

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

BUREAU OF INDIAN STANDARDS

MINUTES

Meeting	Day & Date	Time
16 th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	04 th September 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

The list of attendees is given at [Annexure A](#).

ITEM 0 GENERAL

0.1 Welcome Address by Member Secretary

Ms. Uroosa Warsi, Member Secretary, welcomed all attendees to the 16th meeting of the Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12 and invited members to introduce themselves. She requested members to maintain decorum throughout the meeting. Acknowledging that members may have differing opinions, she emphasized the importance of reaching a consensus on the agenda items. She then handed over the proceedings to the Chairperson for his opening remarks and the formal commencement of the meeting.

0.2 Opening Remarks by Chairperson

Lt Gen Sunil Kant, the Chairperson, warmly welcomed all members in attendance and expressed his appreciation for the dedication and significant contributions of the Member Secretary, Ms. Uroosa Warsi. He informed the committee that the Member Secretary would provide a briefing on the changes in the structure and processes of the sectional committee.

The Chairperson raised two key concerns: firstly, the limited feedback on circulated documents, and urged members to actively contribute their valuable input to enhance the quality of the committee's work. Secondly, he stressed the importance of addressing issues holistically, aligning with the objectives of the Bureau of Indian Standards and national interests. He concluded by inviting the Member Secretary to proceed with the meeting.

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 29th May 2024.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 a) The Committee noted the scope of the Committee.

b) The Committee accepted the participation request of the following members in the working panels. Members were also informed that they may submit requests to the Member Secretary for participation in any working panel relevant to their area of expertise.

Sl. No.	Working Panels	Members
1)	MHD 12 : P1 - Gloves	● Shri Manmohan Singh Gulati
2)	MHD 12 : P3 - Syringes, Needles and Ampules	● Shri Praveen Kumar Sharma
3)	MHD 12 : P5 - Sterilization of Healthcare Products	● Dr. Sanjay Rajput ● Shri Kulveen Singh Bali ● Ms. Kavitha Kulkarni ● Shri Vishnu Shankar Vyas
4)	MHD 12 : P7 - Transfusion Equipment	● Shri Manoj A.
5)	MHD 12 : P8 - Cold Chain Equipment	● Shri Anshuman Tuli ● Shri Shivley Sageer

2.2 a) The Committee accepted the co-option request of Shri Vishnu Shankar Vyas (E.I. DuPont India Pvt Ltd).

b) The Committee rejected the co-option request of the Medical Technology Association of India (MTAI).

2.3 The Committee noted the contents of Item 2.3 of the agenda.

2.4 The Committee noted the contents of Item 2.4 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 The Committee noted the contents of Item 4.1 of the agenda.

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

5.1 a) The Committee decided to adopt ISO 11608-1:2022 ‘Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems’ as Part 2 of this standard is already adopted and in Part 2 reference is made to Part 1. The draft standard will be wide-circulated for a period of one month.

b) The Committee decided to adopt the following ISO standard to revise the existing older versions. The draft standard will be wide-circulated for a period of one month.

Sl. No.	ISO No.	ISO Title
1)	ISO 11040-4:2024	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized sub assembled syringes ready for filling

5.2 The Committee noted the contents of Item 5.2 of the agenda.

ITEM 6 DRAFT UNDER PREPARATION

6.1 The Committee decided to circulate the following P-draft to all members for a period of 30 days.

S. No.	Title
1)	Walk-in-Freezer Specification
2)	Vaccine Refrigerator or Combined Refrigerator and Water-Pack Freezer Powered by Solar Direct Drive System General Requirements and Testing Methods

6.2 The Committee noted the contents of Item 6.2 of the agenda.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 a) IRGMA has put forth their suggestion to incorporate GOVT OF INDIA RULES Banned Chlorinated Gloves in the standard IS 15354 (Part 1): 2023 ‘Single Use Medical Examination Gloves Part 1 Gloves Made from Rubber Latex or Rubber Solution — Specification (Second Revision)’.

The concerns of IRGMA were noted. The Committee deliberated on this matter in detail and observed that GOVT OF INDIA Rules is the law of land and everyone has to follow the same.

The Committee also decided to recommend the standard to the panel MHD 12 : P1 - Gloves for a detailed analysis and further deliberation.

b) The Committee decided to withdraw IS 4148:1989 ‘Surgical rubber gloves — Specification (First Revision)’ being obsolete and unsafe usage as there is high risk of spread of nosocomial infections from re-use of Surgical Gloves.

ITEM 8 NEW SUBJECTS

8.1 The Committee deliberated and decided the following:

Sl. No.	Title	Remarks
1)	Fowler bed	Allotted to Working Panel 9 ‘Medical Furniture’.
2)	Burn sheet	Additionally, the drafts will be circulated to all members for their inputs.

8.2 The Committee deliberated and decided the following:

Sl. No.	Name of Equipment	Remarks
1)	Plasma Sterilizer	Allotted to Working Panel 5 ‘Sterilization of Healthcare Products’ Decision taken to adopt ISO 22441:2022
2)	PM Line	Allotted to Working Panel 6 ‘Infusion Equipment’
3)	3-way stop cock	
4)	Dome kit with flushing system	Clarification with DoP is required
5)	Coronary microcatheter	Allotted to Working Panel 4 ‘Catheters’
6)	E.P. Catheters (multipolar and uni directional and bi-directional)	
7)	Mother and child catheter assembly	

8)	CSE Set	Clarification with DoP is required
9)	Epidural Set (Adult and Paediatric)	Allotted to Working Panel 4 ‘Catheters’
10)	Spinal Needle (Adult and Paediatric)	Allotted to Working Panel 3 ‘Syringes, Needles and Ampules’
11)	ETO sterilisation system	Allotted to Working Panel 5 ‘Sterilization of Healthcare Products’
12)	Physiodispenser	Clarification with DoP is required
13)	Dialysis Chair	Allotted to Working Panel 9 ‘Medical Furniture’
14)	Cell Separator (Apheresis machine)	Allotted to Working Panel 7 ‘Transfusion Equipment’
15)	Hydraulic Bed	Allotted to Working Panel 9 ‘Medical Furniture’

ITEM 9 TECHNICAL ISSUES

9.1 The Committee noted the contents of Item 9.1 of the agenda.

ITEM 10 INTERNATIONAL ACTIVITIES

10.1 The Committee noted the contents of Item 10.1 of the agenda.

10.2 The Committee decided to circulate the list of standards published by ISO/TC 76, ISO/TC 84, and ISO/TC 198, along with their adoption status, to all members for a period of 15 days. Members were requested to review the list, identify the standards that should be adopted as Indian Standards, and provide justifications for their recommendations.

ITEM 11 PROGRAMME OF WORK

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

11.2 The Committee noted the contents of Item 11.2 of the agenda.

ITEM 12 REVIEW OF INDIAN STANDARDS

12.1 The Committee decided to circulate the list of pre-2000 standards, along with the recommendations of the working panel, to all members for a period of 10 days. Members were requested to review the list and provide their comments and/or approval on the recommendations.

12.2 The Committee noted the contents of Item 12.2 of the agenda.

ITEM 13 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

13.1 The Committee noted the contents of Item 13.1 of the agenda.

ITEM 14 DATE AND PLACE OF NEXT MEETING

As per the approved Annual Meeting Calendar the committee decided to have the next meeting on 27th November 2024.

Quarter	Q1 Apr-June 2024	Q2 July-Sept 2024	Q3 Oct-Dec 2024	Q4 Jan-Mar 2025
Date	29 th May 2024 Wednesday	04 th Sept 2024 Wednesday	27 th Nov 2024 Wednesday	5 th Feb 2025 Wednesday

ITEM 15 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 <i>(Chairperson)</i>	In-Personal Capacity
2)	Ms. Kavitha Kulkarni	3M India Limited, Bengaluru
3)	Ms. Prabha Hegde	3M India Limited, Bengaluru
4)	Shri Rajiv Nath	Association of Indian Medical Device Industry, New Delhi
5)	Shri Anshuman Tuli	B Medical Systems India Private Limited, New Delhi
6)	Ms. Ishita Dhingra	B. Braun Medical India Private Limited, New Delhi
7)	Shri Dev Chopra	Boston Scientific India Private Limited, Gurugram
8)	Shri Praveen Kumar Sharma	Hindustan Syringes and Medical Devices Limited, Ballabgarh, Faridabad
9)	Shri Harpreet Singh <i>(Representative)</i>	Indian Rubber Gloves Manufacturers Association, New Delhi
10)	Shri Vikash Anand	Indian Rubber Gloves Manufacturers Association, New Delhi
11)	Shri Amit Sharma	Kalam Institute of Health Technology, Vishakhapatnam
12)	Shri Mohan Ragul	Kalam Institute of Health Technology, Vishakhapatnam
13)	Shri Donald S.K.	Kanam Latex India Private Limited, Kottayam
14)	Shri Hitesh Kumar	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)
15)	Shri Shivley Sageer	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)
16)	Dr. Navneet Dhaliwal	Post Graduate Institute of Medical Education and Research, Chandigarh
17)	Dr. Sanjay Rajput	Shriram Institute for Industrial Research, Delhi
18)	Shri Manoj A.	Terumo Penpol Private Limited, Thiruvananthapuram
19)	Shri Kulveen Singh Bali	In-Personal Capacity

BIS Directorate General:

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