

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

अस्पताल योजना विषय समिति की बीसवीं बैठक, एम.एच.डी-14

Twentieth Meeting of the Hospital Planning Sectional Committee, MHD-14

कार्यव्रत | MINUTES

Date	13 th October 2023 (Friday)
Time	05:00 PM
Venue	Virtual (Webex)
Chairperson	Dr. Anil Kumar Additional Deputy Director General, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

ATTENDEES: -

S.No.	Organization	Member	Member type
1	Directorate General of Health Services, New Delhi	Dr. Anil Kumar	Chairperson
2	Boston Scientific India Private Limited, Gurugram	Mr. Dev Chopra	Alternate Member
3	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	Principal Member
		Ms. Shyamni Sasidharan	Alternate Member
		Mr. Aniruddh Singh Negi	Young Professional
4	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Sharad Pandey	Alternate Member
5	Federation of Indian Chambers of Commerce and Industry, New Delhi	Dr Vikas Malhotra	Alternate Member
6	Hindu Rao Hospital, Delhi	Dr. Harsh Vardhan Singh	Principal Member
7	ICMR - National Institute of Virology, Pune	Dr. Himanshu Kaushal	Alternate Member
8	India Medtronic Private Limited, Gurugram	Ms. Latika Vats	Alternate Member

ITEM 0 WELCOME AND OPENING REMARKS

0.1 Welcome Address by Member Secretary

Mr. Prasanth Vinjamuri, Scientist-C and Member Secretary of MHD 14, welcomed the members to 20th meeting of the Hospital Planning Sectional Committee on the behalf of **Head (MHD)**.

0.2 Opening Remarks by Chairperson

Dr. Anil Kumar, Hon'ble Chairperson of MHD 14 appreciated the members present for sparing their valuable time for participating in the meeting. He emphasized on personal involvement and contribution of all the members, experts and interested stakeholders in formulating Indian Standards and solicited the co-operation of all the members to deliberate on each agenda item to reach a fruitful decision.

Considering the importance of topics to be discussed in the meeting, Hon'ble Chairman, MHD-14, requested to commence the meeting.

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING.

The committee formally confirmed the minutes of the last (Nineteenth) meeting of the Hospital Planning Sectional Committee, MHD-14, which was held on 15 June 2023 in hybrid mode.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION ACTIVITY OF BIS

2.1 The Committee took note of the current composition.

2.2 The Committee took note of members who have not participated in last two meetings. Further the Committee decided to forward a letter to respective members regarding participation.

2.3 The Committee approved all the organizations / institutions listed for joining MHD14 and its Sub-committees.

ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

3.1 & 3.2 Since no comments were received, the Committee approved the document for finalization.

3.3 The Committee approved the four documents listed for publication.

ITEM 4 DRAFT STANDARDS/AMMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

The Committee approved the listed ISO Standards / Amendments for wide circulation. Further the committee also approved the documents for finalization if no comments were received during wide circulation period.

ITEM 5 INTERNATIONAL ACTIVITIES

- 5.1** The current status of ISO liaison of MHD14 was explained to the members of the Committee.
- 5.2** The current status of nominations of members onto various ISO Technical Committees and Working Groups were presented to the committee.
- 5.3** The request for nomination of members of NABL as experts on ISO TC 212 and its working groups was discussed and finalized as follows

TC / WG	Technical Committee / Working Group Title	Experts Nominated
ISO TC 212	Clinical laboratory testing and in vitro diagnostic test systems	1. Mr. N. Venkateswaran, CEO, NABL 2. Mr. Pankaj Johri, Director & Head, Medical Lab Vertical, NABL 3. Ms. Gayathri, Joint Director, Medical Lab Vertical, NABL
ISO TC 212 WG1	Quality and Competence in Medical Laboratory	1. Mr. N. Venkateswaran, CEO, NABL 2. Mr. Pankaj Johri, Director & Head, Medical Lab Vertical, NABL 3. Ms. Gayathri, Joint Director, Medical Lab Vertical, NABL
ISO TC 212 WG2	Reference Systems	1. Mr. N. Venkateswaran, CEO, NABL 2. Mr. Pankaj Johri, Director & Head, Medical Lab Vertical, NABL 3. Ms. Gayathri, Joint Director, Medical Lab Vertical, NABL
ISO TC 212 WG5	Laboratory biorisk management	1. Mr. N. Venkateswaran, CEO, NABL 2. Mr. Pankaj Johri, Director & Head, Medical Lab Vertical, NABL 3. Ms. Gayathri, Joint Director, Medical Lab Vertical, NABL

- 5.4** Nomination of Mr. Prasanth Vinjamuri, Scientist-C & Member Secretary, BIS to *ISO TC 210 WG7 Good engineering maintenance management* was approved.

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Twentieth Meeting of the Hospital Planning Sectional Committee, MHD-14

कार्यसूची | AGENDA

Date	13 th October 2023 (Friday)
Time	05:00 PM
Venue	Virtual (Webex) Meeting link: https://bismanak.webex.com/bismanak/j.php?MTID=m055f611f6883d1cbd440a90ca3c40bfa Meeting number: 2515 941 3583 Password: mhd14 (64314 from video systems)
Chairman	Dr. Anil Kumar Additional Deputy Director General, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India
Member Secretary	Prasanth Vinjamuri, Scientist-C & Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards

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2.3 Requests have been received from the following for joining the Committee:

Sl. No.	Organization	Nomination
1.	AIIMS Kalyani, West Bengal	<ul style="list-style-type: none"> • Dr. Tummidi Santosh, MD Pathology, PDC, PDCC (Associate Professor) • Dr. Sibasis Sahoo, MD Biochemistry (Associate Professor)
2.	AIIMS Mangalagiri, Andhra Pradesh	<ul style="list-style-type: none"> • Dr. Desai Vidya Sripad, Addl. Professor & HoD, Biochemistry • Dr. Sumit Rai, Professor & HoD Microbiology
3.	Clinical Development Services Agency (CDSA), Translational Health Science and Technology Institute (THSTI)	<ul style="list-style-type: none"> • Dr. Sucheta Banerjee Kurudkar, (Principal Scientist-II), PhD Biochemistry, Auditor NABL & NABH, Visiting faculty in BIS NITS for Laboratory Quality 5gmt..
4.	Association of Indian Medical Device Industry (AiMed)	Nominations to be received
5.	Centre of Excellence for Medical Device Regulations & Standards, IIT- Madras	<ul style="list-style-type: none"> • Dr. S. Ramakrishnan (PhD), Professor in Biomedical Engineering

The committee may consider the nominations.

ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

3.1 Following draft Indian Standards have completed wide circulation.

Sl No.	Document no.	Title	Wide Circulation	Comments received (Yes / No)
1)	MHD/14/23491 (Identical to ISO 20417:2021)	Medical devices Information to be supplied by the manufacturer	Wide-circulated on: 05.09.2023 Last date of comments: 05.10.2023	No

3.2 No comments have been received and the above documents may be taken up for finalization

The Committee may kindly consider.

3.3 The following documents in the form of final proof are ready for publication

S.No	Document Number	Designation	Title
1	MHD 14 (18421)	IS 23485 : 2019 (Amd-1 July-2023)	Medical devices - Quality management system requirements and essential principles of safety and performance for medical devices Amendment - 1
2	MHD 14 (20130)	IS 18374 : 2023 / ISO 23162 : 2021	Basic semen examination Specification and test methods
3	MHD 14 (20111)	IS 18376 : 2023 / ISO/TR 20416 : 2020	Medical Devices — Post-Market Surveillance for Manufacturers
4	MHD 14 (20106)	IS 17922 (Part 1) : 2023 IEC 62366-1 : 2015 + AMD 1 : 2020	Medical Devices Part 1 Application of Usability Engineering (First Revision)

The committee may approve final proofs for publication

ITEM 4 DRAFT STANDARDS/AMMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

Sl No.	Document no.	Title
1)	ISO 20658: 2023	Requirements for the collection and transport of samples for medical laboratory examination
2)	IEC/TR 80002-1:2009	Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software
3)	IEC/TR 80002-3:2014	IEC/TR 80002-3:2014 Medical device software — Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
4)	ISO 5741: 2023	Healthcare organization management — Pandemic response — Temporary medical facility

The committee may consider the documents for finalization, if no comments are received during wide circulation period.