BUREAU OF INDIAN STANDARDS

(MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT)

MINUTES

Twentieth Meeting of Health Informatics Sectional Committee, MHD 17

Chaired by :
Sh. Rajendra Prasad (Vice-Chairperson)
Philips India Limited, Bengaluru

Member Secretary :
 Sh. Chandan Kumar
 Scientist-C/Deputy Director
 Bureau of Indian Standards

Meeting Date and Time : 24 July 2023 (Monday), 02:30 pm

ITEM 0. General

The list of participants is attached as Annex-1.

At the outset, the Committee was informed that the meeting will be chaired by Vice-Chairperson Sh. Rajendra Prasad (M/s Philips India Limited, Bengaluru) in absence of Chairperson Dr. Ashok Kumar who was unable to join due to unavoidable circumstances.

ITEM 0.1 Welcome Address by the Member Secretary

Sh. Chandan Kumar, Member Secretary extended a warm welcome to the Vice-chairperson and all the members present in the Twentieth Meeting of Health Informatics Sectional Committee, MHD 17. He appreciated the members for their active contributions in supporting the national standardization activity in the field of Health Informatics. He also complimented the Committee for ensuring strong representation of BIS(India) at the ISO platform.

He solicited the cooperation of the members while discussing the agenda.

ITEM 0.2 Opening Remarks by the Vice-Chairperson

Sh. Rajendra Prasad, Vice-Chairperson, MHD 17 welcomed all the members to the Twentieth Meeting of the MHD 17 Sectional Committee and requested the Member Secretary to start the discussions as per the Agenda.

Item 1   Formal Confirmation of Minutes of the Previous Meeting

1.1 The Committee approved the minutes of previous (Nineteenth) meeting circulated vide BIS DG letter No. MHD 17/A-2.19 dated 07 June 2023 without any change.

ITEM 2. Scope and Composition of the Sectional Committee

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

2.2 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. Continua Health Alliance India
   ii. Indian Institute of Technology, Kanpur

The Committee decided to co-opt Koita Institute for Digital Health, IIT Bombay and requested the Secretariat to send a letter to the institute seeking acceptance of offer for co-option and details of representatives.

The Committee decided to write to Directorate General Armed Forces Medical Service, New Delhi to confirm if it is still interested in the committee work and review the nominations of their representatives accordingly.

The Committee deliberated on the co-option request received from M/s Novel Medicare Solutions Pvt. Ltd. It was decided to get more details from the organization and also identify other such organizations which provide EHR/EMR software solutions so that appropriate decision could be taken in the next meeting.

ITEM 3. Draft Indian Standards for Finalization

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

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
2. MHD/17/22694 (Identical To: ISO 13120:2019) Health Informatics — Syntax to represent the content of healthcare classification systems Classification Markup Language ClaML
3. MHD/17/22702 (Identical To: ISO/TS 82304-2:2021) Health software — Part 2 Health and wellness appsQuality and reliability
4. MHD/17/22697 (Identical To: ISO 20302:2022) Health informatics — Health cards Numbering system and registration procedure for issuer identifiers

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)

6. MHD/17/22700 (Identical To: ISO 23903:2021) Health Informatics — Interoperability and integration reference architecture Model and framework

7. MHD/17/22695 (Identical To: ISO 17117-1:2018) Health informatics — Terminological resources Part 1 Characteristics

8. MHD/17/22690 (Identical To: ISO 13119:2022) Health Informatics — Clinical knowledge resources Metadata (First Revision)

9. MHD/17/22698 (Identical To: ISO 21860:2022) Health informatics — Reference standards portfolio RSP Clinical imaging

10. MHD/17/22693 (Identical To: ISO 12381:2019) Health Informatics — Explicit time-related expressions for healthcare-specific problems

11. MHD/17/22701 (Identical To: ISO 16278:2016) Health informatics — Categorial structure for terminological systems of human anatomy

12. MHD/17/22696 (Identical To: ISO/TS 17117-2:2022) Health informatics — Terminological resources Part 2 Implementation Capability(TIC)

13. MHD/17/22691 (Identical To: ISO 13972:2022) Health Informatics — Clinical information models Characteristics structures and requirements

ITEM 4. Draft Indian Standards for Approval for Wide Circulation

4.1 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:

1.ISO/IEEE 11073-10201:2020 Health informatics - Point-of-care medical device communication Part 10201 domain information model

2. ISO/IEEE 11073-10404:2022 Health informatics - Personal health device communication Part 10404 device specialization - Pulse oximeter

3. ISO/IEEE 11073-10407:2022 Health informatics — Device interoperability — Part 10407: Personal health device communication — Device specialization — Blood pressure monitor

4. ISO/IEEE 11073-10408:2022 Health informatics — Device interoperability — Part 10408: Personal health device communication — Device specialization — Thermometer

5. ISO/IEEE 11073-10415:2022 Health informatics — Device interoperability — Part 10415: Personal health device communication — Device specialization — Weighing scale

6. ISO/IEEE 11073-10419:2019 Health informatics — Personal health device communication — Part 10419: Device specialization — Insulin pump

7. ISO/IEEE 11073-10420:2022 Health informatics — Device interoperability — Part 10420: Personal health device communication — Device specialization — Body composition analyzer

8. ISO/IEEE 11073-20601:2022 Health informatics — Device interoperability — Part 20601: Personal health device communication — Application profile — Optimized exchange protocol

9. Amendment No. 1 to ISO 11615:2017 (Amd 1:2022) Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

10. 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

In addition to the above, the Committee decided to adopt **ISO/TR 4421:2023** 'Health informatics — Introduction to Ayurveda informatics' and approved the wide circulation of the document for a period of one month.

The Committee also decided to share the list of standards published by ISO/TC 215 and SC 1 along with their status of adoption among the committee members to solicit recommendations regarding the standards which 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.

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 (Categorial 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 is being deliberated in the Subcommittee. 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.

The Committee noted that Dr. Sakshi Sharma, who was included in the Subcommittee in the last meeting to represent Ministry of AYUSH had been repatriated to Ministry of AYUSH from BIS. As recommended by Ministry of AYUSH, it was decided to include Dr. Raghavendra Naik, who is currently on deputation to BIS from Ministry of AYUSH to represent Ministry of AYUSH on the Subcommittee in place of Dr. Sakshi Sharma. It was also decided to withdraw the membership of Dr. Sakshi Sharma from the Working Groups of ISO/TC 215 and nominate Dr. Naik as an expert on the following WGs of ISO/TC 215:
   (i)   WG 10 – Traditional Medicine
   (ii)   WG 6 – Medicine and Pharmacy Business
   (iii)   WG 11 – Personalized Digital Health

6.2 Telehealth Subcommittee [MHD 17:2]

Mr. Gaur Sunder, CDAC, Pune (Convener, MHD 17:2) informed the Committee that the composition of the Subcommittee has been finalized as given below:

1. Mr. Gaur Sunder, C-DAC, Pune *(Convenor)*
2. Prof. Jayanta Mukhopadhyay, IIT Kharagpur
3. Mr. Jai Ganesh Udayasankaran, Sri Sathya Sai Central Trust, Puttaparthi
4. Dr. Ashvini Goel, Telemedicine Society of India(TSI)
5. Dr. S B Gogia, In personal capacity
6. Dr. Vijay Prakash Mathur (Professor-in-charge, Dept of Telemedicine, AIIMS), Indian Dental Association
7. Dr. Oommen John, Society for Administration of Telemedicine and Health Care Informatics (SATHI)
8. Ms. Manisha Mantri, NRCeS MoHFW / C-DAC Pune
9. Mr. Shailendra S. Narwariya, TeleHealth/TeleICU, C-DAC Pune
10. Mr. Rajesh Kumar Kaushish, eSanjeevaniOPD, MoHFW / C-DAC Mohali
11. Mr. Chandan Kumar, Scientist-C, BIS *(Member Secretary)*

He informed that CDAC team is preparing the Table of Contents (ToC) document which will serve as the structure of the proposed standard and the Subcommittee will call a meeting to deliberate on the ToC and drafting process.

6.3 Disability Informatics Subcommittee [MHD 17:3]

The Committee reviewed the composition of the MHD 17:3 Subcommittee and the Member Secretary briefed the Committee about the status of the ongoing project i.e. the standardization of the minimum/core data set for disability informatics. The Committee approved the recommendation of including an expert from NRCeS, CDAC, Pune on the Subcommittee.

It was informed the base questionnaire for collection of data related to persons with disabilities has been prepared and the data types for each field are being defined for which the existing standards on the topic are being referred. The draft document has been shared with NRCeS for expert inputs/feedback and based on these inputs, further decisions regarding the document will be taken in the next meeting.

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

As the current set of ISO/IEC standards on cybersecurity of network-connected medical devices are currently being considered for withdrawal/revisions, it was recommended by Convener Sh. Rajendra Prasad (Vice-Chairperson, MHD 17) to wait for some progress on that front. After the draft standards are circulated by ISO/IEC, a small panel would be constituted to review the documents.

6.5 Medical Icons – Panel [MHD 17:P1]

Dr. S B Gogia, Convenor, MHD 17:1 informed the Committee about the status of the PWI/TR 6231 'Standardizing Graphical content within Health IT (HIT)' document which has completed CD balloting stage on 07 July 2023 and he is working on resolution of the comments received which will shared with the Secretariat.

Considering the future prospect of the project, the Committee requested Dr. Gogia to reconstitute/strengthen the Panel by co-opting suitable experts and coordinate with them for making the standardization process more efficient.

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 10.1 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.

7.2 The Committee noted the nominations received for participation in the upcoming plenary and WG meetings of ISO/TC 215 and SC 1 during 8-16 Nov 2023 in Arlington, USA. However, as few nominations including from Ministry of AYUSH were yet to be received and the participation of representative from Ministry of AYUSH is crucial for the smooth progress of the Ayurveda Informatics projects under WG 10, it was decided to request them for sending the nominations at the earliest. Subsequently, all the nominations received may be sent for consideration of the Chairperson, MHD g17 and the nominations approved by him will be put up to the Competent Authority in BIS for final approval as per BIS guidelines.

7.3 The Committee deliberated on the proposal regarding hosting the Plenary and Working Group Meetings of ISO/TC 215 in India in the month of Oct/Nov 2024. Considering the growing significance of digital health in the Indian healthcare system and the contribution of India in the standardization activity under ISO/TC 215, the Committee recommended that BIS(India) may host the Plenary and Working Group Meetings of ISO/TC 215 from 20-25 October 2024 in New Delhi.

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 based on the Secretariat remarks:

S.No.	Indian Standards	Due Date	Secretariat Remarks	Decision of the Committee
1.	IS/ISO/IEEE 11073-10101 : 2004	Sept 2023	Base standard revised. Proposed for reaffirm and revise.	Reaffirm and revise by adopting ISO/IEEE 11073-10101:2020 (*Item 4.1*)
2.	IS/ISO/IEEE 11073-20601 : 2016	Sept 2023	Base standard revised. Proposed for reaffirm and revise.	Reaffirm and revise by adopting ISO/IEEE 11073-20601:2022 (*Item 4.1*)
3.	IS/ISO/IEEE 11073-30200 : 2004	Sept 2023	Base standard valid. Proposed for reaffirmation	Reaffirm w.e.f due date for a period of 5 years
4.	IS/ISO 11616 : 2017	Sept 2023	Base standard valid. Proposed for reaffirmation	Reaffirm w.e.f due date for a period of 5 years
5.	IS/ISO 17090-2 : 2015	Sept 2023	Base standard valid. Proposed for reaffirmation	Reaffirm w.e.f due date for a period of 5 years
6.	IS/ISO 21549-5 : 2015	Sept 2023	Base standard valid. Proposed for reaffirmation	Reaffirm w.e.f due date for a period of 5 years
7.	IS/ISO 27799 : 2016	Sept 2023	Base standard valid. Proposed for reaffirmation	Reaffirm w.e.f due date for a period of 5 years

ITEM 9. 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 10. 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 (October-December) quarter is scheduled be held on 13 October 2023.

ITEM 11. Any Other Business

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

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Annex-1

Members Present:

S.No.	Member/Representative	Organization
1.	Sh. Rajendra Prasad *(Vice-Chairperson)*	Philips India Limited, Bangalore
2.	Dr. S B Bhattacharyya	In personal capacity
3.	Dr. S B Gogia	In personal capacity
4.	Prof. Supten Sarbadhikari	In personal capacity
5.	Sh. Gaur Sunder	Centre for Development of Advanced Computing (C-DAC), Pune
6.	Dr. Rakesh Narayan	Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi
7.	Dr. Bhavana Parasher	CSIR-IGIB, New Delhi
8.	Dr. Vijay Prakash Mathur	Dental Council of India, Mumbai
9.	Sh. Atantra Das Gupta	Disease Management Association of India, Mumbai
10.	Dr. N. K. Singh	Digital Health Associates Private Limited, New Delhi
11.	Dr. Manpreet Kaur	Digital Health Associates Private Limited, New Delhi
12.	Ms. Akshita Tyagi	Digital Health Associates Private Limited, New Delhi
13.	Prof. Soumya Kanti Ghosh	Indian Institute of Technology, Kharagpur
14.	Dr. Asha Sharma	Indian Nursing Council, New Delhi
15.	Dr. V. Kalaiselvan	Indian Pharmacopeia Commission, Ghaziabad
16.	Dr. Arvind Sivaramakrishnan	Karkinos Healthcare Private Limited, Bengaluru
17.	Dr. Anjali Kulkarni	Karkinos Healthcare Private Limited, Bengaluru
18.	Sh. Hariesh Ramanathan M	Karkinos Healthcare Private Limited, Bengaluru
19.	Dr. Nidhi Bhatnagar	Maulana Azad Medical College, New Delhi
20.	Dr. Raghavendra Naik	Ministry of AYUSH, New Delhi
21.	Dr. Atul Mohan Kochhar	NABH, New Delhi
22.	Dr. Punam Bajaj	NABH, New Delhi
23.	Ms. Neeta	NABH, New Delhi
24.	Sh. Pankaj Johri	NABL, Gurugram
25.	Dr. Bhumi Rajyaguru	NABL, Gurugram
26.	Sh. Haribabu A.	NABL, Gurugram
27.	Ms. Manisha Sharma	NHSRC, New Delhi
28.	Dr. Pushpanjali Swain	National Institute of Health & Family Welfare, New Delhi
29.	Dr. Sudip Paul	North-Eastern Hill University, Shillong
30.	Sh. Jai Ganesh Udayasankaran	Sri Sathya Sai Central Trust, Puttaparthi
31.	Dr. Ashvini Goel	Telemedicine Society of India, Lucknow
32.	Sh. Chandan Kumar *(Member Secretary)*	Bureau of Indian Standards, New Delhi