Mons pubis, labia, clitoris, and perineum: keratinized, stratified squamous structure with sweat glands, sebaceous glands, and hair follicles Vulvar vestibule mucosa: non-keratinized	Fibromuscular canal composed mainly of smooth muscle with a lining of aglandular, non-keratinized stratified squamous epithelium
pH	3.5–4.7	Premenarche: 7.0 Reproductive age: 3.8–4.4 Menopause: 6.5–7.0 (without hormone therapy); 4.5–5.0 (with hormone replacement therapy)
Microflora	Lipophilic and non-lipophilic diphtheroids; coagulase-negative staphylococci, micrococci, and lactobacilli; streptococci; Gram-negative rods; Gram-negative bacilli; *Neisseria*; *Gardnerella vaginalis*; and/or yeasts	*Lactobacillus* spp., *Atopobium vaginae*, *Megasphaera* spp., *Leptotrichia* spp., *Gardnerella vaginalis*, *Staphylococcus aureus*, and/or *Candida albicans*

Physiological pH for vulva is about 3.5 – 4.7 and that of vagina is around 3.8 to 4.4 in reproductive age[3]

	SAP or combination)	pH Requirement in the draft standard for Sanitary Towels and not for Sanitary Napkins. Further, type of absorbent filler is not clarified i.e wood pulp or SAP or combination)	pH value 5.5 – 8.5 for Sanitary Towels	(Page no. 10 of the document)
Uganda				

Vulvar pH could be expected to fall between values for the skin (estimated at pH 4.7) and the vagina (average pH 3.5), with reports ranging from 3.8 to 4.2 during the menstrual cycle.[3] For women with a normal, active menstruation cycle, the vaginal pH is typically between 3.8 and 5.0.[4]

Skin pH is affected by a great number of endogenous factors, e.g. skin moisture, sweat, sebum, anatomic site, genetic predisposition and age.[5] In addition, exogenous factors like detergents, application of cosmetic products, occlusive dressings as well as topical antibiotics may influence the skin pH.[6]

It is well known fact that physiological pH of skin surface is acidic, and may vary basis anatomic site.[5,6]

There are "physiologic gaps" in the acid barrier depending on skin site, particularly the interdigital spaces and intertriginous areas-axillae, groin and inframammary zone. The pH is higher in these regions compared to other skin sites.[6]

c. Impact on pH in vaginal and perineal area after use of sanitary napkins:

In an investigator blinded cross over study to characterize the cutaneous effect and suitability of modern sanitary pads for menstrual protection, vulvar area were slightly acidic with pH values ranging from 4.53 to 4.62 both at the prior menstrual and after each menstrual cycle. No significant difference was found between the prior-menstrual and after each menstrual cycle.[7]

Clinical study by Petra Hanke-Baier, et al demonstrated that the mean vaginal pH was reported around 6.5 during menstruation compared to 4.4 during the intermenstrual visits and that there was no evidence that wearing the pads had any influence on the vaginal pH.[8]

d. Clinical importance of maintaining acidic pH of Vulva: Protection from infections & irritation

The vulva is the first line of defense to protect the genital tract from infection. The normal vaginal flora, acidic vaginal pH, and vaginal discharge are all components of the innate defense mechanisms that protect against vulvovaginal infections. Maintenance of the vulval microbiota ratio is anticipated to play a key role in overall vulvovaginal health. Vulvar flora may also affect the proliferation of exogenous pathogens that cause vaginal and urinary tract infections.[3] Due to the proximity of the vulva to the anal, vaginal and urethral orifices, it is continuously exposed to opportunistic pathogens, and relies on a naturally acidic environment (pH 3.8-4.2) to inhibit pathogen colonisation.[9]

Lactobacilli are the major form of protective commensal bacteria in the vaginal mucosa. Lactobacilli limit the colonization of transient and pathogenic bacteria by producing antibacterial substances, hydrogen peroxide and lactic acid, which acidify the uppermost layers of the intimate skin. Lactobacilli protect against opportunistic infections by acidifying the vagina and producing antimicrobial substances, such as lactic acid and hydrogen peroxide.[10] Similarly, in keratinized squamous epithelia like that of the labia majora, resident microbiota such as Cutibacterium acnes promotes reduces skin pH via production of short-chain fatty acids.[11]

e. Impact of Exogenous factors on pH of Vulva

Occlusion leads to an increasing in vulval skin hydration accompanied by an increase in pH, from its normal slightly acidic condition to near neutrality. pH can also exert an effect on microbial populations by altering the antimicrobial properties of fatty acids on the skin. The protonated form of the acid is more active than the unprotonated form, so as the pH approaches the pKa of the acid, antimicrobial activity increases. As microorganisms vary in their susceptibility to fatty acids, relatively small changes in pH can influence the numbers and kinds of organisms that thrive in a population. Small changes in vulval skin pH can provide ecological advantage to organisms finding more favorable conditions with regard to hydrogen ion concentration.[12] There is inconclusive evidence as to the impact of disposable pad use and bacterial vaginosis, as well as reproductive tract infections especially in relation to prolonged wear time.[13]

For products to be used for daily vulvar cleansing, clinical practice guidelines recommend women to use a pH-balanced, hypoallergenic cleansing agent. Being pH friendly is one of the key attribute of intimate female hygiene products. Lactic acid–based liquids with an acidic pH may augment skin homeostasis and have been shown to be helpful in vaginal infections as an adjuvant therapy but not as a treatment[3]

f. Post Marketing Safety Data (PMSD) data over the past 3 years (Kenvue Product)

Post-market surveillance is conducted by manufacturers to collect and evaluate experience gained from the use of the products that have been placed in the market and to identify the need for any action to be taken with the products. For the period from 01 January 2019 to 30 September 2023, through the review of AEs received by the company, no new safety signals related to Stayfree branded sanitary protection products in India have been identified. The Stayfree branded products in scope continue to have a favorable safety profile for the intended use in India. The company will continue routine monitoring of AEs associated with the use of Stayfree and Carefree branded sanitary protection products.

We would also like to highlight the process of **Safety assessment for sanitary napkins at Kenvue:**

- The risk/safety assessment is done on raw materials and finished products sequentially.

Summary

Sanitary pads typically are in direct contact with Vulva, groin and skin of buttocks. Physiological pH for vulva is about 3.5 – 4.7 in reproductive age with reports ranging from 3.8 to 4.2 during the menstrual cycle. For women with a normal, active menstruation cycle, the vaginal pH is typically between 3.8 and 5.0 and has been also reported to be around 6.5 during menstruation. Vulva is first line of defense to protect from genital tract from infections. The normal vaginal flora, acidic vaginal pH, and vaginal discharge are all components of the innate defense mechanisms that protect against vulvovaginal infections Due to the proximity of the vulva to the anal, vaginal and urethral orifices, it is continuously exposed to opportunistic

pathogens, and relies on a naturally acidic environment (pH 3.8-4.2) to inhibit pathogen colonization. Lactobacilli protect against opportunistic infections by acidifying the vagina and producing antimicrobial substances such as lactic acid and hydrogen peroxide. Being pH friendly is one of the attributes of intimate female hygiene products. No safety signals related to Stayfree branded sanitary protection products in India have been identified basis review of Adverse Events done for the period from 01 January 2019 to 30 September 2023

References:

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13. Guide to Menstrual Hygiene materials. UNICEF. May 2019. Available from: URL: https://www.unicef.org/media/91346/file/UNICEF-Guide-menstrual-hygiene-materials-2019.pdf

Annexure III

Technical document for Wood Pulp and standard considerationUnderstanding on Wood pulp:

Before we go into Wood pulp, let's understand what a Sanitary Protection

Product/Napkin is.A sanitary napkin is a menstrual protection product and made up of

three basis layer –

- Top sheet- Absorb menstrual fluid and retains it inside the core, gives comfort on the skin
- Absorbent core – for absorption of menstrual fluid, holding it under pressure and maintaining the durability of the product
- Barrier – for protection from leakage

These layers are held by an adhesive together. Depending on the product design it can have tabs for consumer to wear it or adhesive covered with paper to hold it in place on the undergarment.

The absorbent core is major component in a sanitary napkin. It is majorly made of Cellulosic wood pulpwhich also naturally derived biodegradable polysaccharide in the product.

The fibres of these cellulose pulp used in hygiene industry, for sanitary napkins, is of longer length andsuitable fibre diameter that help in pulp pad formation, effective distribution of menstrual fluid, and provide high pad durability.

The wood pulp also referred as Fluff pulp is produced utilizing the world's best fluff pulp fibre. 90% of the world's wood pulp is made by Kraft process. The Kraft process (also known as Kraft pulping or sulfate process) is a process for conversion of wood into wood pulp, which consists of almostpure cellulose fibres.

Kraft pulping removes most of the lignin present originally in the wood. The hydrophobic nature of lignin interferes with the formation of the hydrogen bonds between cellulose (and hemicellulose) in thefibres needed for the strength of the pad. Researchers suggest that it is desirable to do delignification ata lower pH. Further the pulp is bleached using Elemental Chlorine-free bleaching process.

$$2\ NaClO3 + H2SO4 + SO2 \rightarrow 2\ ClO2 + 2\ NaHSO4$$

Chlorine dioxide is used alone in ECF (elemental-chlorine-free) bleaching sequences. It is used at moderately acidic pH (3.5 to 6). The use of chlorine dioxide minimizes the amount of organochlorine compounds produced. Chlorine dioxide (ECF technology) currently is the most important bleaching method worldwide. About 95% of all bleached kraft pulp is made using chlorine dioxide in ECF bleaching sequences.

The pads made with pure wood pulp would always be therefore more towards the acidic side. (It is alsoimportant to consider if the modification to the Absorbent core sis to be considered it will lead to impacton the access and affordability. Refer to **Annexure IV**, which details the same)

This concludes that basis the wood fluff pulp process manufacturing, the key component of a Sanitarypad, i.e. the absorbent core, if contains wood pulp, would be acidic in nature.

BIS Standard Consideration:

If we look at the BIS standard IS 5405:2019 (Second revision), section 3.2 mentions “An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt, or foreign material.

The standards permit the use of Cellulose pulp and wood pulp alone as the main component of the absorbent core in the sanitary pad.

Additionally, the standard also prescribes Sanitary Napkins under various Types

a) Thick napkins, and
b) Thin napkins

With a note, clearly depicting that 'The thin napkins contain a compressed sheet of absorbent materialin the core, whereas thick napkins are referred as fluff pulp napkins'.

This clearly states that thick napkins should contain Wood Fluff Pulp, and if thick napkins are made with Wood Fluff Pulp, the napkins would tend to be on an acidic side of the spectrum, due to the intrinsicproperties of the wood pulp.

Wood pulp also helps in maintaining the sustainability objective, on account of its biodegradability andis more environmental friendly.

References:

a) https://en.wikipedia.org/wiki/Fluff_pulp
b) https://en.wikipedia.org/wiki/Kraft_process
c) https://en.wikipedia.org/wiki/Bleaching_of_wood_pulp#:~:text=Chlorine%20dioxide,-Chlorine%20dioxide%2C%20ClO&text=2%20NaClO3%20%2B%20H2,2%20ClO2%20%2B%202%20NaHSO&text=Chlorine%20dioxide%20is%20sometimes%20used,pH%20(3.5%20to%206).
d) Y. NI, G.J. KUBES and A.R.P. VAN HElNlNGEN , Mechanism of Chlorate Formation During Bleaching of Kraft Pulp with Chlorine Dioxide

Annexure IV

Sanitary Protection access, affordability, and impact on sustainability goals in India

We have collated information on sanitary protection and practices in India, to drive the point on accessand affordability.

At the outset, we, would like to congratulate the Governments for its relentless support and contributions in several important decisions and an increased momentum on health and hygiene of girls child and womenwith the continued and sustained efforts through schemes such as Beti Bachao Beti Padhao Yojna, MahilaE-Haat, Working Women Hostel, One Stop Centre Scheme etc which are positively impacting the lives ofmany. We place on record our wholehearted support to this intention of Government and do appreciate theefforts in this regard.

Further, the Union Government and the State Governments have actively promoted the cause of menstrualhygiene. The government itself launched the National Menstrual Hygiene Scheme under the 'Rashtriya Kishor Swasthya Karyakram' program in 2014. The objective of the scheme was to promote menstrual hygiene among adolescent girls in rural areas by supplying as well as training self-help groups to make sanitary napkins.

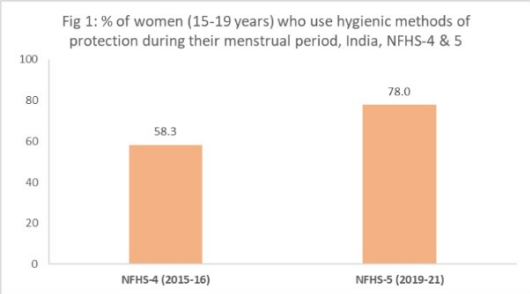
Market Dynamics to consider access and affordability.

A recent Press Release (3rd Aug 2023) shared by Ministry of Women and Child Development, highlights the ministry has implemented schemes since2011 to increase awareness among adolescent girls as well as to increase access to and use of high quality sanitary napkins. The press release also quoted that, Department of Health Research under Ministry of Health and Family Welfare (MoHFW) carries out research and studiesto look into the newer methods of managing menstrual health and other sustainable alternatives to sanitarynapkins for their safety, acceptability, affordability, efficacy and feasibility among women in public healthprogram setting[b].

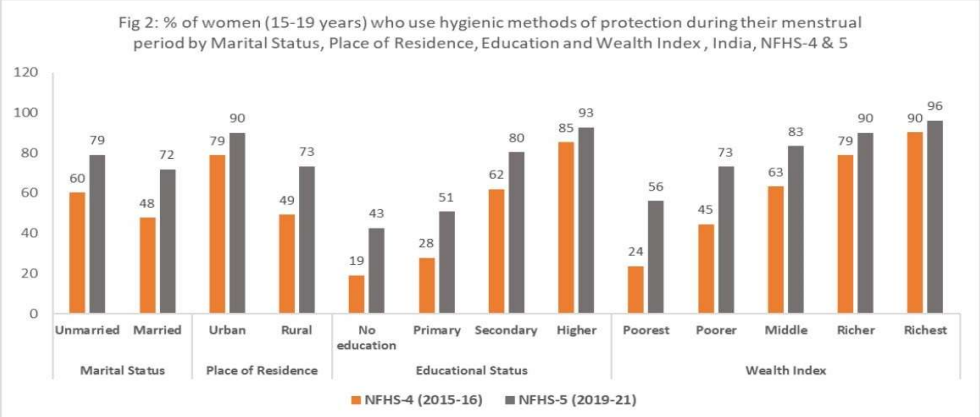
A study published in BMC Public Health Journal in Nov 2022, concluded that in Rural India, adolescent women with higher education, from general category, with medium mass media exposure, and from richestwealth quintile were more likely to use hygienic methods exclusively and suggested state- and district- specific menstrual hygiene policies to improve the universal access to hygienic methods among adolescentwomen in rural India[c].

Key insights from National Family and Health Survey, NFHS-5 (2019-2021) about Menstrual hygiene among Adolescent Girls state that there are 242 million adolescents aged 10-19 in India comprising 18% of the total population and among them 116 million are girls. The onset of menstruation is one of the mostimportant changes that occur among adolescent girls. The use of a hygienic method of menstrual management is imperative for her health and personal hygiene and, vital to her empowerment, and dignity.

The below figure from this report shows that 78% of adolescent girls use a hygienic method of sanitary protection during their menstrual cycle (2019-21), a substantial increase from the 58.3% reported about fiveyears back.



One of the determinants for the use of a hygienic method of protection during their menstrual cycle is wealthindex as shown in below figure referenced in the report[a].



We bring this information to the attention of the respected chair in order to offer perspective that the imposement of a standard which does not consider the different technologies used in Sanitary Napkins, maylead to issues with access, as well as affordability. This could be detrimental to the progress achieved through the policies that Government of India is pursuing.

Menstrual hygiene continues to be amongst the most challenging development issues even today.

Not only do deep taboos, myths and misinformation create the illusion that menstruation is inherently shameful but in countries like India, women and girls often lack access to hygienic sanitary materials and basic facilities such as Sanitary Napkins which are necessary for good menstrual hygiene management.

The biggest barrier to using a Sanitary Napkin is its access. “Sanitary Protection: Every Woman’s Health Right” a study by AC Nielsen reveals only 12 % of India’s 355 million women use sanitary napkins.

A study conducted by the Post Graduate Institute of Medical Education and Research in 2018 pointed out that while 80% of the women are aware of sanitary napkins, a mere 30% of them use it.

Access to sanitary napkins and consequent sanitary hygiene is recognized as one of biggest public health issue in the Country and various ministries under the guidance of Hon'ble PM's office have implemented schemes to ensure availability of sanitary napkins free of cost or at discounted prices.

We believe strongly that standards needed to ensure the safety and effectiveness of products are a criticallyimportant aspect of quality that should be universally enforced. At the same time, it is possible that standards may have unintended consequences including impact on price and access to consumers.

Based on recent market research (MAT August 2023 Nielsen report) carried out within India, the landscape of Sanitary protection is divided into Napkins, Liners and Tampons, of which 99% consumers use Napkinsduring their menstrual cycle. Out of the Napkins segment, about ~ 71% of the market segment for Sanitarynapkins constitute Thick pads (Wood Pulp based products). From a technology and manufacturingperspective the utilization of wood fluff pulp provides a safe and effective sanitary solution for women ata price which makes them accessible to a large proportion of the population.

	Volume (mil pads)	Volume
Only Pulp Based Sanitary Napkins	6924	71%

TOTAL Sanitary Napkin	
Napkins	99.0%
Liners	0.9%
Tampons	0.1%

For reference, about ~105 mm households in India use Pulp based Sanitary Napkins per year, consuming about 65.8 napkins per year per household (Nielsen RMS and Kantar Household Panel). With the new standard, modification would be needed to the pulp based pads, and would impact the large majority of users in the country to manage menstrual hygiene.

The industry would need to look at alternative technologies, such as introducing super absorbent polymers(SAP) or undertaking such product design interventions to develop a product that meets the expectations ofuser and satisfies the range specified in the Sanitary napkin standard. This change in the composition froma pure wood fluff pulp to a combination of wood fluff pulp and/or other components (like SAP) would leadto increased costs. This would shift the dynamic on the 'affordability' attribute of a Sanitary napkin furtheralienating and create additional barriers to consumers for usage of safe and effective pads to maintain hygiene.

The introduction of a superabsorbent polymer in sanitary pads to achieve pH requirements poses a challengein meeting both sustainability requirements, as mandated by the Ministry of Environment, and in managing the waste burden on municipal corporations. This issue arises from the fundamental difference between thetwo materials. The current use of wood pulp in sanitary pads is in line with sustainability goals, as it is biodegradable. However, the superabsorbent polymer (SAP) is not biodegradable. This change would consequently lead to an increased accumulation of non-biodegradable plastic waste in the environment, which runs counter to the Government of India's sustainable environmental objectives.

Additionally, the inclusion of SAP in sanitary pads would complicate the management of solid waste. Sincepolymers do not biodegrade and cannot be segregated, they would impose additional

challenges on the existing waste disposal systems and further burden the municipal corporations tasked with handling solid waste.

In summary, any change in sanitary napkin affordability can have a profound impact on access in developing countries. Even a minor price change can burden low-income households, making these essential products unaffordable. This, in turn, may force women to resort to unsanitary alternatives, risking their health. Reduced affordability also exacerbates "period poverty," hindering women's ability to attend school or work regularly. Moreover, this can lead to reduced availability and limited distribution of sanitary

napkins, compounding the challenges of menstrual hygiene, education, and overall well-being for womenin these regions.

References:

a) https://india.unfpa.org/sites/default/files/pub-pdf/analytical_series_2_-_menstrual_hygience_among_adolescents_-_insights_from_nfhs-5_final.docx.pdf
b) https://pib.gov.in/PressReleasePage.aspx?PRID=1945842
c) https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-022-14622-7

C) Shri Prashant Jadhav, Procter & Gamble – India

We kindly request you to include following topics in the agenda if feasible and as time permits:

Topic	Details
Proposed amendment of phthalates inclusion in the Sanitary Napkins (IS 5405) to be postponed	• As Industry is already busy in BIS certification work, publishing new amendment amid such preparation will add complexity • If this is expected to be included soon, then overall timelines for mandatory certification to be relaxed
Sampling Plan Inconsistency (IS 5405 & IS 17509)	• There is an inconsistency between sampling plans specified in the standards vs Manual corresponding to IS 5405 & IS 17509) • Though sampling plans (= Levels of Control) is recommendatory as per the footnotes, clause 7 in Annex C, expects sample plan in the manual to be followed
Biocompatibility Evaluation of Raw Materials as per ISO 10993 to be made Optional in the Baby Diaper (IS 17509) or removed	• These evaluation principles in ISO 10993 are applicable for medical devices and therefore not appropriate for evaluation of products like Diapers, Sanitary napkins and other adult incontinence products • Govt. of India (CDSCO) also does not consider general hygiene products as Medical Devices & therefore removed these products from the Medical Devices Classification list in 2022. • Even if we adopt Medical Devices Principles of India, that would be Class-A (non-sterile, non-measurable device). For such devices, no biocompatibility data is asked and an Undertaking under essential principle checklist is provided by the manufacturer. • It is not intended that ISO 10993 provide a rigid set of test methods, including pass/fail criteria, as this might result in either an unnecessary constraint on the development and use of novel medical devices, or a false sense of security in the general use of medical devices. • As per ISO 10993 Part 1 If the combination of all materials, chemicals and processes has an established history of safe use in the intended application, then further characterization and biological evaluation might not be necessary. For device extractables and leachable that have known toxicological data relevant to the intended dose and for which route and frequency of exposure that indicate adequate safety margins exist, the need for further testing is likely to be minimal or non-existent. • As per US-FDA Acceptance Checklist for Low-Risk Medical Devices (Class I): A biocompatibility to be carried out on tissue-contacting components. OR exception is given through a statement “A statement

	that biocompatibility testing is not needed with a rationale that considers all relevant endpoints • Performing Biocompatibility evaluation of each raw material (& continuous changes thereafter) is a huge work and cost burden (100s of raw material) on the Industry. Considering above points, it is requested to make Biocompatibility Evaluation optional in baby diaper standard in line with Sanitary Napkins.

ANNEX 9
(Item 6.3)

COMMENTS ON PUBLISHED STANDARDS

Doc: TXD 36 (xxxxx)

Draft **AMENDMENT NO. 1**

TO

IS 17508 : 2020 DISPOSABLE ADULT INCONTINENCE DIAPER — SPECIFICATION

(*Page* 4, *clause* **7.6**) **—** Insert the following new clause at the end: -

‘**7.7 Phthalate Test**

The amount of phthalate present in adult incontinence diaper shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.’

ANNEX 10
(Item 7.*1*)

INTERNATIONAL ACTIVITIES

CIB (Committee Internal Ballot), N59 - Draft ISO TC 338 Strategic Business Plan for comments

International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации

STRATEGIC BUSINESS PLAN – ISO/TC 338 MENSTRUAL PRODUCTS

Executive summary

The strategic business plan for ISO/TC 338 Menstrual Products outlines the need for international standards in the menstrual product industry. The document emphasizes the importance of aligning ISO's work with business environment needs and trends, ensuring prioritization and adequate resources for projects.

The business environment of the ISO/TC 338 is characterized by the importance of menstrual health and the need for products that support physical, mental, and social well-being. It is described in terms of qualitative and quantitative factors. Qualitatively, the focus is on achieving menstrual health for women, girls, and all people who menstruate. Quantitatively, the document presents demographic considerations, market size, distribution, and pressures on margins. Menstrual products play a crucial role in allowing individuals who menstruate to participate fully in society. However, there is a lack of harmonized international standards for menstrual products, which can hinder their availability and safety.

The market for menstrual products is significant, with 300 million people menstruating daily. The market size is projected to reach USD 33.1 billion by 2030, driven by both mature and growth markets. The demand for environmentally sustainable products and the emergence of reusable alternatives also impact the industry. However, the industry faces challenges such as margin pressures, pricing pressures, distribution costs, import dependence, and high competition.

The establishment of international standards for menstrual products can address these challenges by ensuring product safety, quality, and performance while promoting innovation and sustainability. Standards for menstrual products can also contribute to achieving various Sustainable Development Goals related to poverty, health, education, gender equality, water and sanitation, reduced inequalities, and responsible consumption and production.

In conclusion, the strategic business plan highlights the need for international standards in the menstrual product industry to improve access, ensure safety, and support sustainable development.

1 Introduction

1.1 *ISO technical committees and business planning*

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 *International standardization and the role of ISO*

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 Business Environment of the ISO/TC 338

2.1 *Description of the Business Environment: Qualitative factors*

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of ISO/TC 338, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Menstrual health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in relation to the menstrual cycle. As per the globally accepted definition of menstrual health, achieving menstrual health implies that women, girls, and all people who menstruate throughout their life-course, are able to, among other critical aspects, care for their bodies during menstruation such that their preferences, hygiene, comfort, privacy, and safety are supported. They should also be able to experience a positive and respectful environment in relation to the menstrual cycle, free from stigma and psychological distress and decide whether and how to participate in all spheres of life, including civil, cultural, economic, social, and political, during all phases of the menstrual cycle1. Standards for menstrual products can contribute to these by

- determining a globally relevant and acceptable definition of quality of menstrual products in terms of performance (fitness for purpose) and safety
- reducing barriers to availability and accessibility of products in different regions.
- contributing to a positive and constructive global narrative around menstruation and making it easier for consumers to access information about menstruation and menstrual products.

Everyday 300 million people menstruate, and thus, access to safe products is a prerequisite to being able to participate in and contribute to society fully, which benefits the individual and society at large. Menstrual products exist to enable people who menstruate to carry on with their normal lives, as much as possible. Menstrual products are used on or inside the body by those who have access to and can afford them. The scope of ISO/TC 338 includes all manufactured menstrual products intended for collecting or absorbing menstrual fluid during the menstrual cycle. This includes products for internal and external use as well as single- and multiple-use products. Examples of products include single and multiple use menstrual pads, tampons, panty liners, menstrual underwear, menstrual cups, menstrual discs, sponges etc.

Other products used on or inside the body like condoms, plasters, and wound dressings, are highly regulated, tested and monitored2. However, there is a lack of global, harmonized standards that ensure the safety of the contents and physical properties of menstrual products for both people and the planet. Standardization in the area of menstrual products is a step in the direction of broadening access to safe and effective menstrual products for all people who menstruate when and where they need them.

2.1.1 Diversity in markets for menstrual products

[1] Hennegan J, Winkler IT, Bobel C, Keiser D, Hampton J, Larsson G, Chandra-Mouli V, Plesons M, Mahon T. Menstrual health: a definition for policy, practice, and research. Sex Reprod Health Matters. 2021 Dec;29(1):1911618. doi: 10.1080/26410397.2021.1911618. PMID: 33910492; PMCID: PMC8098749.

[2] Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

Mature markets in high-income countries (HICs) pose very different challenges than those of growth markets in low- and middle-income countries (LMICs).

Mature markets have reached saturation in terms of market penetration but offer growth opportunities on account of product innovation – both in existing product categories like disposable products (pads, tampons etc.) and new categories like reusable products (menstrual cups, reusable pads and menstrual underwear etc.). Growth markets offer an opportunity for increasing 1) market penetration due to urbanization, 2) gender equality and 3) awareness of menstrual health. This has, in turn, spurred 1) industry investment in product innovations to reach the wide spectrum of low-, medium- and high-income consumers, 2) promotional strategies for driving aspirational demand for products, and 3) distribution strategies for reaching remote territories. However, margin pressures in growth markets, which are detailed below, also pose challenges for industry stakeholders trying to enhance product access in these markets. Standards should ensure that while people who menstruate have improved access, the performance and safety of products is not compromised on account of increasing costs of materials, distribution, innovations etc., and reducing prices to reach lower wealth quintiles.

Historically, disposable products have formed a majority share of the menstrual product market. However, new innovations are slowly catching the attention of consumers. The market share of reusable products is still fairly small across both growth and mature markets3 but preliminary evidence indicates that both external and internal reusable products have good acceptability amongst consumers in growth [4,5,6,7] and mature markets. As innovations in existing product categories and the advent of new categories continue to grow and expand the choice available to consumers, standards should ensure that products are safe and meet common benchmarks for performance.

With growing awareness of the environmental impact of our consumption practices, consumers continuously search for more sustainable alternatives including in menstrual products. In contexts, where waste management infrastructure is still evolving, there are also environmental concerns regarding disposable menstrual products, which hold around 97 percent of the world market. The impact on wastewater infrastructure in HIC settings has also been noted. The lack of appropriate waste management systems and the variety of the different waste management systems places different demands on suitable product solutions8. A menstrual product standard can provide guidance to policy makers and referral to already existing and accepted standards in the area (e.g., ISO 14040, ISO 17088 and any others) for

- Appropriate handling of existing products and
- innovation of more sustainable menstrual products-both disposable and reusable

The menstrual product standard(s) that ISO/TC 338 will develop can also ensure that sustainability parameters are defined so that innovation of more sustainable menstrual products – both disposable and reusable, can be encouraged. Additionally, recent research shows that

[3] https://leap.rhsupplies.org/#/menstrual-hygiene

[4] Shah, Shobha & Nair, Rajesh & Shah, Pankaj & Modi, Dhiren & Desai, Shrey & Desai, Lata. (2013). Improving quality of life with new menstrual

hygiene practices among adolescent tribal girls in rural Gujarat, India. Reproductive health matters. 21. 205-213. 10.1016/S0968-8080(13)41691-9.

[5] Garikipati, S., and Boudot, C. (2017) To Pad or Not to Pad: Towards Better Sanitary Care for Women in Indian Slums. J. Int. Dev., 29: 32– 51. doi: 10.1002/jid.3266.

[6] Hennegan, J., Dolan, C., Wu, M. et al. Schoolgirls' experience and appraisal of menstrual absorbents in rural Uganda: a cross- sectional evaluation of reusable sanitary pads. Reprod Health 13, 143 (2016). https://doi.org/10.1186/s12978-016-0260-7

[7] Wilson, E. & Reeve, J. & Pitt, A. & Sully, B. & Julious, S. (2012). INSPIRES: Investigating a reusable sanitary pad intervention in a rural educational setting - evaluating the acceptability and short-term effect of teaching Kenyan school girls to make reusable sanitary towels on absenteeism and other daily activities: a partial preference parallel group, cluster randomised control trial.

[8] Reproductive Health Supplies Coalition. (2022). Webinar series on menstrual management

menstrual product standards can enable innovation by providing entrepreneurs and product developers with a platform of safety requirements. This saves them time, effort and other resources in figuring out the measures needed to place a safe product on the market9.

Increasing consumer demand for environmentally sustainable products has also led to the emergence of products that falsely claim to be compostable and are oxo-degradable in some regions. Standards can also safeguard consumers against such products by providing reference to existing standards that define biodegradability and compostability e.g., ISO 17088.

Standards for menstrual products can also help governments achieve various Sustainable Development Goals (SDGs). Unfortunately, menstruation is not mentioned, specifically, under any of the SDGs, nonetheless, the matter can be connected to several of them and standards on menstrual products can drive the sustainable development in these areas. The most significant SDGs to menstrual products include SDGs 1 (no poverty), 3 (health and well-being), 4 (quality education), 5 (gender equality), 6 (clean water and sanitation), 10 (reduced inequalities) and 12 (responsible consumption and production)10. Ensuring that all people who menstruate have access to safe menstrual products helps to improve menstrual health.

2.2 *Quantitative Indicators of the Business Environment*

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the ISO/TC:

Demographic considerations (consumer)

Everyday 300 million people menstruate. Most people who menstruate do so between three to seven days each month for about 40 years, which amounts to around 2400 days in a lifetime, meaning a person is expected to use up to 12-15,000 single-use products in a lifetime. Aside from ensuring access to safe products and creating market pathways for different product categories, standards can enhance consumers' ability to make an informed choice, with the fundamental principle that all consumers should have this right. Additionally, standardizing menstrual products can have a destigmatizing effect, which increases gender equality[11].

Market size and distribution

The menstrual product market size was valued at USD 21.2 Billion in 2022 and is projected to reach USD 33.1 Billion by 2030, growing at a compound annual growth rate (CAGR) of 4.9 percent from 2023 to 203012.

The continuing importance of mature markets in the segment of menstrual products is demonstrated by its projected market growth. According to the Annual & Sustainability Report published in 2022 by Essity AB, a leading hygiene products manufacturer, the highest usage of menstrual products was witnessed in Western Europe, followed by North America and Eastern Europe 202013. As per the same source, women in Western Europe aged 10 to 54 use more

[9] Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

[10] ISO. 2020. How ISO Standards Help Meet the SDGs. ISO: Standards. Available online: https://www.iso.org/sdgs.html.

[11] Ibid. Klinter, L. (2021).

[12] https://www.verifiedmarketresearch.com/product/feminine-hygiene-products-market/

[13] Essity AB. (2022). Annual and Sustainability Report. https://www.essity.com/sustainability/sustainability-reporting-governance-and-data/annual-and-sustainability-report/

than 380 units of menstrual products per year. Europe is projected to account for 34 percent of market growth by 2023. The United States market for menstrual products reached a size of USD

26.5 Billion in 2022 with a projected five-year CAGR of 4.93 percent. As discussed in the section on qualitative factors, these statistics indicate that while mature markets have achieved saturation in terms of market penetration, there is significant growth potential from innovations across existing product categories like disposable pads and tampons and new consumer categories like reusable pads and menstrual cups.

The increasing importance of growth markets is reflected in both the potential for increasing market penetration and product innovations. The growing overall potential market size due to increase in menstruating population is also a contributor. In LMICs, the largest manufacturers are experiencing double-digit growth in market size annually, led by manufacturers in India and China.

Currently, there are an estimated 1.67 billion menstruators across low- and middle-income countries. 90 percent of people who menstruate in upper-middle-income countries use consumer menstrual products, compared to 62 percent in lower-middle-income countries and 39 percent in low-income countries. India and China are the two countries driving market growth in these regions overall due to the population size, manufacturing intensity and relative trade openness. Amongst lower-middle-income and upper-middle-income countries, India and China respectively account for 45-46 percent of the use of menstrual products.14 Ethiopia, the Democratic Republic of the Congo, Uganda and Sudan account for 51 percent of all menstruators among all low- income countries.

The total Asia Pacific market stood at USD 11.96 billion in 202015. In 2023 by comparison, the market size of menstrual products in China alone was approximately USD 11.37 billion with a five-year projected CAGR of 6.16 percent16 and in India, it was estimated at USD 6.2 billion with a five-year projected CAGR of 4.76 percent[17].

Pressures on margins

With changing dynamics of the menstrual product market globally and efforts to improve access and affordability, there are increasing pressures on margins. Many of these pressures were exacerbated during the COVID19 crisis that impacted supply chains globally[18]. Standards are needed to ensure these pressures do not result in lower quality products.

Pricing pressures

A study conducted by Mann Global Health stated that in Kenya, disposable pads are available at price points which are 2.3 times that of the lowest price per pack and in India, the range is up to

9.4 times the lowest price per pack.19 This indicates efforts on the part of manufacturers to expand the price range and reach across wealth quintiles. Another study states that 46 percent of all consumers are from lower-middle income countries while they contribute only 32 percent of overall global spend on menstrual products20. This data reflects manufacturer's efforts in the last

[14] Weinberger M, Eva G, Gold J, Bellows N, Reidy M, Sanders R, and Skibiak J. LEAP: Landscape and Projection of Reproductive Health Supply Needs. Reproductive Health Supplies Coalition. (2021). https://leap.rhsupplies.org/#/menstrual-hygiene

[15] https://www.fortunebusinessinsights.com/feminine-hygiene-products-market-103530

[16] https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/china

[17] https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/india

[18] Access to menstrual health supplies during COVID-19-What have we learnt. (2021). https://medium.com/its-about-supplies/access- to-menstrual-health-supplies-during-covid-19-what-have-we-learnt-%C2%B9-ec8b55e5f390

[19] Landscaping Supply Side Factors to Menstrual Health Access. (2021). Mann Global Health. https://www.rhsupplies.org/uploads/tx_rhscpublications/Landscaping_Supply_Side_Factors_to_Menstrual_Health_Access.pdf

[20] Ibid. Weinberger et al. (2021). LEAP Report.

two decades to increase market penetration in lower-middle income countries. Increasing competition and the high price sensitivity of the market puts pressure on margins for menstrual products.

Distribution costs

In many lower-middle income countries, distribution and logistics infrastructure for the last mile is highly fragmented. Many manufacturers in LMICs are using highly competitive distribution strategies to reach areas where menstrual products were not commercially available till now. They include but are not limited to menstrual product dispensers and pads dispensed in the form of rolls at the point of use, last mile distribution models that include menstrual products as part of a basket of health products and services e.g., Kasha, Triggerise and many others. Other distribution strategies include leveraging traditional fast moving consumer goods (FMCG) and medical product supply chains, which also require marketers to take into account increasing distribution margins in a highly competitive category. These efforts also put additional cost pressures on manufacturers as they try to ensure that products are available at the last mile.

Import dependence

Most of the growth markets are either dependent on imports of final products or of raw materials. India, which is the largest growth market amongst LMICs, is the top importer of menstrual pad raw materials in terms of number of import shipments, followed by Bangladesh and Vietnam21. China, the United States of America, and Japan are the key exporters of materials. Many LMICs, including those that have manufacturing capacity like India and Vietnam, are also dependent on import of the finished products. Uganda, Sri Lanka, India, Namibia, Pakistan, Bangladesh, Kenya are some of the largest importers of menstrual pads globally (in terms of number of shipments) and India, China and South Africa are the largest exporters22. This means that in many of these countries, higher export and import taxes put additional pressures on margins, especially in LMICs where consumers are more price sensitive. After the COVID19 crisis, global supply chains have also been challenged and the cost of logistics has exacerbated these pressures.

High degree of competition

In addition to the cost and pricing constraints that influence individual market players, the sheer number of players that have entered the market across different product types has increased competition in the industry manifold. For example, India has at least 20 disposable menstrual pad brands, 16 reusable menstrual pad brands, 5 tampon brands and 24 menstrual cup brands. Similarly, Kenya, Nigeria and Tanzania have 25, 19 and 13 disposable menstrual pad brands respectively also. In most LMICs, the majority market share belongs to the large multinational corporations. However, slowly there are a number of local brands - either locally manufactured or imported that have grown and captured some market share. In India and a few other countries,

there has also been an impetus for small scale cottage industries to manufacture and distribute disposable and reusable sanitary pads.

The increasing number of small and medium sized players have led to improved access to affordable products. However, without clarity on safety requirements for menstrual products, it has also led to unregulated products with unsubstantiated claims coming into the market,

[21] https://www.volza.com/p/sanitary-napkin-raw-material/import/

[22] https://www.volza.com/p/sanitary-pads/buyers/

especially in the case of LMICs. Standardization can help ensure that while access to affordable products is improved, quality is assured simultaneously.

In higher income countries, sustainability related innovation is one of the key drivers of growth in disposable and reusable menstrual product categories.23 In this context, research and development costs in a highly competitive market can put additional pressures on margins. Standards can ensure that quality and innovation go hand in hand as part of such development efforts.

Existing regulations[24],[25]

Many countries have standards for disposable menstrual pads but only a few countries in Africa and India have developed standards for reusable menstrual pads. Some regulation is available on insertion products from the US FDA and Standards Australia - namely tampons and menstrual cups respectively. The United Nations General Marketplace now offers technical specifications for disposable and reusable sanitary pads, tampons and menstrual cups. Within the EU there is a voluntary label manufacturers can apply for, called the EU Ecolabel. In Europe there is also an association of the nonwovens and related industries (EDANA) which has developed a code of practice for tampon manufacturers and a guide for supply chain information for absorbent hygiene care products. However, across the board, there is a high degree of variability in the specifications covered in standards in different countries and there is need for harmonization.

Regulatory and economic classification of products also varies widely. Menstrual products are mostly categorized as medical devices, therapeutic goods or consumer products in different countries and regions. For example, in most European countries they fall under the General Product Safety Directive, which means there is no obligation for manufacturers to list the composition of the product or perform biocompatibility testing. Whereas in the USA menstrual products are considered a medical device, with additional testing requirements. There are also countries that classify menstrual products in other categories, for example the legislation in Thailand covering this area is the Ministry of Public Health's Cosmetic Act. In Australia there is specific legislation for tampons, where all tampons on the internal market need to comply with Therapeutic Goods (Standards for Tampons) (TGO 103). In Japan menstrual products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. A list of known national and/or regional regulations and standards on menstrual products (not comprehensive) is given in Annexure A.

Given the complexity and variability in classification and specifications around the world, and in many instances lack of clear requirements, ISO standardization can help bridge the gap where regulations are not clear or strong enough.

An international standard in the area of menstrual products would be useful in addressing the issues identified above, as requirements of testing and transparency can reduce the information asymmetry between producers and consumers regarding product safety, performance and fitness to

purpose. These matters should be addressed on a global level, since they apply to all consumers of these products, globally.[26]

[23] Ibid. Essity AB Annual and Sustainability Report. (2022).

[24] Mahajan T, Joshi S. 2021. Development and compliance of standards for menstrual products in South Asia and Africa. Development Solutions Inc. and Reproductive Health Supplies Coalition

[25] Original proposal for TC 338

[26] Ibid. Klinter, L. (2021).

3 Benefits expected from the work of the ISO/TC 338

The principal benefit expected from the work of ISO/TC 338 is the standardization in the field of menstrual products and the future deliverables produced by the committee contribute to the improvement of safety and performance of menstrual products. The standard is expected to benefit all stakeholder categories including consumers, manufacturers, other supply chain stakeholders, governments, and the environment.

Anticipated benefits of the work of ISO/TC 338 committee include but are not limited to:

- Addressing the widespread gap in standardization of menstrual products for safety, fitness for purpose and quality control globally, which will drive demand.
- Creation of a common definition of fitness of purpose and safety of menstrual products for use by the consumer
- Increasing consumers' ability to make informed choices, with the fundamental principle that all consumers should have this right, and the associated consumer protections.
- Destigmatizing menstruation and menstrual products, contributing to greater gender equality
- Harmonization of national and regional standards, reducing the duplication of standards work at national level and gaining learning opportunities across borders
- Facilitate trade and increase market access by reducing regulatory barriers and cost involved in conducting business across geographies
- Standardization of menstrual products will ensure that the minimum requirements are the same all over the world and facilitate fair practices in international trade of commodities.
- Stimulating innovation by providing market newcomers with a platform of safety requirements, cutting back on their time to market
- Diversifying the product offering on a historically homogeneous market as a result of increased innovation
- Support Governments in reaching Sustainable Development Goals including but not limited to those related to Gender, WASH, Health and Education

4 Representation and participation in the ISO/TC 338

4.1 *Membership*

ISO/TC 338 committee at present has 26 Participating members and 16 Observing members (as of [date of publication]). The list of current members of the TC and their corresponding national standards bodies may be accessed at: https://www.iso.org/committee/8933440.html?view=participation

4.2 *Analysis of the participation*

ISO/TC 338 works towards increasing stakeholder engagement to reflect the complexity, size, requirements, needs and diversity.

ISO/TC 338 identifies, recognizes and appreciates the importance of broad representation of members from different regions of the world. The current composition of the committee contains representation from North America, South America, the Middle East, Australia, Africa, Europe and Asia. The committee continuously works towards a well-balanced geographical spread by seeking participation from LMICs, small- and medium-sized enterprises (SMEs), stakeholders including manufacturers of different types of menstrual products, technical experts for different aspects of performance, safety (materials, bioburden, environmental etc) and health, consumers and government to a greater degree.

4.3. Liaison relationship

Existing liaison relationships are:

- UNFPA - United Nations Population Fund
- EDANA ‘European Disposables and Nonwovens Association – EDANA

These ISO committees have been identified as collaboration partners, however not overlapping in scope.

Liaison Committees to ISO/TC 338:

- ISO/TC 6 Paper, board and pulps
- ISO/TC 6/SC 2 Test methods and quality specifications for paper and board
- ISO/TC 173/SC 3 Aids for ostomy and incontinence

Liaison Committees from ISO/TC 338:

- ISO/TC 38 Textiles
- ISO/TC 133 Clothing sizing systems - size designation, size measurement methods and digital fittings

- ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics
- ISO/TC 173/SC 3 Aids for ostomy and incontinence
- ISO/TC 194 Biological and clinical evaluation of medical devices
- ISO/TC 210 Quality management and corresponding general aspects for products with a health purpose including medical devices

5 Objectives of the ISO/TC and strategies for their achievement

5.1 *Defined objectives of the ISO/TC 338*

1. To create standards for menstrual products that meet the requirements of the industry, as well as consumers and other concerned stakeholders throughout the world.
2. To identify terminology and prepare definitions for standardization in the field of menstrual products.
3. To provide clear guidance to menstrual product manufacturers on the safety, performance of menstrual products and reference to existing guidelines on manufacturing processes.
4. To provide clear guidance to the testing laboratories on the methods of evaluation of performance of different menstrual products and consumers on the safety requirement of menstrual products.
5. To continue working closely with other ISO/TCs to avoid repetition and conflict.

5.2 *Identified strategies to achieve the ISO/TC's defined objectives*

ISO/TC 338 intends to use a variety of strategies to achieve its objectives and create overall priorities for the TC. The strategies will include but will not be limited to the following:

a. Prioritizing the project by forming different groups such as task group, working group etc to discuss and deliberate various sections of the standards such as scope, terms and definition and technical details.
b. Wherever possible, parallel meetings would be planned with the task group and working group with the experts from different fraternities. This would assist ISO to come up with the standard within scheduled time.
c. Working groups with a small group of experts would also be planned to draft the working document which would be further discussed in the main meeting. This would ease the process of discussion and finalization in the main meeting.
d. Wherever required and available, data published in reputed research journals, magazines and output of in-house R&D from members and external experts etc. will be considered while drafting technical specifications.
e. Regulatory requirements of different countries would also be taken into account while drafting the working document.
f. Develop consensus on terminologies used among different stakeholders engaged in the standardization to ensure equitable representation of consumer interests.

g. Arrangement for physical plenary meetings would be planned at least once in an year with the option to attend virtually to allow for maximum participation
h. For work-items and projects, virtual meetings or hybrid meetings will be encouraged and the frequency of the meeting for task groups and work groups would be increased to ensure development of outputs in a timely manner.
i. Project teams will be developed for each work-item with a designated project leader for efficient and timely completion of outputs.
j. Attempting to liaise with as many other relevant TCs as necessary to carry out the work of the technical committee and liaising with other global organizations outside of TCs as is appropriate and practical.
k. Increasing LMIC participation by:
    - Exploring the possibility to co-locate plenary meetings whenever possible with other ISO TCs and members and the meeting would also be arranged in a LMICs
    - Capacity building initiatives from ISO and SIS as well as advocacy in the menstrual health community to encourage LMICs to participate in ISO/TC 338

6 Factors affecting completion and implementation of the ISO/TC 338 work programme

The following factors have been identified which may affect, to a lesser or greater degree, the development of standards in accordance with the objectives and strategies of this business plan:

a. Many types of products are covered in the scope of ISO/TC 338. This implies challenges of applicability of test methods, raw materials, relevant expertise, etc. to the various product categories. Additionally, scientific data is not publicly available equally for all product categories. Specifications within product categories will also vary.
b. Variance in legal classification and related regulatory frameworks of menstrual products from consumer products to medical devices across countries can affect the approach towards creation and final implementation of the standard
c. Variation in legislation and infrastructure relating to disposal and waste management of menstrual products across country and regional contexts may affect the implementation of the standard
d. Increased cost of testing to comply with the standard may limit adoption among SMEs.
e. Stigmatization of menstruation affects the standardization, adoption and implementation at every level
f. Technical specifications established in different countries and regions can reflect social and cultural norms and pose barriers for harmonization under one unifying standard.

7 Structure, current projects and publications of the ISO/TC

7.1 *Overall Structure of the TC*

The current structure of ISO/TC 338 is:

- AHG 1 Terminology
- TG 1 Strategic Business Plan
- WG 1 General Requirements

The ISO Central secretariat oversees global standards development. The Technical Management Board (TMB) reports to the Central Secretariat and oversees TC operations. ISO/TC 338 develops ISO standards and is administered by Swedish Institute for Standards (SIS). The ISO/TC 338 oversees work groups that develop menstrual product standards. The working groups and task groups take on topics that are discussed and voted on by participating countries and national standard boards and mirror committees.

7.2 *Current projects and publications*

Ad Hoc, Task- and working groups of ISO/TC 338

Adhoc group 1: terminology

- an ad hoc group works on the related terminologies and defining terms related to menstrual products.

Task group 1: Strategic Business Plan

- a task group to draft the ISO/TC 338 Strategic business plan

Working Group 1: General requirements

- a working group developing standard for general safety, performance and health requirements of menstrual products.

7.3 *Stakeholders*

Priority stakeholders for the current work programme are identified as:

- National, regional and international consumer representation bodies
- Academic and Research bodies
- Representations from industry and commerce, including manufacturers and other supply chain stakeholders
- Government representatives

Information on ISO online

The link below is to the TC's page on ISO's website:

https://www.iso.org/committee/8933440.html

Click on the tabs and links on this page to find the following information:

- About (Secretariat, Committee Manager, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools
- Work programme (published standards and standards under development)

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work

Annexure A

S.No	Country	Standard	Authority
1.	Australia	AS 2869:2008 Tampons - Menstrual Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)	Standards Australia
2.	ARSO**	DARS 653:2017 for disposable sanitary napkins DARS 1575:2017 for reusable sanitary napkins	African Organization for Standardization
3.	Bangladesh	BDS 1261:2016 Sanitary Towels Mandatory	Bangladesh Standards and Testing Institute
4.	China	GB/T 8939—2018, Sanitary absorbent pads (panty liner) GB/T 39391—2020, Sanitary absorbent pants GB/T XXXX—20XX, Disposable tampons (in DIS stage, will be published)	Standardization Administration of the People's Republic of China
5.		EAS 96-1: Sanitary towels Specification-Disposable (2008)	

	East African Community*	FDEAS:96- Sanitary towels- Specification- Reusable (2019)	East African Standards Committee
6.	European Union	EU Ecolable for Absorbent hygiene produts and reusable menstrual cups)	EU Ecolabel

7.	Egypt	ES :2023 TAMPONS	Egyptian Organization for Standardization and Quality
8.	Ethiopia	ES: 6345- Sanitary Pads- Specification-Disposable (2018) ES: 6346- Sanitary Pads- Specification-Reusable (2018)	Ethiopian Standards Agency
9.	Ghana	GS 1248:2019: Specification for single-use disposable sanitary towels (pads) for external use	
10.	Indonesia	SNI 16-6363-2000: Sanitary Pads (2000, was taken under revision in 2015)	National Standardization Agency of Indonesia (Badan National Standardisasi - BSN)
11.	India	IS 5405:2019 for disposable sanitary napkins (1980, revised in 2019) IS 17514:2021 for reusable sanitary napkins	Bureau of Indian Standards
12.	Japan	PFSB No. 0325-17: Standards for Approval of Sanitary Napkins (2015)	Japanese Industrial Standards
13.	Kenya	DKS: 2881- Disposable Maternity Pads-Specification (2018) KS 2925:2020- Kenya Standard-Textiles-Reusable Sanitary Towels-Specification First Edition (2020)	Kenya Bureau of Standards
14.	Malawi	MS 890:2013 SANITARY TOWELS – SPECIFICATION (2013) MS 1445:2018- Reusable sanitary towels-Specification (2018)	Malawi Bureau of Standards
15.	Nigeria	NIS 291 (2018) Disposable Sanitary Pads	
16.	Pakistan	PS: 1449-1979 for disposable sanitary napkins	Pakistan Standards and Quality Control Authority
17.	South Africa	SANS: 1043 for disposable sanitary napkins (2010) SANS: 1812 for reusable sanitary napkins (2019)	South Africa Bureau of Standards (SABS)
18.	South Korea	MFDS Quasi-drugs Group 1 (A) (2009)	Korean Ministry of Food and Drug Safety
19.	Tanzania	TZS: 1659- Disposable Sanitary Towels - Specifications (2014) TBS: 6136- Reusable Sanitary Towels – Specifications (2nd Edition - 2019)	Tanzania Bureau of Standards
20.	United States of America	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)	US FDA
21.	UNGM	Technical Specifications for Disposable Sanitary pads, Reusable Menstrual Pads and Menstrual cups (2021)	UNICEF, UNFPA, UNHCR

22.	Uganda	UBS: 1782- Disposable Sanitary Towels - Specifications (2017)	Uganda National Bureau of Standards

		US: 1782- Reusable sanitary towels — Specification (2017)	
23.	Vietnam	TCVN 10585:2014 Sanitary Pads for Women	Directorate for Standards, Metrology and Quality (TCVN)
24.	Zambia	HS Code: 4818.40 (import guidelines 2011) for sanitary napkins	Zambia Bureau of Standards
25.	Zimbabwe	ZWS: 730- Manufacture of Sanitary Pads (2015)	Standards Association of Zimbabwe
		ZWS 1023: Reusable sanitary pads (2019)	

*Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda
**36 member countries of United Nations Economic Commission for Africa and the African Union

ANNEX 11
(Item 7.2)

INTERNATIONAL ACTIVITIES

Minutes of the panel meeting for WG 1 'general requirement' and Adhoc Group for terminology

ISO/TC 338/WG 1 "General requirements"
Convenorship: BIS
Convenor: Sivakumar S Mr

Minutes of the 3rd meeting of ISO/TC338/WG1 held on 6th and 7th Sep23

Document type	Related content	Document date	Expected action
Meeting / Minutes	Meeting: VIRTUAL 6 Sep 2023	2023-10-12	INFO by 2023-09-05

Description
Dear Members,

Please find attached herewith the minutes of the meeting. Kindly let me know if any of the points are missing.
Thanks & regards,
S. Sivakumar
Convenor of ISO/TC338/WG1

Meeting minutes - 3rdmeeting of ISO/TC 338Menstrual products – General requirements, Working Group 1

Dates: 6th and 7th September 2023
Zoom meeting

Time: 10.00- 12.30 CET/ 13.30- 16.00 IST on each day
Mode: Virtual meeting

1. Opening of the meeting

Convenor, S.Sivakumar opened the meeting and welcomed all attendees to the first WG 1 meeting.

2. Roll call of delegates

Committee Manager Jenny Acaralp called the names of members one by one and requested them to introduce themselves. The convenor S. Sivakumar and committee manager, Jenny Acaralp also introduced themselves to themselves.

See attendance list below.

3. Adoption of the agenda

The agenda (N15) was adopted as it is without any modification.

4. Recap of the discussions held during the 2nd meeting of WG 1

- The convenor briefed the members about the points which were discussed during the 2nd meeting of the WG1.

- It was informed by the committee manager Mrs. Jenny that a Ballot voting has been initiated to change the title of WG1 from “General requirements” to “Safety, Performance and General Requirements of menstrual products”.

- The convenor informed that the revised outline of the working document N14 “General and Safety Requirements of Menstrual Products” as finalized during the 2nd meeting was circulated among the members and comments / inputs were received from a few of the members.

- Further, it was informed that the comments / inputs received from all the members on N14 outline of the working document alongwith inputs from the convenor were consolidated and a revised working document N 17 was prepared and circulated to the members prior to this meeting.

5. Review of working document / existing resources

- The convenor then invited the members to review the revised working document N17 in which the earlier comments / inputs from the members have also been included. The changes suggested by the members during the meeting were incorporated in the N 17 document in “track changes” mode.

The following discussions were made during the meeting:

- Scope of the document is revised to include internal and external products intended for single and multiple use. Now, the revised scope of the document is decided as

”This document specifies general and safety requirements for menstrual products from a user perspective and covers internally and externally used products intended for single and multiple use.”

- Clause 4 shall be renamed to “General”.

- Manufacturing should be compliant to GMP. If not as a minimum the requirements given in Annex B are met.

- Clause 5.3.1 shall be renamed to “Single and multiple use materials”.

- Optional requirements can be included additionally. This clause may deal with the claims which needs to be scientifically or statistically validated for performance and safety.

- The manufacturer would be confused by Clause 6.1, so it is imperative to clearly distinguish between the safety of menstrual cups and that of tampons.

- Menstrual products shall not be causing irritation by mechanical abrasion/stresses and shall be free from any kind of foreign matters.

- Internally worn products shall be resistant to linting and the residual fibres may be as minimal as possible during use and after removal.

- Internally worn menstrual products shall be easily removable after use (To be rephrased to be common for menstrual cups and other internally worn products as well.)
- The protective coating can prevent fibre loss from tampons.

- Products shall be designed and manufactured in such a way that that cutting and similar hazards associated with sharp points, edges or projections are limited as much as possible. The percentage of fibres left inside shall be mentioned.

- Removal of internally worn menstrual product shall have cord or any pulling system and shall have enough resistance/strength to withstand.

- Tolerance limits for the chemical residues can be given in the Normative Annex.

- If tolerance is given, it won't be applicable in future. The tolerance limits shall be reviewed periodically.

- Impossible to set limits for all chemicals, specific topological requirement have to be find and basic information shall be given for topological substance information.

- Menstrual products shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the menstrual products are composed or which they contain, when the menstrual products are used as intended or in a reasonably foreseeable condition of use,, the particular use of a product and the resulting exposure conditions.

- Manufacturers shall describe....” that implies labeling/indication on package etc. So small working group shall revise the sentences focusing on the concept of this subclause, i.e chemical assessment and safety and separate labeling related argument.

- Clause 6.4,requirements shall be applicable only on the final product.

- Materials in contact with the skin or exposure to materials may also be tested based on risk assessment.

- The material shall show reactivity as 'None to low cytotoxic' / minimum 70 % of viable cells (To refer the standard for the low and very low levels).

- Clause 6.4.2 shall be renamed to "Irritation and skin sensitization".

- The standard of testing may not be mentioned here directly. Can be given in notes.

- Other test protocols such as cosmetic, OECD methods may also be considered. Wherever possible, non-animal tests or In-vitro test may be conducted.

- Testing of Pyrogenicity may not be required. Can be included in risk assessment.

- Microbiological requirements shall be added which includes cleaning efficacy for reusable products, TSS risk for internal products, microlimits for release if applicable.

- Exposure Based Risk Assessment (EBRA) Principles Applied to Feminine Hygiene Products shall be referred.

- Size and shape shall be included in this clause (removed from clause 4.2) and need standardization of sizes and shape of the products.

7. Any other business

The convenor invited members to participate in the smaller working groups and they can share their comments.

8. Closure of the meeting

The comments received will be reviewed and inputs and requested all members to participate in the smaller working groups.

Minutes of meeting for ISO TC 338_ AHG1

ISO/TC 338/AHG 1 **N 25**

ISO/TC 338/AHG 1 "Terminology"
Convenorship: **BIS**
Convenor: **Mahajan Tanya Ms**

Minutes of meeting for ISO TC 338_ AHG1

Document type	Related content	Document date Expected action
Meeting / Minutes	Meeting: VIRTUAL 30 Oct 2023	2023-11-02

Description

Minutes of meetings 5th and 6th of AHG1 to review comments received on Terminology document

Minutes of meeting for ISO TC 338/ AHG1

Virtual Meetings (5th and 6th)

Date: 27th September 2023; 30th October 2023

A. Opening of the meeting

Convener opened the meeting and explained that the objective of the meeting is to address comments received on the circulated Terminology document.

B. Adoption of the agenda

The agenda shared before the meeting was adopted by all members present. Attendance list for both meetings has been included as Annexure I.

C. Updation of the Terminology document

Primary purpose of the meetings was to review the comments received on the Terminology document through wide circulation and make changes in the document accordingly. Comments received were reviewed in detail and changes were made in the Terminology document pursuant to detailed discussions with members present for the two meetings.

1. Comments were received on inclusion/exclusion of maternity pads as part of the scope. The AHG1 believes that since this is an important point of discussion, it should be referred to the entire TC and discussed in plenary. If the TC decides to include maternity pads in the scope, definitions related to the same (maternity pads, lochia etc.) will need to be included in the Terminology document.
2. Terms related to light, medium and heavy menstruation were included in the document with the purpose of soliciting inputs from members on definitions. No clear definitions were available, however, a few members shared references that can be used to define these specifications from the perspective of performance of menstrual products eg. absorbing or collecting capacity. These inputs are collated as part of Annexure II and can be used by WG1 as they discuss the performance specifications. Once consensus on these has been achieved, they may be considered for inclusion in the Terminology document.

3. The following changes were made to the terminology document in response to the comments received through wide circulation:

- Use of alternate terms was clarified for menstruation, menstruators, single use products, multiple use products
- Additional terms suggested were added including those
    - related to the single use menstrual products e.g. adhesive, air permeability, bleaching, embossing, superabsorbent, fragrance, colorant etc.
    - related to environmental impact e.g. incineration, landfill, biochar, sustainability, biodegradation etc.
    - related to bleaching that can impact end of life options for menstrual products
    - that describe the different types of menstrual products mentioned in the documents till date e.g. menstrual pads, tampons, menstrual cups etc.
- Many terms that were derived from ISO references were streamlined e.g. polymers, antibacterial and antifungal properties etc.
- Some terms including absorptive and collecting capacity were re-framed in line with comments received
- Multiple terms related to ISO 10993 were included in the original document e.g. biocompatibility, cytotoxocity, biological safety, skin sensitizatio etc. These were streamlined to reflect the original ISO definitions and the context of menstrual products and all terms related to the subject of risk assessment were included as sub-terms under the umbrella term of risk assessment, for clarity
- Differentiation between vagina, vulva and relative microbiomes was clarified as this would be relevant for determining microbiological safety parameters
- Washing and drying added with reference to ISO 6330 to provide guidance on methods of washing and drying for test methods related to textile based reusable menstrual products

D. Closure of the meeting

The second meeting was closed with the following recommendations:

- Point 1 above to be referred to the TC secretariat for discussion
- Point 2 above to be passed onto WG1 for use in development of performance specifications
- Revised Terminology document to be shared with the TC secretariat for next steps

Annexure I: Attendee List

Attendee List - 5th Meeting (27th September 2023)

Ms. Tanya Mahajan, BIS

Mr. Nirav Mehta, BIS

Mr. Dharmbeer, BIS

Dr. E. Santhini, BIS

Ms. Elisa Gusberti, UNI

Ms. Armelle Davy-Bevilacqua, AFNOR

Ms. Hui Cai, SAC

Ms. Charlotte Persson, AFNOR

Ms. Louise Klinter, SIS

Attendee List - 6th Meeting (30th October 2023)

Ms. Tanya Mahajan, BIS

Mr. Dharmbeer, BIS

Dr. E. Santhini, BIS

Ms. Elisa Gusberti, UNI

Ms. Jenny Acaralp, SIS

Dr. Mr. Eckard Jantzen, DIN

Annexure II: Inputs for defining light, medium and heavy menstruation

IN-103	Add text	Included Only for guidance as individual perception of flow can vary. Cycle blood flow was classified in tertiles as light (<36.5 mL). Reference: Menstrual Bleeding Patterns Among Regularly Menstruating Women, American Journal of Epidemiology, Vol. 175, No. 6, February 20, 2012.
US-104	For technical definitions the definition needs to be meaningful to interpret.	Suggest a volume to duration metric and needs to be inclusive of various types of products (tampon/pad/sanitary napkins etc.) Here are some examples for consideration: • International Federation of Gynecology and Obstetrics: Light bleeding less than 5mL and generally associated with a shorter duration of 1 to 2 days. • Proposed definition: *Mild bleeding means that you are soaking less than 1 regular tampon in more than 3 hours.* • Propose to align definition with FDA's established absorbency ranges for tampons found in 21 CFR 801.430 (e)(1) (this is the only established range found)
IR/1-105	Up to 30 ml	---
AU-106	AU feels that the definitions of level of menstruation should be kept broad. Each menstrual product type will require different absorbency requirements and may need to use more than three levels of menstruation to be described for use in labelling.	Suggest the following definitions: Light Menstruation - where the user requires a minimal level of absorbency. Medium Menstruation - where the user requires a medium / moderate level of absorbency. Heavy Menstruation - where the level of absorbency is higher than average. Additional levels may perhaps be obtained by combining two adjacent terms eg "Light to Medium"
SLSI-107	These three types of menstruations are highly subjective. Body weight, body structure, health conditions, natural or	**light menstruation:** Discharge of less than 30 ml of blood and mucosal tissue during a menstrual cycle

	native factors may affect to the type of menstruation in a menstruator. So it is a highly biased subject to define those in a standard. **Suggestion:** Therefore, isn't it good to include a note saying that these three types of menstruations are subjective person to person. When trying out to define them through the performance of the menstrual products (absorbent menstrual products particularly) * Ultra-thin sanitary pads are recommended for lighter menstrual flows (absorbency requirement = minimum 20 ml per pad) *Regular sanitary pads are recommended for medium flow (absorbency requirement = minimum 30 ml per pad) and *Heavy floe sanitary pads are recommended for heavy flow + menorrhagia. (absorbency requirement = minimum 50 ml per pad)	**medium menstruation/ regular menstrual flow:** Discharge of 30 ml to 80 ml of blood and mucosal tissue during a menstrual cycle **heavy menstruation/ heavy menstrual flow:** Discharge of more than 80ml of menstrual fluid and mucosal tissue during a menstrual cycle
SE-108	Ex light menstruation	Defined by persons who consider their menstruation light, etc. Consider adding a note to 3.26.1-3 about "Flow ranges to be decided"
US-109	Are these definitions meant to be used across the lifecycle/span of products in this industry? vs technical definition Is the total amount of flow someone experiences during a period?	Need clarification - Suggest adding another definition for absorbency ranges. Suggest for a technical definition that there be a volume/duration.
FR-110	Menses volume is different among countries and understanding of light, medium and heavy menstruation is different. In addition, we don't see the need to define the menstruation grade for now. Proposal is to put the	a definition to be written further when standard's protocol will be defined

	definition on hold until we have a need in the following standard clauses	
IN-111	Add text	Included Only for guidance as individual perception of flow can vary. Cycle blood flow was classified in tertiles medium (>36.5 and ≤72.5 mL). Reference: Menstrual Bleeding Patterns Among Regularly Menstruating Women, American Journal of Epidemiology, Vol. 175, No. 6, February 20, 2012
US-112	For technical definitions the definition needs to be meaningful to interpret.	Suggest a volume to duration metric and needs to be inclusive of various types of products (tampon/pad/sanitary napkins etc.) Here is an example for consideration: • Proposed definition: *Moderate bleeding means that you are soaking more than 1 regular tampon in 3 hours.*
IR/2-113	30-60 ml	---
SLSI-114	In the draft at the end of 3.26.3 it was said that attention must be given when distinguishing heavy menstrual flow and menorrhagia. But when it comes to the market, products are categorized as regular menstrual flow and heavy menstrual flow. There are no specific products for menorrhagia patients. They also purchase the heavy flow category. Therefore, isn't it good to define the heavy menstrual flow value including the menorrhagia condition too. If not, a person who is suffering from menorrhagia would not get the expected benefit. Spellings of "mennorrhagia" should be corrected	"Menorrhagia"
SE-115	"Mennorrhagia" is misspelled	Change to "menorrhagia"
FR-116	Menses volume is different among countries and understanding of light, medium and heavy menstruation is different. In addition, we don't see the need to define the menstruation grade for now. Proposal is to put the definition on hold until we have a need in the following standard clauses	a definition to be written further when standard's protocol will be defined

IN-117	Add text	Included Only for guidance as individual perception of flow can vary. Cycle blood flow was classified in tertiles heavy (>72.5 mL). Reference: Menstrual Bleeding Patterns Among Regularly Menstruating Women, American Journal of Epidemiology, Vol. 175, No. 6, February 20, 2012 But does not consider **menorrhagia** or **hypermenorrhoea**
SE-118		Change “during” to “When”; Consider defining a threshold value for menorrhagia (>80 ml/cycle or a cycle that lasts more than seven days or both)
US-119	For technical definitions the definition needs to be meaningful to interpret.	Suggest a volume to duration metric and needs to be inclusive of various types of products (tampon/pad/sanitary napkins etc.) Here are some examples for consideration: • Proposed definition: *Heavy bleeding means that you are soaking 2 or more regular tampons in 3 hours.* • *ACOG: Bleeding that soaks through one or more tampons or pads every hour for several hours in a row and typically lasts more than 7 days.* *Additional detail (optional) - Menstrual flow with blood clots that are as big as a quarter or larger.*
MC -120	During defining heavy menstruation, care must be taken to distinguish between heavy menstruation and mennorrhagia, which can be a sign of a disorder or health issue.	Not everyone knows what mennorrhagia is, should this be removed or an explanation added?
IR/3-121	More than 60 ml	----
SE-122	Add Menstrual flow?	Consider adding a definition of menstrual flow

1) Concerning the definitions for heavy , light and medium menstruation:

Here are a group of definitions from various references:

Hypomenorrhea

length of cycle is normal but flow is shorter and scant

Hypermenorrhea

length of cycle is normal but flow is heavy for a normal duration

Menorrhagia (prolonged bleeding)

bleed more than normal or cause your periods to last longer than the average 5-7 day cycle

Metorrhagia

bleeding occurs in between cycles.

Normal amount of blood flow= 35-150 ml, no more than 8 pads a day with no more than 2 heavy days

Ref.: menstruation and abnormalities, chapter 4, Dr. Kandula

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Polymenorrhea

frequent menstrual periods occurring more often than the typical 21- to 35-day menstrual cycle

Oligomenorrhea (Infrequent Periods)
you often don't get your periods for more than 35 days and as a result have only four to nine periods in a year.

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Menorrhagia (heavy menstruation):

Menorrhagia is excessive menstrual bleeding. It can be described as menses that lasts longer than 7 days; menses that occurs more frequently than every 21 days; menses that is heavy enough to require lifestyle modifications; excessive clotting; or intermenstrual bleeding.

Ref.:Tolu Oyelowo,Mosby's Guide to Women's Health, A Handbook for Health Professionals, Chapter 23 – Menorrhagia 2007, Pages 157-160.

Menorrhagia

Excessive menstrual bleeding occurring at regular cyclic intervals (cycles are usually but not necessarily of normal length) that interferes with the woman's physical, social, emotional, and/or material quality of life. In the recent past, this definition included a quantity of blood loss: blood loss greater than 80 mL per cycle

Ref.: Angela Sadlon, ND, Textbook of Natural Medicine (Fifth Edition),2020, Pages 1570-1574.e1-197 – Menorrhagia

Menorrhagia

Heavy menstrual bleeding (HMB) is defined as excessive menstrual blood loss, which interferes with a woman's physical, social, emotional, and or material quality of life . In clinical research, HMB has an objective definition wherein a total menstrual blood loss of 80 mL or greater is considered as HMB

Ref.: *Jane J. Reavey et al.,* Obesity and Gynecology (Second Edition) Chapter 19 - Obesity and menstrual disorders ,2020, Pages 171-177

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Menorrhagia (heavy menstrual bleeding)

Heavy menstrual bleeding (formerly called menorrhagia) is when your periods are extremely heavy or prolonged that it interferes withyour daily life is never normal. "Heavy" means that your period lasts longer than 7 days or that you lose more blood than is typical during menstruation. You may bleed so much that you have to change your tampon or pad every hour for several hours back-to-back. You may pass blood clots the size of a quarter or even larger.

You may have heavy periods if you:

- need to change your pad or tampon every 1 to 2 hours, or empty your menstrual cup more often than is recommended.
- need to use 2 types of sanitary product together, such as a pad and a tampon
- have periods lasting more than 7 days
- pass blood clots larger than about 2.5cm (the size of a 10 p coin)
- bleed through to your clothes or bedding
- avoid daily activities, like exercise, or take time off work because of your periods
- feel tired or short of breath a lot

ANNEX 12
(Item 7.3)

INTERNATIONAL ACTIVITY

Agenda of plenary meeting of ISO/TC 338 ‘Menstrual Product’

ISO/TC 338 **N 60**

ISO/TC 338 "Menstrual products"
Secretariat: **SIS**
Committee manager: **Acaralp Jenny Mrs**

Agenda 3rd Plenary Meeting ISO/TC 338 Menstrual Products

Document type	Related content	Document date Expected action
Meeting / Agenda	Meeting: VIRTUAL 8 Dec 2023	2023-10-17

International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации

NOTICE OF MEETING / DRAFT AGENDA

Date 2023-10-17	**Reference** ISO/TC 338 **N 60**
Number and title of TC/*Numéro et titre du TC* **ISO/ TC 338 Menstrual Products**	
Secretariat/*Secrétariat* SIS, Swedish Institute for Standards Jenny Acaralp +46 70 7162057 jenny.acaralp@sis.se	**Meeting/*Réunion*** Meeting dates / *Dates de la réunion*: Friday, 8 December at 13.00-17.00 (CET)
Host/*Invitant*	**Place/*Lieu*** Address/*Adresse*: Zoom Tel: +46 8 - 555 520 57

Registration for the meeting is open in the ISO Meeting tool: https://sd.iso.org/meetings/134768

P-and O-members are invited to inform the secretariat of the committee concerned, within one month of the receipt of this notice of meeting, of their intention to be represented at the meeting, the approximate number of their delegates and their need for interpretation.

Whenever possible, the names of delegates (or observers) and the name of the head of the delegation should also be sent to the secretariat of the committee concerned at least one month before the opening of the meeting.

Les membres (P) et (O) sont invités, dans un délai d'un mois à partir de la réception de la présente convocation, à faire connaître au secrétariat du comité concerné leur intention d'êtrereprésentés à la réunion, le nombre approximatif de leurs délégués et leur besoin en matière d'interprétation.

Dans la mesure du possible, une liste indiquant les noms des délégués (ou observateurs), ainsi que le nom du chef de la délégation, devrait également parvenir au secrétariat concerné unmois au moins avant l'ouverture de la réunion.

For more information about meetings, see
the brochure 'My ISO Job', available at:
http://www.iso.org/iso/my_iso_job.pdf

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Agenda item

V02/2019

1.Opening of the meeting (December 8, at 13.00)
2. Roll call of delegates
3.Work environment: Presentation on the Code of ConductDirect link to Code of Conduct
4. Adoption of the agenda Doc. ISO/TC 338 N 60
5. Appointment of the drafting committee
6. Report of the ISO/TC 338 Secretariat
7. Information from ISO/CS, ISO Central Secretariat
8. Progress reports **8.1 WG 1 General Requirements** **8.2 Ad hoc group Terminology** **8.3 Task group Strategic Business plan**
9.Conclusions of these reports and actions to be taken
10. Liaison reports **10.1 EDANA** **10.2 UNFPA** **10.3 ISO/TC 6 Paper board and pulps / SC 2 Test methods and quality specifications for paper and board** **10.4 ISO/TC 173 SC 3 Aids for ostomy and incontinence**
11. Requirements concerning a subsequent meeting, offers to host
12. Any other business **12.1 ISO/TC 338 dedicated committee website** **12.2 Website Maintenance Task group** **12.3 Meeting feedback survey**
13. Approval of resolutions
Closure of the meeting (December 8, at 17.00)