MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

BUREAU OF INDIAN STANDARDS

MINUTES

Meeting	Day & Date	Time
15th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	**29th May, 2024 Wednesday**	**02:30 PM**

Chairperson: Lt Gen Sunil Kant, In-Personal Capacity

Member Secretary: Ms. Uroosa Warsi, Scientist 'C'/Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards

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The list of attendees is given at ***Annexure A***.

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES BY MEMBER SECRETARY

Ms. Uroosa Warsi, Member Secretary welcomed the members to 15th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee and introduced herself to the committee members and acknowledged the previous member secretary Ms Harshada Kadam for her immense contribution.

She appreciated the members present for sparing their valuable time to participate in this meeting. Meeting commenced with the introduction of the members.

0.2 OPENING REMARKS BY CHAIRPERSON

The Chairperson extended a warm welcome to the member secretary Ms. Uroosa Warsi and all the members of the committee, expressing the committee's commitment to providing her with maximum support. He acknowledged the outstanding contributions of the previous member secretary, Ms. Harshada Ganesh Kadam. Emphasizing the need for active participation and fruitful discussions among members, he underscored the importance of professionalism and a comprehensive perspective in decision-making. He then invited the member secretary to commence the proceedings.

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The Committee formally confirmed the minutes of the last meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12 held on 12th March, 2024.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The Committee noted the contents of Item 2.1 of the agenda.

2.2 The Committee noted the contents of Item 2.2 of the agenda.

2.3 The Committee, after reviewing the functional category-wise breakdown, decided to send co-option requests to state government organizations, consumer groups, and other institutions of national importance to ensure the representation from all stakeholders.

The Committee also decided to review the representation of industry and industry associations, noting that some organizations are represented in both categories.

2.4 The Committee decided that if membership renewal requests from the following organizations are received within 15 days, they will be circulated to Committee members for consideration. In case no request is received within this period, these organizations will remain withdrawn from the Committee.

Sl. No.	Organisation
1)	Becton Dickinson India Private Limited, Gurugram
2)	Lady Irwin College, New Delhi

2.5 The Committee decided to circulate EI DuPoint membership renewal request, along with the requests from the organizations mentioned in Item 2.4, to Committee members for consideration for a period of two weeks.

2.6 The Committee noted the contents of Item 2.6 of the agenda.

ITEM 3 DRAFT STANDARDS / AMENDMENTS UNDER PRINT

3.1 The Committee noted the contents of Item 3.1 of the agenda.

ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

4.1 a) The Committee decided to finalize the following draft Indian Standards for publication.

Sl. No	Document No.	Title
1)	MHD/12/19717	Blood Donor Couch Specification
2)	MHD/12/24230	Specification for refrigerator or combined refrigerator and water pack freezer intermittent mains powered - compression cycle- general requirement and test method
3)	MHD/12/24231	Specification for Vaccine carrier - General requirements and test method

b) The Committee noted that the following documents are currently in wide circulation and requested for inputs from the experts. If no comments will be received, the same shall be finalized after consultation with the chairperson.

Sl. No	Document No.	Title	Last date for comments
1)	MHD/12/25421	Infusion Equipment for Medical Use Part 2 Closures for Infusion Bottles	06/06/2024
2)	MHD/12/25422	Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles	06/06/2024
3)	MHD/12/25423	Infusion Equipment for Medical Use Part 5 Burette Infusion Sets for Single Use Gravity Feed	06/06/2024
4)	MHD/12/25424	Infusion Equipment for Medical Use Part 6 Freeze Drying Closures for Infusion Bottles	06/06/2024
5)	MHD/12/25425	Infusion Equipment for Medical Use Part 7 Caps Made of Aluminium-Plastics Combinations for Infusion Bottles	06/06/2024
6)	MHD/12/25426	Infusion equipment for medical use Part 8 Infusion sets for single use with pressure infusion apparatus	06/06/2024
7)	MHD/12/25428	Infusion Equipment for Medical Use Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment	06/06/2024
8)	MHD/12/25429	Infusion Equipment for Medical Use Part 10 Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment	06/06/2024
9)	MHD/12/25430	Infusion Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment	06/06/2024
10)	MHD/12/25431	Infusion Equipment for Medical Use Part 12 Check Valves for Single Use	06/06/2024
11)	MHD/12/25432	Infusion Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact	06/06/2024
12)	MHD/12/25433	Infusion Equipment for Medical Use Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact	06/06/2024
13)	MHD/12/25434	Infusion Equipment for Medical Use Part 15 Light-Protective Infusion Sets for Single Use	06/06/2024
14)	MHD/12/25435	Aseptic Processing of Health Care Products Part 3 Lyophilization	06/06/2024
15)	MHD/12/25436	Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies	06/06/2024
16)	MHD/12/25437	Aseptic Processing of Health Care Products Part 5 Sterilization in Place	07/06/2024

17)	MHD/12/25439	Aseptic Processing of Health Care Products Part 6 Isolator Systems	07/06/2024
18)	MHD/12/25440	Aseptic Processing of Health Care Products Part 7 Alternative Processes for Medical Devices and Combination Products	07/06/2024
19)	MHD/12/25441	Hypodermic Needles for Single Use Colour Coding for Identification (First Revision)	07/06/2024
20)	MHD/12/25443	Medical Devices Transfusion Set and Blood Bag Compatibility Test Method	07/06/2024
21)	MHD/12/25444	Sterile Packaged Ready for Filling Glass Cartridges	07/06/2024
22)	MHD/12/25445	Medical Devices Non-Electrically Driven Portable Infusion Devices	07/06/2024
23)	MHD/12/25446	Sterilization of Health Care Products Microbiological Methods Part 3 Bacterial Endotoxin Testing	07/06/2024
24)	MHD/12/25448	Stainless Steel Needle Tubing for the Manufacture of Medical Devices Requirements and Test Methods	07/06/2024
25)	MHD/12/25449	Intravascular Catheters Sterile and Single-Use Catheters Part 1 General Requirements Second Revision	07/06/2024
26)	MHD/12/25583	Intravascular Catheters Sterile and Single-Use Catheters Part 4 Balloon Dilatation Catheters (Second Revision)	07/06/2024
27)	MHD/12/25584	Intravascular Catheters Sterile and Single-Use Catheters Part 7 Peripherally Inserted Central Catheters	07/06/2024
28)	MHD/12/25585	Sterilization of Health Care Products Radiation Substantiation of Selected Sterilization Dose: Method VDmaxSD	07/06/2024
29)	MHD/12/25586	Sterilization of Health Care Products Moist Heat Requirements for the Development Validation and Routine Control of a Sterilization Process for Medical Devices	07/06/2024
30)	MHD/12/25589	Sterile Hypodermic Syringes for Single Use Part 4 Syringes with Re-use Prevention Feature	07/06/2024
31)	MHD/12/25590	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 2 Double-Ended Pen Needles	07/06/2024

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

a) The Committee decided to adopt the following ISO standards. The draft standards will be circulated within the committee for a period of 15 days. If no comments will be received, the draft standards will be wide-circulated for a period of one month.

Sl. No	ISO No.	ISO Title
1)	ISO 11608-1:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems
2)	ISO 8871-1:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
3)	ISO 8871-2:2020	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization
4)	ISO 8871-3:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count
5)	ISO 8871-3:2003/Amd 1:2018	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count — Amendment 1
6)	ISO 8871-4:2006	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods
7)	ISO 8871-5:2016	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing
8)	ISO 8872:2022	Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods
9)	ISO 11040-6:2019	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling
10)	ISO 11040-7:2015	Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling
11)	ISO 11040-8:2016	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes
12)	ISO 15378:2017/Amd 1:2024	Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) — Amendment 1: Climate action changes
13)	ISO 11608-3:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths
14)	ISO 11608-4:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 4: Needle-based injection systems containing electronics
15)	ISO 11608-5:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions
16)	ISO 11608-6:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 6: On-body delivery systems
17)	ISO 11608-7:2016	Needle-based injection systems for medical use — Requirements and test methods — Part 7: Accessibility for persons with visual impairment

b) The Committee decided to adopt the following ISO standards to revise the existing older versions. The draft standards will be circulated within the committee for a period of 15 days. If no comments will be received, the draft standards will be wide-circulated for a period of one month.

Sl. No	ISO No.	ISO Title
1)	ISO 8362-2:2024	Injection containers and accessories — Part 2: Closures for injection vials
2)	ISO 13408-1:2023	Aseptic processing of health care products — Part 1: General requirements
3)	ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

c) The Committee decided to circulate the list of standards published after 2022 by ISO/TC 76, ISO/TC 84 and ISO/TC 198, along with their status of adoption among the members for a period of 15 days, requesting them to identify and share the standards that should be adopted as Indian Standards.

ITEM 6 DRAFT UNDER PREPARATION

6.1 The Committee noted the contents of Item 6.1 of the agenda.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 The Committee decided to withdraw IS 4148:1989 'Surgical rubber gloves - Specification (*First Revision*)' and requested members to give their technical justification for further processing.

ITEM 8 NEW SUBJECTS

8.1 The Committee noted that BIS has offered Internship to students to expose them to the standardization ecosystem at the national and international levels. As part of their internships, students were assigned the task of preparing a pre-standardization document for New Work Item proposals on the following subjects:

Sl. No.	Title
1)	Hospital furniture
2)	Burn sheet

Additionally, the Committee requested members to provide a list of manufacturers of the aforementioned medical equipment.

ITEM 9 TECHNICAL ISSUES

9.1 The Committee decided to withdraw IS/ISO 14161:2009 due to its duplication with existing standard.

ITEM 10 INTERNATIONAL ACTIVITIES

10.1 The Committee noted that the meeting of ISO/TC 84 is scheduled to be held from 7th October to 10th October 2024 in Copenhagen, Denmark and requested members to send their nominations within two weeks to participate in the meeting as a part of Indian delegation.

10.2 The Committee approved the decision to seek P-membership in IEC PC 130 'Cold Storage Equipment for Medical Use'.

10.3 The Committee noted the contents of Item 10.3 of the agenda.

10.4 The Committee noted the contents of Item 10.4 of the agenda.

10.5 The Committee noted the contents of Item 10.5 of the agenda.

ITEM 11 PROGRAMME OF WORK

11.1 The Committee noted the contents of Item 11.1 of the agenda.

11.2 Review of Indian Standards (pre-2000 Standards)

11.2.1 The Committee noted the contents of Item 11.2.1 of the agenda.

11.2.2 The Committee noted that the panel on pre-2000 standards will review the pre-2000 standards in its upcoming meeting.

11.3 Review of Indian Standards (as per 5-year cycle)

11.3.1 The Committee noted the contents of Item 11.3.1 of the agenda.

11.3.2 The Committee noted the contents of Item 11.3.2 of the agenda.

11.3.3 The Committee noted and decided the following:

Sl. No.	IS Number	IS Title	Remarks
1)	IS 12227 : 2020/ISO 8537 : 2016	Sterile Single-Use Syringes, With or Without Needle, for Insulin (*Second Revision*)	The Committee decided to reaffirm the standard
2)	IS 3120 : 1999	Baby incubators - Specification (*Second Revision*)	The Committee decided that the panel on pre-2000 standards will review these standards.
3)	IS 3829 (Part 1) : 1999	Specification for steam sterilizers: Part 1 horizontal cylindrical and horizontal rectangular steam sterilizers, pressure type (For Hospital and Pharmaceutical Use) (*Second Revision*)	
4)	IS 3993 : 1993	Trays, instruments - Specification (*Second Revision*)	
5)	IS 3994 : 1993	Bowls,wash - Specification (*Second Revision*)	
6)	IS 5022 : 1989	Sterilizer, instruments, table model (*Third Revision*)	
7)	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (*First Revision*)	
8)	IS/ISO 10555-4 : 2013	Sterile, single - Use intravascular catheters: Part 4 balloon dilatation catheters	The committee noted that the standard is currently under adoption (MHD/12/25583)

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 The Committee noted the contents of Item 12.1 of the agenda.

ITEM 13 DATE AND PLACE OF NEXT MEETING

As per the approved Annual Meeting Calendar the committee decided to have the next meeting on 28th August, 2024.

Quarter	Q1 Apr-June 2024	Q2 July-Sept 2024	Q3 Oct-Dec 2024	Q4 Jan-Mar 2025
Date	29th May 2024, Wednesday	28th Aug 2024, Wednesday	27th Nov 2024, Wednesday	5th Feb 2025, Wednesday

ITEM 14 ANY OTHER BUSINESS

There being no other business, the meeting ended with hearty thanks to the chair and all the members present.

ANNEXURE A

LIST OF ATTENDEES

Sl. No.	Member Name	Organization
1)	**Lt. Gen Sunil Kant (*Chairperson*)**	In-Personal Capacity
2)	Ms. Kavitha Kulkarni	3M India Limited, Bengaluru
3)	Ms. Prabha Hegde	3M India Limited, Bengaluru
4)	Shri Asok Kumar Raghavan Nair	Asia Pacific Medical Technology Association (APACMed), Gurugram
5)	Shri Kamlesh R. Shah	Association of Indian Medical Device Industry, New Delhi
6)	Shri Ravi Abraham	Association of Indian Medical Device Industry, New Delhi
7)	Ms. Ishita Dhingra	B. Braun Medical India Private Limited, New Delhi
8)	Shri Nikhil Pandey	B. Braun Medical India Private Limited, New Delhi
9)	Shri Dev Chopra	Boston Scientific India Private Limited, Gurugram
10)	Ms. Shyamni Sasidharan	Central Drugs Standard Control Organization, New Delhi
11)	Shri Praveen Kumar Sharma	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad
12)	Shri Manmohan Singh Gulati	Indian Rubber Gloves Manufacturers Association, New Delhi
13)	Shri Naveen Kumar Reddy	Indian Rubber Gloves Manufacturers Association, New Delhi
14)	Ms. Himani Gupta	Johnson and Johnson Private Limited, Mumbai
15)	Shri Amit Sharma	Kalam Institute of Health Technology, Vishakhapatnam
16)	Shri Mohan Ragul	Kalam Institute of Health Technology, Vishakhapatnam
17)	Shri Donald S.K.	Kanam Latex India Private Limited, Kottayam
18)	Shri Abraham C. Jacob	Kanam Latex India Private Limited, Kottayam
19)	Shri Bansidhar S. Dhurandhar	Microtrol Sterilisation Services Private Limited, Mumbai
20)	Shri Hitesh Kumar	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)
21)	Shri Shivley Sageer	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)
22)	Dr. Navneet Dhaliwal	Post Graduate Institute of Medical Education and Research, Chandigarh
23)	Shri Sanjay Rajput	Shriram Institute for Industrial Research, Delhi
24)	Shri Manoj A.	Terumo Penpol Private Limited, Thiruvananthapuram

25)	Shri Kulveen Singh Bali (*Physically*)	In-Personal Capacity

BIS Directorate General:

1)	Ms. Uroosa Warsi (Member Secretary)	Scientist 'C'/Deputy Director, MHD, Bureau of Indian Standards