## BUREAU OF INDIAN STANDARDS MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

# AGENDA

Sectional	Committee	Meeting No:	Date, Day & Time		
Health Informatics Sectional Committee (MHD 17)		24 <sup>th</sup> Meeting	19 <sup>th</sup> July 2024, Friday <b>03:30 PM</b>		
via Webex platform					
Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m4d2c74d939a2914e0d99dcc172a153 09 Meeting Number: 2511 462 3936					
Password: Mhd@17_2	<b>Password</b> : Mhd@17_2024				
ChairpersonDr. Ashok Kumar (In personal capacity) Ex. Addl. Director General (HAG), Central Health Services, Ministry of Health & Family Welfare, Govt. of India					
Member Secretary	ry Ms. Uroosa Warsi Scientist 'C'/ Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards				

#### ITEM 0 GENERAL

#### 0.1 Welcome Address by Member Secretary

#### 0.2 Opening Remarks by The Chairperson

#### ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

**1.1** The minutes of the 23<sup>rd</sup> meeting of Health Informatics Sectional Committee (MHD 17) held on 02<sup>nd</sup> April 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no: MHD/17/A-2.23 dated 06<sup>th</sup> April 2024.

#### **1.2** No comments have been received so far.

The Committee may formally confirm the minutes.

#### ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Health Informatics Sectional Committee (MHD 17) is as follows:

(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 please note.

**2.2** The present composition of Health Informatics Sectional Committee (MHD 17) along with participation status of members is enclosed at <u>*Annexure A*</u>.

2.3 The present composition of Working Groups under MHD 17 is enclosed at <u>Annexure B</u>.

2.4 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, <u>any member remaining absent from two consecutive</u> <u>meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become</u> <u>automatically disqualified to continue as the member of the Sectional Committee.</u>

2.5 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-third of the committee composition, as far as possible.

The committee may please note and review the composition.

#### ITEM 3 DRAFT STANDARDS / AMENDMENTS UNDER PRINT

3.1 The following Draft Indian Standards are currently under print:

Sl. No.	Document No.	Title		
1)	MHD/17/23687 (Identical To: ISO/TR 4421:2023)	Health Informatics - Introduction to Ayurveda Informatics		
2)	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)		
3)	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		
4)	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)		
5)	MHD/17/23773 (Identical To: ISO/IEEE 11073-10201:2020)	Health informatics - Device interoperability Part 10201 Point-of-care medical device communication - Domain information model (First Revision)		
6)	MHD/17/23774 (Identical To: IS/ISO/IEEE 11073-10404:2022)	Health informatics - Device interoperability Part 10404 Personal health device communication - Device specialization - Pulse oximeter (First Revision)		
7)	MHD/17/23775 (Identical To: ISO/IEEE 11073-10407:2022)	Health informatics - Device interoperability Part 10407 Personal health device communication - Device specialization - Blood pressure monitor (First Revision)		
8)	MHD/17/23776 (Identical To: ISO/IEEE 11073-10408:2022)	Health informatics - Device interoperability Part 10408 Personal health device communication - Device specialization - Thermometer (First Revision)		
9)	MHD/17/23777 (Identical To: ISO/IEEE 11073-10415:2022)	Health informatics - Device interoperability Part 10415 Personal health device communication - Device specialization - Weighing scale (First Revision)		
10)	MHD/17/23778 (Identical To: ISO/IEEE 11073-10419:2019)	Health informatics - Personal health device communication Part 10419 Device specialization - Insulin pump (First Revision)		
11)	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)		
12)	MHD/17/25053 (Identical To: ISO 10781:2023)	Health Informatics - HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM) (First Revision)		
13)	MHD/17/25054 (Identical To: ISO/IEEE 11073-10425:2019)	Health Informatics - Personal Health Device Communication Part 10425 Device Specialization - Continuous Glucose Monitor (CGM) (First Revision)		

14)	MHD/17/25055 (Identical To: ISO 21549-5:2023)	Health Informatics - Patient Healthcard Data Part 5 Identification Data (First Revision)
15)	MHD/17/25056 (Identical To: ISO 29585:2023)	Health Informatics - Framework for Healthcare and Related Data Reporting
16)	MHD/17/25057 (Identical To: ISO 41064:2023)	Health Informatics - Standard Communication Protocol - Computer-Assisted Electrocardiography

The Committee may kindly note.

#### ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

4.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

Sl. N o	Document No.	Title	Last date for comments	Comments received (Yes/No)
1)	MHD/17/25676 (Identical To: ISO 21549-7:2024)	Health informatics - Patient Healthcard Data Part 7 Medication Data (First Revision)	18 July 2024	No
2)	MHD/17/25677 (Identical To: ISO 22077-1:2022)	Health Informatics - Medical Waveform Format Part 1 Encoding Rules	18 July 2024	No
3)	MHD/17/25679 (Identical To: ISO/IEEE 11073-10101:2020)	Health Informatics - Device Interoperability Part 10101 Point-of-Care Medical Device Communication - Nomenclature (First Revision)	18 July 2024	No
4)	MHD/17/25680 (Identical To: ISO/TS 14265:2024)	Health Informatics - Classification of Purposes for Processing Personal Health Information (First Revision)	18 July 2024	No
5)	MHD/17/25681 (Identical To: ISO/TS 17251:2023)	Health informatics - Business Requirements for a Syntax to Exchange Structured Dose Information for Medicinal Products (First Revision)	18 July 2024	No

**4.2** No comments have been received and the above documents may be taken up for finalization.

The Committee may kindly consider.

# ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

5.1 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user-friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

The Committee may kindly note.

#### ITEM 6 DRAFT UNDER PREPARATION

6.1 There are currently no indigenous subject drafts under preparation.

The Committee may kindly note.

#### 6.2 Commenting on P-Drafts by Members of Technical Committee

**6.2.1** P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein <u>any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.</u>

**6.2.2** The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

- (a) Agree
- (b) Agree (with comments\*)
- (c) Don't agree (with comments\*)
- (d) No Comments, as it is not related to my area of expertise.

**6.2.3** The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

#### ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 No comments have been received on published Indian Standards.

The committee may kindly note.

#### ITEM 8 NEW SUBJECTS

8.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define a thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

The Committee may kindly deliberate.

#### ITEM 9 TECHNICAL ISSUES

9.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

#### ITEM 10 REVIEW OF WORKING GROUPS UNDER MHD 17

#### 10.1 Health Informatics - AYUSH Working Group, MHD 17:1

Convener to share updates.

#### 10.2 Telehealth and Virtual Care Working Group, MHD 17:2

Convener to share updates.

#### 10.3 Disability Informatics Working Group, MHD 17:3

Convener to share updates.

#### 10.4 Medical Icons Working Group, MHD 17:4

Convener to share updates.

**10.5** Cybersecurity of Network-connected Medical Devices Working Group, MHD 17:5 Convener to share updates.

#### ITEM 11 INTERNATIONAL ACTIVITIES

11.1 Participating (P) Membership in ISO/IEC

11.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical Committees/Subcommittees of ISO are given below:

Sl. No.	Liaison Committee of ISO	Type of Membership
1)	ISO/TC 215 'Health Informatics'	Participating Member
2)	ISO/TC 215/SC 1 'Genomics Informatics'	Participating Member

11.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation's interests and send the comments to BIS 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. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

#### The Committee may kindly note

#### 11.2 **Participation of Working Group Experts in ISO Technical Committees**

11.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specific tasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body – NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the absence of contributions through attendance to WG meetings or by correspondence, will be removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

11.2.2 The following members are occupying coveted position in various Working Groups of ISO as 'Expert'.

Sl.		
No	Name	Working Group Number/ Title
•		

		ISO/TC 215/JWG 7
1)	Mr. Pankaj Johri	Joint ISO/TC 215 - IEC/SC 62A WG: Safe, effective and
		secure health software and health IT systems, including
		those incorporating medical devices
		ISO/TC 215/WG 2
		Systems and Device Interoperability
		ISO/TC 215/SC 1/AHG 1
		Secondary use of genomics data
		ISO/TC 215/SC 1/WG 1
		Genomics data sharing
2)	Dr. Rintu Kutum	
		ISO/TC 215/TF 5
		AI technologies in health informatics
		ISO/TC 215/WG 11
		Personalized digital health
		ISO/TC 215/SC 1/WG 1
		Genomics data sharing
		ISO/TC 215/WG 10
3)	Dr. Bhavana Prasher	Traditional Medicine
5)		ISO/TC 215/WG 11
		Personalized digital health
		ISO/TC 215/WG 6
		Pharmacy and medicines business
		ISO/TC 215/TF 5
		AI technologies in health informatics
		ISO/TC 215/WG 1
		Architecture, Frameworks and Models
4)	Mr. Gaur Sunder	ISO/TC 215/WG 3
		Semantic content
		ISO/TC 215/WG 4
		Security, Safety and Privacy
		ISO/TC 215/TF 5
		AI technologies in health informatics
		ISO/TC 215/WG 10
		Traditional Medicine
		ISO/TC 215/WG 11
	5) Dr. S B Bhattacharayya	Personalized digital health
5)		ISO/TC 215/WG 3
		Semantic content
		ISO/TC 215/WG 4
		Security, Safety and Privacy
		ISO/TC 215/WG 6 Dharmagy and medicines hyginage
		Pharmacy and medicines business

		ISO/TC 215/TF 5
		AI technologies in health informatics
		ISO/TC 215/TF 7
		Telehealth and Virtual Care (TVC) Standards
6)	Col. (Dr.) Ashvini Goel	ISO/TC 215/WG 11
0)	(Retd.)	Personalized digital health
		ISO/TC 215/WG 3
		Semantic content
		ISO/TC 215/WG 4
		Security, Safety and Privacy
		ISO/TC 215/TF 7
_	Mr. Jai Ganesh	Telehealth and Virtual Care (TVC) Standards
7)	Udayasankaran	ISO/TC 215/WG 2
		Systems and Device Interoperability
8)	Prof Jayanta	ISO/TC 215/TF 7
0)	Mukhopadhyay	Telehealth and Virtual Care (TVC) Standards
		ISO/TC 215/TF 7
		Telehealth and Virtual Care (TVC) Standards
		ISO/TC 215/WG 11
		Personalized digital health
9)	Dr. S B Gogia	
		ISO/TC 215/WG 2
		Systems and Device Interoperability
		ISO/TC 215/WG 3
		Semantic content
		ISO/TC 215/WG 10
10)	Ms. Ankita Srivastava	Traditional Medicine
		ISO/TC 215/WG 11
		Personalized digital health
11)	Dr. Ashok Kumar	ISO/TC 215/WG 10
		Traditional Medicine
12)	Dr. D C Katoch	ISO/TC 215/WG 10
12)		Traditional Medicine
12)	Ms. Manisha Mantri	ISO/TC 215/WG 10
13)		Traditional Medicine
	Dr. Raghavendra Naik	ISO/TC 215/WG 10
		Traditional Medicine
1 4		ISO/TC 215/WG 11
14)		Personalized digital health
		ISO/TC 215/WG 6
		Pharmacy and medicines business

15)	Mr. Haribabu A	ISO/TC 215/WG 10 Traditional Medicine
16)	Dr. N. K. Singh	ISO/TC 215/WG 11 Personalized digital health
17)	Mr. Rajendra Prasad	ISO/TC 215/WG 2 Systems and Device Interoperability
18)	Dr. Isha Garg	ISO/TC 215/WG 3 Semantic content
19)	Dr. Susheel Oommen John	ISO/TC 215/WG 3 Semantic content
20)	Col. (Retd.) R. N. Ghosh	ISO/TC 215/WG 3 Semantic content

11.2.3 The nomination of above members as 'Expert' to ISO Working Groups has been considered by BIS based on the recommendations of the Sectional Committee taking into account that he/she would actively participate in the projects concerned. By accepting an appointment as an Expert, the respective members are committing to actively participate in the Working Group to which he/she is appointed and to fulfill the obligations associated with participation. The Working Group Experts are also required to inform the National Mirror Committee (i.e. the concerned BIS Technical Committee that has the liaison with the ISO Technical Committee) of their contribution and progress of the work. The level of contribution of the nominated Working Group Experts may be reviewed and decision may be taken regarding continuation/ termination of nomination.

The Committee may kindly consider.

#### 11.3 Identification of Working Group Experts in ISO Technical Committees

11.3.1 India (BIS) is not participating in the following Working Groups of ISO as no Experts have been nominated by BIS in these WGs:

Sl. No.	Working Group Number/ Title		
1)	ISO/TC 215/JWG 1		
-)	Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics)		
2)	ISO/TC 215/TF 1		
_/	Task Force on Quantities and Units to be used in e-health		
3) ISO/TC 215/TF 3			
5)	Outreach & Communications		
4)	ISO/TC 215/TF 6		
.,	Process and quality improvement		
5)	ISO/TC 215/SC 1/TF 2		
2)	Cross-SDO genomics coordination		

11.3.2 The Organizations / Members may propose for nomination of experts in the above WGs

considering the following:

- (a) The knowledge and expertise of the expert in the subject area.
- (b) The willingness of the member to fulfill the responsibilities and expectations and commitment to devote ample time for international standardization activities.

The Committee may kindly consider.

#### 11.4 Harmonization of Indian Standards with International Standards

11.4.1 ISO comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the ISO Standards published against the existing National Standards, current trade practices, consumer expectations, global trends, etc and decide for review of the published National Standards. In the process, Sectional Committees after a close scrutiny of the ISO Standards, may decide on adoption/adaptation of the ISO Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is not undertaken in case the ISO Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage. The Sectional Committees while reviewing such ISO Standards also explore the possibility of adopting such ISO Standards exist.

11.4.2 The list of Standards published by the TCs and SCs of ISO/TC 215 along with their status of adoption is given at <u>Annexure C</u>.

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

#### ITEM 12 PROGRAMME OF WORK

12.1 The present Programme of Work of Health Informatics Sectional Committee (MHD 17) is available at BIS website: <u>https://www.services.bis.gov.in/php/BIS 2.0/bisconnect/pow new</u>.

The Committee may kindly note.

12.2 The progress of development of Indian Standards at various stages is given below:

Stage	No. of Documents
Under Print	16
Under Development	05

#### ITEM 13 REVIEW OF INDIAN STANDARDS

#### 13.1 Review of Standards as per 5-year cycle

**13.1.1** As per the policy of BIS, the Indian Standards which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

**13.1.2** With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards which are due for revision.

13.1.3 There are currently no Indian Standards due for review in 2024-2025.

The Committee may kindly note.

#### ITEM 14 DATE AND PLACE OF NEXT MEETING

14.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 17 is scheduled on 04<sup>th</sup> October 2024.

Quarter	Q1	Q2	Q3	Q4
	Apr-June 2024	July-Sept 2024	Oct-Dec 2024	Jan-Mar 2025
Date	02 <sup>nd</sup> April 2024,	19 <sup>th</sup> July 2024,	04 <sup>th</sup> Oct 2024,	10 <sup>th</sup> Jan 2025,
	Tuesday	Friday	Friday	Friday

The Committee may kindly note.

#### ITEM 15 ANY OTHER BUSINESS

#### ANNEXURE A (<u>Item 2.2</u>)

#### **COMPOSITION OF HEALTH INFORMATICS SECTIONAL COMMITTEE**

S.					ipation tus
No ·	Organization	Member Name	Role	22 <sup>nd</sup> TC Meetin	23 <sup>rd</sup> TC Meetin
1)	In Personal Capacity	Dr. Ashok Kumar	Chairperson	<b>g</b>	<b>g</b> 1
2)	In Personal Capacity	Dr S. B. Bhattacharyya	Principal Member	1	1
3)	In Personal Capacity	Dr. S.B. Gogia	Principal Member	1	1
4)	In Personal Capacity	Dr. Rangasayee R	Personal Capacity	1	1
	All India Institute of	Dr. Sidhartha Satpathy	Principal Member		
5)	Medical Sciences, New Delhi	Dr. Mahesh R.	Alternate Member	1	0
	Denn	Dr. Vikas H.	Alternate Member		
6)	Boston Scientific India Private Limited,	Shri Prashanth Prabhakar	Alternate Member	- 1	0
0)	Gurugram	Shri Dev Chopra	Principal Member		0
7)	Central Council for	Dr. Rakesh Narayanan V	Alternate Member	1	0
7)	Research in Ayurvedic Sciences, New Delhi	Dr. N. Srikanth	Principal Member		0
8)	Centre for Development of Advanced Computing,	Shri Praveen K. Srivastava	Alternate Member	0	1
8)	Pune	Shri Gaur Sunder	Principal Member	0	1
9)	CSIR - Institute of Genomics and Integrative Biology, New Delhi	Dr. Bhavana Parasher	Alternate Member	1	0
	Digital Health Associates	Dr. N. K. Singh	Principal Member		
10)	Private Limited, New Delhi	Dr. Manpreet Kaur	Alternate Member	1	1
11)	Indian Dental Association,	Dr. Vijay Prakash	Principal	0	1

	Mumbai	Mathur	Member		
		Dr. Ashok Dhoble	Alternate Member	•	
	Indian Institute of	Prof Soumya Kanti Ghosh	Alternate Member		
12)	Technology Kharagpur, Kharagpur	Prof Jayanta Mukhopadhyay	Principal Member	1	0
	Indian Nursing Council,	Dr Sandhya Gupta	Alternate Member		
13)	New Delhi	Dr Asha Sharma	Principal Member	0	1
	Karkinos Healthcare	Mr. Arvind Sivaramakrishnan	Principal Member		
14)	Private Limited, Bengaluru	Dr. Anjali Anant Kulkarni	Alternate Member	1	0
15)	Maulana Azad Medical	Dr. Nidhi Bhatnagar	Principal Member	0	1
15)	College, New Delhi	Dr. Amod. L. Borle	Alternate Member	0	1
16)	National Accreditation Board for Hospitals and	Dr. Atul Mohan Kochhar	Principal Member	1	1
10)	Healthcare Providers, New Delhi	viders, Dr. Punam Bajaj	Alternate Member	1	1
	National Accreditation	Mr. Pankaj Johri	Principal Member		
17)	Board for Testing and Calibration Laboratories,	Ms. Bhumi Rajyaguru	Alternate Member	1	1
	Gurugram	Mr. Haribabu A.	Alternate Member		
18)	National Health Systems Resource Centre, New	Dr. Ranjan Choudhury	Principal Member	1	1
10)	Delhi	Ms. Manisha Sharma	Alternate Member		1
19)	North-Eastern Hill	Dr. Sudip Paul	Principal Member	1	1
	University, Shillong	Shri Shyamal Mandal	Alternate Member		Ĩ
20)	Philips India Limited, Gurugram	Shri A V A Rajendra Prasad	Vice-Chairper son	1	1
21)	Public Health Foundation	Dr. Pushkar Kumar	Principal Member	1	1
<sup>21</sup>	of India, New Delhi	Mr. Dilip Kumar Jha	Alternate Member		1

22)	Sankara Nethralaya, Chennai	Dr. Sheila John	Principal Member	1	1
23)	Society for Administration of Telemedicine and	Mr. Chinmoy Lye	Principal Member	0	1
23)	Health Care Informatics, New Delhi	Dr. Susheel Oommen John	Alternate Member	0	1
24)	Sri Sathya Sai Central Trust, Anantapur	Shri Jai Ganesh Udayasankaran	Principal Member	1	1
25)	Telemedicine Society of	Shri Baljit Singh Bedi	Principal Member	1	1
23)	India, Lucknow	Col. (Dr) Ashvini Goel (Retd.)	Alternate Member	I	1
26)	Trivedi School of Biosciences, Ashoka	Dr. Rintu Kutum	Principal Member	1	1
20)	University, Sonipat	Dr. Mayank Garg	Alternate Member	1	1

#### ANNEXURE B (<u>Item 2.3</u>)

### <u>Composition of Health Informatics – AYUSH Working Group [MHD 17:1]</u>

S. No.	Organization	Member Name	Role
1)	In Personal Capacity	Dr. S. B. Bhattacharyya	Convener
2)	CSIR - Institute of Genomics and Integrative Biology, New Delhi	Dr. Bhavana Parasher	Expert
3)	Centre for Development of Advanced Computing, Pune	Ms. Manisha Mantri	Expert
4)	Ministry of AYUSH, New Delhi	Dr. D C Katoch	Expert
5)	LITD, Bureau of Indian Standards	Ms. Ankita Srivastav	Expert
6)	AYUSH Department, BIS, New Delhi	Dr. Raghvendra Naik	Expert

#### **Composition of Telehealth and Virtual Care Working Group [MHD 17:2]**

S. No.	Organization	Member Name	Role
1)	Centre for Development of Advanced Computing, Pune	Mr. Gaur Sunder	Convener
2)	Centre for Development of Advanced Computing, Pune	Ms. Manisha Mantri	Expert
3)	Indian Dental Association, Mumbai	Dr. Vijay Prakash Mathur	Expert
4)	Indian Institute of Technology Kharagpur, Kharagpur	Prof. Jayanta Mukhopadhyay	Expert
5)	Society for Administration of Telemedicine and Health Care Informatics, New Delhi	Dr. Susheel Oommen John	Expert
6)	Sri Sathya Sai Central Trust, Anantapur	Mr. Jai Ganesh Udayasankaran	Expert
7)	Telemedicine Society of India, Lucknow	Col. (Dr.) Ashvini Goel (Retd.)	Expert
8)	In Personal Capacity	Dr. S.B. Gogia	Expert

S. No.	Organization	Member Name	Role
1)	In Individual Capacity	Mr. Rangasayee R	Convener
2)	Dhwani Foundation, Bengaluru	Ms. Manju Kuchhal	Expert
3)	Sri Sathya Sai Central Trust, Anantapur	Mr. Jai Ganesh Udayasankaran	Expert
4)	In Personal Capacity	Mr. V S Basavaraju	Expert
5)	In Personal Capacity	Ms. Deepa Palaniappan	Expert
6)	NRCeS, CDAC, Pune	Ms. Manisha Mantri	Expert

#### **Composition of Disability Informatics Working Group [MHD 17:3]**

#### Composition of Medical Icons Working Group [MHD 17:4]

S. No.	Organization	Member Name	Role
1)	In Individual Capacity	Dr. S. B. Gogia	Convener
2)	In Individual Capacity	Col. (Retd.) R. N. Ghosh	Expert
3)	In Individual Capacity	Dr. Isha Garg	Expert
4)	SATHI, New Delhi	Mr. Chinmoy Lye	Expert
5)	Trivedi School of Biosciences, Ashoka University, Sonipat	Dr. Mayank Garg	Expert

#### <u>Composition of Cybersecurity of Network-connected Medical Devices Working Group</u> [MHD 17:5]

S. No.	Organization	Member Name	Role
1)	Philips India Limited, Bengaluru	Shri Rajendra Prasad	Convener
2)	In Individual Capacity	Dr. S. B. Bhattacharyya	Expert

2)	Indian Institute of Technology	Prof Jayanta	Expert
3)	Kharagpur	Mukhopadhyay	

#### ANNEXURE C (*Item 11.4.2*)

#### **ISO STANDARDS PUBLISHED UNDER ISO/TC 215**

#### Standard published under ISO/TC 215/SC 1 Genomics Informatics

S. No.	ISO No.	ISO Title	Status of adoption	Corresponding IS /Doc No.
1)	ISO/TS 4424:2023	Genomics informatics — Data elements and their metadata for describing the tumor mutation burden (TMB) information of clinical massive parallel DNA sequencing	Not adopted	NA
2)	ISO/TS 4425:2023	Genomics informatics — Data elements and their metadata for describing the microsatellite instability (MSI) information of clinical massive parallel DNA sequencing	Not adopted	NA
3)	ISO 4454:2022	Genomics informatics — Phenopackets: A format for phenotypic data exchange	Not adopted	NA
4)	ISO/TS 8376:2023	Genomics informatics — Requirements for interoperable systems for genomic surveillance	Not adopted	NA
5)	ISO/TS 8392:2023	Genomics informatics — Description rules for genomic data for genetic detection products and services	Not adopted	NA
6)	ISO/TS 20428:2024	Genomics Informatics — Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records	Old edition adopted	IS 17798 : 2022/ ISO/TS 20428:2017
7)	ISO 21393:2021	Genomics informatics — Omics Markup Language (OML)	Not adopted	NA
8)	ISO/TS 22690:2021	Genomics informatics — Reliability assessment criteria for high-throughput gene-expression data	Not adopted	NA
9)	ISO/TS 22692:2020	Genomics informatics— Quality control metrics for DNA sequencing	Not adopted	NA
10)	ISO/TS 22693:2021	Genomics informatics — Structured clinical gene fusion report in electronic health records	Not adopted	NA
11)	ISO/TS 23357:2023	Genomics informatics — Clinical genomics data sharing specification for next-generation sequencing	Not adopted	NA

12)	ISO	Health informatics — Genomic Sequence	Adopted	IS 17887 : 2022	
		Variation Markup Language (GSVML)	Adopted	15 17667 . 2022	

#### Standard published under ISO/TC 215 Health Informatics

S. No.	ISO No.	ISO Title		Corresponding IS /Doc No.
1)	ISO 1828:2012	Health informatics — Categorial structure for terminological systems of surgical procedures	Adopted	IS/ISO 1828 : 2012
2)	ISO/TR 4421:2023	Health informatics — Introduction to Ayurveda informatics	Under adoption	MHD/17/23687
3)	ISO/TS 5044:2023	Health informatics — Information model for quality control of traditional Chinese medicinal products	Not adopted	NA
4)	ISO/TS 5118:2022	Health informatics — Categorial structure of representation for evaluation of clinical practice guidelines of traditional Chinese medicine	Not adopted	NA
5)	ISO/TS 5346:2022	Health informatics — Categorial structure for representation of traditional Chinese medicine clinical decision support system	Not adopted	NA
6)	ISO 5477:2023	Health informatics — Interoperability of public health emergency preparedness and response information systems	Not adopted	NA
7)	ISO/TS 5499:2024	Health informatics — Clinical particulars — Core principles for the harmonization of therapeutic indications terms and identifiers	Not adopted	NA
8)	ISO/TS 5568:2022	Health informatics — Traditional Chinese medicine — Labelling metadata of human biological sample information	Not adopted	NA
9)	ISO/TS 5777:2024	Health informatics — The architecture of internet healthcare service network	Not adopted	NA
10)	ISO/TR 6231:2024	Health informatics — Standardizing graphical content	Not adopted	NA
11)	ISO/TS 5569:2023	Health informatics — Conceptual data model for Chinese medicinal herbs	Not adopted	NA
12)	ISO/TR 9143:2023	Health informatics — Sex and gender in electronic health records	Not adopted	NA

13)	ISO/TS 9321:2024	Health informatics — General requirements of multi-centre medical data collaborative analysis	Not adopted	NA
14)	ISO 10159:2011	Health informatics — Messages and communication — Web access reference manifest	Adopted	IS/ISO 10159 : 2011
15)	ISO 10781:2023	Health informatics — HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)	Under adoption & Old edition adopted	MHD/17/25053 (IS/ISO 10781 : 2015)
16)	ISO/IEEE 11073-00103 :2015	Health informatics — Personal health device communication — Part 00103: Overview	Adopted	IS/ISO/IEEE 11073-00103 : 2015
17)	ISO/IEEE 11073-10101 :2020	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature	Under adoption & Old edition adopted	MHD/17/25679 (IS/ISO/IEEE 11073-10101 : 2004)
18)	ISO/IEEE 11073-10102 :2014	Health informatics — Point-of-care medical device communication — Part 10102: Nomenclature — Annotated ECG	Adopted	IS/ISO/IEEE 11073-10102 : 2014
19)	ISO/IEEE 11073-10103 :2014	Health informatics — Point-of-care medical device communication — Part 10103: Nomenclature — Implantable device, cardiac	Adopted	IS/ISO/IEEE 11073-10103 : 2014
20)	ISO/IEEE 11073-10201 :2020	Health informatics — Device interoperability — Part 10201: Point-of-care medical device communication — Domain information model	Under adoption & Old edition adopted	MHD/17/23773 (IS/ISO/IEEE 11073-10201 : 2004)
21)	ISO/IEEE 11073-10206 :2024	Health informatics — Device interoperability — Part 10206: Personal health device communication — Abstract content information model	Not adopted	NA
22)	ISO/IEEE 11073-10207 :2019	Health informatics — Personal health device communication — Part 10207: Domain information and service model for service-oriented point-of-care medical device communication	Adopted	IS/ISO/IEEE 11073-10207 : 2019
23)	ISO/IEEE 11073-10404 :2022	Health informatics — Device interoperability — Part 10404: Personal health device communication — Device specialization — Pulse oximeter	Under adoption & Old edition adopted	MHD/17/23774 (IS/ISO/IEEE 11073-10404 : 2010)

24)	ISO/IEEE 11073-10406 :2012	Health informatics — Personal health device communication — Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)	Adopted	IS/ISO/IEEE 11073-10406 : 2012
25)	ISO/IEEE 11073-10407 :2022	Health informatics — Device interoperability — Part 10407: Personal health device communication — Device specialization — Blood pressure monitor	Under adoption & Old edition adopted	MHD/17/23775 (IS/ISO/IEEE 11073-10407 : 2010)
26)	ISO/IEEE 11073-10408 :2022	Health informatics — Device interoperability — Part 10408: Personal health device communication — Device specialization — Thermometer	Under adoption & Old edition adopted	MHD/17/23776 (IS/ISO/IEEE 11073-10408 : 2010)
27)	ISO/IEEE 11073-10415 :2022	Health informatics — Device interoperability — Part 10415: Personal health device communication — Device specialization — Weighing scale	Under adoption & Old edition adopted	MHD/17/23777 (IS/ISO/IEEE 11073-10415 : 2010)
28)	ISO/IEEE 11073-10417 :2017	Health informatics — Personal health device communication — Part 10417: Device specialization — Glucose meter	Adopted	IS/ISO/IEEE 11073-10417 : 2017
29)	ISO/IEEE 11073-10418 :2014	Health informatics — Personal health device communication — Part 10418: Device specialization — International Normalized Ratio (INR) monitor	Adopted	IS/ISO/IEEE 11073-10418 : 2014
30)	ISO/IEEE 11073-10418 :2014/Cor 1:2016	Health informatics — Personal health device communication — Part 10418: Device specialization — International Normalized Ratio (INR) monitor — Technical Corrigendum 1	Adopted	IS/ISO/IEEE 11073-10418 : 2014
31)	ISO/IEEE 11073-10419 :2019	Health informatics — Personal health device communication — Part 10419: Device specialization — Insulin pump	Under adoption & Old edition adopted	MHD/17/23778 (IS/ISO/IEEE 11073-10419 : 2016)
32)	ISO/IEEE 11073-10420 :2022	Health informatics — Device interoperability — Part 10420: Personal health device communication — Device specialization — Body composition analyzer	Under adoption & Old edition adopted	MHD/17/23779 (IS/ISO/IEEE 11073-10420 : 2012)
33)	ISO/IEEE 11073-10421 :2012	Health informatics — Personal health device communication — Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)	Adopted	IS/ISO/IEEE 11073-10421 : 2012

34)	ISO/IEEE 11073-10422 :2017	Health informatics — Personal health device communication — Part 10422: Device specialization — Urine analyser	Adopted	IS/ISO/IEEE 11073-10422 : 2017
35)	ISO/IEEE 11073-10424 :2016	Health informatics — Personal health device communication — Part 10424: Device specialization — Sleep apnoea breathing therapy equipment (SABTE)	Adopted	IS/ISO/IEEE 11073-10424 : 2019
36)	ISO/IEEE 11073-10424 :2016/Cor 1:2018	Health informatics — Personal health device communication — Part 10424: Device specialization — Sleep apnoea breathing therapy equipment (SABTE) — Technical Corrigendum 1	Adopted	IS/ISO/IEEE 11073-10424 : 2019
37)	ISO/IEEE 11073-10425 :2019	Health informatics — Personal health device communication — Part 10425: Device specialization — Continuous glucose monitor (CGM)	Under adoption & Old edition adopted	MHD/17/25054 (IS/ISO/IEEE 11073-10425 : 2016)
38)	ISO/IEEE 11073-10427 :2018	Health informatics — Personal health device communication — Part 10427: Device specialization — Power status monitor of personal health devices	Adopted	IS/ISO/IEEE 11073-10427 : 2018
39)	ISO/IEEE 11073-10441 :2015	Health informatics — Personal health device communication — Part 10441: Device specialization — Cardiovascular fitness and activity monitor	Adopted	IS/ISO/IEEE 11073-10441 : 2015
40)	ISO/IEEE 11073-10442 :2015	Health informatics — Personal health device communication — Part 10442: Device specialization — Strength fitness equipment	Adopted	IS/ISO/IEEE 11073-10442 : 2015
41)	ISO/IEEE 11073-10471 :2010	Health informatics — Personal health device communication — Part 10471: Device specialization - Independant living activity hub	Adopted	IS/ISO/IEEE 11073-10471 : 2010
42)	ISO/IEEE 11073-10472 :2012	Health Informatics — Personal health device communication — Part 10472: Device specialization — Medication monitor	Adopted	IS/ISO/IEEE 11073-10472 : 2012
43)	ISO/IEEE 11073-20101 :2004	Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard	Adopted	IS/ISO/IEEE 11073-20101 : 2004
44)	ISO/IEEE 11073-20601 :2022	Health informatics — Device interoperability — Part 20601: Personal health device communication — Application profile — Optimized exchange protocol	Under adoption & Old edition adopted	MHD/17/23754 (IS/ISO/IEEE 11073-20601 : 2016)

45)	ISO/IEEE 11073-20701 :2020	Health informatics — Device interoperability — Part 20701: Point-of-care medical device communication — Service oriented medical device exchange architecture and protocol binding	Not adopted	NA
46)	ISO/IEEE 11073-20702 :2018	Health informatics — Point-of-care medical device communication — Part 20702: Medical devices communication profile for web services	Adopted	IS/ISO/IEEE 11073-20702 : 2018
47)	ISO/IEEE 11073-30200 :2004	Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected	Adopted	IS/ISO/IEEE 11073-30200 : 2004 ISO/IEEE 11073-30200
48)	ISO/IEEE 11073-30200 :2004/Amd 1:2015	Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected — Amendment 1	Adopted	IS/ISO/IEEE 11073-30200 : 2004
49)	ISO/IEEE 11073-30400 :2012	Health informatics — Point-of-care medical device communication — Part 30400: Interface profile — Cabled Ethernet	Adopted	IS/ISO/IEEE 11073-30400 : 2012
50)	ISO/IEEE 11073-40101 :2022	Health informatics — Device interoperability — Part 40101: Foundational — Cybersecurity — Processes for vulnerability assessment	Not adopted	NA
51)	ISO/IEEE 11073-40102 :2022	Health informatics — Device interoperability — Part 40102: Foundational — Cybersecurity — Capabilities for mitigation	Not adopted	NA
52)	ISO 11073-90101 :2008	Health informatics — Point-of-care medical device communication — Part 90101: Analytical instruments — Point-of-care test	Adopted	IS/ISO 11073-90101 : 2008
53)	ISO/TR 11147:2023	Health informatics — Personalized digital health — Digital therapeutics health software systems	Not adopted	NA
54)	ISO 11238:2018	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances	Adopted	IS 18199 : 2023/ ISO 11238:2018
55)	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	Under adoption & Old edition adopted	MHD/17/23688 (IS/ISO 11239 : 2012)
56)	ISO 11240:2012	Health informatics — Identification of medicinal products — Data elements and structures for the	Adopted	IS/ISO 11240 : 2012

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		unique identification and exchange of units of measurement		
57)	ISO 11615:2017	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information	Adopted	IS/ISO 11615 : 2017
58)	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 — Amendment 1	Under adoption	MHD/17/23689
59)	ISO 11616:2017	Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information	Adopted	IS/ISO 11616 : 2017
60)	ISO/TS 11633-1:201 9	Health informatics — Information security management for remote maintenance of medical devices and medical information systems — Part 1: Requirements and risk analysis	Adopted	IS 18198 (Part 1) : 2023 ISO/TS 11633-1:2019
61)	ISO/TR 11633-2:202 1	Health informatics — Information security management for remote maintenance of medical devices and medical information systems — Part 2: Implementation of an information security management system (ISMS)	Adopted	IS 18218 (Part 2) : 2023 ISO/TR 11633-2:2021
62)	ISO/TR 11636:2009	Health Informatics — Dynamic on-demand virtual private network for health information infrastructure	Adopted	IS 17762 : 2022
63)	ISO 12052:2017	Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management	Adopted	IS/ISO 12052 : 2017
64)	ISO/TR 12300:2014	Health informatics — Principles of mapping between terminological systems	Not adopted	NA
65)	ISO/TR 12309:2009	Health informatics — Guidelines for terminology development organizations	Not adopted	NA
66)	ISO/TR 12310:2015	Health informatics — Principles and guidelines for the measurement of conformance in the implementation of terminological systems	Not adopted	NA
67)	ISO 12381:2019	Health informatics — Explicit time-related expressions for healthcare-specific problems	Adopted	IS/ISO 12381 : 2019
68)	ISO/TR 12773-1:200 9	Business requirements for health summary records — Part 1: Requirements	Not adopted	NA
69)	ISO/TR 12773-2:200	Business requirements for health summary records — Part 2: Environmental scan	Not adopted	NA

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70)	ISO 12967-1:202 0	Health informatics — Service architecture (HISA) — Part 1: Enterprise viewpoint	Adopted	IS/ISO 12967-1 : 2009
71)	ISO 12967-2:202 0	Health informatics — Service architecture (HISA) — Part 2: Information viewpoint	Adopted	IS 18302 (Part 2) : 2023 ISO 12967-2:2020
72)	ISO 12967-3:202 0	Health informatics — Service architecture (HISA) — Part 3: Computational viewpoint	Adopted	IS/ISO 12967-3 : 2009
73)	ISO/TR 13054:2012	Knowledge management of health information standards	Not adopted	NA
74)	ISO 13119:2022	Health informatics — Clinical knowledge resources — Metadata	Adopted	IS/ISO 13119 : 2022
75)	ISO 13120:2019	Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)	Adopted	IS/ISO 13120 : 2019
76)	ISO/TR 13128:2012	Health Informatics — Clinical document registry federation	Not adopted	NA
77)	ISO 13131:2021	Health informatics — Telehealth services — Quality planning guidelines	Not adopted	NA
78)	ISO/TS 13582:2015	Health informatics — Sharing of OID registry information	Not adopted	NA
79)	ISO 13606-1:201 9	Health informatics — Electronic health record communication — Part 1: Reference model	Adopted	IS 18301 (Part 1) : 2023 ISO 13606-1:2019
80)	ISO 13606-2:201 9	Health informatics — Electronic health record communication — Part 2: Archetype interchange specification	Adopted	IS 18301 (Part 2) : 2023 ISO 13606-2:2019
81)	ISO 13606-3:201 9	Health informatics — Electronic health record communication — Part 3: Reference archetypes and term lists	Adopted	IS 18301 (Part 3) : 2023 ISO 13606-3:2019
82)	ISO 13606-4:201 9	Health informatics — Electronic health record communication — Part 4: Security	Adopted	IS 18301 (Part 4) : 2023 ISO 13606-4:2019
83)	ISO 13606-5:201	Health informatics — Electronic health record communication — Part 5: Interface specification	Adopted	IS 18301 (Part 5) : 2023

	9			ISO 13606-5:2019
84)	ISO 13940:2015	Health informatics — System of concepts to support continuity of care	Adopted	IS/ISO 13940 : 2015
85)	ISO 13972:2022	Health informatics — Clinical information models — Characteristics, structures and requirements	Adopted	IS/ISO/TS 13972 : 2022
86)	ISO 14199:2015	Health informatics — Information models — Biomedical Research Integrated Domain Group (BRIDG) Model	Not adopted	NA
87)	ISO/TS 14265:2024	Health informatics — Classification of purposes for processing personal health information	Under adoption & Old edition adopted	MHD/17/25680 (IS/ISO/TS 14265 : 2011)
88)	ISO/TR 14292:2012	Health informatics — Personal health records — Definition, scope and context	Not adopted	NA
89)	ISO/TS 14441:2013	Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment	Adopted	IS/ISO/TS 14441 : 2013
90)	ISO/TR 14639-1:201 2	Health informatics — Capacity-based eHealth architecture roadmap — Part 1: Overview of national eHealth initiatives	Not adopted	NA
91)	ISO/TR 14639-2:201 4	Health informatics — Capacity-based eHealth architecture roadmap — Part 2: Architectural components and maturity model	Not adopted	NA
92)	ISO/TR 14872:2019	Health informatics — Identification of medicinal products — Core principles for maintenance of identifiers and terms	Not adopted	NA
93)	ISO/TR 16056-1:200 4	Health informatics — Interoperability of telehealth systems and networks — Part 1: Introduction and definitions	Adopted	Withdrawn/sup erseded
94)	ISO/TR 16056-2:200 4	Health informatics — Interoperability of telehealth systems and networks — Part 2: Real-time systems	Adopted	Withdrawn/sup erseded
95)	ISO/TS 16277-1:201 5	Health informatics — Categorial structures of clinical findings in traditional medicine — Part 1: Traditional Chinese, Japanese and Korean medicine	Not adopted	NA
96)	ISO 16278:2016	Health informatics — Categorial structure for terminological systems of human anatomy	Adopted	IS/ISO 16278 : 2016
97)	ISO	Health informatics — HL7 Personal Health	Not	NA

	16527:2023	Record System Functional Model, Release 2 (PHR-S FM)	adopted	
98)	ISO/TS 16791:2020	Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers	Adopted	IS 18216 : 2023 ISO/TS 16791:2020
99)	ISO/TS 16843-1:201 6	Health informatics — Categorial structures for representation of acupuncture — Part 1: Acupuncture points	Not adopted	NA
100)	ISO/TS 16843-2:201 5	Health informatics — Categorial structures for representation of acupuncture — Part 2: Needling	Not adopted	NA
101)	ISO/TS 16843-3:201 7	Health informatics — Categorial structures for representation of acupuncture — Part 3: Moxibustion	Not adopted	NA
102)	ISO/TS 16843-4:201 7	Health informatics — Categorial structures for representation of acupuncture — Part 4: Meridian and collateral channels	Not adopted	NA
103)	ISO/TS 16843-5:201 9	Health Informatics — Categorial structures for representation of acupuncture — Part 5: Cupping	Not adopted	NA
104)	ISO/TS 16843-6:202 2	Health informatics — Categorial structures for representation of acupuncture — Part 6: Acupuncture effects	Not adopted	NA
105)	ISO 17090-1:202 1	Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services	Adopted	IS/ISO 17090-1 : 2023
106)	ISO 17090-2:201 5	Health informatics — Public key infrastructure — Part 2: Certificate profile	Adopted	IS/ISO 17090-2 : 2015
107)	ISO 17090-3:202 1	Health informatics — Public key infrastructure — Part 3: Policy management of certification authority	Adopted	IS/ISO 17090-3 : 2021
108)	ISO 17090-4:202 0	Health informatics — Public key infrastructure — Part 4: Digital signatures for healthcare documents	Adopted	IS/ISO 17090-4 : 2020
109)	ISO 17090-5:201 7	Health informatics — Public key infrastructure — Part 5: Authentication using Healthcare PKI credentials	Adopted	IS/ISO 17090-5 : 2017
110)	ISO 17115:2020	Health informatics — Representation of categorial structures of terminology (CatStructure)	Adopted	IS 17771 : 2022 ISO 17115 : 2020
111)	ISO	Health informatics — Terminological resources	Adopted	IS/ISO 17117-1

	17117-1:201 8	— Part 1: Characteristics		: 2018
112)	ISO/TS 17117-2:202 2	Health informatics — Terminological resources — Part 2: Implementation Capability (TIC)	Adopted	IS/ISO/TS 17117-2 : 2022
113)	ISO/TR 17119:2005	Health informatics — Health informatics profiling framework	Not adopted	NA
114)	ISO/TS 17251:2023	Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products	Under adoption & Old edition adopted	MHD/17/25681 (IS 17767 : 2022/ISO/TS 17251:2016)
115)	ISO 17439:2022	Health informatics — Development of terms and definitions for health informatics glossaries	Not adopted	NA
116)	ISO/TR 17522:2015	Health informatics — Provisions for health applications on mobile/smart devices	Adopted	IS 17763 : 2022 ISO/TR 17522:2015
117)	ISO 17523:2016	Health informatics — Requirements for electronic prescriptions	Adopted	IS 17769 : 2022
118)	ISO/TR 17791:2013	Health informatics — Guidance on standards for enabling safety in health software	Adopted	IS/ISO/TR 17791 : 2013
119)	ISO/TS 17938:2014	Health informatics — Semantic network framework of traditional Chinese medicine language system	Not adopted	NA
120)	ISO/TS 17948:2014	Health informatics — Traditional Chinese medicine literature metadata	Not adopted	NA
121)	ISO/TS 17975:2022	Health informatics — Principles and data requirements for consent in the collection, use or disclosure of personal health information	Adopted	IS/ISO/TS 17975 : 2022
122)	ISO/TS 18062:2016	Health informatics — Categorial structure for representation of herbal medicaments in terminological systems	Not adopted	NA
123)	ISO 18104:2023	Health informatics — Categorial structures for representation of nursing practice in terminological systems	Not adopted	NA
124)	ISO 18232:2006	Health Informatics — Messages and communication — Format of length limited globally unique string identifiers	Not adopted	NA
125)	ISO/TR 18307:2001	Health informatics — Interoperability and compatibility in messaging and communication standards — Key characteristics	Not adopted	NA

126)	ISO 18308:2011	Health informatics — Requirements for an electronic health record architecture	Adopted	IS/ISO 18308 : 2011
127)	ISO 18530:2021	Health informatics — Automatic identification and data capture marking and labelling — Subject of care and individual provider identification	Not adopted	NA
128)	ISO/TR 18638:2017	Health informatics — Guidance on health information privacy education in healthcare organizations	Not adopted	NA
129)	ISO/TS 18790-1:201 5	Health informatics — Profiling framework and classification for Traditional Medicine informatics standards development — Part 1: Traditional Chinese Medicine	Not adopted	NA
130)	ISO 18812:2003	Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles	Not adopted	NA
131)	ISO/TS 18864:2017	Health informatics — Quality metrics for detailed clinical models	Not adopted	NA
132)	ISO/TR 19231:2014	Health informatics — Survey of mHealth projects in low and middle income countries (LMIC)	Not adopted	NA
133)	ISO/TS 19256:2016	Health informatics — Requirements for medicinal product dictionary systems for health care	Not adopted	NA
134)	ISO/TS 19293:2018	Health informatics — Requirements for a record of a dispense of a medicinal product	Adopted	IS 17764 : 2022
135)	ISO/TR 19669:2017	Health informatics — Re-usable component strategy for use case development	Not adopted	NA
136)	ISO/TS 19844:2018	Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances	Not adopted	NA
137)	ISO/TR 20055:2018	Health informatics — Person-owned document repository for PHR applications and health information exchange	Not adopted	NA
138)	ISO 20301:2014	Health informatics — Health cards — General characteristics	Adopted	IS/ISO 20301 : 2014
139)	ISO 20302:2022	Health informatics — Health cards — Numbering system and registration procedure for issuer identifiers	Adopted	IS/ISO 20302 : 2022
140)	ISO/TS	Health informatics — Framework of event data	Not	NA

	20405:2018	and reporting definitions for the safety of health software	adopted	
141)	ISO/TS 20440:2023	Health informatics — Identification of medicinal products — Implementation guidelines for 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	Not adopted	NA
142)	ISO/TS 20443:2017	Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information	Not adopted	NA
143)	ISO/TS 20451:2017	Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information	Not adopted	NA
144)	ISO/TR 20514:2005	Health informatics — Electronic health record — Definition, scope and context	Adopted	IS/ISO/TR 20514 : 2005
145)	ISO/TR 20831:2017	Health informatics — Medication management concepts and definitions	Adopted	IS 17770 : 2022
146)	ISO/TS 21089:2018	Health informatics — Trusted end-to-end information flows	Not adopted	NA
147)	ISO 21090:2011	Health informatics — Harmonized data types for information interchange	Adopted	IS/ISO 21090 : 2011
148)	ISO 21091:2013	Health informatics — Directory services for healthcare providers, subjects of care and other entities	Adopted	IS 17766 : 2022
149)	ISO 21298:2017	Health informatics — Functional and structural roles	Not adopted	NA
150)	ISO/TR 21332:2021	Health informatics — Cloud computing considerations for the security and privacy of health information systems	Not adopted	NA
151)	ISO/TS 21526:2019	Health informatics — Metadata repository requirements (MetaRep)	Not adopted	NA
152)	ISO/TS 21547:2010	Health informatics — Security requirements for archiving of electronic health records — Principles	Adopted	IS 17852 : 2022
153)	ISO/TR 21548:2010	Health informatics — Security requirements for archiving of electronic health records — Guidelines	Not adopted	NA

ISO 21549-1:201 3	Health informatics — Patient healthcard data — Part 1: General structure	Adopted	IS/ISO 21549-1 : 2013
ISO 21549-2:201 4	Health informatics — Patient healthcard data — Part 2: Common objects	Adopted	IS/ISO 21549-2 : 2014
ISO 21549-3:201 4	Health informatics — Patient healthcard data — Part 3: Limited clinical data	Adopted	IS/ISO 21549-3 : 2014
ISO 21549-4:201 4	Health informatics — Patient healthcard data — Part 4: Extended clinical data	Adopted	IS/ISO 21549-4 : 2014
ISO 21549-5:202 3	Health informatics — Patient healthcard data — Part 5: Identification data	Under adoption & Old edition adopted	MHD/17/25055 (IS/ISO 21549-5 : 2015)
ISO 21549-6:200 8	Health informatics — Patient healthcard data — Part 6: Administrative data	Adopted	IS 21549 (Part 6) : 2008
ISO 21549-7:202 4	Health informatics — Patient healthcard data — Part 7: Medication data	Under adoption & Old edition adopted	MHD/17/25676 (IS/ISO 21549-7 : 2016)
ISO 21549-8:201 0	Health informatics — Patient healthcard data — Part 8: Links	Adopted	IS/ISO 21549-8 : 2010
	Health Informatics — Terminology resource map quality measures (MapQual)	Not adopted	NA
ISO 21667:2010	Health informatics — Health indicators conceptual framework	Not adopted	NA
ISO/TR 21730:2007	Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices	Not adopted	NA
ISO/HL7 21731:2014	Health informatics — HL7 version 3 — Reference information model — Release 4	Not adopted	NA
ISO/TS 21831:2020	Information model of Chinese materia medica processing	Not adopted	NA
	21549-1:201 3 ISO 21549-2:201 4 ISO 21549-3:201 4 ISO 21549-4:201 4 ISO 21549-4:201 4 ISO 21549-5:202 3 ISO 21549-6:200 8 ISO 21549-7:202 4 ISO 21549-8:201 0 ISO/TS 21564:2019 ISO 21667:2010 ISO/TR 21730:2007 ISO/TS	21549-1:201 3Health informatics — Patient healthcard data — Part 1: General structureISO 21549-2:201 4Health informatics — Patient healthcard data — Part 2: Common objectsISO 21549-3:201 4Health informatics — Patient healthcard data — Part 3: Limited clinical dataISO 21549-4:201 4Health informatics — Patient healthcard data — Part 4: Extended clinical dataISO 21549-5:202 3Health informatics — Patient healthcard data — Part 5: Identification dataISO 21549-6:200 8Health informatics — Patient healthcard data — Part 5: Identification dataISO 21549-6:200 4Health informatics — Patient healthcard data — Part 6: Administrative dataISO 21549-7:202 4Health informatics — Patient healthcard data — Part 7: Medication dataISO 21549-8:201 0Health informatics — Patient healthcard data — Part 7: Medication dataISO 21564:2019 0Health informatics — Patient healthcard data — Part 8: LinksISO/TS 21667:2010Health informatics — Terminology resource map quality measures (MapQual)ISO 1SO/TR 21730:2007Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devicesISO/HL7 21731:2014Health informatics — HL7 version 3 — Reference information model — Release 4 ISO/TS	21549-1:201 3Health informatics — Patient healthcard data — Part 1: General structureAdoptedISO 21549-2:201 4Health informatics — Patient healthcard data — Part 2: Common objectsAdoptedISO 21549-3:201 4Health informatics — Patient healthcard data — Part 3: Limited clinical dataAdoptedISO 21549-3:201 4Health informatics — Patient healthcard data — Part 3: Limited clinical dataAdoptedISO 21549-4:201 4Health informatics — Patient healthcard data — Part 4: Extended clinical dataAdoptedISO 21549-5:202 3Health informatics — Patient healthcard data — Part 5: Identification dataUnder adoption & Old edition adoptedISO 21549-6:200 4Health informatics — Patient healthcard data — Part 6: Administrative dataUnder adoptedISO 21549-7:202 4Health informatics — Patient healthcard data — Part 7: Medication dataUnder adoptedISO 21549-7:202 4Health informatics — Patient healthcard data — Part 8: LinksMoter adoptedISO 21549-8:201 0Health informatics — Patient healthcard data — Part 8: LinksNot adoptedISO 1SO/TS 1SO/TS 1SO/TR 21667:2010Health Informatics — Terminology resource map quality measures (MapQual)Not adoptedISO/TR 21730:2007Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic ompatibility (management of uninentional electromagnetic interference) with medical devicesNot adoptedISO/HL7 1731:201

167)	ISO/TR 21835:2020	Health informatics — Personal health data generated on a daily basis	Adopted	IS 17765 : 2022
168)	ISO 21860:2020	Health Informatics — Reference standards portfolio (RSP) — Clinical imaging	Adopted	IS/ISO 21860 : 2020
169)	ISO 22077-1:202 2	Health informatics — Medical waveform format — Part 1: Encoding rules	Under adoption	MHD/17/25677
170)	ISO 22077-2:202 3	Health informatics — Medical waveform format — Part 2: Electrocardiography	Under adoption & Old edition adopted	MHD/17/24645 (IS/ISO/TS 22077-2 : 2015)
171)	ISO 22077-3:202 3	Health informatics — Medical waveform format — Part 3: Long-term electrocardiography	Under adoption & Old edition adopted	MHD/17/24647 (IS/ISO/TS 22077-3 : 2015)
172)	ISO/TS 22077-4:201 9	Health informatics — Medical waveform format — Part 4: Stress test electrocardiography	Not adopted	NA
173)	ISO/TS 22077-5:202 1	Health informatics — Medical waveform format — Part 5: Neurophysiological signals	Not adopted	NA
174)	ISO/TS 22218-1:202 3	Health informatics — Ophthalmic examination device data — Part 1: General examination devices	Not adopted	NA
175)	ISO/TS 22218-2:202 3	Health informatics — Ophthalmic examination device data — Part 2: Specular microscope	Not adopted	NA
176)	ISO/TS 22220:2011	Health informatics — Identification of subjects of health care	Adopted	IS/ISO/TS 22220 : 2011
177)	ISO/TS 22272:2021	Health Informatics - Methodology for analysis of business and information needs of health enterprises to support standards based architectures	Adopted	IS/ISO/TS 22272 : 2021
178)	ISO 22287:2024	Health informatics — Workforce roles and capabilities for terminology and terminology services in healthcare (term workforce)	Not adopted	NA
179)	ISO/TS 22558:2019	Health informatics — Classification of traditional Chinese medicine data sets	Not adopted	NA
180)	ISO 22600-1:201 4	Health informatics — Privilege management and access control — Part 1: Overview and policy management	Adopted	IS/ISO 22600-1 : 2014

181)	ISO 22600-2:201 4	Health informatics — Privilege management and access control — Part 2: Formal models	Adopted	IS/ISO 22600-2 : 2014
182)	ISO 22600-3:201 4	Health informatics — Privilege management and access control — Part 3: Implementations	Adopted	IS/ISO 22600-3 : 2014
183)	ISO/TS 22691:2021	Health informatics — Token-based health information sharing	Not adopted	NA
184)	ISO/TR 22696:2020	Health informatics — Guidance on the identification and authentication of connectable Personal Healthcare Devices (PHDs)	Adopted	IS 17851 : 2022 ISO/TR 22696:2020
185)	ISO/TS 22703:2021	Health informatics — Requirements for medication safety alerts	Not adopted	NA
186)	ISO/TS 22756:2020	Health Informatics — Requirements for a knowledge base for clinical decision support systems to be used in medication-related processes	Adopted	IS 17768 : 2022
187)	ISO/TS 22773:2019	Health Informatics — Categorial structures for the representation of the decocting process in traditional Chinese medicine	Not adopted	NA
188)	ISO/TS 22789:2010	Health informatics — Conceptual framework for patient findings and problems in terminologies	Not adopted	NA
189)	ISO/TS 22835:2018	Health informatics — Information model of combination of decoction pieces in Chinese medicines	Not adopted	NA
190)	ISO 22857:2013	Health informatics — Guidelines on data protection to facilitate trans-border flows of personal health data	Adopted	IS 17797 : 2022 ISO 22857:2013
191)	ISO/TS 23303:2020	Health informatics — Categorial structure for Chinese materia medica products manufacturing process	Not adopted	NA
192)	ISO/TR 23358:2022	Health informatics — A case study on establishing standardized measurement data in cardiac examination reports	Not adopted	NA
193)	ISO/TS 23535:2022	Health informatics — Requirements for customer-oriented health cloud service agreements	Not adopted	NA
194)	ISO/TS 23541-1:202 1	Health informatics — Categorial structure for representation of 3D human body position system — Part 1: Bones	Not adopted	NA
195)	ISO	Health informatics — Interoperability and	Adopted	IS/ISO 23903 :

	23903:2021	integration reference architecture — Model and framework		2021
196)	ISO/TS 24289:2021	Health informatics — Hierarchical file structure specification for secondary storage of health-related information	Not adopted	NA
197)	ISO/TR 24290:2023	Health informatics — Datasets and data structure for clinical and biological evaluation metrics in radiotherapy	Not adopted	NA
198)	ISO/TR 24291:2021	Health informatics — Applications of machine learning technologies in imaging and other medical applications	Not adopted	NA
199)	ISO 25237:2017	Health informatics — Pseudonymization	Adopted	IS/ISO 25237 : 2017
200)	ISO 27269:2021	Health informatics — International patient summary	Adopted	IS 17888 : 2022
201)	ISO/TS 27527:2010	Health informatics — Provider identification	Adopted	IS/ISO/TS 27527 : 2010
202)	ISO 27789:2021	Health informatics — Audit trails for electronic health records	Adopted	IS 18303 : 2023/ ISO 27789:2021
203)	ISO/TS 27790:2009	Health informatics — Document registry framework	Not adopted	NA
204)	ISO 27799:2016	Health informatics — Information security management in health using ISO/IEC 27002	Adopted	IS/ISO 27799 : 2016
205)	ISO/HL7 27931:2009	Data Exchange Standards — Health Level Seven Version 2.5 — An application protocol for electronic data exchange in healthcare environments	Not adopted	NA
206)	ISO/HL7 27932:2009	Data Exchange Standards — HL7 Clinical Document Architecture, Release 2	Not adopted	NA
207)	ISO/HL7 27951:2009	Health informatics — Common terminology services, release 1	Not adopted	NA
208)	ISO/HL7 27953-1:201 1	Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance — Part 1: Framework for adverse event reporting	Not adopted	NA
209)	ISO/HL7 27953-2:201 1	Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance — Part 2: Human pharmaceutical reporting requirements for ICSR	Not adopted	NA
210)	ISO/TR 28380-1:201 4	Health informatics — IHE global standards adoption — Part 1: Process	Not adopted	NA

211)	ISO/TR 28380-2:201 4	Health informatics — IHE global standards adoption — Part 2: Integration and content profiles	Not adopted	NA
212)	ISO/TR 28380-3:201 4	Health informatics — IHE global standards adoption — Part 3: Deployment	Not adopted	NA
213)	ISO 29585:2023	Health informatics — Framework for healthcare and related data reporting	Under adoption & Old edition adopted	MHD/17/25056 (IS/ISO/TR 22221 : 2006)
214)	ISO 41064:2023	Health informatics — Standard communication protocol — Computer-assisted electrocardiography	Under adoption & Old edition adopted	MHD/17/25057 (IS/ISO 11073-91064 : 2009)
215)	IEC 80001-1:202 1	Application of risk management for IT-networks incorporating medical devices — Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software	Not adopted	NA
216)	IEC/TR 80001-2-1:2 012	Application of risk management for IT-networks incorporating medical devices — Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples	Not adopted	NA
217)	IEC/TR 80001-2-2:2 012	Application of risk management for IT-networks incorporating medical devices — Part 2-2: Guidance for the communication of medical device security needs, risks and controls	Adopted	IS/IEC/TR 80001-2-2 : 2012
218)	IEC/TR 80001-2-3:2 012	Application of risk management for IT-networks incorporating medical devices — Part 2-3: Guidance for wireless networks	Not adopted	NA
219)	IEC/TR 80001-2-4:2 012	Application of risk management for IT-networks incorporating medical devices — Part 2-4: General implementation guidance for Healthcare Delivery Organizations	Not adopted	NA
220)	IEC/TR 80001-2-5:2 014	Application of risk management for IT-networks incorporating medical devices — Part 2-5: Application guidance — Guidance for distributed alarm systems	Not adopted	NA
221)	IEC/TR 80001-2-8:2	Application of risk management for IT-networks incorporating medical devices — Part 2-8:	Not adopted	NA

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	016	Application guidance — Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2		
222)	IEC/TR 80001-2-9:2 017	Application of risk management for IT-networks incorporating medical devices — Part 2-9: Application guidance — Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities	Not adopted	NA
223)	ISO/TR 80001-2-6:2 014	Application of risk management for IT-networks incorporating medical devices — Part 2-6: Application guidance — Guidance for responsibility agreements	Not adopted	NA
224)	ISO/TR 80001-2-7:2 015	Application of risk management for IT-networks incorporating medical devices — Application guidance — Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1	Not adopted	NA
225)	ISO 81001-1:202 1	Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts	Not adopted	NA
226)	IEC 81001-5-1:2 021	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle	Not adopted	NA
227)	IEC 82304-1:201 6	Health software — Part 1: General requirements for product safety	Adopted	IS/IEC 82304-1 : 2016
228)	ISO/TS 82304-2:202 1	Health software — Part 2: Health and wellness apps — Quality and reliability	Adopted	IS/ISO/TS 82304-2 : 2021