

# MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

## *Bureau of Indian Standards*

### MINUTES

#### 14<sup>TH</sup> MEETING OF ORTHOPAEDIC INSTRUMENTS, IMPLANTS AND ACCESSORIES SECTIONAL COMMITTEE, MHD 02

Date: 08-08-2023	Time: 11:00 AM
Venue: Online (BIS WebEx Platform)	
Chairperson: Dr. Sudhir Kumar (In-Personal capacity)	Member Secretary: Vinit Vidyadhar Bansod. (Scientist-B)

### **ITEM 0 GENERAL**

#### **ITEM 0.1 WELCOME ADDRESS BY MEMBER SECRETARY**

Ms. Gurpreet Kaur, earlier Member Secretary, greeted all the members present in the meeting.

She introduced Mr. Vinit Vidyadhar Bansod as the new Member Secretary of Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02. Meeting commenced with the introduction of the members.

#### **ITEM 0.2 OPENING REMARKS BY THE CHAIRMAN**

Dr. Sudhir Kumar, Chairperson, welcomed the members present in the meeting. He urged the committee members for active participation in the technical deliberations of the committee meeting.

*The list of participants is given in ANNEX A.*

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

The committee formally confirmed the minutes of the last (Thirteenth) meeting of the Orthopaedic Instruments, Implants and Accessories Sectional Committee (MHD 02), held on August 10, 2022 via Video Conferencing (Webex).

### **ITEM 2 PROCESS REFORMS IN STANDARDIZATION**

**2.1** The process reforms in respect of standards formulation activity were discussed during the meeting. The details of discussion are enclosed at **ANNEX B**.

**2.2** The committee approved the proposed annual meeting calendar for MHD 02, as given below:

<b>Quarter</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>
<b>Date</b>	August 8, 2023 (Current)	November 16, 2023 (Thursday)	28 <sup>th</sup> Feb, 2024 (Wednesday)

### ITEM 3 SCOPE AND COMPOSITION OF COMMITTEE

3.1 The Committee noted the scope of the Sectional Committee.

3.2 The Committee noted the present composition of the committee and decided to send letters to the organizations, representatives of which have not attended any or any two of the last three meetings of the sectional committee.

3.3 The Committee decided to remove Food and Drugs Laboratory, Vadodara from its composition.

3.4 The Committee accepted the co-option request received from **Healthium Medtech, Bangalore.**

**Principal Member:** Mayank Rohatgi, Head – Government Affairs, Healthium Medtech Limited

### ITEM 4 DRAFT STANDARDS FOR FINALIZATION

In absence of comments on the Wide Circulation Draft, the Committee decided to finalize the following draft Indian Standard for publication:

Sl No.	Document No.	Title	Doc Type
1)	MHD/02/19659	Orthopaedic Gouge Forceps Lanes Pattern Specification ( <i>First Revision</i> )	Revision
2)	MHD/02/21085	Specification for Stirrup Bohlers ( <i>First Revision</i> )	Revision

### ITEM 5 DRAFT STANDARDS FOR APPROVAL FOR WIDE CIRCULATION

5.1 The committee decided to adopt the following ISO standards to revise the existing older versions:

Sl No.	ISO	Title
1)	ISO 12891-2: 2020 <i>(Revision of IS/ISO 12891-2: 2014)</i>	Retrieval and analysis of surgical implants — Part 2: Analysis of retrieved surgical implants
2)	ISO 13179-1: 2021 <i>(Revision of IS/ISO 13179-1: 2014)</i>	Implants for surgery — Coatings on metallic surgical implants — Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders
3)	ISO 5832-9:2019 <i>(Revision of IS/ISO 5832-9 : 2007)</i>	Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel
4)	ISO 6474-1:2019 <i>(Revision of IS/ISO 6474-1: 2010)</i>	Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina
5)	ISO 6474-2:2019 <i>(Revision of IS/ISO 6474-2: 2012)</i>	Implants for surgery — Ceramic materials — Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement

<b>Sl No.</b>	<b>ISO</b>	<b>Title</b>
6)	ISO 13782:2019 <i>[Revision of IS 5347(Part 17): 2002/ISO 13782: 1996]</i>	Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications
7)	ISO 21535:2023 <i>(Revision of IS/ISO 21535: 2007)</i>	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants
8)	ISO 21536:2023 <i>(Revision of IS/ISO 21536: 2007)</i>	Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants

**5.2** The committee decided to adopt the following ISO standards.

<b>Sl. No.</b>	<b>ISO</b>	<b>Title</b>
1)	ISO/TR 17327-2: 2021	Non-active surgical implants — Implant coating — Part 2: Reference standards related to coatings
2)	ISO 5832-12: 2019	Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy
3)	ISO 5832-14: 2019	Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy
4)	ISO 5834-3:2019	Implants for surgery — Ultra-highmolecular-weight polyethylene — Part 3: Accelerated ageing methods
5)	ISO 5834-4:2019	Implants for surgery — Ultra-highmolecular-weight polyethylene — Part 4: Oxidation index measurement method
6)	ISO 5834-5:2019	Implants for surgery — Ultra-highmolecular-weight polyethylene — Part 5: Morphology assessment method
7)	ISO 7206-12: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells
8)	ISO 7206-13: 2016	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
9)	ISO 7207-2:2011	Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials
10)	ISO 14243-5: 2019	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint

The draft standards will be wide-circulated for a period of one month. The committee decided to finalize the documents for publication in case no comments are received on the wide circulation documents.

## **ITEM 6 DRAFTS UNDER PREPARATION**

**6.1** The working drafts of the following new subjects will be shared within the committee for more input and comments.

- i) Battery Operated Dermatome
- ii) Arthroscopy System
- iii) Battery-operated drill
- iv) Pneumatic Drill

## **ITEM 7 INTERNATIONAL ACTIVITIES**

**7.1** The committee noted the contents of Item no. 7.1 of the agenda.

**7.2** The committee approved the upgradation of its membership in ISO/TC 150/SC 4 'Bone and Joints Replacement' from 'Observing member' to 'Participating member'.

**7.3** The committee noted the contents of Item 7.3. It was decided to circulate the list of ISO standards within the committee for consideration for adoption.

## **ITEM 8 REVIEW OF INDIAN STANDARDS & PROGRAMME OF WORK**

It was decided to periodically circulate the standards that were published before the year 2000 for the perusal of members.

## **ITEM 9 TECHNICAL ISSUES**

The committee decided to drop its O-membership of ISO/TC 150/SC 6 'Active Implants' as active implants does not fall under the scope of the committee. Further, MHD 06 'Medical and Surgical Cardiology Equipment Sectional Committee' is already P-member on the subject and the National Mirror committee for ISO/TC 150/SC 6.

## **ITEM 10 ISSUES ARISING OUT OF PREVIOUS MEETINGS**

The committee noted the contents of Item no. 10 of the agenda.

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

In accordance with the approved annual meeting calendar, the upcoming meeting of the MHD 02 Sectional Committee is tentatively scheduled for November 16, 2023.

## **ITEM 12 ANY OTHER BUSINESS**

The meeting concluded with closing remarks of Hon'ble Chairperson.

**ANNEX A**  
(Item 0)

**LIST OF PARTICIPANTS**

**MEMBERS PRESENT:**

<i>Sr No.</i>	<i>Organization</i>	<i>Member Name</i>
1.	In Personal Capacity, Greater Noida	Dr. Sudhir Kumar ( <b>Chairperson</b> )
2.	Artificial Limbs Manufacturing Corporation of India (ALIMCO), Kanpur	Shri A.K. Singh
3.	Artificial Limbs Manufacturing Corporation of India (ALIMCO), Kanpur	Shri Vishal Shukla
4.	BBraun Medical (India) Pvt. Ltd., Delhi	Ms. Gayatri Garg
5.	CSIR-Central Glass & Ceramic Research Institute (CGCRI), Kolkata	Dr. Biswanath Kundu
		Dr. Vamsi K. Balla
		Dr. Subhadip Bodhak
6.	Central Drugs Standard Control Organization, New Delhi (CDSCO)	Shri Ajai Basil ( <i>Representative</i> )
7.	Green Surgicals (P) Ltd., Vadodara	Shri Kalpesh Pal Shri Nitesh Shri Virat } ( <i>Representatives</i> )
8.	India Medtronic Pvt. Ltd., Gurugram	Shri Amit Kumar ( <i>Representative</i> )
9.	Indian Institute of Technology, Kanpur	Dr. Kantesh Balani
10.	Kalam Institute of Health Technology, Vishakhapatnam	Smt. Sushmita Roy
		Syed Mustafiz
		Nandhini ( <i>Invitee</i> )
		Amit Kumar Sharma ( <i>Invitee</i> )
11.	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram	Dr. Manoj Komath
12.	Stryker India Pvt. Ltd	Shri Gajender Sharma
13.	Healthium Medtech, Bangalore	Shri Mayank Rohatgi ( <i>Invitee</i> )
		Shri Raajjhesh ( <i>Invitee</i> )

**BIS DIRECTORATE GENERAL:**

Sl. No	Name	Designation
1.	Ms. Gurpreet Kaur	Scientist-B/Assistant Director, MHD, Bureau of Indian Standards
2.	Shri Vinit Vidyadhar Bansod	Scientist-B/Assistant Director, MHD, Bureau of Indian Standards

## **ANNEX B**

*(Item 2.1)*

### **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.

#### **B-1 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.

#### **B-2 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.

#### **B-3 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.

#### **B-4 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.

#### **B-5 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.

#### **B-6 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.

#### **B-7 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.

#### **B-8 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.

#### **B-9 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.

#### **B-10 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.