भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

21st Meeting of Medical Laboratory Instruments Sectional Committee, MHD 10

Minutes

दिनांक तथा दिन **DATE & DAY**	09 Apr 2024, Tuesday
समय **TIME**	11:00 AM
स्थान **VENUE**	**Hybrid Meeting**
चेयरमैन **CHAIRMAN**	**Dr Sudip Kumar Datta** Addl. Professor and Head, Department of Laboratory Medicine, AIIMS, New Delhi
सदस्य सचिव **MEMBER SECRETARY**	**Mr. Pawan Kumar** Scientist-B and Assistant Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards mhd10@bis.gov.in; mhd@bis.gov.in

ITEM 0 GENERAL

0.1 Mr. Pawan Kumar, Scientist B, MHD welcomed the members to 20th meeting of Medical Laboratory Instruments Sectional Committee MHD 10. He appreciated the members present for sparing their valuable time to participate in this meeting.

0.2 Shri A R Unnikrishnan, Head (MHD), BIS extended a warm welcome to the attendees of the 21st meeting of the Medical Laboratory Instruments Sectional Committee MHD 10. He informed the committee that during the formulation of a standard, the document goes through a number of steps/blocks, vie Documents Under Consideration, Documents Under Development and Documents under publication. The number of documents in these blocks represents current work in hand of the committee. When the documents are cleared from one block, new documents should bring in, to maintain dynamic balance of standard development in the committee. He also summarized the work done by the committee in the

last financial year, mentioning 8 published standards, 2 standards are under publication and 12 standards are under development.

He mentioned the significant increase in meeting attendance (30.43 to 82.76) and efficiency index (36.89 to 43.64) instantiated by reforms introduced by BIS in the preceding year. He discussed about various parameters i.e. no. of standards published, commenting on drafts, meeting attendance and no. of wide circulation draft etc. based on which efficiency index for technical committees is calculated. He also discussed his meeting with the Secretary, DoP, MoC&F regarding standard development in the healthcare sector. He urged the members to increase the work in hand by identifying more subject for standard development relevant to the current committee. He also encouraged the members to identify any suitable international committee (ISO/IEC etc.) having scope similar to MHD 10 for liaison. He concluded his remarks by urging the committee members for active and fruitful deliberations.

0.3 Dr. Sudip Kumar Datta, Chairperson, extended a warm welcome to the esteemed members of the 21st meeting of the Medical Laboratory Instruments Sectional Committee, MHD 10. He expressed his appreciation for the remarks shared by Shri A R Unnikrishnan, Head (MHD), BIS, and affirmed his support for them. He informed the committee that a number of new subjects has been discussed and approved in the past few meetings. He also highlighted the forthcoming development of working drafts by constituting working groups during the current meeting. This will expand the portfolio of standards under the current committee. Emphasizing the importance of active participation, he encouraged members to engage in fruitful discussions to ensure the success of the meeting.

He requested the Member Secretary to take up the agenda items for discussion.

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

ITEM 1 CONFIRMATION TO THE MINUTES OF THE LAST MEETING

The Committee formally confirmed the minutes of the last (i.e., 20th) meeting of the Medical Laboratory Instruments Sectional Committee (MHD 10), held on 06 Feb, 2024, Tuesday via Video Conferencing (Webex).

ITEM 2 SCOPE AND COMPOSITION OF THE SECTIONAL COMMITTEE

2.1 The committee noted the current scope of the Medical Laboratory Instruments Sectional Committee MHD 10. The committee decided to constitute a working group for updating scope of MHD 10. The working group consisted of following members:

Sr. No.	Organization	Representative
1	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Kumar Datta
2	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar
3	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Neelesh Kumar
4	National Centre for Disease Control, New Delhi	Dr. MONIL SINGHAI

2.2 The Committee noted the current composition of the Medical Laboratory Instruments Sectional Committee (MHD 10) attached at ANNEX A of agenda.

2.3 The membership of following organization was terminated on attendance:

Sl. No.	Organization
1.	Becton Dickinson India Private Limited, Gurugram, New Delhi
2.	Magnus Opto Systems India Private Limited, New Delhi

2.4 The committee reviewed the existing composition of MHD 10 and concluded that it is well-balanced, with no vacancies available at present. It was suggested that any new experts could be engaged in specialized working groups instead of being added to the main committee. In the view of above, following is the status of co-option received:

Sl. No.	Organization	Nomination	Current status
1.	Siemens Healthcare Private Limited, Bangalore	Nivedita Mitra, Senior Key Expert	Co-Option request not accepted.

2.5 The committee noted information provided at agenda item 2.5

ITEM 3 DRAFT INDIAN STANDARDS UNDER PRINT

The committee noted information provided on agenda item 3.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

The committee noted information provided on agenda item 4.

ITEM 5 DRAFT STANDARD/ AMENDMENT FOR APPROVAL FOR APPROVAL FOR WIDE CIRCULATION

The committee decided to wide-circulate following documents for the period of 90 days dispensing P-draft stage:

Sl. No.	Document No.	Standard No.	Title
1.	MHD/10/25168	IS 5155	Specification for pipettes, ostwald - Folin type
2.	MHD/10/25169	IS 6942	Specification for flask, roux, bacteriological, with or without offset neck (1000 ml Nominal Capacity)
3.	MHD/10/25170	IS 6944	Specification for bottle, bijou, bacteriological
4.	MHD/10/25171	IS 7039	Specification for tube, culture, screw cap
5.	MHD/10/25172	IS 8501	Specification for anaerobic jar
6.	MHD/10/25173	IS 9430	Specification for tube, haemometer
7.	MHD/10/25174	IS 11383	Specification for thin-walled glass capillary pipettes

The committee also assigned following expert for commenting on important standards being wide circulated:

Sl. No.	Standard No.	Title	Assigned expert
1.	IS 6944	Specification for bottle, bijou, bacteriological	Col Mahadevan Kumar, Bharati Vidyapeeth Medical College, Pune
2.	IS 7039	Specification for tube, culture, screw cap	Dr. Monil Singhai, National Centre for Disease Control, New Delhi
3.	IS 8501	Specification for anaerobic jar	Dr. Sumit Rai, All India Institute of Medical Sciences, Mangalagiri

ITEM 6 DRAFT UNDER PREPARATION

The committee decided to Constitution of Working Groups for the preparation of the working draft for following subjects:

Sl. No.	Subject	Designated expert
1	Clinical centrifuges	- Mr. Sunil Saraf, Remi Elektrotechnik Limited, Mumbai - Dr. Rajarshi Kar, University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi
2	LBC (liquid-based cytology) brush	Representatives from Becton Dickinson India Private Limited
3	Lab plasticware - filter tips for standard pipettes	- Dr Desai Vidya Sripad, All India Institute of Medical Sciences, Mangalagiri - Representatives from Tarsons - Representatives from Axygen

4	Gradient thermocycler	- Dr. Saswati Das, Dr Ram Manohar Lohia Hospital, New Delhi, - Representatives from Thremofisher - Representatives from Eppendorf
5	Platelet Incubator with Agitator	- Mr. Sunil Saraf, Remi Elektrotechnik Limited, Mumbai - Shri Manoj A., Terumo Penpol Private Limited, Thiruvananthapuram
6	Anaerobic Workstation	- Dr. Sumit Rai, All India Institute of Medical Sciences, Mangalagiri
7	Vortex Mixer	- Mr. Sunil Saraf, Remi Elektrotechnik Limited, Mumbai - Dr. Rajarshi Kar, University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi
8	Double Beam UV Spectrophotometer	- Dr Desai Vidya Sripad, All India Institute of Medical Sciences, Mangalagiri
9	HPLC System specifications	- Dr Desai Vidya Sripad, All India Institute of Medical Sciences, Mangalagiri

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 The committee decided to Constitution of Working Group to resolve the comment received on IS 4381: 1967 provided on agenda item.7.1 (Annexure 2 of agenda). The working group comprises of following experts:

Sr. No.	Organization	Representative
1	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Kumar Datta
2	ICMR- National Institute of Cancer Prevention Research, Noida	Dr. Ruchika Gupta
3	Magnus Opto Systems India Private Limited, New Delhi	Shri Harmeet Singh Ahuja

7.2 The committee accepted the comments received on IS 7183:1973. Decided to wide-circulate the revised document for the period of 90 days.

7.3 The committee accepted the comments received on IS 7039:1973 Decided to wide-circulate the revised document for the period of 90 days.

ITEM 8 NEW SUBJECTS

8.1 The committee noted information provided on agenda item 8.1.

8.2 The committee thoroughly deliberated on each of the new work items proposed listed in agenda item 8.2 and following the status:

Sl. No.	Approved NWIPs	Recommendations
1.	Refrigerated Superspeed Centrifugation system.	The subject was approved as NWIP under MHD 10
2.	High speed centrifuge	
3.	Mini centrifuge	
4.	Stacked variable-temperature incubator shaker.	
5.	Water jacketed CO2 Incubator	
6.	Rotary shaker	
7.	Pipette Controller	
8.	384 Well white frame plates	
9.	Pipette controllers with double safety valve and hydrophobic filter.	
10.	Microloader tips	
11.	Dual Platform Rocker	
12.	Sledge microtome	
13.	Gel documentation system	
14.	Micro-Slide	
15.	Handheld pH Meter with probe	
16.	Magnetic stirrer	
17.	Test tube mixer (tube rotator/rotating)	
18.	Rocker shaker/reciprocal shaker	
19.	UV transilluminator	

8.3 The committee noted information provided on agenda item 8.3. The chairperson requested the committee members to go through the list provided and identify subjects pertaining with the scope of MHD 10 sectional committee.

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 As MHD 10 does not have liaison with international technical committees, members are encouraged to identify any suitable ISO committee having scope similar to MHD 10. The following international technical committees has scope similar to MHD 10:

S. No.	TC No.	Name	Recommendations
1	IEC/ TC 66	Safety of measuring, control and laboratory equipment	The committee decided to obtain P-membership
2	ISO/TC 48	Laboratory equipment	The committee decided to obtain role of document monitor and Ballot monitor

9.2 The committee decided to nominate Dr. Sudip Kumar Datta, Chairperson, MHD 10 to ISO/TC 76/WG 2 “Rigid Container Systems and related accessories for parenteral and injectables”.

It was noted during discussions that ovulation thermometers are not utilized in medical laboratories, thus it is suggested that they may not be incorporated into MHD 10. However, to ensure consistency among the standards across various sectional committees of MHD, it is recommended to include ovulation thermometers. This is in line with existing standards such as IS 12622:1989 for medical thermometers for hypothermia and IS 4529:1968 for specification of glass tubes for medical thermometers, which are already part of MHD 10.

In light of this, members are encouraged to share their perspectives on this matter within the week. Any comments received will be discussed in the upcoming meeting. If no comments are received, it will be assumed that members approve the proposed inclusion of ovulation thermometers in MHD-10.

ITEM 10 PROGRAMME OF WORK

10.1 The Committee noted the present program of work of Medical Laboratory Instruments Sectional Committee (MHD 10).

10.2 The committee decided to withdraw IS 12622: 1989 Medical thermometers for hypothermia, subnormal range - Specification, IS 4529: 1968 Specification for glass tubes for medical thermometers.

The committee also recommended to withdraw IS 3055 (Part 1) 1994 Clinical thermometers: Part 1 solid stem type - Specification (Second Revision) and IS 3055 (Part 2) : 2004 Clinical thermometers: Part 2 enclosed scale type - Specification (Third Revision) based on the recommendations of Minamata Convention.

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

11.1 The following standards are identified by BIS secretariat for transfer from MHD 12 to MHD 10 as it is more relevant to the scope of MHD 10:

S.no.	IS No.	Title	Scope
1	IS 14193	Ovulation thermometers - Specification	This standard specifies requirements, methods of sampling and tests for ovulation thermometers of mercury-in-glass, maximum indicating. solid-stem type, intended for measurement-of deep body- temperature of human-beings.

The issue was discussed in the 20th meeting of MHD 10, It was noted during discussions that ovulation thermometers are not utilized in medical laboratories, thus it is suggested that they may not be incorporated into MHD 10. However, to ensure consistency among the standards across various sectional committees of MHD, it is recommended to include ovulation thermometers. This is in line with existing standards such as IS 12622:1989 for medical

thermometers for hypothermia and IS 4529:1968 for specification of glass tubes for medical thermometers, which are already part of MHD 10.

In light of this, members were encouraged to share their perspectives on this matter within the week and comments were requested via email dated 06 March 2024. The received comments were discussed with the chairperson, and it was decided that the MHD 10 will not accept IS 4529: 1968 specification of glass tubes for medical thermometers, since it does not fall under the scope of MHD 10.

11.2 The committee noted information provided on agenda item 11.2.

ITEM 12 DATE AND PLACE OF NEXT MEETING

Based on the discussion with the chairperson, the following meeting calendar dates are being proposed. It is emphasized that once the dates are finalized, they will not be subject to change. Therefore, it is requested to block calendars well in advance. Furthermore, as reiterated by the Honorable Chairperson, *the second quarterly meeting, scheduled for Tuesday, July 9, 2024, will be conducted in person (physical).*

	Q1, 2024-25	Q2, 2024-25	Q3, 2024-25	Q4, 2024-25
	April	July	November	February
MHD10	Tuesday, April 9, 2024	Tuesday, July 9, 2024	Tuesday, November 12, 2024	Tuesday, February 4, 2025

ITEM 13 ANY OTHER BUSINESS

The committee noted information provided on agenda item 13.

It is learnt that large volumes of vacutainers is being produced domestically and it is imperative to ensure their quality and interoperability. In light of this, it is proposed to recommend the line ministry to issue a Quality Control Order (QCO) for IS 10867:2018 (ISO 6710:2017). Following the implementation of the QCO, adherence to IS 10867:2018 (ISO 6710:2017) will become mandatory for manufacturers. Implementing such a QCO will serve several critical purposes:

1. **Enhanced Safety and Quality:** Standardizing vacutainer production according to IS 10867:2018 (ISO 6710:2017) will ensure that these medical devices meet rigorous safety and quality standards. This will reduce the risk of defects or substandard products reaching healthcare facilities and patients, ultimately safeguarding public health.

2. **Improved Interoperability:** Ensuring compliance with international standards promotes interoperability among vacutainers and associated medical equipment. This means that vacutainers manufactured in line with IS 10867:2018 (ISO 6710:2017) will be compatible with a wide range of medical devices, enhancing efficiency and reducing errors in laboratory processes.
3. **Reduction in Turnaround Time:** By adhering to standardized specifications outlined in IS 10867:2018 (ISO 6710:2017), manufacturers can streamline their production processes. Consistently manufactured vacutainers will lead to fewer discrepancies, minimizing delays in procurement, inventory management, and laboratory testing procedures. This, in turn, will contribute to faster diagnosis and treatment for patients, ultimately improving healthcare outcomes.

Given these reasons, the committee decided to recommend to the Central Marks Department – 1 (CMD -1) of BIS to issue Quality Control Order (QCO) for IS 10867: 2018 (ISO 6710:2017) : Single - Use containers for human venous blood specimen collection (First Revision)

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

ANNEX A

List of participants

S. No.	Organization	Member Name	Role
1	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Datta	Chairperson
		Dr. Tushar Sehgal	Alternate Member
2	All India Institute of Medical Sciences, Mangalagiri	Dr Desai Vidya Sripad	Principal Member
		Dr. Sumit Rai	Alternate Member
		Dr. Nichenametla Gautam	Alternate Member
3	Association of Indian Medical Device Industry, New Delhi	Shri C.S.Prasad	Alternate Member
4	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar	Principal Member
5	CSIR - National Physical Laboratory, New Delhi	Dr. Rajesh	Alternate Member
		Dr. G. Sumana	Principal Member
6	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Neelesh Kumar	Principal Member
7	Directorate General of Health Services, New Delhi	Dr. Naresh Panchal	Principal Member
8	Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune	Dr. Chandrashekhar G Raut	Principal Member
9	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Saswati Das	Alternate Member
		Dr.Arvind Kumar Achra	Young Professional
10	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Praveen Kumar Sharma	Principal Member
11	ICMR - National Institute of Cancer Prevention Research, Noida	Dr. Ruchika Gupta	Principal Member
12	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Umair Bargir	Young Professional
13	Indian Council of Medical Research, New Delhi	Dr. Suchita Markan	Principal Member
	Kalam Institute of Health Technology, Vishakhapatnam	Shri Pramod	Young Professional

		Shri Suraj Suresh Naik	Principal Member
14	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Dr. Gayathri S	Principal Member
		Shri Ashok Kumar	Alternate Member
15	National Centre for Disease Control, New Delhi	Smt. Dr. MONIL SINGHAI	Principal Member
16	Remi Elektrotechnik Limited, Mumbai	Shri Sunil Saraf	Principal Member
17	Schott Glass India Private Limited, Pune	Shri Anand Bakshi	Principal Member
		Shri Lalatendu Behera	Alternate Member
18	Shriram Institute for Industrial Research, Delhi	Shri Manish Rawat	Principal Member
		Shri Surabhi Gupta	Alternate Member
19	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Shri D S Nagesh	Principal Member
		Shri. Vinodkumar V	Alternate Member
		Ms Amrutha C	Alternate Member
20	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.	Principal Member
21	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Dr. Rajarshi Kar	Alternate Member
		Dr. Charu Jain	Young Professional
22	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Rajni Dawar	Principal Member
23	Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi	Shri M. A. U. Khan	Principal Member
		Shri B. K. Mukhopadhyay	Alternate Member