

**MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT**

**BUREAU OF INDIAN STANDARDS**

**MINUTES**

<b>Meeting</b>	<b>Day &amp; Date</b>	<b>Time</b>
<b>14<sup>th</sup> Meeting of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06</b>  [via WebEx platform]	<b>August 02, 2023, Wednesday</b>	<b>12 P.M.</b>

**Chairperson:** Dr. Deepak Kumar Satsangi (In Personal Capacity)

**Member Secretary:** Mr. Pawan Kumar, Scientist-B, MHD, BIS, New Delhi

**Members Present**

<b>S.No</b>	<b>Name</b>	<b>Organization</b>
<b>1.</b>	Dr. Deepak Kumar Satsangi	In Personal Capacity
<b>2.</b>	Dr. Milind P Hote	AIIMS, New Delhi
<b>3.</b>	Shri Dev Chopra	Boston Scientific India Private Limited, Gurugram
<b>4.</b>	Dr. Ramashankar P	JIPMER, Puducherry
<b>5.</b>	Shri Aaditya Vats	Johnson and Johnson Private Limited, Mumbai
<b>6.</b>	Shri Gautam A	Johnson and Johnson Private Limited, Mumbai
<b>7.</b>	Ms. Indu V Nair	TTK Healthcare Limited, Chennai
<b>8.</b>	Sruthi Saladula	Andhra Pradesh MedTech Zone, Andhra Pradesh
<b>9.</b>	Sushmita	Andhra Pradesh MedTech Zone, Andhra Pradesh
<b>10.</b>	Syed Mustafiz	Andhra Pradesh MedTech Zone, Andhra Pradesh
<b>11.</b>	Mohini Mehta	Andhra Pradesh MedTech Zone, Andhra Pradesh

**BIS Directorate General:**

1. Shri Unnikrishnan A R, Scientist-F and Head, MHD, BIS
2. Ms. Uroosa Warsi, Scientist-B, MHD, BIS
3. Shri Karthik Reddy, Scientist-B, MHD, BIS

## **ITEM 0 : GENERAL**

**0.1** Shri Unnikrishnan A R, Scientist-F and Head, MHD welcomed the members to 14<sup>th</sup> meeting of Medical and Surgical Cardiology Equipment Sectional Committee. He appreciated the members present for sparing their valuable time to participate in this meeting. He also introduced Mr. Pawan Kumar as the new member secretary of medical and surgical cardiology instruments sectional committee MHD 06.

**0.2** Dr. Deepak Kumar Satsangi, Chairperson, welcomed the members present for the 14<sup>th</sup> meeting of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06. He urged committee members for active deliberations for making the meeting successful. He requested Member Secretary to take up the agenda items for discussion.

## **ITEM 1 : CONFIRMATION OF MINUTES OF THE LAST MEETING**

The Committee formally confirmed the minutes of last (13<sup>th</sup>) meeting of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06 held on 16<sup>th</sup> Dec 2022 through video conferencing.

## **ITEM 2 : PROCESS REFORMS IN STANDARDIZATION ACTIVITY OF BIS**

**2.1** Ms. Uroosa Warsi, presented a PowerPoint presentation on the process reforms to streamline the standardization related activities. The details of discussion are enclosed at **ANNEX 1**. The committee members noted and appreciated the process reforms.

**2.2** The Committee approved the following meeting calendar for the period of 2023-2024

<b>Quarter</b>	<b>Q2</b> July-Sept 2023	<b>Q3</b> Oct-Dec 2023	<b>Q4</b> Jan-Mar 2024
<b>Date</b>	<b>2nd Aug 2023,</b> <b>Wednesday (Current)</b>	<b>7<sup>th</sup> December 2023,</b> <b>Thursday</b>	<b>20<sup>th</sup> February 2024,</b> <b>Tuesday</b>

## **ITEM 3 : SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE**

**3.1** The committee noted the current scope of sectional committee. The committee decided that Dr. Ramashankar P, JIPMER, Puducherry to become convener of the Cardiothoracic and Vascular Surgery Sub Committee under the current sectional committee. The committee also suggested the name of Dr. Santosh for the convener of cardiology sub-committee.

**3.2** The committee noted the current composition of the Medical and Surgical Cardiology Equipment Sectional Committee. The committee suggested to send a reminder to non-attendees of last three meetings to update their representation in order to enhance active participation and better deliberation in the upcoming meetings.

**ITEM 4 : DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION**

The Draft Indian Standards listed in Item 4 of the agenda have completed their wide-circulation period. The committee requested to share the document with all committee members for their input within a span of 15 days. In the absence of any technical comments during this timeframe, the standards will be finalized with consultation of chairperson.

**ITEM 5 : DRAFT STANDARDS / AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION**

The committee decided to wide-circulate ISO/TR 12417-2:2022 Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 2: Local regulatory information, for a period of 30 days dispensing P-draft stage. If no comments received the documents will be finalized in consultation with chairperson. If technical comments received, the same will be discussed in the next committee meeting.

**ITEM 6 : DRAFTS UNDER PREPARATION**

The following drafts are under preparation:

- Electric operated sternum saw system
- Battery operated sternum saw system
- Rotablation Machine

The committed suggested to circulate working draft among the committee members for a period of 30 days for their perusal and further deliberation.

**ITEM 7 : COMMENTS ON PUBLISHED STANDARD**

The committee noted the information provided at Item 7 of the agenda.

**ITEM 8 : NEW SUBJECTS**

The committee noted the information provided at Item 8 of the agenda.

**ITEM 9 : INTERNATIONAL ACTIVITIES**

The committee noted the information provided at Item 9 of the agenda.

In view of active deliberation and sufficient technical capabilities in the present sectional committee, the committee decided to acquire P-membership in ISO/TC 150/SC 6.

**ITEM 10 : PROGRAMME OF WORK (INCLUDING PERIODIC REVIEW OF INDIAN STANDARDS)**

10.1 The committee noted the current programme of work of the committee provided in Annex 4 of agenda.

10.2 Review of Indian standards published before year 2000

The list of Indian Standard under MHD 06 which are published prior to year 2000 is given at Annex 5 of agenda.

The committee deliberated and decided that the following two standards published before year 2000 may be withdrawn as these are obsolete.

<b>S. No</b>	<b>IS No.</b>	<b>Title</b>	<b>Status</b>
1.	IS 6779 : 1989	Thoracic Surgery Instruments - Forceps Dissecting and Ligature Mixer s Pattern	Recommended for withdrawal
2.	IS 7971 : 1987	Tourniquet Cardiovascular Rumel-Belmonts Pattern	Recommended for withdrawal

**ITEM 11 : DATE AND PLACE OF NEXT MEETING**

The next meeting of Medical and Surgical Cardiology Instruments Sectional Committee would be tentatively held on 7<sup>th</sup> Dec 2023 as per the convenience of members and Chairperson, MHD 06.

**ITEM 12 : ANY OTHER BUSINESS**

There being no other business, the meeting ended with a vote of thanks to hon'ble chair and all the members present.

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**ANNEX 1**  
**PROCESS REFORMS IN STANDARDIZATION ACTIVITY**

It was informed to the committee that BIS has instituted several process reforms in respect of formulation of Indian Standards and it is essential that the committee members are fully aware of these reform measures. The presentation of these measures before the committee would give the members an excellent bird's-eye view of the new reforms in Standardization activity.

**STANDARDS NATIONAL ACTION PLAN (SNAP)**

**Standards National Action Plan (SNAP) 2022-2027** is one of the major transformational initiatives launched by BIS and the document has been developed after a series of consultations with various stakeholders and interested parties. SNAP would serve as a roadmap for standardization and will play an important role in steering the national standardization efforts.

The committee noted that the SNAP document is available in BIS website under the link <https://www.bis.gov.in/wp-content/uploads/2023/05/SNPbookBilingual.pdf>. The committee also noted the subject areas in the health/ healthcare sector that are to be taken up for standardization by 2027 as per the assigned priorities.

**STANDARDIZATION PORTAL**

The committee noted the functioning of revamped standards portal and appreciated the efforts taken by BIS in digitization of various stages of Standardization activity and encouraged the members to enhance the use of IT tools and to effectively utilize the services of the portal in the best possible manner so as to increase the efficiency of operations.

**ROLLING ANNUAL ACTION PLAN FOR 2023-24**

The importance of rolling annual action plan which is an annual strategic roadmap document that helps in monitoring the progress of standards development at various stages was discussed.

## **IDENTIFICATION OF NEW AREAS FOR STANDARDIZATION**

The relevance and strategic significance of BIS as the National Standards Body needs to be augmented. This would require identification of new emerging areas where standardisation could benefit the society at large.

The committee noted that this can be achieved through the annual programme for standardization for Central/State Ministries/ Departments & Industry Associations, effective utilization of Standardization Cells, interaction with the faculty of Prominent Technical Institutes, subscription of important Scientific Journals & Magazines etc. The members were requested to suggest the details of scientific journals and periodicals that are relevant to the work of the committee which can be subscribed by BIS.

## **CREATION OF POOL OF EXPERTS**

Considering the diverse and specialized nature of standardization, there is a need to create a pool of experts in committees so that they can contribute towards standards formulation in various areas.

The committee noted that this would include experts in individual capacity as well as specialist organisations who can contribute and urged the members to volunteer as well as suggest the names of organizations that can be included as experts so as to assist BIS in increasing its network of experts. The committee also noted the various committee management strategies and the standards promotion activities adopted by BIS to fulfil its various objectives.

## **STAKEHOLDER MANAGEMENT**

The technical committees form the backbone of the standardisation infrastructure of BIS. The committee noted that the increased participation of various stakeholders in standard formulation process needs to be sustained which would strengthen the standardization activities of BIS.

## **ANNUAL CALENDAR OF SECTIONAL COMMITTEE MEETINGS**

The meetings of sectional committees are normally convened once in three months in consultation with the Chairperson. For effective planning of the meeting, an Annual Meeting Calendar need to be prepared in advance.

The committee noted that the advance information on meeting dates would help the members to plan their meeting schedule among other commitments.

## **RESEARCH PROJECTS**

It was discussed that the formulation/ review/ revision of the standards is primarily based on the technical inputs provided by the committee members. However, it would be prudent to ensure that adequate research inputs from various sources in the form of authentic data are available to BIS which would strengthen the standards setting process. The various R & D schemes available in this context were briefed to the committee members.

## **PARTICIPATION AT INTERNATIONAL MEETINGS AT ISO/IEC LEVEL AND NEW WORK ITEM PROPOSALS RECEIVED FROM ISO/IEC**

It is important for BIS, as the National Standards Body and the founder member of ISO and IEC, to contribute effectively on the international front. The committee noted that the strategic participation and effective contribution to international standardisation activities would result in high visibility of the country in the international forum.

Further, as a part of the national standards strategy, it is also expected that the committee members give a closer examination of the New Work Item Proposals received from ISO/IEC from the Indian industry perspective as well.

**PARTICIPATION IN NATIONAL AND INTERNATIONAL EVENTS**

The need and importance of participation in national and international events that are relevant to the area of scope of the committee was discussed. The members were requested to inform BIS about any such events so that BIS officers as well as the committee members can ensure effective participation in these events.