

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

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

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

कार्यव्रत | MINUTES

Date	05/01/2023
Time	11:00 AM

Venue	Virtual (Webex)
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Chairman	Dr. Anil Kumar Additional Deputy Director-General Government of India Ministry of Health and Family Welfare Directorate General of Health Services
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ATTENDEES: -

Sl no.	Organization	Name
1)	Directorate General of Health Services , New Delhi	Dr Anil Kumar (<i>Chairman</i>)
2)	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma
3)	Boston Scientific India Private Limited, Gurugram	Shri Dev Chopra Shri Prashanth Prabhakar
4)	Federation of Indian Chambers of Commerce and Industry, New Delhi	Dr. Yash Paul Bhatia
5)	Hospital Services Consultancy Corporation (India) Limited, Noida	Shri Vinod Kumar
6)	ICMR - National Institute of Virology, Pune	Dr Himanshu Kaushal
7)	Indian Medical Association, New Delhi	Dr J. A. Jayalal
8)	National Accreditation Board for Hospitals and Healthcare Providers, New Delhi	Dr Atul Mohan Kochhar
9)	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Shri N. Venkateswaran Ms. Rozina
10)	National Health Systems Resource Centre, New Delhi	Ms. Manisha Sharma
11)	Philips India Limited, Gurugram	Shri Rajendra Prasad
12)	School of Planning and Architecture, New Delhi	Dr Shri Anil Dewan
13)	UL India Private Limited, Bengaluru	Shri Prabhu Hotter (Guest)

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BIS DIRECTORATE GENERAL: -

1)	Shri P. V. Mathew	Scientist-E & Head (MHD)
2)	Vinit Vidyadhar Bansod (Member Secretary)	Scientist B/Assistant Director, MHD, BIS

ITEM 0 OPENING REMARKS BY CHAIRMAN

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 (Seventeenth) meeting of the Hospital Planning Sectional Committee, MHD-14, which was held on 26 August 2022 in hybrid mode.

ITEM 2 SCOPE AND COMPOSITION OF COMMITTEE

The committee noted the scope and current composition of the sectional committee given at ANNEX A.

ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

3.1 The committee deliberated and approved the comments received on the following wide-circulation drafts and further decided to finalize the documents for publication if no comments are received at the end of wide-circulation period.

Sl no.	Document no. and title	Remarks	Wide Circulation	Comments
1)	MHD14(18414) ISO/TR 24971: 2020 'Medical devices — Guidance on the application of ISO 14971 (First Revision)'	Revision of IS/ISO/TR 24971: 2013 ' Medical devices - Guidance on the application of ISO 14971'	Wide-circulated on: 21 December 2022 Last date of comments: 20 January 2023	Name: SHRI S.B. SINHA Email ID: sbsinha@hotmail.com Comment: The Draft can be approved as it is identical to International standard. No amendments are required
2)	MHD 14 (20106) IEC 62366-1: 2015 CSV 'Medical Devices Part 1 Application of Usability	Superseding IS/IEC 62366-1 : 2015 'Medical Devices Part 1 Application of Usability	Wide-circulated on: 21 December 2022 Last date of comments:	Name: SHRI S.B. SINHA Email ID: sbsinha@hotmail.com Comment: This needs to be approved without any amendment

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	Engineering'	Engineering to Medical Devices'	20 January 2023	
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3.2 The committee deliberated and decided to finalize the following documents for publication.

Sl No.	Document no.	Title
1)	MHD14(20111) ISO/TR 20416 : 2020	'Medical devices Post-market surveillance for manufacturers'
2)	MHD14(20126) ISO/TS 20914 : 2019	'Medical laboratories Practical guidance for the estimation of measurement uncertainty'
3)	MHD14(20130) ISO 23162 : 2021	'Basic semen examination Specification and test methods'

ITEM 4 DRAFT STANDARDS/AMMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

The committee deliberated and decided to wide-circulate the following ISO standards for a period of one month.

no.	ISO Standard	Scope	Remarks
1)	ISO 15189:2022 Medical laboratories — Requirements for quality and competence	<p>Synopsis:</p> <p>This fourth edition (ISO 15189:2022) cancels and replaces the third edition (ISO 15189:2012), which has been technically revised. It also replaces ISO 22870:2016.</p> <p>The main changes are as follows: — Alignment with ISO/IEC 17025:2017 resulted in the management requirements now appearing at the end of the document; — Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated; — Increased emphasis on risk management.</p> <p>Scope:</p> <p>This document (ISO 15189:2022) specifies requirements for quality and competence in medical</p>	<p>Revising IS/ISO 15189:2012, and</p> <p>Superseding IS 17723 : 2021/ISO 22870:2016 Point-of-care testing POCT Requirements for quality and competence</p>

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		<p>laboratories.</p> <p>This document is applicable to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.</p> <p>This document is also applicable to point-of-care testing (POCT).</p> <p>NOTE International, national, or regional regulations or requirements can also apply to specific topics covered in this document.</p>	
2)	<p>ISO 5258:2022 Healthcare organization management — Pandemic response (respiratory) — Drive-through screening station</p>	<p>Scope of ISO 5258:2022: This document specifies the operation of a drive-through screening station (DTSS) for mass testing as part of pandemic response management.</p> <p>NOTE COVID-19 is an exemplary disease for which such a station is developed.</p>	—
3)	<p>ISO 5472:2022 Healthcare organization management — Pandemic response (respiratory) — Walk-through screening station</p>	<p>Scope of ISO 5472:2022: This document specifies the operation of a walk-through screening station (WTSS) for mass testing as part of pandemic response management.</p> <p>NOTE COVID-19 is an exemplary disease for which such a station is developed.</p>	—

Further, the committee decided to finalize the documents for publication if no comments are received during wide-circulation.

ITEM 5 TECHNICAL ISSUES

The committee deliberated and decided to accept the transfer request of IS/ISO 80369-7:2016 from MHD-12 to MHD-14. Further, **ISO 80369-7:2021** will be wide-circulated for a period of 1 month. In absence of comments the document will be finalized for publication.

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ISO 80369-7:2021 will revise and replace IS/ISO 80369-7:2016.

ITEM 6 INTERNATIONAL ACTIVITIES

The committee noted the following ISO ballots which are currently open for comments.

Chairman, MHD-14, requested the committee members to examine the ISO ballot documents which are shared by BIS from time to time and provide their technical comments.

Sl. No.	TC/ SC/ WG	Title of ballot	Ballot circulation date	Last date of comments
1.	210	(Systematic Review of) ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications	2-Nov-22	18-Feb-23
2.	212	ISO/TS 22583:2019 Guidance for supervisors and operators of point-of-care testing (POCT) devices	2-Nov-22	18-Feb-23
3.	304	ISO/DIS 7101 Healthcare quality management systems — Requirements	17-Nov-22	13-Jan-23
4.	210	Design Specification outline for the fourth edition of IEC 60601-1	Will be circulated	24-Feb-23
5.	304	ISO/NP 20364 Guidance for healthcare organizations' response to the surging diagnostic demands in a pandemic	Will be circulated	09-Mar-23

ITEM 7 PROGRAM OF WORK

The committee noted the present program of work given at ANNEX C of the agenda.

ITEM 8 DATE AND PLACE OF NEXT MEETING

The date and place of next meeting will be decided in consultation with Hon'ble Chairman, MHD-14.

ITEM 9 ANY OTHER BUSINESS

The meeting concluded with closing remarks of the Hon'ble Chairman.