



BUREAU OF INDIAN STANDARDS

(MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT)

MINUTES

21st Meeting of Health Informatics Sectional Committee, MHD 17

Chaired by :

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

Meeting Date and Time : 13 Oct 2023 (Friday), 10:30 am

ITEM 0. General

The list of participants is attached as [Annex-1](#).

ITEM 0.1 Welcome Address by the Member Secretary

Sh. Chandan Kumar, Member Secretary extended a warm welcome to the Chairperson, Vice-Chairperson and all the members present in the 21st Meeting of Health Informatics Sectional Committee, MHD 17. He conveyed his gratitude to all the participants for sparing their valuable time to join the meeting.

He delivered a presentation providing an overview of the standardization initiatives undertaken by BIS in the realm of Digital Health/Health Informatics through the MHD 17 Committee. The presentation has been distributed to all committee members.

ITEM 0.2 Opening Remarks by the Vice-Chairperson

Dr. Ashok Kumar, Chairperson of MHD-17, extended a warm welcome to the Vice-Chairperson and all members at the 21st meeting of the MHD-17 Sectional Committee. He conveyed his delight at the substantial attendance of members in the meeting, which represented a diverse group of stakeholders. He also conveyed his happiness that the meeting coincided with the eve of World Standards Day. He commended the members for their active and significant contributions over the years, specifically acknowledging their efforts in formulating over a hundred Indian standards in the field of Health Informatics.



Item 1 Formal Confirmation of Minutes of the Previous Meeting

1.1 The Committee approved the minutes of previous (Twentieth) meeting circulated vide BIS DG letter No. MHD 17/A-2.19 dated 08 September 2023 without any change.

ITEM 2 BIS Guidelines for Research & Development Projects for Formulation and Review of Standards

The Committee noted the BIS Guidelines for Research & Development Projects for Formulation and Review of Standards and members were encouraged to propose R&D projects for formulation and review of standards as per the scope of MHD 17 in line with the guidelines.

ITEM 3. Draft Indian Standards for Finalization

The Committee deliberated on the Draft Indian Standards which had completed the wide circulation stage and as no comments were received on these documents during the WC period, it was decided to finalize the following documents for publication:

- 1. MHD/17/23688 (Identical to: ISO 11239:2023)** Health informatics — Identification of medicinal products Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms units of presentation routes of administration and packaging (First Revision)
- 2. MHD/17/23689** Health Informatics — Identification of Medicinal Products Data Elements and Structures for the Unique Identification and Exchange of Regulated Medicinal Product Information Amendment - 1
- 3. MHD/17/23687 (Identical to: ISO/TR 4421:2023)** Health Informatics — Introduction to Ayurveda Informatics

For the documents for which Wide Circulation period was not over, the Committee decided that if no comments are received on the documents during the WC phase, the documents will be finalized after the last date for comments is over. In case any comments are received on any of the documents which need deliberation in the committee, these will be discussed and resolved in the next meeting before taking further decision. The documents are listed below:

- 1. MHD/17/23754 (Identical to: ISO/IEEE 11073- 20601:2022)** Health informatics — Device interoperability: Part 20601 Personal health device communication Application profile — Optimized exchange protocol (First Revision)



2. MHD/17/23773 (Identical to: IS/ISO/IEEE 11073-10201:2022) Health informatics — Device interoperability: Part 10201 Point-of-care medical device communication — Domain information model (First Revision)

3. MHD/17/23775 (Identical to: ISO/IEEE 11073- 11407:2022) Health informatics — Device interoperability: Part 10407 Personal health device communication — Device specialization — Blood pressure monitor (First Revision)

4. MHD/17/23776 (Identical to: ISO/IEEE 11073- 11408:2022) Health informatics — Device interoperability: Part 10408 Personal health device communication— Device specialization— Thermometer (First Revision)

5. MHD/17/23778(Identical to: ISO/IEEE 11073- 10419:2019) Health informatics— Personal health device communication: Part 10419 Device specialization — Insulin pump (First Revision)

6. MHD/17/23779 (Identical to: IS/ISO/IEEE 11073-10420:2022) Health informatics — Device interoperability: Part 10420 Personal health device communication — Device specialization — Body composition analyzer (First Revision)

ITEM 4. Draft Indian Standards for Approval for Wide Circulation

4.1 It was decided to circulate the list of standards published by ISO/TC 215 and SC 1 along with their status of adoption among the members requesting them to identify and share the standards that should be adopted as Indian Standards.

ITEM 5. New Subjects

5.1 The Committee was informed that any new proposals for standardization can be submitted online on the BIS website www.bis.gov.in.

A presentation on ‘Clinical Evaluation of Digital Therapeutics’ was made by Dr. N. K. Singh, Digital Health Associates Private Limited, New Delhi. The Committee appreciated the relevance of the subject and suggested to get the relevant details of the ongoing work related to Digital Therapeutics in ISO/TC 215 before proceeding further. It was decided to nominate Dr. Singh as an expert on WG 11 ‘Personalized Digital Health’ of ISO/TC 215.

ITEM 6. Review of Subcommittees/Panels under MHD 17

6.1 Health Informatics – AYUSH Subcommittee [MHD 17:1]

The Committee was briefed about the status of the ongoing projects ISO/TS 6204 (Categorical structures for representation of Ayurvedic medicinal water — Decocting process) and the proposed New Work Item Proposal (NWIP) on Information Model of Prakriti. It was informed that the comments received on ISO/TS 6204 during the CD Ballot stage have been resolved and the



resolution of comments has been shared with the Secretariat. The submission of Form-04 and working draft for NWIP on Information Model of Prakriti will be deliberated in the next Subcommittee meeting. The Committee also noted the progress on the project started under WG 6 ‘Pharmacy and Medicine Business’ to document gaps and/or challenges with ISO 11239 (Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging) in the context of traditional medicine.

6.2 Telehealth Subcommittee [MHD 17:2]

Mr. Gaur Sunder, CDAC, Pune (Convener, MHD 17:2) informed the Committee that the CDAC team has prepared the Table of Contents (ToC) document which will serve as the structure of the proposed standard. This document has been shared among all the members of the Subcommittee for their feedback/comments and a meeting will be called soon to deliberate on the ToC and drafting process.

6.3 Disability Informatics Subcommittee [MHD 17:3]

Prof. R. Rangasayee, Convener of MHD 17:3, informed the Committee that Ms. Manisha Mantri has joined the MHD 17:3 Subcommittee as a representative of NRCeS, CDAC, Pune. In the Subcommittee's 4th Meeting on October 10, 2023, Ms. Mantri emphasized the necessity to bifurcate the existing work into two segments: Disability Informatics-Format for Disability Data Exchange and a separate standard for Disability Survey and Reporting. The Subcommittee has resolved to conduct its next meeting in Bengaluru on November 29th and 30th, 2023, with a face-to-face interaction.

6.4 Cybersecurity of Network-connected medical devices – Panel [MHD 17:P2]

Convener Sh. Rajendra Prasad (Vice-Chairperson, MHD 17) was requested to reconstitute the panel and finalize its scope and ToR.

6.5 Medical Icons – Panel [MHD 17:P1]

On the recommendation of Dr. S B Gogia, Convenor, MHD 17:P1, it was decided to reconstitute the Panel and the new composition is as follows:

1. Dr. S. B. Gogia, In personal capacity (Convener)
2. Col.(Retd.) R. N. Ghosh, In personal capacity
3. Dr. Isha Garg, In personal capacity
4. Sh. Chinmoy Lye, SATHI, New Delhi
5. Sh. Chandan Kumar (Member Secretary)

Dr. Gogia briefed the Committee about the status of ISO/CD TR 6231 ‘Health Informatics – Standardizing Graphical Content’ which has completed CD stage and the resolution of comments received on the CD ballot will be discussed in the Arlington meetings (8-16 Nov 2023) of ISO/TC



215/WG 3 ‘Semantic Content’. He also briefed the Committee about the two new work items which will be proposed by him to WG3, one dealing with guidelines for icons and graphics creation and other one linking icons and graphics with terminologies.

ITEM 7. International Organization for Standardization (ISO)

7.1 The Committee noted the information about the scope of ISO/TC 215 ‘Health Informatics’ and ISO/TC 215/SC 1 ‘Genomics Informatics’ as mentioned in *Item 7.1 of the Agenda*.

The Committee noted the information regarding the P-membership of BIS(India) on ISO/TC 215 and ISO/TC 215/SC 1 which makes it mandatory for us to vote on all draft standards and other documents circulated by TC 215 Secretariat seeking votes/comments.

In order to strengthen India’s participation in ISO/TC 215 activities, the Committee decided to nominate the following experts on the Working Groups of ISO/TC 215 as given below:

S.No.	Expert	Member of	Nominated on
1.	Dr. N. K. Singh, Digital Health Associates Private Limited, New Delhi	MHD 17	ISO/TC 215/WG 11
2.	Dr. S. B. Bhattacharyya, In personal capacity	MHD 17	ISO/TC 215/WG 4
3.	Col.(Retd.) R. N. Ghosh, In personal capacity	MHD 17:P1	ISO/TC 215/WG 3
4.	Dr. Isha Garg, In personal capacity	MHD 17:P1	ISO/TC 215/WG 3

7.2 The Committee noted the Indian delegation scheduled to participate in the Plenary and Working Group meetings of ISO/TC 215 and SC 1 from 8-16 Nov in Arlington, VA, USA. The Chairperson emphasized the significance of the delegation's successful engagement in these meetings and recommended that the Head of Delegation conduct a comprehensive review of all presentations in advance to ensure uniformity, coordination, and understanding among the delegates. The Committee was apprised of a planned briefing meeting for this purpose, facilitating a thorough review of all presentations and the finalization of India's stance on agenda topics.

7.3 Hosting ISO/TC 215 Plenary and WG Meeting in India in 2024: Considering the schedule of IEC GM 2024 during 21-25 Oct 2024 in Edingurgh, UK, the Committee recommended to postpone the meeting and reschedule it in consultation with ISO/TC 215 Secretariat/leadership.

ITEM 8. Programme of Work

8.1 The Committee was informed that the current programme of work of Health Informatics Sectional Committee, MHD 17 is available on the BIS portal which is updated in real-time: https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/pow_new .



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

The Committee deliberated on the list of standards due for review and decided as follows:

S.No.	Indian Standards	Due Date	Decision of the Committee
1.	IS/ISO 11615 : 2017	Oct 2023	Reaffirm and Amend (Amd 1 published to ISO 11615:2017 in 2022 already under adoption)
2.	IS/ISO 21549-7 : 2016	Oct 2023	Reaffirm
3.	IS/ISO/IEEE 11073-10419 : 2016	Nov 2023	Revise by adopting ISO/IEEE 11073-10419:2019 (Document already under WC)
4.	IS/ISO/IEEE 11073-10422 : 2017	Nov 2023	Reaffirm
5.	IS/ISO/IEEE 11073-91064 : 2009	Nov 2023	Reaffirm
6.	IS/ISO/TS 22077-2 : 2015	Nov 2023	Revise by adopting ISO/TS 22077-2:2023 (Document to be put under WC for one month)
7.	IS/ISO/TS 22077-3 : 2015	Nov 2023	Revise by adopting ISO/TS 22077-3:2023 (Document to be put under WC for one month)
8.	IS/ISO/IEEE 11073-10201 : 2004	Dec 2023	Revise by adopting ISO/IEEE 11073-10201:2020 (Document already under WC)
9.	IS/ISO/IEEE 11073-20101 : 2004	Dec 2023	Reaffirm
10.	IS/ISO/IEEE 11073-30300 : 2004	Dec 2023	Reaffirm
11.	IS/ISO/IEEE 11073-30400 : 2012	Dec 2023	Reaffirm

ITEM 9. Scope and Composition of the Sectional Committee

9.1 The Committee noted its scope and liaisons with ISO/TC 215 'Health Informatics' and ISO/TC 215/SC 1 'Genomics Informatics' Committees.

9.2 The Committee noted the BIS guidelines regarding composition of the sectional committee and reviewed its composition as given at *Annex 2 to the Agenda*.

While reviewing the composition, 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. Directorate General Armed Forces Medical Service, New Delhi
- ii. HIMSS India Chapter, Bengaluru
- iii. InformDS Technologies Private Limited, Bengaluru



iv. Centre for Health Informatics, New Delhi (as it is under NIHF which is already a member of the committee and separate membership is not required)

It was also decided to send letters to the organizations which have failed to attend last two consecutive meetings requesting them to review the nominations of their representatives and also to inform that failure to participate in two consecutive SC meetings will lead to termination of the membership.

9.2.1 The Committee approved the co-option of Public Health Foundation of India and noted the nominations of following representatives received:

- (a) Dr. Pushkar Kumar, Director-Trainings (Principal Member)
- (b) Mr. Dilip Kumar Jha, Deputy Project Director, Training Division (Alternate Member)

9.2.2 The Committee approved the co-option of Sankara Nethralaya, Chennai and decided to write to its President for nominating its representatives on MHD 17 with a request that Dr. Sheila John may be nominated as one of the representatives.

ITEM 10. Action taken report on the Minutes of Previous Meeting/Issue arising out of the previous meetings

The Committee noted the Action taken report on the minutes of the previous meeting as given at *Annex-4* to the Agenda.

ITEM 11. Date and Place for the Next Meeting

The Committee noted the Annual Calendar for 2023-24 approved by Chairperson, MHD 17 as per which the next meeting (January-March) quarter is scheduled be held on 19 January 2024.

ITEM 12. Any Other Business

Sh. Rizwan Koita from the Koita Centre for Digital Health recommended the development of a roadmap for the Committee. He was requested to prepare and submit a white paper outlining this roadmap for distribution among all members. Subsequent deliberations on this matter will take place in the upcoming meeting.

There being no other business to discuss, the meeting ended with a hearty vote of thanks to the Chairperson and the members.



Annex-1

Members Present:

S.No.	Member/Representative	Organization
1.	Dr. Ashok Kumar (Chairperson)	In personal capacity
2.	Sh. Rajendra Prasad (Vice-Chairperson)	Philips India Limited, Bangalore
3.	Dr. S B Bhattacharyya	In personal capacity
4.	Dr. S B Gogia	In personal capacity
5.	Prof. R. Rangasayee	In personal capacity
6.	Dr. Sidhartha Satpathy	All India Institute of Medical Sciences, New Delhi
7.	Sh. Dev Chopra	Boston Scientific India Private Limited, Gurugram
8.	Sh. Gaur Sunder	Centre for Development of Advanced Computing (C-DAC), Pune
9.	Dr. Rakesh Narayan	Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi
10.	Dr. Bhavana Parasher	CSIR-IGIB, New Delhi
11.	Dr. Vijay Prakash Mathur	Dental Council of India, Mumbai
12.	Sh. Atantra Das Gupta	Disease Management Association of India, Mumbai
13.	Dr. N. K. Singh	Digital Health Associates Private Limited, New Delhi
14.	Dr. Manpreet Kaur	Digital Health Associates Private Limited, New Delhi
15.	Ms. Akshita Tyagi	Digital Health Associates Private Limited, New Delhi
16.	Dr. Pramod Jacob	dWise Healthcare IT Solutions Pvt. Ltd, Bengaluru
17.	Prof. Soumya Kanti Ghosh	Indian Institute of Technology, Kharagpur
18.	Dr. Sandhya Gupta	Indian Nursing Council, New Delhi
19.	Dr. Arvind Sivaramakrishnan	Karkinos Healthcare Private Limited, Bengaluru
20.	Dr. Anjali Kulkarni	Karkinos Healthcare Private Limited, Bengaluru
21.	Sh. Hariesh Ramanathan M	Karkinos Healthcare Private Limited, Bengaluru
22.	Sh. Rizwan Koita	Koita Centre for Digital Health, IIT Bombay, Mumbai
23.	Ms. Surbhi Goel	Koita Centre for Digital Health, IIT Bombay, Mumbai
24.	Dr. Nidhi Bhatnagar	Maulana Azad Medical College, New Delhi
25.	Dr. Raghavendra Naik	Ministry of AYUSH, New Delhi
26.	Dr. Atul Mohan Kochhar	NABH, New Delhi
27.	Dr. Punam Bajaj	NABH, New Delhi
28.	Ms. Neeta	NABH, New Delhi
29.	Dr. Bhumi Rajyaguru	NABL, Gurugram
30.	Sh. Kiran Vaska	National Health Authority, New Delhi
31.	Sh. Vikram Pagaria	National Health Authority, New Delhi
32.	Sh. Pankaj Sharma	National Health Authority, New Delhi
33.	Ms. Manisha Sharma	NHSRC, New Delhi
34.	Dr. Pushpanjali Swain	National Institute of Health & Family Welfare, New Delhi
35.	Dr. Shyamal Mandal	North-Eastern Hill University, Shillong



36. Dr. Sudip Paul
37. Dr. Oommen John
38. Sh. Chinmoy Lye
39. Sh. Jai Ganesh Udayasankaran
40. Dr. Ashvini Goel
41. Dr. Rintu Kutum
42. Dr. Mayank Garg
43. Sh. Chandan Kumar
(Member Secretary)
- North-Eastern Hill University, Shillong
Society for Administration of Telemedicine and
Healthcare Informatics, New Delhi
Society for Administration of Telemedicine and
Healthcare Informatics, New Delhi
Sri Sathya Sai Central Trust, Puttaparthi
Telemedicine Society of India, Lucknow
Trivedi School of Biosciences, Ashoka University,
Sonipat
Trivedi School of Biosciences, Ashoka University,
Sonipat
Bureau of Indian Standards, New Delhi