

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
Bureau of Indian Standards

MINUTES

**19th Meeting: Obstetric and Gynaecological Instruments and Appliances Sectional
Committee, MHD-03**

Meeting Date: 11 August 2023

Time: 1400 hrs

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

ITEM 0 WELCOME ADDRESS AND OPENING REMARKS

0.1 Opening Remarks by Chairperson

Dr. Suneeta Mittal, Chairperson (MHD-03) extended a warm welcome to the members of Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD-03

0.2 Welcome address by Member Secretary

Gurpreet Kaur, Scientist-B, MHD welcomed all the members to the 19th meeting. She briefly introduced the members of the committee.

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The committee confirmed the minutes of the last (18th) meeting held on 03.02.2023 through WebEx.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION

2.1 The member secretary briefly presented the process reforms instituted by BIS, details of which is placed at **Annexure-B**.

2.2 Annual Meeting Calendar

The committee noted and approved the annual meeting calendar as proposed.

Quarter	Q2	Q3	Q4
Date	6th Oct, 2023 (Friday)	8th Dec, 2023 (Friday)	1 st Mar, 2024 (Friday)

ITEM 3 SCOPE AND COMPOSITION OF COMMITTEE

3.1 The committee decided to modify the scope as follows:

Current Scope	Modified Scope
a. To formulate Indian Standards for instruments, appliances, and medical devices, used in obstetrics and gynaecology and for contraception. b. To coordinate with the work of <i>ISO/TC 157 'Non-systemic</i>	a. To formulate Indian Standards for instruments, appliances, medical devices used in obstetrics and gynaecology and for contraception and STI Barrier prophylactics . b. To coordinate with the work of <i>ISO/TC 157 'Non-systemic</i>

<i>contraceptives and STI barrier prophylactics.'</i>	<i>contraceptives and STI barrier prophylactics.'</i>
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3.2 It was decided to send co-option request to IIT-Madras, Chennai.

3.3 The committee noted the attendance of member organizations. It was decided to seek fresh nominations from Government organizations.

3.4 The committee accepted the co-option of following experts:

- a. Dr Puneet Manocha, Managing Director, MHL Healthcare Limited
- b. Mr Gaurav Saraogi, Managing Director, Chemco Plastic Industries Pvt. Ltd.

ITEM 4 DRAFT STANDARDS FOR FINALIZATION

The committee deliberated on the following draft standards which were due for finalization:

Sr No.	Doc No.	Title	Comments
1	20943	MTP Suction Apparatus – Specification Part 3 Electrically Operated (Third Revision)	Dr Minakshi Rohilla: Regarding workmanship and finish of the steel cannula, it is best to avoid bright polish as it might cause glare of light in the operation theatre (9.1.3).
2	21403	NSV Instruments – Specification	No comments received
3	21503	PPIUCD Insertion Forceps – Specification	Dr Minakshi Rohilla: The overall weight of PPIUCD Forceps to be reduced as it is bulky and heavy when used in comparison to other instruments.

It was decided to include the above-mentioned comments and finalize the drafts respectively.

ITEM 5 DRAFT STANDARDS FOR APPROVAL FOR WIDE CIRCULATION

The committee approved the adoption of the following ISO Standards and Amendments:

- a. ISO 7439:2023 Copper-bearing contraceptive intrauterine devices — Requirements and tests
- b. ISO 16037: 2002/ AMD 1:2011 Rubber condoms for clinical trials — Measurement of physical properties — Amendment 1
- c. ISO/TR 24484:2023 Female condoms — Use of ISO 25841 and the quality management of female condoms

The drafts will be widely circulated for a period of 30 days.

ITEM 6 DRAFTS UNDER PREPARATION

The committee noted the contents of Item 6 of the Agenda. The documents at 6.1 and 6.2 of the Agenda to be circulated for a period of 30 days. In case of detailed comments to be provided, the comments can be forwarded until 60 days of circulation.

ITEM 7 INTERNATIONAL ACTIVITIES

The committee noted the contents of Item 7 of the Agenda. The committee appreciated the contribution of the Indian Delegation at the 38th Meeting of ISO/TC 157 at Edinburgh, UK. The committee also extended heartfelt regards to Dr K Sivakumar for receiving the ISO Excellence Award 2023 for his contribution to ISO/TC 157.

ITEM 8 REVIEW OF STANDARDS & PROGRAMME OF WORK

8.1 It was decided to circulate the revision drafts for IS 7080 (Part 1) and IS 7080 (Part 2), which are to be drafted in line with the revised IS 7080 (Part 3)/Doc 20943 for further inputs of the members.

8.2 The committee noted the present programme of work

ITEM 9 ANY OTHER BUSINESS

The meeting concluded with a vote of thanks to honourable chair and all the members.

ANNEXURE-A

LIST OF ATTENDEES

Sr No.	Member Name	Organization
1	Dr Suneeta Mittal (Chairperson)	In-personal capacity
2	Dr K Sivakumar	In-personal capacity
3	Dr Malabika Roy	In-personal capacity
4	Dr. J.B. Sharma	All India Institute of Medical Sciences, New Delhi
5	Dr Raman Mohan Singh	Central Drug Testing Laboratory, Mumbai
6	Dr K. P. Bhuvana	CIPET, Chennai
7	Mr Vinod Kumart	Corporate Channel India Pvt. Ltd., Udaipur
8	Mr Ramnick Dargia	Corporate Channel India Pvt. Ltd., Udaipur
9	Ms. Smitha L. G.	HLL Lifecare Limited, Thiruvananthapuram
10	Dr Sujoy Kumar Guha	Indian Institute of Technology, Kharagpur
11	Mr P J Reddy	Indus Medicare Ltd., Hyderabad
12	Ms Sushmita Roy	Kalam Institute of Health Technology, Vishakhapatnam
13	Mr Syed Mustafiz	Kalam Institute of Health Technology, Vishakhapatnam
14	Dr Suvankar	Office of Development Commissioner MSME, New Delhi
15	Mr Ranjit Gaikwad	Pregna International Ltd., Pune
16	Prof. Minakshi Rohilla	Postgraduate Institute of Medical Education & Research, Chandigarh
17	Dr Shera Mathew	Rubber Research Institute of India, Kottayam
18	Mr Anupam Rai	SMB Corporation of India, Mumbai
19	Mr Brij Balaji Singh	TTK Healthcare Limited, Chennai
20	Dr Puneet Manocha	MHL Healthcare Limited, Muzaffarnagar
21	Mr Gaurav Saraogi	Chemco Plastic Industries Pvt. Ltd., Mumbai
22	Ms Rupande Sampat	Chemco Plastic Industries Pvt. Ltd., Mumbai

ANNEXURE-B

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.