

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

Resolutions of Sectional Committee Meeting

Sectional Committee	Meeting No:	Date & Time
Electromedical, Diagnostic Imaging and Radiotherapy Equipment, (MHD 15)	14	03 September 2024 (Tuesday) 11hrs – 13hrs
<p style="text-align: center;">Chairperson Dr S. Ramakrishnan Indian Institute of Technology Madras, Chennai</p>	<p style="text-align: center;">Member Secretary Gurpreet Kaur, Sc C, MHD, BIS</p>	

Resolution 1 (Item 2.5)

The Committee decided to review the co-option request of Mr. Srinivasa Reddy, SS Innovations, Gurugram after further information.

Resolution 2 (Item 3)

The document MHD/15/25328 *Medical electrical equipment – Dosimeters with ionization chambers as used in Radiotherapy* was finalized by Committee for publication.

Resolution 3 (Item 4)

The Committee approved for adoption of all the proposed IEC Standards for revision. It was decided to wide circulate the draft standards for a period of one-month.

Resolution 4 (Item 7.2)

The Committee decided to constitute two panels as of now:

P1: Devices/Tools used in radiation, imaging, and therapeutics (to be split in further WGs as per requirement); and

P2: Electromedical Equipment

for formulation of standards on the subjects at Item 7.2. The below list to be reviewed by the members for their inputs.

S. No.	Subject	Timeline	Panel/WG	Expert(s) identified (Remarks)
1	Angiography Machine: Monoplane/Bi-plane Digital Subtraction Angiography Machine	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	The following manufacturers identified for inputs: <ol style="list-style-type: none"> 1. Allengers Medical Systems Limited, Chandigarh 2. Siemens Healthcare Private Limited, Gurugram

				3. Philips India Limited, Gurugram
2	CO2 Laser	Mar 2025	P2: Electromedical Equipment	Manufacturers to be identified
3	Fluid warmer	Mar 2025	P2: Electromedical Equipment	Anaesthesia expert to be identified for inputs
4	TEG machine (Thromboelastography - Method of testing the efficiency of blood coagulation)	Dec 2025	P2: Electromedical Equipment	Anaesthesia expert/General Medicine/ Haematology expert to be identified for inputs.
5	Continuous Renal Replacement Therapy machine	Dec 2025	P2: Electromedical Equipment	Nephrology expert
6	Polysomnography machine	Aug 2026	P2: Electromedical Equipment	Pulmonary Medicine/General Medicine
7	Cobalt 60 Teletherapy Machine	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	To be checked for existing IEC standards
8	Tomotherapy	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	
9	Pocket dosimeter	Aug 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	
10	Water Phantom/slab phantom/Computed Tomography Dose Index Phantom/Anthropomorphic radiation therapy phantoms	Aug 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	<ol style="list-style-type: none"> IEC to be checked for CTDI (WG 44) Anthropomorphic radiation therapy phantoms is a new technology and experts to be identified.

11	Microwave ablation generator with probes.	Aug 2025	P2: Electromedical Equipment	
12	Cryoablation system	Aug 2025	P2: Electromedical Equipment	Manufacturers to be identified
13	Robotic DSA system.	Aug 2026	P1: Devices/Tools used in radiation, imaging, and therapeutics	FDA standards to be checked if no existing IEC standards available.
14	CO2 angiography system.	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	
15	Xenon inhalation system for CBF	Aug 2026	P2: Electromedical Equipment	
16	Interferential therapy unit	Aug 2025	P2: Electromedical Equipment	
17	Laser Scanning unit (Used in Pain management can be called as scanning laser therapy equipment)	Dec 2025	P2: Electromedical Equipment	Anaesthesia, Palliative care expert to be identified
18	X-Ray view box	Mar 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	
19	Continuous Renal Replacement Therapy (CRRT) Machine	Dec 2025	P2: Electromedical Equipment	
20	Body Composition Monitor	Mar 2025	P2: Electromedical Equipment	Physiology expert to be identified
21	Portable X ray Machine	Mar 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	IEC is currently taking up the subject
22	Thermoablation instrument	Aug	P2:	

		2025	Electromedical Equipment	
23	Laser alignment tool	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	
24	Winston lutz test tool for SRS and SBRT	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	Panacea Medical Technologies Private Limited, Bengaluru identified for inputs
25	Radiation Field alignment test tools with radiopaque markers	Dec 2025	P1: Devices/Tools used in radiation, imaging, and therapeutics	A separate sub group can be formed for Radiation field detection/analyzers.
26	Radiovisiography Machine (RVG)	Aug 2026	P1: Devices/Tools used in radiation, imaging, and therapeutics	Manufacturers to be identified. Inputs to be taken from MHD 08
27	Orthopantomogram Machine (OPG)	Aug 2026	P1: Devices/Tools used in radiation, imaging, and therapeutics	

Resolution 5 (Item 7.3)

Sr No. 1 and 2 to be circulated to the Committee.

Sr No. 3 to be adopted.

Resolution 6 (Item 8)

The Committee advised BIS and its Central Marks Dept. to take up the issue with CDSCO, AERB along with Industry inputs. The IS 7620 series to be proceeded with the withdrawal.

Resolution 7 (Item 9.4.1)

S.No.	Ballot Reference	Project Title	Vote	Designated Experts	Level of Interest
1.	62/509/Q	Preliminary Work Item (PWI): "Establishing the	In favour of	Dr S Ramakrishnan,	HIGH

		credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification.	establishment of the Preliminary Work Item	Chairperson	
2.	62/513/Q	Establishment of an Ad-Hoc Group 11: 'Establishing the credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification'	In favour of setting up of Ad hoc group and the appointment of mentioned convener, no experts nominated		
3.	62A/1556/NP	PNW TS 62A-1556 ED1: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	In favour of the document, sent as Committee Draft for vote	GE Healthcare	HIGH
4.	62A/1559/CD	IEC TS 81001-2-2 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls	No comments sent	MHD 17	HIGH
5.	62A/1577/DC	Document for Comment - IEC 60447: Basic and safety principles for man-machine interface, marking and identification - Actuating principles	No comments sent	MHD 17	HIGH
6.	62C/905/CDV	IEC 60601-2-64/AMD1 ED1: Amendment 1 - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential	In favour		

		performance of light ion beam medical electrical equipment			
7.	62C/907/CDV	IEC 63322 ED1: Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources	In favour	1. Dr Pratik Kumar, AAIMS 2. Ms. Dhivya T, Panacea Medical	HIGH
8.	62C/911/CD	IEC 63465 ED1: Calibration and quality control in the use of radionuclide calibrators	No comments sent	1. AERB members 2. Dr Pratik Kumar	HIGH
9.	62C/912/CDV	IEC 61675-2 ED 3: Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging	In favour	3. AERB members 1. Dr Pratik Kumar	HIGH
10.	62C/916/CD	IEC 60601-2-93 ED1: Medical electrical equipment - Part 2-93: Particular requirements for the basic safety and essential performance of neutron capture therapy equipment	No comments sent		MEDIUM

Resolution 8 (Item 9.4.2)

S.No.	Ballot Reference	Project Title	Designated Experts	Level of Interest
1.	62/518/DC	Comments requested from ACOS on the Draft IEC Guide 127: Guidelines for safety related risk assessment and risk reduction for collaborative safety system being developed by the ACOS Task Force on Collaborative Safety		MEDIUM
2.	62/519/Q	Questionnaire on the Nomination of a TC 62 representative in SC 65A/JWG 21 Artificial intelligence – Functional Safety and AI systems - Requirements	MHD 17	MEDIUM
3.	62/517/DC	Document for Comments - Guidance on use of AI by IEC Technical Committees	MHD 17	MEDIUM

4.	62/520/CD	IEC 63450 ED1: Testing of Artificial Intelligence / Machine Learning-enabled Medical Devices	MHD 17, Chairperson (MHD 15)	MEDIUM
5.	62A/1606/NP	PNW 62A-1606 ED1: Packaging for non-sterile medical devices – Requirements for packaging systems	MHD 12	MEDIUM
6.	62A/1609/NP	PNW 62A-1609 ED1: Health software and health IT systems safety, effectiveness and security - Part 5-2: Security Risk Management for Manufacturers	MHD 17	
7.	62C/918/CD	IEC 60601-2-92 ED1: Medical electrical equipment - Part 2-92: Particular requirements for the basic safety and essential performance of MRI based image guided radiotherapy equipment for use with electron accelerators		HIGH
8.	62C/922/Q	Questionnaire on the revision of IEC 60976:2007, Medical electrical equipment – Medical electron accelerators – Functional performance characteristics		
9.	62C/923/CD	IEC 63321 ED1: Medical electrical equipment - Functional performance characteristics for X-ray-based image-guided radiotherapy equipment	Radiotherapy experts, Siemens, Varian, Dr Manoj Semwal (AMPI)	HIGH
10.	62D/2133/CDV	IEC 80601-2-23 ED1: Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment		HIGH
11.	62D/2136/CDV	IEC 80601-2-60AMD1 ED2: Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	MHD 08	HIGH

Resolution 9 (Item 11.1.2)

The Committee took the following decisions on Pre 2000 standards:

S.No.	IS Number	IS Title	Remarks
1	IS 7620 (Part 1): 1986	Specification for diagnostic medical X-ray equipment: Part 1 General and safety requirements (First Revision)	Refer to Resolution 6
2	IS 7620 (Part 2): 1986	Specification for diagnostic medical X-ray equipment: Part 2 Performance requirements (First Revision)	Refer to Resolution 6
3	IS 7620 (Part 3): 1991	Medical electrical equipment - Diagnostic X-ray equipment: Part 3	Refer to Resolution 6

		radiation safety requirements	
4	IS 11393: 1985	Specification for scintillation counters	Draft Under Preparation
5	IS 11753: 1986	Specification for electrical impedance plethysmograph	Draft Under Preparation
6	IS 13709: 1993	Medical electrical equipment - Dental X-ray equipment radiation safety	To be withdrawn/superseded by IS 13450 (Part 2/Sec 63) and IS 13450 (Part 2/Sec 65)

Resolution 10 (Item 11.2.3)

The Committee reaffirmed the standards due for review in Q3.