



**BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT**

AGENDA

Twentieth Meeting of Health Informatics Sectional Committee, MHD 17

Chairperson:

Dr. Ashok Kumar (*In personal capacity*)
Ex. Addl. Director General (HAG),
Central Health Services,
Ministry of Health & Family Welfare,
Govt. of India

Member Secretary:

Chandan Kumar
Scientist-C/Deputy Director,
Bureau of Indian Standards

Date/Day	24 July 2023, Monday
Time	02.30 PM
Webex Link	https://bismanak.webex.com/bismanak/j.php?MTID=m3ad89d61b875ca20a4cb402f5c7902f3

ITEM 0 General

ITEM 0.1 Welcome address by Head (MHD)

ITEM 0.2 Opening Remarks by the Chairperson

ITEM 1 Formal confirmation of minutes of the previous meeting

1.1 The minutes of the Nineteenth meeting of Health Informatics Sectional Committee, MHD 17 held on 28 April 2023 duly approved by Chairperson, MHD 17 were circulated vide BIS DG letter No. MHD 17/A-2.19 dated 07 June 2023 to all members. No comments have been received on the minutes.

The Committee may kindly formally confirm the minutes.

ITEM 2 Scope and Composition of the Sectional Committee

2.1 The scope of the Health Informatics Sectional Committee, MHD 17 is given below:

Scope: (a) Standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of health systems.

(b) To coordinate with the work of :

- i. ISO/TC 215 'Health Informatics' : (P-member)
- ii. ISO/TC 215/SC 1 'Genomics Informatics' : (P-member)

The Committee may review its scope.

2.2 The present composition of MHD 17 is given at [Annex-1](#). The Committee may note and review its composition according to the following BIS guidelines, keeping reasonable and manageable number of members on the committee:

- a) Consumer interests shall, as far as possible, predominate. In case non-industry interests are less than two third, it may be reviewed to ensure that 2/3rd of the total representation on the committee is from non-industry.
- b) Only relevant organizations/ government departments/ consumer organizations/ regulatory bodies that are related to the subject may be offered representation
- c) Non-active members to be withdrawn and young professionals who can contribute in the working of the committee may be co-opted. The committee may deliberate on the same and advise.

ITEM 3 Draft standards for finalization

The list of Draft Indian Standards which have completed/are under wide circulation after the last meeting is given at [Annex-2](#).

The Committee may please deliberate and decide.

ITEM 4 Draft standards for approval for wide circulation

4.1 The list of standards published by IEC/TC 215 and SC 1 along with their status of adoption is available as online spreadsheet on <https://bit.ly/tc215mhd17>.

The Committee may please deliberate and recommend the standards to be adopted as Indian Standards.

ITEM 5 New Subjects

5.1 New proposals for standardization may be submitted on the BIS website www.bis.gov.in.

The Committee may please note.

ITEM 6 Review of Subcommittees/Panels under MHD 17

6.1 Health Informatics-AYUSH Subcommittee, MHD 17:1 – Convener/Member Secretary to share updates.

6.2 Telehealth and Virtual Care Subcommittee, MHD 17:2 – Convener/Member Secretary to share updates.

6.3 Disability Informatics Subcommittee, MHD 17:3 – Convener/Member Secretary to share updates.

6.4 Panel on Medical Icons – Convener/Member Secretary to share updates.

6.5 Panel on Cybersecurity of Network-connected Medical Devices – Convener/Member Secretary to share updates.

The Committee may please review.

ITEM 7 International Activities

7.1 India(BIS) is a Participating(P)-Member on the following ISO committee/subcommittee, for which MHD 17 acts as the National Mirror Committee(NMC):-

- a) ISO/TC 215 Health Informatics [P-Member]
- b) ISO/TC 215/SC 1 Genomics Informatics [P-Member]

As a P-member, it is obligatory to vote on all draft standards and other documents circulated by ISO/TC 215 Secretariat seeking votes/comments. It is reiterated that the members should carefully examine the documents taking into consideration nation's interests and send their comments keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation.

7.2 The next Plenary/Working Group meetings of ISO/TC 215 and SC 1 have been scheduled during 8-16 Nov 2023 in Arlington, USA.

The Schedule of the Meetings is attached at [Annex-3](#).

An email dated 8 June 2023 was circulated for seeking nominations for participation in the meetings. The following two nominations have been received:

- (a) Dr. SB Bhattacharyya, In personal capacity – for participation in WG 10, WG 11, WG 6, TF5 Meetings
- (b) Dr. S B Gogia, In personal capacity – for participation in WG 3, WG 11 and TF 7 Meetings

The Committee may please deliberate and finalize the Indian Delegation for participation in the ISO/TC 215, SC 1 Plenary and WG meetings from 8-17 Nov 2023 in Arlington, USA.

7.3 ISO/TC 215 Plenary Meeting Secretariat has approached BIS(India) to host the Plenary and WG meetings of ISO/TC 215 in India in the month of Oct/Nov 2024.

MHD 17, as the National Mirror Committee for ISO/TC 215 may please deliberate and decide.

ITEM 8 Programme of Work

8.1 The programme of work of Health Informatics Sectional Committee, MHD 17 is available at the BIS portal:

https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/pow_new .

The Committee may please note.

8.2 Review of Indian Standards (as per 5-year cycle)

As per the policy of the BIS, the Indian Standards that have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned sectional committee for their reaffirmation/revision/withdrawal/amendment; the review is to be done based on the latest technology developments/industrial trends world over as well as their application in the Indian context. The committee may review the standards based on their usage, salability and

relationship with regulatory bodies, and recommend for their retainment/withdrawal. A policy decision has been taken by the BIS management to withdraw all those Indian Standards which are no longer required by the industry and/or trade.

The list of Indian Standards which are due for review in July-Sept Quarter is as follows:

S.No.	Indian Standards	Due Date
1.	IS/ISO/IEEE 11073-10101 : 2004	Sept 2023
2.	IS/ISO/IEEE 11073-20601 : 2016	Sept 2023
3.	IS/ISO/IEEE 11073-30200 : 2004	Sept 2023
4.	IS/ISO 11616 : 2017	Sept 2023
5.	IS/ISO 17090-2 : 2015	Sept 2023
6.	IS/ISO 21549-5 : 2015	Sept 2023
7.	IS/ISO 27799 : 2016	Sept 2023

The review analysis for the above standards have been circulated through the portal. The Committee may please deliberate and decide regarding the reaffirmation/withdrawal of the standards.

ITEM 9 Action taken report on the Minutes of Previous Meeting/Issue arising out of the previous meetings

Action taken report on the minutes of the previous meeting is given at [Annex-4](#).

The Committee may please note.

ITEM 10 Date and place for the next meeting

As per Annual Calendar for 2023-24 approved by Chairperson, MHD 17, the next meeting of MHD 17 is scheduled on 13 Oct 2023. The quarter-wise meeting schedule is given below:

Quarter	Meeting Date
April-June	28 April 2023 (Conducted)
July-September	24 July 2023
October-December	13 October 2023
January 2024-March 2024	19 January 2024

ITEM 11 Any other business

ANNEX-1
(Item 3.1)
Committee Composition

S.No.	Organization	Name	Attendance
1.	In Personal Capacity	Dr. Ashok Kumar (<i>Chairman</i>)	3/3
2.	In Personal Capacity	Dr. R. Rangasayee	2/2
3.	In Personal Capacity	Dr. S. B. Bhattacharyya	3/3
4.	In Personal Capacity	Dr. S. B. Gogia	3/3
5.	In Personal Capacity	Prof. Suptendranath Sarbadhikari	3/3
6.	All India Institute of Medical Sciences, New Delhi	Dr. Nirupam Madaan	1/3
7.	Boston Scientific India Private Limited, Gurugram	Sh. Prashant Prabhakar Sh. Dev Chopra (AM)	1/3
8.	Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi	Dr. N. Srikanth Dr. Rakesh Narayanan V (AM)	3/3
9.	Centre for Development of Advanced Computing, Pune	Sh. Gaur Sunder Sh. Praveen K. Srivastava (AM)	3/3
10.	Centre for Health Informatics, New Delhi	Sh. Ankit Tripathi Sh. Gaurav Sharma (AM)	1/3
11.	Confederation of Indian Industry, New Delhi	Sh. Vibhav Garg Sh. Surendra Singh Rawat (AM)	1/3
12.	Continua Health Alliance India	Sh. Ananda Sen Gupta Dr Abhishek Sen(AM)	0/3
13.	CSIR-Institute of Genomics and Integrative Biology, New Delhi	Dr. Bhavana Parasher	3/3
14.	Directorate General Armed Forces Medical Service, New Delhi	Brig. Ramesh Kaushik Col. Sanjay Patole(AM)	0/3
15.	Disease Management Association of India, Mumbai	Sh. Atantra Das Gupta Ms Mevish P Vaishnav (AM)	2/3
16.	dWise Healthcare IT Solutions Private Limited, Bengaluru	Dr Pramod D Jacob Dr Joseph Alexander(AM) Shri Sreejith P (YP)	2/3
17.	HIMSS India Chapter, Bengaluru	Sh. Jeyaseelan Jeyaraj Sh. Philip Cherian (AM) Dr Nitiraj Gandhi (YP)	1/3
18.	Indian Dental Association, Mumbai	Dr Vijay Prakash Mathur Dr Ashok Dhoble (AM)	1/3
19.	Indian Institute of Technology Delhi, New Delhi	Prof. Subrat Kar	3/3

20.	Indian Institute of Technology Kanpur, Kanpur	Prof. Arnab Bhattacharya	0/3
21.	Indian Institute of Technology Kharagpur, Kharagpur	Prof. Jayanta Mukhopadhyay Prof. Soumya Kanti Ghosh (AM)	3/3
22.	Indian Medical Association, New Delhi	Dr Jayesh M. Lele Dr Pankaj Mutneja (AM)	1/3
23.	Indian Nursing Council, New Delhi	Dr Asha Sharma Dr Sandhya Gupta (AM)	3/3
24.	Indian Pharmacopoeia Commission, Ghaziabad	Dr V. Kalaiselvan Shri Shatrunajay Shukla (AM)	2/3
25.	InformDS Technologies Private Limited, Bengaluru	Dr Randeep Singh Sh. Pawan Jain (AM) Sh. Parag Agarwal (YP)	1/3
26.	Karkinos Healthcare Private Limited, Bengaluru	Sh. Arvind Sivaramakrishnan Dr. Anjali Anant Kulkarni (AM) Sh. Hariesh Ramanathan M (YP)	0/0
27.	Maulana Azad Medical College, New Delhi	Dr. Nidhi Bhatnagar Dr. Amod Borle (AM) Dr. Madan Mohan Manjhi (YP)	2/3
28.	Ministry of AYUSH, New Delhi	Dr D C Katoch	1/3
29.	Ministry of Electronics and Information Technology, New Delhi	Sh. Rashid Shaban	2/3
30.	Ministry of Health and Family Welfare, New Delhi	Director, eHealth Deputy Director, eHealth (AM)	1/3
31.	National Accreditation Board for Hospitals and Healthcare Providers, New Delhi	Dr Atul Mohan Kochhar Dr Punam Bajaj (AM) Ms. Neeta (YP)	2/3
32.	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Sh. Pankaj Johri Ms. Bhumi Rajyaguru Sh. Haribabu A. (AM)	3/3
33.	National Health Authority, New Delhi	Dr. J. L. Meena	1/3
34.	National Health Systems Resource Centre, New Delhi	Dr. Ranjan Chaudhary Ms. Manisha Sharma (AM) Ms. Rupali Vasant Mhaskar (YP)	3/3
35.	National Institute of Health & Family Welfare, New Delhi	Prof. Pushpanjali Swain Dr Ankur Yadav (AM)	2/3
36.	North-Eastern Hill University, Shillong	Dr Sudip Paul Sh. Shyam Mandal (AM)	2/3



37.	Philips India Limited, Gurugram	Sh. Rajendra Prasad <i>(Vice-Chairman)</i>	3/3
38.	Society for Administration of Telemedicine and Healthcare Informatics, New Delhi	Dr. Susheel Oommen John	2/3
39.	Sri Sathya Sai Central Trust, Puttaparthi	Sh. Jai Ganesh Udayasankaran	3/3
40.	Telemedicine Society of India, Lucknow	Sh. Baljit Singh Bedi Col. (Dr) Ashvini Goel (Retd.)(AM)	3/3

ANNEX-2

(Item 3)

Documents under Wide Circulation – for finalization

S.No	Document Number	Document Title	Document Stage	WC Date	Last Date for Comments
1	MHD/17/22699 (Identical To: ISO/TS 22272:2021)	Health Informatics Methodology for analysis of business and information needs of health enterprises to support standards based architectures	WC-Draft	18-06-2023	18-07-2023
2	MHD/17/22694 (Identical To: ISO 13120:2019)	Health Informatics Syntax to represent the content of healthcare classification systems Classification Markup Language ClaML	WC-Draft	18-06-2023	18-07-2023
3	MHD/17/22702 (Identical To: ISO/TS 82304-2:2021)	Health software Part 2 Health and wellness apps Quality and reliability	WC-Draft	18-06-2023	18-07-2023
4	MHD/17/22697 (Identical To: ISO 20302:2022)	Health informatics Health cards Numbering system and registration procedure for issuer identifiers	WC-Draft	18-06-2023	18-07-2023
5	MHD/17/22692 (Identical To: ISO/TS 17975:2022)	Health Informatics Principles and data requirements for consent in the collection use or disclosure of personal health information First Revision	WC-Draft	18-06-2023	18-07-2023
6	MHD/17/22700 (Identical To: ISO 23903:2021)	Health Informatics Interoperability and integration reference architecture Model and framework	WC-Draft	18-06-2023	18-07-2023
7	MHD/17/22695 (Identical To: ISO 17117-1:2018)	Health informatics Terminological resources Part 1 Characteristics	WC-Draft	18-06-2023	18-07-2023
8	MHD/17/22690 (Identical To: ISO 13119:2022)	Health Informatics Clinical knowledge resources Metadata (First Revision)	WC-Draft	18-06-2023	18-07-2023
9	MHD/17/22698 (Identical To: ISO 21860:2022)	Health informatics Reference standards portfolio RSP Clinical imaging	WC-Draft	18-06-2023	18-07-2023
10	MHD/17/22693 (Identical To: ISO 12381:2019)	Health Informatics Explicit time-related expressions for healthcare-specific problems	WC-Draft	18-06-2023	18-07-2023
11	MHD/17/22701 (Identical To: ISO 16278:2016)	Health informatics Categorical structure for terminological systems of human anatomy	WC-Draft	18-06-2023	18-07-2023



S.No	Document Number	Document Title	Document Stage	WC Date	Last Date for Comments
12	MHD/17/22696 (Identical To: ISO/TS 17117-2:2022)	Health informatics Terminological resources Part 2 Implementation Capability(TIC)	WC-Draft	18-06-2023	18-07-2023
13	MHD/17/22691 (Identical To: ISO 13972:2022)	Health Informatics Clinical information models Characteristics structures and requirements	WC-Draft	18-06-2023	18-07-2023

ANNEX-3

(Item 7.2)

Schedule of the ISO/TC 215 and SC 1 Plenary and Working Group(WG) Meetings from 8-16 Nov 2023 in Arlington, USA

Date	Q1	Q2	Q3	Q4
8 Nov 2023 (Wednesday)	WG 11	WG 11	WG 11	WG 11
9 Nov 2023 (Thursday)	WG 11 WG 10	WG 11 WG 10	WG 11+WG 10	WG 11
10 Nov 2023 (Friday)	AHG 5+WG 11 WG 4	AHG 5+WG 11 WG 4	WG 11 WG 4	
13 Nov 2023 (Monday)	WG 2 WG 6 WG 1 SC 1 WG 3	WG 2 WG 6 WG 1 SC 1 WG 3	WG 2 WG 6 TF 7 SC 1 WG 3	WG 2 WG 6 TF 7 SC 1 WG 3
14 Nov 2023 (Tuesday)	WG 2 WG 6 WG 1 SC 1 WG 3	WG 2 WG 6 WG 1 SC 1 WG 3	WG 2 WG 6 TF 5 SC 1 WG 3	WG 2 WG 6 TF 5 SC 1 WG 3
15 Nov 2023 (Wednesday)	WG 2 WG 6 SC 1 JWG 1 TF 6	WG 2 WG 6 SC 1 JWG 1 TF 6	WG 2 WG 6 SC 1 JWG 1 + WG 3 TF 3	WG 2 WG 6 SC 1 JWG 1 + WG 3 TF 3
16 Nov 2023 (Thursday)	Delegation Meetings	SC 1 Plenary	TC 215 Plenary	

Note : Chairperson's Advisory Group (CAG) meetings will be held virtually prior to these meetings.

TC 215 = Health Informatics

SC 1 = Genomics Informatics

WG 1 = Architecture, Frameworks and Models

WG 2 = Systems and Device Interoperability

WG 3 = Semantic content

WG 4 = Security, Safety and Privacy

WG 6 = Pharmacy and medicines business

WG 10 = Traditional Medicine

WG 11 = Personalized digital health

TF 3 = Outreach & Communications

TF 5 = AI technologies in health informatics

TF 6 = Process and quality improvement

TF 7 = Telehealth and Virtual Care (TVC) Standards

AHG 5 = Safe, Effective and Secure Digital Therapeutics

JWG 1 = Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics)

ANNEX-4

(Item 9)

Action Taken on the minutes of the previous meeting of MHD 17

S. No.	Item of the last minutes	Decision	Action taken by BIS
1.	3.1	The Committee decided to withdraw the representation of the following organizations from the composition due to their lack of participation/interest in the committee work: i. Delhi Institute of Pharmaceutical Sciences and Research, New Delhi ii. India Medtronic Private Limited, Gurugram	Action completed.
2.	3.2	The Committee deliberated on the co-option request received from Karkinos Healthcare Private Limited, New Delhi and approved the same. It was decided to seek the nominations of their representatives on the Committee in the desired format.	Email sent. Nominations received from the organization.
3.	3.3	The Committee deliberated on the co-option request received from Trivedi School of Biosciences, Ashoka University, Sonipat and approved the same. It was decided to seek the nominations of their representatives on the Committee in the desired proforma.	Email sent. Nominations yet to be received.
4.	4	The Committee decided to finalize the following Draft Indian Standards for publication without any change as no comments were received on the documents during the wide circulation stage : 1.MHD/17/21223 Health informatics - Public key infrastructure : Part 1 Overview of digital certificate services 2.MHD/17/21207 Health informatics - Electronic health record communication : Part 5 Interface specification 3.MHD/17/21195 Health informatics - Electronic health record communication : Part 1 Reference model 4.MHD/17/21211 Health informatics - Service architecture(HISA): Part 3 Computational viewpoint 5.MHD/17/21204 Health informatics - Electronic health record communication : Part 3 Reference archetypes and term lists 6.MHD/17/21224 Health informatics - Public key infrastructure : Part 3 Policy management of certification authority 7.MHD/17/21204 Health informatics - Electronic health record communication : Part 3 Reference archetypes and term lists 8.MHD/17/21209 Health informatics - Service architecture(HISA) : Part 1 Enterprise viewpoint	Documents sent for publication.

		<p>9.MHD/17/21196 Health informatics - Electronic health record communication : Part 2 Archetype interchange specification</p> <p>10.MHD/17/21205 Health informatics - Electronic health record communication : Part 4 Security</p> <p>11.MHD/17/21225 Health informatics - Electronic health record communication : Part 4 Security</p> <p>12.MHD/17/21210 Health informatics - Service architecture(HISA): Part 2 Information viewpoint</p> <p>13.MHD/17/21212 Health informatics - Audit trails for electronic health records</p>	
5.	5.1	<p>The Committee decided to initiate the adoption of the latest editions of the following ISO Standards to revise their corresponding Indian Standards and approved the wide circulation of these ISO documents for a period of one month:</p> <p>1.ISO/IEEE 11073-10201:2020 Health informatics - Point-of-care medical device communication Part 10201 domain information model</p> <p>2. ISO/IEEE 11073-10404:2022 Health informatics - Personal health device communication Part 10404 device specialization - Pulse oximeter</p> <p>3. ISO/IEEE 11073-10407:2022 Health informatics — Device interoperability — Part 10407: Personal health device communication — Device specialization — Blood pressure monitor</p> <p>4. ISO/IEEE 11073-10408:2022 Health informatics — Device interoperability — Part 10408: Personal health device communication — Device specialization — Thermometer</p> <p>5. ISO/IEEE 11073-10415:2022 Health informatics — Device interoperability — Part 10415: Personal health device communication — Device specialization — Weighing scale</p> <p>6. ISO/IEEE 11073-10419:2019 Health informatics — Personal health device communication — Part 10419: Device specialization — Insulin pump</p> <p>7. ISO/IEEE 11073-10420:2022 Health informatics — Device interoperability — Part 10420: Personal health device communication — Device specialization — Body composition analyzer</p> <p>8. ISO/IEEE 11073-20601:2022 Health informatics — Device interoperability — Part 20601: Personal health device communication — Application profile — Optimized exchange protocol</p> <p>9. ISO/TS 17975:2022 Health informatics — Principles and data requirements for consent in the collection, use or disclosure of personal health information</p> <p>10. ISO 13119:2022 Health informatics — Clinical knowledge resources — Metadata</p>	Documents put up for wide circulation/under process.

		11. ISO 13972:2022 Health informatics — Clinical information models — Characteristics, structures and requirements	
6.	5.2	<p>The Committee decided to initiate the adoption the following ISO Standards and approved the wide circulation of these documents for a period of one month:</p> <ol style="list-style-type: none"> 1. ISO 16278:2016 Health informatics — Categorical structure for terminological systems of human anatomy 2. ISO 17117-1:2018 Health informatics — Terminological resources — Part 1: Characteristics 3. ISO/TS 17117-2:2022 Health informatics — Terminological resources — Part 2: Implementation Capability (TIC) 4. ISO 20302:2022 Health informatics — Health cards — Numbering system and registration procedure for issuer identifiers 5. ISO 21860:2020 Health Informatics — Reference standards portfolio (RSP) — Clinical imaging 6. ISO/TS 22272:2021 Health Informatics - Methodology for analysis of business and information needs of health enterprises to support standards based architectures 7. ISO 23903:2021 Health informatics — Interoperability and integration reference architecture — Model and framework 8. ISO 12381:2019 Health informatics — Explicit time-related expressions for healthcare-specific problems 9. ISO 13120:2019 Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClAML) 10. ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability 	Action completed.
7.	7.1	The Committee decided to reaffirm/reaffirm and revise/withdraw the standards as per <i>Item 7.1</i> of the Minutes.	Action completed.