BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

AGENDA
21st Meeting of Health Informatics Sectional Committee, MHD 17

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

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

Date/Day	13 October 2023, Friday
Time	10.30 AM
Webex Link	https://bismanak.webex.com/bismanak/j.php?MTID=m191312d654543fdac3dd582f98641a53

ITEM 0 General

ITEM 0.1 Welcome address by Head (MHD)

ITEM 0.2 Opening Remarks by the Chairperson

ITEM 1 Formal confirmation of minutes of the previous meeting

1.1 The minutes of the Twentieth meeting of Health Informatics Sectional Committee, MHD 17 held on 24 July 2023 duly approved by the Chairperson for the meeting were circulated vide BIS DG letter No. MHD 17/A-2.20 dated 08 September 2023 to all members. No comments have been received on the minutes.

The Committee may kindly formally confirm the minutes.

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

The BIS Guidelines for Research & Development Projects for Formulation and Review of Standards is placed at Annex-1.

The Committee may kindly note. Members are 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 standards for finalization

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

The Committee may please deliberate and decide.

ITEM 4 Draft standards for approval for wide circulation

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

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

ITEM 5 New Subjects

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

The Committee may please note.

ITEM 6 Review of Subcommittees/Panels under MHD 17

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

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

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

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

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

The Committee may please review.

ITEM 7 International Activities

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

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

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

7.2 The next Plenary/Working Group meetings of ISO/TC 215 and SC 1 have been scheduled during 8-16 Nov 2023 in Arlington, USA in which an Indian delegation comprising of the following members have been recommended by Chairperson, MHD 17 for participation in the meetings:

S.No.	Member	Meetings to be attended	Date	Funding
1.	Dr. S. B. Bhattacharyya, In personal capacity	WG 10	9 Nov 2023	Full Funding by BIS
		WG 11	8-10 Nov 2023	
		WG 6	13-15 Nov 2023	
		TF5	14 Nov 2023	
		TC 215 and SC 1 Plenary Meetings	16 Nov 2023	
2.	Dr. S. B. Gogia, In personal capacity	WG 11	8-10 Nov 2023	Full Funding by BIS
		WG 3	13-14 Nov 2023	
		TF 7	13 Nov 2023	
3.	Dr. Raghavendra Naik, Ministry of AYUSH (Member, Health Informatics-AYUSH Subcommittee)	WG10	9 Nov 2023	Funding by Ministry of AYUSH
		WG 11	8-10 Nov 2023	
		WG 6	13-15 Nov 2023	
		TC 215 Plenary Meetings	16 Nov 2023	
4.	Ms. Ankita Srivastava, Scientist-D, BIS (Member, Health Informatics-AYUSH Subcommittee)	WG10	9 Nov 2023	Full Funding by BIS
		WG 11	8-10 Nov 2023	
5.	Mr. Chandan Kumar, Scientist-C, BIS (Member Secretary, MHD 17)	WG10	9 Nov 2023	Full Funding by BIS
		WG 11	8-10 Nov 2023	
		WG 3	13-15 Nov 2023	
		TF 7	13 Nov 2023	
		TC 215 and SC 1 Plenary Meetings	16 Nov 2023	

** WG 3 = Semantic Content, WG 6 = Medicine and Pharmacy Business, WG 10 = Traditional Medicine, WG 11 = Personalized Digital Health, TF5 = AI technologies in health informatics, TF7 = Telehealth and Virtual Care Standards, SC 1 = Genomics Informatics*

The delegation proposal has been put up for further consideration and approval of the Competent Authority in BIS.

As the meeting is in hybrid mode, other members who are nominated on the respective WGs are requested to register and attend the meetings virtually under intimation to BIS.

The Committee may kindly note.

7.3 Hosting ISO/TC 215 Plenary and WG Meeting in India in 2024: In the last meeting, the Committee had recommended to host the ISO/TC 215 Plenary and WG Meetings in New Delhi during 20-24 Oct 2024. However, these dates coincide with the IEC General Meeting 2024 which is scheduled during 21-25 Oct 2024 in Edinburgh, UK. As IEC General Meeting is organized on a very big scale and several TC 215 experts may also like to participate in the IEC GM, it is proposed to reschedule to the ISO/TC 215 meeting to be hosted in India.

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

ITEM 8 Programme of Work

8.1 The programme of work of Health Informatics Sectional Committee, MHD 17 is available at the BIS portal: https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/pow_new .

The Committee may please note.

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

As per the policy of the BIS, the Indian Standards that have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned sectional committee for their reaffirmation/revision/withdrawal/amendment; the review is to be done based on the latest technology developments/industrial trends world over as well as their application in the Indian context. The committee may review the standards based on their usage, salability and relationship with regulatory bodies, and recommend for their retainment/withdrawal. A policy decision has been taken by the BIS management to withdraw all those Indian Standards which are no longer required by the industry and/or trade.

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

S.No.	Indian Standards	Due Date
1.	IS/ISO 11615 : 2017	Oct 2023
2.	IS/ISO 21549-7 : 2016	Oct 2023
3.	IS/ISO/IEEE 11073-10419 : 2016	Nov 2023
4.	IS/ISO/IEEE 11073-10422 : 2017	Nov 2023
5.	IS/ISO/IEEE 11073-91064 : 2009	Nov 2023
6.	IS/ISO/TS 22077-2 : 2015	Nov 2023
7.	IS/ISO/TS 22077-3 : 2015	Nov 2023
8.	IS/ISO/IEEE 11073-10201 : 2004	Dec 2023
9.	IS/ISO/IEEE 11073-20101 : 2004	Dec 2023
10.	IS/ISO/IEEE 11073-30300 : 2004	Dec 2023
11.	IS/ISO/IEEE 11073-30400 : 2012	Dec 2023

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

ITEM 9 Scope and Composition of the Sectional Committee

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

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

(b) To coordinate with the work of :

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

The Committee may review its scope.

9.2 The present composition of MHD 17 is given at Annex-3. The Committee may note and review its composition according to the following BIS guidelines, keeping reasonable and manageable number

of members on the committee:

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

9.2.1 As directed by DG, BIS, Public Health Foundation of India (PHFI) was approached for associating with BIS in the standardization activity under Medical Equipment and Hospital Planning Division Council and the technical committees under it. In response, PHFI has expressed interest in becoming a member of MHD 17 Sectional Committee among other committees and has nominated the following representatives:
(a) Dr. Pushkar Kumar, Director-Trainings (Principal Member)
(b) Mr. Dilip Kumar Jha, Deputy Project Director, Training Division (Alternate Member)

The Committee may deliberate and decide.

9.2.2 An email dated 04 October 2023 has been received from Dr. Sheila John representing Sankara Nethralya, Chennai with a request for becoming a member of the MHD 17 Committee.

The Committee may deliberate and decide.

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

Action taken report on the minutes of the previous meeting is given at Annex-4.

The Committee may please note.

ITEM 11 Date and place for the next meeting

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

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

ITEM 12 Any other business

Annex-1

GUIDELINES FOR RESEARCH & DEVELOPMENT PROJECTS FOR FORMULATION AND REVIEW OF STANDARDS

1 INTRODUCTION

Bureau of Indian Standards (BIS), as the National Standards Body of India is responsible for formulating Indian Standards for products, processes and services. In the pursuit of this endeavour, it has so far developed more than 22000 Indian Standards. Action Research and Research & Development Projects have always been part of the standardization process. However, there has been a growing realisation in the context of the increasing diversification, innovation and complexities in the manufacturing sector and evolution of services and also due to the fast pace of changes in the manufacturing and services landscapes, research & development projects have to be made an integral part of the standardization process. The idea is that in principle no standard should be developed without intensive and insightful research work, which is not confined only to the review of the existing literature and focus group discussions on the subject chosen for standardization, but also covers the detailed field level study of the existing processes and practices in product manufacturing and service delivery. This requires a large network of domain area experts to carry out the research & development work. The existing network encompasses only a small segment of experts, who are either associated with technical committees as members or belong to some R&D organizations. The Memorandum of Understanding with the premier educational institutions imparting technical and professional education opens the window to the opportunities to expand this network substantially by utilizing the intellectual capital that resides with the faculty and the research scholars in these institutions. This association is conceived not only as a way to promote research & development work necessary for standards formulation but also to enrich the research ecosystem in these educational institutions.

2 OBJECTIVES

Objectives of this Scheme are to:

2.1 support and commission research & development projects to generate knowledge, empirical data and insights that would help in formulating new standards and updating & upgrading the existing Indian standards;

2.2 expand the network of domain area experts to carryout research & development projects in the areas related to standardization and conformity assessment; and

2.3 enrich the research ecosystem in the educational institutions imparting technical and professional education.

3 RESEARCH & DEVELOPMENT PROJECTS

3.1 Research & development projects under these guidelines are described as follows:

A project aimed at comprehensive, in depth and incisive study of a product, process or service or all taken together in respect of a subject under standardization, encompassing literature review, analysis of the data from secondary sources, collection and analysis of data from primary sources and stakeholder consultations.

3.2 The duration of a project shall not exceed six months counted from the date of the award of the project to acceptance of the final report by the Sectional Committee concerned, provided that the Sectional Committee must not take more than one month to give its decision on the final report. Further provided that the time taken by the Sectional Committee for giving its decision shall not be counted. The Sectional Committee may extend the duration but for not more than 2 months in special circumstances, the reasons for which shall be recorded in the minutes of meeting of the Sectional Committee.

3.3 The upper limit for expenditure for a project shall be Rs 10 lakhs (including taxes) only.

3.4 BIS will publish a list of research & development projects along with Terms of Reference (ToR) on Standardization portal or any other suitable digital platform.

3.5 If any organization or an expert on behalf of an institute wants to propose a research & development project on any new and emerging area in which they have expertise, they can do so through the same platform for the consideration of the Sectional Committee.

4 TERMS OF REFERENCE (ToR)

4.1 The ToR of Research& development project shall be prepared by the Sectional Committee concerned, and shall contain:

a) Title, background and objectives of the study;
b) Expected research methodology (brief information, for example, survey, testing, industry visits, etc.);
c) Scope of study;
d) Outline of the tasks and final deliverables expected from the Proposers;
e) Methods of review, schedule for submitting the 1st draft report and project completion report;
f) Any support or inputs to be provided to the Proposer; and
g) Maximum duration of project and timelines for submission of proposal.

4.2 While preparing the Terms of Reference (ToR) the sectional committee may consider the following points as a research & development project may include one or mix of the following:

a) Secondary research based on internet or published information including authentic data

sources;

b) Survey based research (including industry visits) to ascertain prevailing market conditions and practices, standards in use, industry and consumer preferences, availability of infrastructure, technical capabilities, comparative trends, economic trends;
c) Ascertaining compliance to existing and proposed standards through testing, review of past test reports, other validation and verification checks; and
d) Basic and innovative research to establish normative criteria. Criteria may include performance, health, safety, environmental impact.

5 APPROVAL OF COMISSIONING OF THE RESEARCH AND DEVELOPMENT PROJECTS

5.1 There shall be a Review Committee for approving the projects recommended by the Sectional Committee. The composition of Review Committee shall be as follows:

DDG (SCMD)	: Chairperson
DDG (Standardization) concerned	: Member
DDG (Certification)	: Member
DDG (Labs)	: Member
Officer in-charge for research works in SCMD	: Member Secretary

5.2 The Head of Technical Department concerned and Member Secretary of the Sectional Committee shall apprise the review committee about the project and explain the rationale behind the proposed research & development project.

6 ELIGIBILITY CRITERIA

6.1 The following shall be eligible for carrying out research & development projects under the Scheme:

a) Academic institutions & universities having MoU with BIS and faculties and research scholars thereof;
b) Member(s) of Technical Committees of BIS.

6.2 Faculties and research scholars shall submit proposals through their institute. Members of technical committees belonging to any association/organization shall submit the proposals through their association/organization. Members of technical committees in personal capacity can submit their proposals directly to BIS, however if carrying out a research & development project requires collaboration with any institution/organization, concurrence of the same shall also be submitted.

7 PROCEDURE FOR APPLICATION

7.1 Submission of Proposal

7.1.1 Applications for undertaking research & development projects shall be submitted in the manner prescribed by the Bureau and within the prescribed timelines,

7.1.2 Proposer(s) shall submit their proposal in a "single stage - two envelope bid system" consisting of separately sealed "Technical and Financial proposals". The Technical Proposal shall be submitted as per format prescribed in **Annex A** and the Financial Proposal shall be submitted in the format prescribed as per **Annex B**, clearly specifying expected expenditure against each element such as manpower, equipment (shall not include computer hardware and software), travelling, testing, consumables, stationery, overheads, etc.

7.1.3 There shall be maximum one proposal from one institute on a given subject.

7.1.4 No contractual obligation whatsoever shall arise until a formal agreement is signed and executed between the Bureau and the Proposer.

7.2 The proposals shall inter-alia consist of the following:

7.2.1 In respect of the research & development projects put up by the Bureau:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the project and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the research as proposed.
c) A write up on the understanding of the scope and objectives of the project.
d) Methodology (sampling size, if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Stage wise timelines for completion of the project.

7.2.2 In respect of research & development projects proposed by any expert/organization:

a) Details of the Project team along with the organization/institution associated with;
b) The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project Leader and expert/expert(s) to undertake the study as proposed.
c) Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable;
d) Methodology (sampling size if applicable) to be adopted for the proposed study with a clear road map and time plan for completion of the project;
e) Details of infrastructure facilities available for the project, in the institution and additional facilities required (if any) for carrying out research.
f) Stage wise timelines for the completion of the project

7.3 The Head of the concerned institution while forwarding the application and nominating

the project leader shall certify that:

a) the core facilities (land, buildings, laboratory, manpower and other infrastructure etc.) are available and will be provided to the Project Leader to work on the proposed project,
b) the organization will discharge all its obligations, particularly in respect of management of the financial assistance given, and
c) no other funding is being received/sought for the project proposed to be sanctioned by BIS.

8 PROCEDURE FOR APPROVAL WITHIN BIS

8.1 There shall be a Research Evaluation Committee (REC) to evaluate the proposals received, the composition of which shall be as follows:

DDG (PRT)	: Chairperson
Head (CMD) concerned	: Member
Head (LPPD)	: Member
Head of the Technical Department concerned	: Member
Director Finance	: Member
Two Experts from the Sectional Committee concerned	: Members
Head (SCMD)	: Member Secretary

*The experts shall be nominated by the Sectional Committee and the nominated members shall give a declaration to the effect that there is no conflict of interest with respect to the project.

8.2 The evaluation and selection will be as per Quality and Cost Based Selection (QCBS) method (Rule 192, GFR 2017) which is explained in **Annex C**.

8.3 The criteria for evaluation of technical proposal shall be as under:

Sl No.	**Criteria**	**Max. Marks**	**Score by REC**
1	Profile of key individual/individuals to be associated with the research project	**10**	
2	Experience of the individual/organisation in conducting research projects in the relevant discipline	**20**	
3	Understanding of Scope, Objectives and deliverables	**15**	
4	Methodology	**30**	
5	Work plan/Execution strategy	**15**	
6	Chapterisation, contents and lay out of the proposed report	**10**	
	TOTAL	**100**	

Note: REC may call for a presentation by the proposers if deemed necessary.

8.4 The minimum qualifying marks shall be 70. All the proposals with marks below 70 shall be considered rejected.

8.5 REC may refer back, advise changes for reconsideration or reject any proposal.

8.6 REC shall open the financial proposals (bids) within 7 days from completion of technical evaluation.

8.7 A final score sheet of all the proposers shall be made as detailed in **Annex C** and the proposer getting the highest combined score shall be selected for awarding the project.

8.8 The member secretary (REC) shall send the selected proposals to DG/DDG Standardization concerned, as per their delegated powers, for consideration and approval for sanction of the project.

8.9 After the approval of project, the member secretary (REC) shall inform the concerned technical department and the proposer regarding the decision.

8.10 After the sanction of fund is approved, the draft agreement (prepared in line with model agreement given at **Annex D**, to be modified on case-to-case basis) shall also be prepared by the Member Secretary (Sectional Committee), clearly highlighting the payment term. The Head (Technical Department) shall sign the agreement on behalf of BIS in all cases.

8.11 In case the proposer to whom the project is awarded declines to take up the project, the Research project shall be awarded to the proposer getting the next highest combined score among the qualified proposers.

9 SIGNING OF AGREEMENT AND ISSUING OF SANCTION LETTER

9.1 After receipt of duly signed agreement from the proposer and after the receipt of the approval of competent authority, a sanction letter shall be issued by the concerned Head (Technical Department) to the organization/individual member. The project would be considered to have commenced from the date the sanction letter is issued.

10 FUNDING

10.1 The mode of payment for Research & development projects shall be as follows:

a) First instalment up to a maximum of 30 percent of the total approved project cost would be released after approval of the project.
b) Second instalment to the extent of 50 percent of the approved estimated cost would be released on the submission of progress report along with the report on utilization of the 75 percent of the fund and acceptance of the same by the Sectional Committee.

c) The balance amount shall be released after submission of the final project report along with utilization certificate for the fund released and its acceptance by the Sectional Committee.

10.2 Release of each instalment is subject to satisfactory progress, required stage - wise deliverables and submission of the Utilization Certificate (UC) as per Form GFR12-A of GFR 2017 along with the statement of expenditure (SoE) issued by the Competent Authority.

11 PROGRESS REPORT AND MONITORING OF PROJECT

11.1 The relevant Sectional Committees of BIS will monitor the progress of project to ensure that the project is progressing as per the planned arrangement. However, member secretary of the concerned Sectional Committee under overall coordination of HoD would be the controlling/link officer for Research & Development projects and would constantly monitor the progress of the project every 30-45 days. Any delay in implementation of project should be duly justified by the Project leader and shall be put up to Research Evaluation Committee (REC) for approval.

11.2 The Sectional Committee shall review and give its acceptance of the progress reports submitted, within 3 weeks.

12 SUBMISSION OF FINAL PROJECT REPORT (FPR)

12.1 The FPR must be detailed and should include information about:

a) the original objective(s) of the project,
b) how far these objective(s) have been achieved, and
c) how the results will benefit the development of the national standard(s) and
d) a copy of final working draft of the concerned standard(s) (wherever applicable)
e) include clear inferences, recommendations regarding their use in the proposed standards,
f) all references used, raw data of surveys, sampling, testing and experiments,
g) undertaking that all the information presented is authentic.

12.2 FPR received in BIS would be put up to the concerned Sectional Committee, which will take necessary action for preparation/revision of standard appropriately. The Project leader shall assist in the disposal of comments received on the research project, draft standard and for the preparation of the finalized draft, as may be desired by the Sectional Committee.

12.3 The proposer shall submit the Project Completion Report (PCR), within one month of completion of project along with the Utilization Certificate of the fund released as per Form GFR 12-A of GFR 2017 and the statement of expenditure (issued by the Competent Authority -in case of Govt. organization / Charted Accountant in case of private organization).

13 RESULTS OF RESEARCH & DEVELOPMENT

13.1 Project Leader(s) would be encouraged to publish the results of research & development. While doing so, acknowledgement to the effect that financial assistance was received from BIS

should be made in the research paper(s) published. BIS should be acknowledged in similar type of other published work/press reports.

13.2 One re-print of each research paper(s) published as a result of the work done under the BIS funds shall be sent to BIS as and when published.

14 INTELLECTUAL PROPERTY RIGHTS

14.1 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by Proposer shall be vested with that Party.

14.2 Ownership of any intellectual property, including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights, developed solely by the Bureau shall be vested with that Party.

14.3 The Intellectual Property arising out as an outcome of research project undertaken under these guidelines shall be vested with Bureau.

15 OPERATION OF FUNDS

15.1 The utilization certificate of the funds received in previous instalment (if any) to BIS should be annexed with the Statement of all equipment, books, etc purchased out of the funds certified by the Head of the organization. The name, description of the equipment, cost in rupees, date of purchase, and the name of the supplier to be given in the list. The main purpose/function of the equipment may also be mentioned against each item.

15.2 Any unspent balance lying with the organization should be refunded to BIS after the finalization of the draft immediately, by means of demand draft or online transfer.

15.3 The Head of the concerned standardization department of BIS shall ensure that the project leader submits the utilization certificate in the manner prescribed in Form GFR 12-A of GFR 2017.

15.4 Head of the Standardization department shall also ensure that the operation of funds is monitored strictly as specified in **Annex E**. Further the Project Leader is also fully aware and shall adhere to the obligations of his/her as given in this procedure.

16 OTHER REQUIREMENTS

16.1 Organizations receiving financial assistance for research & development projects from BIS would have to maintain separate accounts for each research project.

16.2 In the event of a Project Leader's absence from his normal place of duty for two months at a stretch, the Head of the organization would need to immediately nominate an Alternate Project Leader(s) to supervise the implementation of the project and such a name has to be approved in advance by BIS. In any event, a Project Leader shall give prior notice to BIS of his intention to stay away from the project.

16.3 Items of equipment, etc should be purchased on the basis of the established rules and procedures of the entity/organization.

16.4 Stock register of all equipment, books, etc purchased out of the funds shall be maintained.

16.5 Any capital-intensive equipment/devices purchased using financial assistance from BIS for research & development projects shall be allowed to be retained by the proposer for their research activity etc.

16.6 The organization shall have to ensure that expenditure with respect to TA/DA are made only as per their own norms but under no circumstances the executive/business class air travel or stay in a five-star hotel is made. The overhead expenses should not be more than 20 percent of the cost of the project.

16.7 The Project Leader must ensure that the concerned organization's newsletter would carry information on the activities and accomplishments of the various projects funded by the BIS.

16 TERMINATION OF PROJECT:

The research & development project can be terminated in case of any of the following:

a) the approval of research & development project may be treated as withdrawn, if the sanctioned research & development project does not commence within one month from the date of receipt of the sanction letter, unless otherwise authorized by BIS;
b) A Proposer may request for the withdrawal of a research & development project even after commencement of the project. In such case the entire fund given till that date shall be refunded to the Bureau; and
c) if the Proposer fails to submit Progress report/Completed Project report within the prescribed timelines.

The REC shall take decision on all cases of termination.

18 RESOLUTION OF DISPUTES

Dispute Resolution: In case of any dispute that cannot be resolved amicably, it shall be referred to Sole Arbitrator appointed by the Director General of the Bureau of Indian standards, whose decision shall be final and binding upon both the parties. The provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time, shall be applicable.

ANNEX A

TECHNICAL PROPOSAL

1. Name of the Proposer and Organization	
2. Project title	

3. Project leader

a) Title: Prof/Dr/Mr/Ms b) Name:		Sex M/F
c) Full official address		
Mobile/Telephone Fax E-mail		
d) Designation		
e) Date of birth		
f) Academic qualifications along with year of completion		
g) Experience		

4. Other members of the research team (give name, address, experience and academic qualifications for each member)

1. Name	Designation: Address: Experience: Academic Qualifications:
1. Name	Designation: Address: Experience: Academic Qualifications:

5. Research support availed/being availed/applied for by the Project leader from different sources, including BIS, during the last 5 years:

Funding agency	Title of the project and reference number	Duration (from mm/yyyy to mm/yyyy)	Percentage of time devoted /being devoted/to be devoted, in man months	Amount in lakh Rs.

6. Details of facilities available with the institute/organization w.r.t. the research & development project

Facilities	Relevance to project
1.	

7. Aims and significance of the project
(Include the current status of work in area, both in India and abroad, with appropriate reference list at the end; identify lacunae, define question to be investigated; list briefly specific objectives of investigation. ethical clearance be enclosed where necessary).

8. The CV of the Project leader and expert/expert(s) to be associated with the projects and a letter from organization authorizing Project leader and expert/expert(s) to undertake the study as proposed.

9. Objective that will be achieved and scope of the project clearly highlighting the need of such study and what would be the final deliverable.

10. Methodology (sampling size if applicable) to be adopted for the proposed study.
11. Road map (Stage wise timelines for the completion of the project) and time table for completion of the project
12. Plan of work, methods and techniques to be used.
13. List of awards and honours conferred on the Project leader with dates.
14. Deliverables
15. Declaration and attestation:

I certify that all the details declared here are correct and complete. Signature of Project leader	Date:

12. Certificate of the institution:

This is to certify that a) we have read the terms and conditions of the BIS Research & Development Guidelines necessary for the compliance of the same. b) the necessary institutional facilities are available and will be provided for the implementation of this research proposal being submitted to the BIS for funding. c) Full account of expenditure will be rendered by the institution.
Name of the head: of the institution Signature with date: Seal:

ANNEX B

FINANCIAL PROPOSAL FORMAT

[To be submitted on letterhead wherever applicable]

To:
Bureau of Indian Standards
Manak Bhavan, 9 Bahadur Shah Zafar Marg
New Delhi – 110002, India

Sub: Financial Proposal for Research & development Project on (Title: _____)
for Bureau of Indian Standards (Research guidelines document no._____dated ---------- 2023).

Dear Sir,

We are pleased to submit our Financial Proposal for Research & Development Project on (Title: _____) for Bureau of Indian Standards as per the terms and conditions of the Research & Development guidelines document (Ref No.: _____ dated: ___-___-2023).

1. We hereby declare that our financial proposal is unconditional in all respects.
2. Our financial proposal is as follows:

3. Cost of the Project:

Sl no.	Budget items	Amount
1	Manpower cost	
2	Consumables [Chemicals, samples, testing glassware, stationery, books etc, information search (from databases)]	
3	Equipment	
4	Travel	
5	Any other/Overhead expenses	
	Total project cost	

*Please write NA in case any item is not applicable

a) The prices should be quoted in Indian Rupees above by the proposer.

b) The quoted price should be inclusive of all applicable taxes and charges.

c) Fund shall be released after deducting TDS as per applicable provisions of GST and income tax.

d) Justification of cost (for each item of equipment, consumables and travel. Quotation(s) for equipment should also be enclosed).

Yours faithfully,

Date: (Signature of the Project leader)

Place: (Name and Designation of the proposer)

Name and Signature of the head of the institution

(Rubber seal of the proposer/institution/organization, as applicable)

ANNEX C

Stage 1: Evaluation of Technical Proposal:

a) The proposal will be evaluated against the criteria defined at clause 8 in these Guidelines. The proposer may be required to provide additional details as deemed necessary by the REC.

b) Upon technical evaluation of each proposal, "Technical marks" out of 100 marks will be assigned to every proposal.

c) The proposals with score 70 or more marks in technical evaluation, will qualify for the evaluation of the financial proposal.

d) The proposer with the highest marks in technical proposal will be awarded 100 "Technical Score" and subsequently other proposers will also be awarded "Technical Score" relative to the highest technical marks for the final composite score calculation purpose e.g., if the highest technical marks is 90 then "Technical Score" is (90/90) × 100 = 100, hence the proposer with highest technical marks will score 100"Technical Score". Similarly, another proposer who scored 80 marks, will get (80/90)x 100 = 88.88 "Technical Score". Following formula will be used for the "Technical Score" (TS) calculation:

$$\text{Technical Score (TS)} = \left\{ \frac{\text{Proposer's Technical Marks}}{\text{Highest Technical Marks}} \right\} \text{ X } 100$$

e) The details of technical evaluation parameters are provided at clause 9.

Stage-2 Evaluation of Financial Proposal

a) The evaluation will be carried out if financial proposals are complete and computationally correct.

b) Upon financial evaluation of each proposal, the lowest financial proposal will be awarded 100 "Financial score". The "Financial Score" of other proposer(s) will be computed by measuring the financial proposal against the lowest financial proposal. Following formula will be used for calculating "Financial Score":

$$\text{Financial Score (FS)} = \left\{ \frac{\text{Lowest Financial proposal}}{\text{Proposer's Financial Proposal}} \right\} \text{ X } 100$$

Stage-3 Computation of Combined Score

The "Combines Score" is a weighted average of the Technical and Financial Scores. The ratio of Technical and Financial Scores is 70:30 respectively. The Combined Score will be derived using the following formula:

$$\text{Combined Score} = [(\text{TS} \times 0.70) + (\text{FS} \times 0.30)]$$

The responsive proposers(s) will be ranked in descending order according to the Combined Score, which is calculated based on the above formula. The highest-ranking proposer asper the Combined Score will be selected for award of Research Project.

ANNEX D

MODEL AGREEMENT

(To be modified on case-to-case basis)

This Deed of Agreement made this _____day of _____(Month & Year) between Bureau of Indian Standards having Head Office at Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi – 110 002 (hereinafter called 'BIS', which expression shall, wherever the context so admits, includes its successors and assigns) on one part and (name of the organization/expert) (hereinafter called _____which expression shall, wherever the context so admits, include their heirs, executors, administrators, legal representative and assigns) of the other part, witness as follows:

1. Whereas (name of the organization/expert) through (name of the Project Leader) has submitted a proposal to BIS pertaining to Research & development project titled _____for consideration and BIS has accepted the proposal.

2. That duration of the Research & development project shall be ___months with periodic and final reviews. The total cost of the project shall be Rs_____/- (Rupees in words) for the complete project. No further expenditure shall be borne by BIS on any account of this project including escalation of time.

3. The fund would be utilised for the specific project/assignment as approved by BIS and shall be spent within the specified time. Any portion of the fund which is ultimately not required for expenditure for the approved purpose shall be duly surrendered to BIS.

4. (Name of the organization/expert) shall not entrust the implementation of the project/assignment approved by BIS for which fund has been received to any other institution/expert or to divert the fund received from BIS as assistance to any other institution/expert/proposer.

5. (Name of the organization/expert) indemnifies BIS from any legal and/or financial encumbrance arising out of any infringement of IPR/licensing of IPR/technology transfer/commercialization.

6. (Name of the organization/expert) shall maintain an audited record in the form of a register for permanent, semi-permanent assets acquired solely or mainly out of BIS fund. Once the Research & development project is completed satisfactorily, the organization taking up the Research project may retain the equipment/devices for their Research & development activities, etc. The equipment procured through BIS fund should bear a label "BIS Funded".

7. BIS shall release the funds for the project as follows:

a) First instalment up to a maximum of 30 percent of the total approved project cost would be released after approval of the project.

b) Second instalment to the extent of 50 percent of the approved estimated cost would be released on the submission of progress report along with the report on utilization of the 75 percent of the fund and acceptance of the same by the Sectional Committee.
c) The balance amount shall be released after submission of the final project report along with utilization certificate for the fund released and its acceptance by the Sectional Committee.

8. The completion of the Research & development project shall remain the responsibility of (name of the organization/expert) even if the project leader is not available due to any reason whatsoever. After completion of the project, a Project Completion Report giving details (objective(s) achieved, raw data of surveys, sampling, testing and experiments) of shall be submitted by the Project leader the original objective(s) of the project,

9. (Name of the organization/expert) shall ensure the completion of the project under the guidance and supervision of any other faculty/researcher, if the nominated project leader would not be available due to any reason. Such a faculty member/researcher can only be nominated with the approval of BIS.

10. In case (name of the organization/expert) is unable to complete the project to the satisfaction of BIS in stipulated time or extended time and leads to termination of the research project, BIS shall be entitled to claim the refund of fund so sanctioned with interest @ 10 percent thereon from (name of the organization/expert).

11. The authority to extend the duration of the project shall rest with BIS.

12. BIS shall have the right to formulate monitoring methodology of the Research & development project.

13. Dispute Resolution: In case of any dispute that cannot be resolved amicably, it shall be referred to Sole Arbitrator appointed by the Director General of the Bureau of Indian standards, whose decision shall be final and binding upon both the parties. The provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time, shall be applicable.

14. Undertaking given by project leader, if any, shall be part of the agreement.

15. (Name of the organization/expert) shall be responsible for discharge of all its obligations of the project through the nominated project leader or any other expert/expert(s) in case of necessity particularly in respect of management of financial assistance given to them. (Name of the organization/expert) shall refund any excess/unutilized amount of the fund to BIS.

16. Release of subsequent instalments is subject to satisfactory progress, required stage - wise deliverables and submission of the Utilization Certificate (UC) as per Form GFR12-A of GFR 2017 along with the statement of expenditure (SoE) issued by the Competent Authority.

17. (Name of the organization/expert) shall ensure that Project leader shall give presentation on the progress of project to BIS as and when directed by BIS for continuation of the project,

and shall assist in the disposal of comments received related to the Research & development Project.

18. The project shall be deemed to have been commenced from the date of release of sanction letter.

19. (Name of the organization/expert) shall ensure that while publishing the results of research & development, acknowledgement to the effect that financial assistance so received from BIS be made in the research papers published/ other published work/ press reports.

20. Procedure for screening/evaluation, selecting, monitoring Research & development projects prescribed in "Guidelines for Research & Development Projects for Formulation and Review of Standards' shall be part of the agreement.

ANNEX E

OPERATION OF FUNDS AND PROGRESS REPORT

1. Title of the Project:	Project number:
2. Name & Address of Project leader:	Date of Commencement: dd/mm/yyyy

3. Details of Equipment Purchased (if any):

Name of equipment	Cost	Supplier	Date of purchase/ placing order for each item of equipment
NOTE - The equipment fund once fixed cannot be enhanced. Project leaders are advised to give authenticated estimates of the cost of equipment. Equipment should invariably be purchased within 1 month from the date of receipt of the fund and/or sanction letter.			

4. Fund received_____.
5. Expenditure made in Rupees: (Please provide the details)

Expenditure	Amount	Taxes (as applicable)	Total
Manpower cost			
Consumables			
Equipment			
Travel			
Others			
Grand Total			

6. Amount saved (if any) from the last instalment: Rs_____.

7. Date on which scheme will complete its normal tenure of months _____.

8. Whether extension beyond normal tenure has been requested. Yes /No.

If yes, justification for extension and programme of work to be completed. Also mention as to why the work could not be completed as per the original plan.

{Extension beyond normal tenure should be requested at the Project Monitoring Session before end of tenure (as given in ToR)}.

9. Constraints (if any) faced in the progress of work and suggestions to overcome them.

10. Any deviation from original plan with its nature and cause.

11. List of publication giving full bibliographic details accrued from this project (copies of the paper (s) should be enclosed).

12. Summary of work done (200 words).

13. Proposed programme of work for the next month (1000 words).

14. Detailed Progress Report enlisting the objectives in beginning briefly (up to five pages maximum).

Signature of Project
leader Date:

Note: No column should be left blank; write not applicable (NA), wherever applicable.

ANNEX-2
(Item 3)
Documents under Wide Circulation – for finalization

S.No	Document Number	Document Title	Document Stage	WC Date	Last Date for Comments
1	MHD/17/23688 (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)	WC-Draft	02-10-2023	01-11-2023
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	WC-Draft	02-10-2023	01-11-2023
3	MHD/17/23687 (Identical To: ISO/TR 4421:2023)	Health Informatics — Introduction to Ayurveda Informatics	WC-Draft	02-10-2023	01-11-2023
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)	Under process for WC-Draft	-	-
5	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)	Under process for WC-Draft	-	-
6	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)	Under process for WC-Draft	-	-
7	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)	Under process for WC-Draft	-	-
8	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)	Under process for WC-Draft	-	-

S.No	Document Number	Document Title	Document Stage	WC Date	Last Date for Comments
9	MHD/17/23778 (Identical To: ISO/IEEE 11073-10419:2019)	Health informatics— Personal health device communication: Part 10419 Device specialization — Insulin pump (First Revision)	Under process for WC-Draft	-	-
10	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)	Under process for WC-Draft	-	-

ANNEX-3

(Item 9.2)

Committee Composition

S.No.	Organization	Name	Attendance
1.	**In Personal Capacity**	**Dr. Ashok Kumar *(Chairman)***	**3/3**
2.	In Personal Capacity	Dr. R. Rangasayee	2/3
3.	In Personal Capacity	Dr. S. B. Bhattacharyya	3/3
4.	In Personal Capacity	Dr. S. B. Gogia	3/3
5.	All India Institute of Medical Sciences, New Delhi	Dr. Sidhartha Satpathy Dr. Mahesh R. (AM) Dr. Vikas H. (YP)	0/3
6.	Boston Scientific India PrivateLimited, Gurugram	Sh. Dev Chopra Sh. Prashant Prabhakar (AM)	1/3
7.	Central Council for Research inAyurvedic Sciences (CCRAS), New Delhi	Dr. N. Srikanth Dr. Rakesh Narayanan V (AM)	3/3
8.	Centre for Development of AdvancedComputing, Pune	Sh. Gaur Sunder Sh. Praveen K. Srivastava (AM)	3/3
9.	Centre for Health Informatics, NewDelhi	Sh. Ankit Tripathi Sh. Gaurav Sharma (AM)	1/3
10.	Confederation of Indian Industry,New Delhi	Sh. Vibhav Garg Sh. Surendra Singh Rawat (AM)	1/3
11.	CSIR-Institute of Genomics andIntegrative Biology, New Delhi	Dr. Bhavana Parasher	3/3
12.	Digital Health Associates Private Limited, New Delhi	Dr. N. K. Singh Dr. Manpreet Kaur (AM) Ms. Akshita Tyagi (YP)	1/1
13.	Directorate General Armed ForcesMedical Service, New Delhi	Brig. Ramesh Kaushik Col. Sanjay Patole(AM)	0/3
14.	Disease Management Association ofIndia, Mumbai	Sh. Atantra Das Gupta Ms Mevish P Vaishnav (AM)	2/3
15.	dWise Healthcare IT SolutionsPrivate Limited, Bengaluru	Dr Pramod D Jacob Dr Joseph Alexander(AM) Shri Sreejith P (YP)	1/3
16.	HIMSS India Chapter, Bengaluru	Sh. Jeyaseelan Jeyaraj Sh. Philip Cherian (AM) Dr Nitiraj Gandhi (YP)	0/3
17.	Indian Dental Association, Mumbai	Dr Vijay Prakash Mathur Dr Ashok Dhoble (AM)	1/3

18.	Indian Institute of Technology Delhi,New Delhi	Prof. Subrat Kar	0/3
19.	Indian Institute of Technology Kharagpur, Kharagpur	Prof. Jayanta Mukhopadhyay Prof. Soumya Kanti Ghosh (AM)	3/3
20.	Indian Medical Association, NewDelhi	Dr Jayesh M. Lele Dr Pankaj Mutneja (AM)	1/3
21.	Indian Nursing Council, New Delhi	Dr Asha Sharma Dr Sandhya Gupta (AM)	3/3
22.	Indian Pharmacopoeia Commission, Ghaziabad	Dr V. Kalaiselvan Sh. Shatrunajay Shukla (AM)	2/3
23.	InformDS Technologies Private Limited, Bengaluru	Dr Randeep Singh Sh. Pawan Jain (AM) Sh. Parag Agarwal (YP)	0/3
24.	Karkinos Healthcare Private Limited, Bengaluru	Sh. Arvind Sivaramakrishnan Dr. Anjali Anant Kulkarni (AM) Sh. Hariesh Ramanathan M (YP)	1/1
25.	Koita Centre for Digital Health, IIT Bombay, Mumbai	Nominations awaited	0/0
26.	Maulana Azad Medical College, NewDelhi	Dr. Nidhi Bhatnagar Dr. Amod Borle(AM) Dr. Madan Mohan Manjhi (YP)	2/3
27.	Ministry of AYUSH, New Delhi	Dr D C Katoch	1/3
28.	Ministry of Electronics and Information Technology, New Delhi	Sh. Rashid Shaban	1/3
29.	Ministry of Health and FamilyWelfare, New Delhi	Sh. Govind Jaiswal Sh. Amit Kumar (AM)	1/3
30.	National Accreditation Board for Hospitals and Healthcare Providers, New Delhi	Dr. Atul Mohan Kochhar Dr. Punam Bajaj (AM) Ms. Neeta (YP)	2/3
31.	National Accreditation Board for Testing and Calibration Laboratories,Gurugram	Sh. Pankaj Johri Ms. Bhumi Rajyaguru Sh. Haribabu A. (AM)	3/3
32.	National Health Authority, New Delhi	Sh. Kiran Vaska Sh. Vikram Pagaria (AM) Sh. Pankaj Sharma (YP)	0/3
33.	National Health Systems Resource Centre, New Delhi	Dr. Ranjan Chaudhary Ms. Manisha Sharma (AM) Ms. Rupali Vasant Mhaskar (YP)	3/3
34.	National Institute of Health & Family Welfare, New Delhi	Prof. Pushpanjali Swain Dr. Ankur Yadav (AM)	3/3

35.	North-Eastern Hill University, Shillong	Dr Sudip Paul Sh. Shyam Mandal (AM)	3/3
36.	Philips India Limited, Gurugram	**Sh. Rajendra Prasad** ***(Vice-Chairperson)***	3/3
37.	Society for Administration of Telemedicine and Healthcare Informatics, New Delhi	Dr. Susheel Oommen John Chinmoy Lye (AM)	2/3
38.	Sri Sathya Sai Central Trust, Puttaparthi	Sh. Jai Ganesh Udayasankaran	3/3
39.	Telemedicine Society of India, Lucknow	Sh. Baljit Singh Bedi Col. (Dr) Ashvini Goel (Retd.)(AM)	3/3
40.	Trivedi School of Biosciences, Ashoka University, Sonipat	Dr. Rintu Kutum Mayank Garg (AM)	0/0

ANNEX-4
(*Item 10*)
Action Taken on the minutes of the previous meeting of MHD 17

S. No.	*Item of the last minutes*	*Decision*	*Action taken by BIS*
1.	**2.2**	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. Indian Institute of Technology, Kanpur ii. Continua Health Alliance, Mumbai	Action completed.
2.	**2.2**	The Committee decided to co-opt Koita Centre 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.	Email sent to KCDH, IIT Bombay. Nominations under process.
3.	**2.2**	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.	Email sent to DGAFMS. Response yet to be received.
4.	**2.2**	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.	The Committee may advise.
5.	**3**	The Committee decided to finalize the following Draft Indian Standards for publication without any change as no comments were received on the documents during the wide circulation stage : **1. MHD/17/22699 (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)	Documents sent for publication.

		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	
6.	**4.1**	The Committee decided to initiate the adoption the following ISO Standards and approved the wide circulation of these documents for a period of one month: **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	Please refer Item 3 of the Agenda.

		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 **11. ISO/TR 4421:2023** Health Informatics — Introduction to Ayurveda	
7.	**8.2**	The Committee decided to reaffirm/reaffirm and revise/withdraw the standards as per *Item 8.2* of the Minutes.	Action completed.