

भारतीय मानक ब्यरो

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

कार्यसूची | AGENDA

Date	05/01/2023
Time	11:00 AM
Venue	Virtual (Webex) Meeting Link: https://bisindia.webex.com/bisindia/j.php?MTID=m2be0dcd8cca0e3c2ac0378d0a228b24a Meeting number: 2510 317 7489 Password: Mhd14@18
Chairman	Dr. Anil Kumar Additional Deputy Director General, Government of India Ministry of Health and Family Welfare Directorate General of Health Services
Member Secretary	Vinit Vidyadhar Bansod Scientist B/Assistant Director, Medical Equipment and Hospital Planning Department Bureau of Indian Standards

ITEM 0 WELCOME AND OPENING REMARKS

- 0.1 Welcome Address by H(MHD)
- 0.2 Opening Remarks by Chairman

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING.

The minutes of the last (Seventeenth) meeting of the Hospital Planning Sectional Committee, held on 26 August 2022 via Webex VC and duly approved by the Chairman, were circulated to all the members vide BIS Directorate General letter no. MHD/14/A-2.17 dated 30 September 2022.

No comments were received regarding the accuracy of recording of the decisions taken in the meeting. The committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF COMMITTEE

2.1 The scope and present composition of the Hospital Planning Sectional Committee is given in ANNEX A.

2.2 Members are also requested to provide their latest details like e-mail ids, phone no., official address etc., to enable the secretariat to make correspondence and send documents/Agenda/Minutes etc. through e-mail. As per the guidelines, use of paper is being reduced by BIS.

ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

4.1 Following draft Indian Standards are under wide circulation.

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 Engineering'	Superseding IS/IEC 62366-1 : 2015 'Medical Devices Part 1 Application of Usability Engineering to Medical Devices'	Wide-circulated on: 21 December 2022 Last date of comments: 20 January 2023	Name: SHRI S.B. SINHA Email ID: sbsinha@hotmail.com Comment: This needs to be approved without any amendment
Comments received on BIS portal are given at ANNEX B				

The committee may deliberate on the comments and in absence of further comments of technical nature, committee may finalize the documents for publication.

4.2 The following documents have completed wide circulation.

Sl No.	Document no. and title	Wide Circulation	Comments
1)	MHD14(20111) ISO/TR 20416 : 2020 'Medical devices Post-market	Wide circulated on: 08 September 2022 Last date of	<i>No comments received</i>

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	surveillance for manufacturers'	comments: 09 October 2022	
2)	MHD14(20126) ISO/TS 20914 : 2019 'Medical laboratories Practical guidance for the estimation of measurement uncertainty'	Wide circulated on: 25 August 2022 Last date of comments: 24 September 2022	<i>No comments received</i>
3)	MHD14(20130) ISO 23162 : 2021 'Basic semen examination Specification and test methods'	Wide circulated on: 25 August 2022 Last date of comments: 24 September 2022	<i>No comments received</i>

Committee may deliberate and finalize the documents for publication.

ITEM 4 DRAFT STANDARDS/AMMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

5.1 The following standards have been recently published by ISO on which BIS (India) voted positively.

Sl no.	ISO Standard	Scope
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 laboratories. This document is applicable to medical laboratories in developing their management</p>

		<p>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>
<p>Revising IS/ISO 15189: 2012, and</p> <p>Withdrawal of IS 17723 : 2021/ISO 22870:2016 Point-of-care testing POCT Requirements for quality and competence</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>

Committee may deliberate and decide.

ITEM 5 TECHNICAL ISSUES

10.1 Transfer of Subject:

Request for transfer of '**IS/ISO 80369-7:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications**' was received from the Hospital Equipment and Surgical Disposable Sectional Committee (MHD-12).

The Indian Standard IS/ISO 80369-7:2016 and the latest version i.e., ISO 80369-7 : 2021 were shared within the committee on **29 November 2022**. Comments were invited by **07 December 2022**. Comments were also requested for revision of **IS/ISO 80369-7:2016** by adopting the latest version i.e. ISO 80369-7 : 2021.

Following comments were received.

Organization:	Rajendra Prasad A.V.A., Philips India Ltd.
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Date:	30 November 2022
Comment:	Our recommendation is to revise /adopt the existing edition IS/ISO 80369-7 : 2016 to the current edition of ISO 80369-7 : 2021.

In absence of comments of technical nature, committee may deliberate and approve the transfer of IS/ISO 80369-7 : 2016 to the Hospital Planning Sectional Committee (MHD-14) and wide circulation of ISO 80369-7 : 2021 for a period of 1 month.

ITEM 6 INTERNATIONAL ACTIVITIES

11.1 India's Participation Status in ISO Technical Committees/Subcommittees.

MHD 14 is responsible for coordination of work related to following ISO Technical Committees:

ISO/TC 210	Quality management and Corresponding general aspects for medical devices	P Member
ISO/TC 212	Clinical laboratory testing and in vitro diagnostic test systems	P Member
ISO/TC 304	Healthcare organization management	P Member

The Committee may please note.

11.2 India being a Participating (P) member on ISO/TC 210, 212 and 304, makes it obligatory to vote on the ballots circulated by ISO from time to time. The BIS Secretariat circulates all documents received from ISO to all the committee members for comments.

11.2.1 The following ISO ballots are currently under circulation for 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

11.3 The standards published by ISO/TC [210](#), [212](#), [304](#) can be viewed by clicking on the TC number. The Committee may kindly examine and identify ISO Standard(s) which may be adopted as Indian Standard(s), keeping in view India's National interests.

ITEM 7 PROGRAM OF WORK

12.1 The present position of work of MHD-14 is enclosed as **ANNEX C**.

The Committee may kindly note.

ITEM 8 DATE AND PLACE OF NEXT MEETING

The Committee may decide the date and place of the next meeting.

ITEM 9 ANY OTHER BUSINESS