BUREAU OF INDIAN STANDARDS

MINUTES

Tenth Meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15

Chairperson :	***Member Secretary :***
Dr. V. R. Singh, Former Director-Grade-Scientist, National Physical Laboratory(NPL), New Delhi,	Chandan Kumar Scientist-C Bureau of Indian Standards

Meeting Date: 27 March 2023, Monday **Time: 02:00 pm**

Item 0 General

Member Secretary welcomed the Chairperson and all the members to the Tenth meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15.

The list of participants is attached as **ANNEX-I**.

Item 1 Confirmation of Minutes of the Last Meeting

1.1 The minutes of the previous (Ninth) meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15, held on 19 July 2022 and circulated to all the members vide letter No. MHD 15/A-2.9 dated 6 September 2022 were formally confirmed by the committee.

Item 2 Action Taken Report on the Minutes of Last Meeting

2.1 The Committee reviewed the action taken report on the minutes of the previous (Ninth) meeting given at **Annex – I of the Agenda.**

Item 3 Composition of Sectional Committee

3.1 The Committee reviewed its composition and the attendance of the members in the last three meetings. It was reiterated that if an organization does not participate in three meetings consecutively without giving any justification, it indicates lack of interest in the committee work and the committee will consider withdrawal of such organizations from its composition.

The Committee decided to follow-up with all organizations from which the nominations of representatives are pending and also for review of their current nominations, wherever required.

ITEM 4 Draft Standards for finalization

4.1 The committee deliberated on the Draft Indian Standards/Amendments which had completed wide circulation stage, and decided as follows:

S.No.	Doc No./Title	WC details	Decision of the Committee
1	**MHD 15 (19886)** (IEC 60601-1-3:2008+AMD 1:2013) Medical electrical equipment Part 1 Particular requirements for the basic safety and essential performance Section 3 Radiation protection in diagnostic X-ray equipment	**WC date**: 11 July 2022 **Last date of comments**: 10 August 2022	As a new amendment has been published to IEC 60601-1-3 in 2021 and the consolidated version is under fresh adoption, the committee decided to drop this document.
2	**MHD 15(19480)** (IEC 60601-2-28:2017) Medical electrical equipment Part 2 Particular requirements for the basic safety and essential performance Section 28 X-ray tube assemblies for medical diagnosis	**WC date**: 11 July 2022 **Last date of comments**: 10 August 2022	This standard refers to the older editions of the general standards (IEC 60601-1-X series). However, as the latest versions of the general standards are under adoption, the committee decided to drop this document and start its adoption process after that.
3	**MHD 15(19481)** (IEC 60601-2-83:2019) Medical electrical equipment Part 2 Particular requirements for the basic safety and essential performance Section 83 Home light therapy equipment	**WC date**: 11 July 2022 **Last date of comments**: 10 August 2022	This standard refers to the older editions of the general standards (IEC 60601-1-X series). However, as the latest versions of the general standards are under adoption, the committee decided to drop this document and start its adoption process after that.

ITEM 5 Draft standards for approval for wide circulation

The Committee decided to initiate the adoption of the following latest versions of IEC standards in order to revise the corresponding Indian Standards and send these documents for wide circulation for a period of one month:

S.No.	IEC standard	To Revise
1.	IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Consolidated version, Edition 3.2)	IS 13450 (Part 1):2018/IEC 60601-1:2012 Medical electrical equipment Part 1 General requirements for basic safety and essential performance (Second Revision)
2.	IEC 60601-1-2:2014+AMD1:2020 (Consolidated version, Edition 4.1)	IS 13450 (Part 1/Sec 2):2018/IEC 60601-1-2:2014 Medical electrical equipment Part 1 General requirements for the basic safety and essential performance Sec 2 Collateral standard electromagnetic disturbances - Requirements and tests (First Revision)

3.	IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 (Consolidated version, Edition 2.2)	IS 13450 (Part 1/Sec 3):2014/IEC 60601-3 : 2008 Medical electrical equipment Part 1 General requirements for basic safety and essential performance Sec 3 Collateral standard radiation protection in diagnostic X-ray equipment
4.	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 (Consolidated version, Edition 2.2)	IS 13450 (Part 1/Sec 6):2020/IEC 60601-1-6:2013 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 6 Collateral standard : Usability
5.	IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 (Consolidated version, Edition 2.2)	IS 13450 (Part 1/Sec 8):2019/IEC 60601-1-8:2006 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 8 Collateral Standard : General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
6.	IEC 60601-1-10:2007+AMD1:2013 +AMD2:2020 (Consolidated version, Edition 1.2)	IS 13450 (Part 1/Sec 10):2019/IEC 60601-1-10:2007 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 10 Collateral standard : Requirements for the development of physiologic closed-loop controllers
7.	IEC 60601-1-11:2015+AMD1:2020 (Consolidated version, Edition 2.1)	IS 13450 (Part 1/Sec 11) : 2020/IEC 60601-1-11:2015 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 11 Collateral Standard Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
8.	IEC 60336:2020 (including Corrigendum 1 published in 2022)	IS/IEC 60336:2005 Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristic
9.	IEC 62366-1:2015 +AMD 1:2020	IS/IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
10.	IEC 60601-2-43:2022	IS 13450 (Part 2/Sec 43) : 2016/IEC 6060-2-43:2010 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 43 X-ray equipment for interventional procedures (First Revision)
11.	IEC 60601-2-45:2011+AMD1:2015 +AMD2:2022 (Consolidated version)	IS 13450 (Part 2/Sec 45) : 2016/IEC 6060-2-43:2011 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 45 mammographic X-ray equipment and mammographic stereotactic devices (First Revision)
12.	IEC 60601-2-54:2022	IS 13450 (Part 2/Sec 54) : 2016/IEC 6060-2-54:2009 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 54 X-ray equipment for radiography and radioscopy

13.	IEC 60601-2-63:2012+AMD1:2017 +AMD2:2021 (Consolidated version)	IS 13450 (Part 2/Sec 63) : 2016/IEC 6060-2-63:2012 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 63 dental extra - Oral X-ray equipment
14.	IEC 60601-2-65:2012+AMD1:2017 +AMD2:2021 (Consolidated version)	IS 13450 (Part 2/Sec 65) : 2016/IEC 6060-2-65:2012 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 65 dental intra - Oral X-ray equipment

It was also decided to initiate the adoption of the following IEC standards and send these documents for wide circulation for a period of one month:

1. **IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 (Consolidated version, Edition 1.2)** Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
2. **IEC 60601-1-12:2014+AMD1:2020 (Consolidated version, Edition 1.1)** Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
3. **IEC 60522-1:2020** Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration
4. **IEC/TR 60522-2:2020** Medical electrical equipment - Diagnostics X-rays - Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

ITEM 6 Review of Programme of Work

6.1 The committee reviewed the present programme of work of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 available at BIS website www.bis.gov.in.

6.2 Review of Indian Standards published before year 2000

The Committee noted the Secretariat's observations on the Indian Standards which were published before 2000. The following decisions were taken:

S.No.	Indian Standard	Decision of the Committee
1.	IS 11393 : 1985 Specification for scintillation counters	The Committee noted that Sh. Sudhakar Mairpadi, Philips India Pvt Ltd had to submit the ARP report on the review of this standard, however, no updates have been received from him. It was informed that Sh. Mairpadi is no more associated with Philips India Pvt Ltd. It was decided to circulate a copy of the standard to the representatives of AERB, BARC and AIIMS for their inputs/comments and further decision will be taken based on the inputs received.

2.	IS 11753 : 1986 Specification for electrical impedance plethysmograph	The Committee noted that the review of this standard was allotted to Mr. Sushil Rana, Recorders and Medicare Systems Pvt Ltd, Panchkula. The review analysis has been submitted by him but the working draft is pending. Mr. Rana had recommended that the standard needs to be revised and the revision work can be done through a R&D project for which he would submit the proposal as BIS Guidelines for R&D Funds. He sought the support of experts from PGIMER (Chandigarh), BARC(Mumbai) and AIIMS (New Delhi) before putting up the proposal for the R&D project and requested BIS to facilitate.
3.	IS 11789 : 1986 Determination of the maximum symmetrical radiation field in the radiation beam from a rotating anode X-ray tube for medical diagnosis	The Committee noted that the standard is based on IEC 60806:1984 which is still valid, however, is under revision with target date of publication in Dec 2022. The Committee decided to adopt the revised version of the standard on its publication to revise IS 11789:1986.

6.3 Other standards due for reaffirmation

The Committee deliberated on the standards due for reaffirmation and decided as follows :

S.No.	Indian Standard	Due date	Decision of the Committee
1.	IS 13450 (Part 1):2018 Medical electrical equipment: Part 1 general requirements for basic safety and essential performance (Second Revision)	March 2023	**Reaffirm and revise -** Standard may be reaffirmed for a period of five years w.e.f due date and revision to be undertaken by adopting the latest edition of the corresponding IEC standard. (Please also see Item 5, S.No.1 above.)
2.	IS 13450 (Part 2/Sec 25):2018 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 25 Electrocardiographs	March 2023	**Reaffirmation** - Standard may be reaffirmed for a period of five years as the corresponding base IEC standard remains valid on date.
3.	IS 13450 (Part 2/Sec 27):2018 Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 27 Electrocardiographic monitoring equipment	March 2023	**Reaffirmation** - Standard may be reaffirmed for a period of five years as the corresponding base IEC standard remains valid on date.
4.	IS/ISO 13450 (Part 2/Sec 10) : 2018 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 10 Nerve and muscle stimulators	March 2023	**Reaffirm and revise -** Standard may be reaffirmed for a period of five years w.e.f due date and revision to be undertaken by adopting the latest edition of the corresponding IEC standard. (Please also see Item 5, S.No.7 above.)

5.	IS/IEC 61689 : 2013 Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz	March 2023	**Reaffirm and revise -** Standard may be reaffirmed for a period of five years w.e.f due date and revision to be undertaken by adopting the latest edition of the corresponding IEC standard. IEC 61689:2022 to be put under wide circulation for a period of one month to initiate the revision process.
6.	IS/IEC 61675 (Part 1):2013 Radionuclide imaging devices - Characteristics and test conditions: Part 1 Positron emission tomographs	March 2023	**Reaffirm and revise -** Standard may be reaffirmed for a period of five years w.e.f due date and revised in due course (under process) by adopting the latest edition of the corresponding IEC standard. IEC 61675-1:2022 to be put under wide circulation for a period of one month to initiate the revision process.
7.	IS 13450 (Part 2/Sec 1):2018 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 1 Electron accelerators in the range 1 MeV to 50 MeV (First Revision)	March 2023	**Reaffirm and revise -** Standard may be reaffirmed for a period of five years w.e.f due date and revised in due course (under process) by adopting the latest edition of the corresponding IEC standard. IEC 60601-2-1:2020 to be put under wide circulation for a period of one month to initiate the revision process.

ITEM 7 Technical Issues

7.1 Review of IS 7620 Series of Indian Standards on X-ray Equipment viz-a-viz IS 13450 Series of Standards

The Committee deliberated on the issue regarding two sets of standards currently available for X-ray equipment i.e. IS 7620 (in 3 parts) and IS 13450 Series (in 6 parts). IS 7620 series of standards were published in late 1980s whereas IS 13450 series of standards were published in 2016 as identical adoptions of the corresponding standards in the IEC 60601-2-X series to supersede the IS 7620 series. However, IS 7620 (Part 1) and (Part 2) are under mandatory certification as per AERB order dated 10 Oct 1994. It was stressed that IS 7620 series has become obsolete with the passage of time and it needs to be withdrawn at the earliest.

Representative from AERB and concerned officials from CMD-I and CMD-III were present during the deliberations. It was agreed by all that CMD-III/CMD-I and AERB would have a joint meeting at the earliest to discuss and resolve the issue and keep MHD updated on the developments in this regard.

ITEM 8 New proposals for standardization

8.1 The Committee was informed that any New Work Item Proposal (NWIP) may be submitted through the BIS website www.bis.gov.in.

8.2 Tuberculoscope and OncoDiagnoscope - The Committee decided to once again write to RRCAT, Indore for submission of the New Work Item Proposals (NWIP) on these two subjects along with their working drafts at the earliest.

ITEM 9 International Electrotechnical Commission (IEC)

The Committee noted the information regarding the P-membership of India on IEC/TC 62 and SC 62A, 62 B, 62C & 62D subcommittees.

9.1.1 The Committee noted the information regarding obligatory voting for BIS(India) on all the ballot documents circulated by the Secretariat of IEC/TC 62 and SC 62A, 62 B, 62C & 62D subcommittees.

9.2 The Committee noted the current nominations of MHD 15 members on WGs of IEC/TC 62 and its SCs.

9.3 The Committee noted the tour report of the Plenary Meetings of IEC/TC 62 and its subcommittees held from 1-4 Nov 2022 in San Francisco, USA in which Dr. V. R. Singh, Chairperson and Mr. Chandan Kumar, Member Secretary, MHD-15 Sectional Committee participated.

ITEM 10 Date and Place for the Next Meeting

The date and place for the next meeting will be scheduled in consultation with the Chairperson.

ITEM 11 Any other business

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

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ANNEX-I

LIST OF PARTICIPANTS :

1.	Dr. V. R. Singh *(Chairperson)*	In personal capacity
2.	Sh. Asok Kumar Raghavan Nair	Asia Pacific Medical Technology Association (APACMed), Gurugram
3.	Dr. Pratik Kumar	All India Institute of Medical Sciences, New Delhi
4.	Sh. Yoginder Nath	Allengers Medical Systems Ltd. , Chandigarh
5.	Sh. Rajesh Sharma	Allengers Medical Systems Ltd. , Chandigarh
6.	Dr. Ranajit Bandopadhayay	Allied Medical Services Pvt. Ltd., Gurugram
7.	Prof. S. D. Sharma	Association of Medical Physicists of India, Mumbai
8.	Sh. R. K. Chaturvedi	Atomic Energy Regulatory Board , Mumbai
9.	Dr. Rajesh Kumar	Bhabha Atomic Research Centre, Mumbai
10.	Dr. P. S. Sarkar	Bhabha Atomic Research Centre, Mumbai
11.	Sh. Prashanth Prabhakar	Boston Scientific India Private Limited, Gurugram
12.	Sh. Arvind Hiwale	Central Drugs Standard Control Organization, New Delhi
13.	Sh. Ajai Basil	Central Drugs Standard Control Organization, New Delhi
14.	Dr. Kavitha Arunachalam	Indian Institute of Technology Madaras, Chennai
15.	Dr. Ratnesh Singh Kanwar	Institute of Nuclear Medicine & Allied Sciences, New Delhi
16.	Sh. Dilip Kumar Chekuri	Kalam Institute of Health Technology, Vishakhapatnam
17.	Ms. Sushmita Roy Chowdhury	Kalam Institute of Health Technology, Vishakhapatnam
18.	Sh. Somnath Basu	Kalam Institute of Health Technology, Vishakhapatnam
19.	Dr. Ranjan Kumar Choudhury	National Health Systems Resource Centre, New Delhi
20.	Ms. Manisha Sharma	National Health Systems Resource Centre, New Delhi
21.	Ms. Valli	Panacea Medical Technologies Pvt. Ltd, Bengaluru
22.	Ms. Dhivya T.	Panacea Medical Technologies Pvt. Ltd, Bengaluru
23.	Sh. Sanjeev Sharma	Postgraduate Institute of Medical Education & Research, Chandigarh
24.	Sh. Sushil Rana	Recorders and Medicare Systems Pvt. Ltd., Panchkula
25.	Sh. Manmohan Singh	Recorders and Medicare Systems Pvt. Ltd., Panchkula
26.	Sh. A. Ganesh Kumar	Siemens Healthcare Private Limited, Gurugram
27.	Dr. Tanuja Dixit	Society for Applied Microwave Electronics Engineering & Research (SAMEER), Mumbai
28.	Sh. Basavaraj Angadi	TUV Rheinland (India) Pvt., Bangalore
29.	Dr. Rahul Umbarkar	Varian Medical Systems International Private Limited, Mumbai
30.	Dr. Rupi Jamwal	VMMC & Safdurjung Hospital , New Delhi
31.	Sh. Dorai Subramaniam	Wipro G E Healthcare Pvt. Ltd., Bengaluru
32.	Sh. Chandan Kumar *(Member Secretary)*	Bureau of Indian Standards, New Delhi

BIS Directorate General:

33.	Sh. Ranjit Kumar	Scientist-D, CMD-I, BIS, New Delhi
34.	Sh. Peeyush Prakash	Scientist-D, CMD-III, BIS, New Delhi