BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Electromedical, Diagnostic Imaging and Radiotherapy Equipment, (MHD 15)	14	03 September, 2024 (Wednesday) 11:00 AM onwards
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=mfe9b7b670d1080b1a771ec00b264cda6 **Meeting Number**: 2517 180 7638 **Password**: Mhd15@Sept3		
Chairperson	Dr. S. Ramakrishnan, Indian Institute of Technology Madras, Chennai	
Member Secretary	Gurpreet Kaur, Sc-C, MHD, BIS	

ITEM 0 GENERAL

0.1 Welcome Address by Member Secretary

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 13th meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, (MHD 15) held on 15 May, 2024, approved by the Chairperson was circulated to all members through the BIS portal vide email dt. 03-06-2024.

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 the Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 is given below:

To prepare Standards for:

a. Electrical equipment concerning diagnostic, surgical, therapeutic and monitoring equipment for various specialties;

b. Ionizing radiation imaging and radiotherapy, dentistry, equipment for radiotherapy, nuclear medicine, and radiation dosimetry.

Liaison: India is a P-member in IEC/TC 62 Medical equipment, software, and systems and its Sub-committees:

(a) SC 62 Medical equipment, software, and systems

(b) SC 62A Common aspects of medical equipment, software, and systems

(c) SC 62B Medical imaging equipment, software, and systems

(d) SC 62C Equipment for radiotherapy, nuclear medicine, and radiation dosimetry

(e) SC 62D Particular medical equipment, software, and systems

The Committee may please note.

2.2 The present composition Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 along with participation status of members is enclosed at ***Annexure-A (Page 11-13)*****.**

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

2.4 The following members were consecutively absent in last two meetings held on 07-02-2024 and 15-05-2024.

Sl. No.	Organisation
1.	Allied Medical Services Private Limited, New Delhi
2.	Elekta Medical Systems India Private Limited, Gurugram
3.	Institute of Nuclear Medicine and Allied Sciences, New Delhi
4.	Intuitive Surgical India Private Limited, Bengaluru
5.	Maulana Azad Medical College, Department of Radiotherapy, New Delhi
6.	Ministry of Commerce and Industry, Department for Promotion of Industry and Internal Trade
7.	Society for Applied Microwave Electronics Engineering and Research (SAMEER), Mumbai

2.4.1 The above members have become inactive by virtue of non-participation in consecutive meetings and by non-participation in fifty percent or more meetings during last year and have been removed.

The Committee may please note.

2.5 The following organizations have requested BIS for representation in the Committee:

Sl No	Organisation	Nomination
1.	In Personal Capacity	Mr. Srinivasa Reddy, SS Innovations, Gurugram

2.6 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 FOR FINALIZATION

3.1 The following draft Indian Standard had been sent for wide circulation:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1.	MHD/15/25328	Medical electrical equipment Dosimeters with ionization chambers as used in Radiotherapy (IEC 60731: 2011+AMD1: 2016 CSV, MOD)	19 May, 2024	No

3.2 No comments have been received and the above document may be taken up for finalization.

The Committee may kindly consider.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft Indian Standards / Amendments are ready for wide circulation:

Sl. No.	Document No./ Standard No.	Title	Remarks
1.	IEC TR 60878: 2022 + COR1: 2023	Graphical symbols for electrical equipment in medical practice	*Revision*
2.	IEC 61675-1: 2022	Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs	*Revision*
3.	IEC 61676: 2023/ COR1: 2024	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	*Revision*

4.	IEC 80601-2-26: 2019 + AMD1: 2024 CSV	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	*Revision*

The Committee may kindly approve.

4.2 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 5 DRAFT UNDER PREPARATION

5.1 There are currently no indigenous subject drafts under preparation.

The Committee may kindly note.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 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 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.

5.2.2 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.

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

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards

The Committee may kindly deliberate.

ITEM 7 NEW SUBJECTS

7.1 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 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.

7.2 The Department of Pharmaceuticals (DoP) is the nodal department for the strategic implementation of National Medical Devices Policy (NMDP), 2023. One of the action points under the roadmap for implementation of strategies under the NMDP include adoption and expansion of Indian Standards for Medical Devices. In this regard, DoP had constituted a committee for prioritizing the setting of Indian Standards for Medical Devices and deliberated on the list of Medical Devices where Indian Standards need to be formulated.

With reference to Electromedical, Diagnostic Imaging and Radiotherapy, there is a need to formulate Indian Standards on the following medical devices:

S. No.	Name of Equipment	Timeline
1.	Angiography Machine: Monoplane / Bi-plane Digital Substraction Angiography Machine	December 2025
2.	**CO2 Laser**	**March 2025**
3.	**Fluid warmer**	**March 2025**
4.	TEG machine (Thromboelastography - Method of testing the efficiency of blood coagulation)	December 2025
5.	Continuous Renal Replacement Therapy machine	December 2025
6.	Polysomnography machine	August 2026
7.	Cobalt 60 Teletherapy Machine	December 2025
8.	Tomotherapy	December 2025
9.	Pocket dosimeter	August 2025
10.	Water Phantom/slab phantom/Computed Tomography Dose Index Phantom/Anthropomorphic radiation therapy phantoms	August 2025
11.	Microwave ablation generator with probes.	August 2025
12.	Cryoablation system	August 2025
13.	Robotic DSA system.	August 2026
14.	CO2 angiography system.	December 2025
15.	Xenon inhalation system for CBF	August 2026
16.	Interferential therapy unit	August 2025
17.	Laser Scanning unit (Used in Pain management can be called as scanning laser therapy equipment)	December 2025
18.	**X-Ray view box**	**March 2025**
19.	Continuous Renal Teplacement Therapy (CRRT) Machine	December 2025

20.	**Body Composition Monitor**	**March 2025**
21.	**Portable X ray Machine**	**March 2025**
22.	Thermoablation instrument	August 2025
23.	Lase alignment tool	December 2025
24.	Winston lutz test tool for SRS and SBRT	December 2025
25.	Radiation Field alignment test tools with radiopaque markers	December 2025
26.	Polysomnography	August 2026
27.	Radiovisiography Machine (RVG)	August 2026
28.	Orthopantomogram Machine (OPG)	August 2026

For the formulation of standards on the above subjects, dedicated Panels may be formed, depending on the scope of MHD 15 as follows:

a. P1: Electromedical Equipment

b. P2: Diagnostic Imaging

c. P3: Radiotherapy Equipment

One or more Working groups may be established under the Panels to focus on these subjects as per the requirement.

The Committee may kindly deliberate and decide further course of action.

7.3 The following New Work Item Proposals (NWIPs) have been received on BIS Portal:

S.No.	Subject	Name of Proposer	Date of Receipt
1	Specification for Dry Well for use in biomedical metrology for the calibration of incubator analyzers.	Sudesh Yadav, CSIR-NPL, New Delhi	22-05-2024
2	Specification for Incubator Analyzer for use in calibration and testing of baby incubator	Sudesh Yadav, CSIR-NPL, New Delhi	16-05-2024
3	IEC 80601-2-78:2019 Medical electrical equipment Part 2-78: Requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	Mohammed Nadeem V, Genrobotic Innovations Pvt. Ltd., Kerala	12-03-2024

The Committee may deliberate and decide.

ITEM 8 TECHNICAL ISSUES

8.1 The technical issues on the Indian Standards as discussed in last meeting is listed:

Sl. No.	Document No./ Standard No. & Title	Issues
1.	IS 7620 (Part 1): 1986 Specification for diagnostic medical X-ray equipment	The Committee decided to withdraw IS 7620 series. However, due to AERB regulation, it

	Part 1 Mechanical and Electrical Safety requirements (*First Revision*)	was decided that CMD III will hold a meeting with AERB regarding withdrawal of IS 7620 and discuss the further actions to be taken. Also, *IS 13450 (Part 2/Sec 54): 2024 Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 54 X-Ray Equipment for Radiography and Radioscopy* to be considered as the applicable standard for X-ray machines.
2.	IS 7620 (Part 2): 1986 Specification for diagnostic medical X-ray equipment Part 2 Performance requirements (*First Revision*)	
3.	IS 7620 (Part 3): 1991 Medical electrical equipment – Diagnostic X-ray equipment Part 3 Radiation safety requirements	

*The Committee may kindly deliberate***.**

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in IEC

9.1.1 BIS participates in the International Standardization activities of the International Electrotechnical Commission (IEC) 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 IEC are given below:

SI. No.	Liaison Committee of ISO	Type of Membership
1.	SC 62 Medical equipment, software, and systems	Participating Member
2.	SC 62A Common aspects of medical equipment, software, and systems	Participating Member
3.	SC 62B Medical imaging equipment, software, and systems	Participating Member
4.	SC 62C Equipment for radiotherapy, nuclear medicine, and radiation dosimetry	Participating Member
5.	SC 62D Particular medical equipment, software, and systems	Participating Member

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by IEC 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 IEC 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 IEC Technical meetings.

The Committee may kindly note.

9.2 Participation of in Experts in projects of IEC Technical Committees

As the role of 'Participating member' in IEC Technical Committees, Sub-committees as well as being registered as an expert in Working Groups (WGs) require sufficient contribution in the projects under the respective SCs/WGs, it is paramount that India is represented by an expert in each of the projects. In order to strengthen the participation of Indian experts in IEC, BIS Secretariat shall now monitor the activities of IEC projects and assign the 'Level of Interest' in consultation with the Committee as:

i. High,
ii. Medium, or
iii. Low

In case if the Level of Interest is High or Medium, the project shall be monitored at every stage and a '***designated expert***' shall be assigned for contributing in the project. The ballots pertaining to each of the stages in the project shall be reviewed by the designated expert(s) for their views/comments which will further be circulated to the members for their consideration and approval. The NMC may also identify projects that can be proposed at IEC, by nominating conveners/project leaders (High level of interest).

The projects with lower level of interest shall be observed by BIS and noted for future reference.

The Committee may kindly note.

9.3 Harmonization of Indian Standards with International Standards

9.3.1 IEC comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the IEC 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 IEC Standards, may decide on adoption/adaptation of the IEC Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is *not undertaken in case the IEC Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage*.

9.3.2 The list of Standards published by IEC/TC 62 along with their status of adoption is given at ***Annexure-B (Page 14-31)***.

The Committee may kindly note and consider revision of IS where the base IEC Standard has been revised.

9.4 Summary of ballots

9.4.1 The Summary of ballots closed since last meeting are given at ***Annexure-C (Page 32-37)*****.**

The Committee may kindly note.

9.4.2 The ballots received from IEC/TC 62 Secretariat and are open during Q2/Q3 are given at ***Annexure-D (Page 38-41)*****.**

The Committee may kindly deliberate and decide further course of action.

9.5 The IEC is now migrating towards the Online Standards Development platform (OSD), a tool for standardization experts for providing their inputs directly to the live document. The experts may kindly peruse the documents in OSD for efficient comment collation and uploading of National comments. The projects under OSD have also been highlighted in Annexure-D which are currently open for commenting.

The Committee may kindly note.

ITEM 10. PROGRAMME OF WORK

10.1 The present programme of work of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 is available at BIS website: www.bis.gov.in.

The Committee may kindly note.

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

Stage	No. of Documents
Under Print	2
Under Development	8

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner. The details in this regard are given below:

Total as per PoW	Under Development	Under Print	Remaining	Under Progress (out of the remaining)	Pending
6	2	-	4	4	-

11.1.2 The list of the above Indian Standards at various stages is given at ***Annexure-E (Page 42)***.

The Committee may kindly review.

11.2 Review of Standards as per 5-year cycle

11.2.1 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.

11.2.2 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.

11.2.3 The list of ISs due for review in 2024-25 is given at ***Annexure-F (Page 43)***.

The Committee may kindly deliberate and decide further course of action.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

The issues arising out of previous meetings have been addressed in corresponding agenda items.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 15 is scheduled on 11th December, 2024.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

ANNEXURE-A

(Item 2.2)

Present composition of MHD 15

S.No.	Organization	Member Name	Role	Attendance
1	Indian Institute of Technology Madras, Chennai	Dr. S. Ramakrishnan	Chairperson	2/2
2	All India Institute of Medical Sciences, New Delhi	Dr. Pratik Kumar	Principal Member	2/2
3	All India Institute of Medical Sciences, New Delhi	Dr. Supriya Mallick	Alternate Member	
4	Allengers Medical Systems Limited, New Delhi	Shri Yoginder Nath	Principal Member	0/0
5	Allengers Medical Systems Limited, New Delhi	Shri Rajesh Sharma	Alternate Member	
6	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri Asok Kumar Raghavan Nair	Principal Member	2/2
7	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri Parveen Jain	Alternate Member	
8	Association of Medical Physicists of India, Mumbai	Dr. Manoj Kumar Semwal	Principal Member	1/2
9	Association of Medical Physicists of India, Mumbai	Dr. Anuj Kumar Tyagi	Alternate Member	
10	Atomic Energy Regulatory Board, Mumbai	Dr. P. K. Dash Sharma	Principal Member	1/2
11	Atomic Energy Regulatory Board, Mumbai	Dr. G.Sahani	Alternate Member	
12	Atomic Energy Regulatory Board, Mumbai	Shri Rajendra Kumar Chaturvedi	Alternate Member	
13	Atomic Energy Regulatory Board, Mumbai	Ms. Mahalakshmi	Principal Member	
14	Bhabha Atomic Research Centre, Mumbai	Dr Rajesh Kumar	Principal Member	2/2
15	Bhabha Atomic Research Centre, Mumbai	Dr P. S. Sarkar	Alternate Member	
16	Bhabha Atomic Research Centre, Mumbai	Shri Ankit Srivastava	Alternate Member	
17	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	Principal Member	1/2
18	Central Drugs Standard Control Organization, New Delhi	Mr. Ajai Basil	Alternate Member	
19	Central Drugs Standard Control Organization, New Delhi	Mr. Soumyaranjan Sahoo	Alternate Member	
20	Defence Bio-Engineering and Electromedical Laboratory, Ministry	Dr. K. Mohanavelu	Principal Member	2/2

	of Defence, Bengaluru			
21	Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	Dr. Jayant Daniel	Alternate Member	
22	Indian Institute of Technology Madras, Chennai	Dr. Kavitha Arunachalam	Principal Member	0/2
23	Integral Institute of Medical Science and Research, Lucknow	Dr. Syed Belal Hassan	Principal Member	0/2
24	Integral Institute of Medical Science and Research, Lucknow	Dr. Sakshi Singh	Alternate Member	
25	Johnson and Johnson Private Limited, Mumbai	Ms. Aishwarya Nair	Alternate Member	1/2
26	Johnson and Johnson Private Limited, Mumbai	Mr. Hemant Sonawane	Principal Member	
27	Kalam Institute of Health Technology, Vishakhapatnam	Shri Santosh Kumar Balivada	Principal Member	1/2
28	Kalam Institute of Health Technology, Vishakhapatnam	Ms. Nandhini	Alternate Member	
29	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Mridul S Kaimal	Alternate Member	
30	National Health Systems Resource Centre, New Delhi	Dr. Ranjan Choudhury	Principal Member	1/2
31	National Health Systems Resource Centre, New Delhi	Ms. Manisha Sharma	Alternate Member	
32	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong	Dr. Vikas K. Jagtap	Alternate Member	1/2
33	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong	Prof. C. Daniala	Principal Member	
34	Panacea Medical Technologies Private Limited, Bengaluru	Ms. Valli	Principal Member	1/2
35	Panacea Medical Technologies Private Limited, Bengaluru	Ms. Dhivya T	Alternate Member	
36	Philips India Limited, Gurugram	Shri A V A Rajendra Prasad	Alternate Member	2/2
37	Recorders and Medicare Systems Private Limited, Haryana	Shri Sushil Rana	Principal Member	1/2
38	Siemens Healthcare Private Limited, Gurugram	Shri Ms. Ramya Santhanam	Alternate Member	2/2
39	Siemens Healthcare Private Limited, Gurugram	Shri A. Ganesh Kumar	Principal Member	
40	TUV Rhineland (India) Private Limited, Mumbai	Shri Basavaraj Angadi	Principal Member	1/2
41	TUV Rhineland (India) Private	Shri Kalyan Verma	Alternate Member	

	Limited, Mumbai			
42	Varian Medical Systems International (India) Private Limited, New Delhi	Dr. Rahul Umbarkar	Principal Member	2/2
43	Varian Medical Systems International (India) Private Limited, New Delhi	Shri Vineet M Gupta	Alternate Member	
44	Varian Medical Systems International (India) Private Limited, New Delhi	Ms. Amita Pipal	Alternate Member	
45	Wipro G.E. Healthcare Private Limited, New Delhi	Shri Dorai. Subramaniam	Principal Member	2/2

ANNEXURE-B

(Item 9.3.2)

List of IEC Standards Published by IEC/TC 62 Secretariat and its Subcommittees

Published standards (IEC/TC 62)	Adopted	Under Development	Not adopted
1	**1**	**-**	**-**
Published standards (IEC/TC 62/SC 62A)	**Adopted**	**Under Development**	**Not adopted**
43	**22**	**1**	**20**
Published standards (IEC/TC 62/SC 62B)	**Adopted**	**Under Development**	**Not adopted**
47	**21**	**20**	**6**
Published standards (IEC/TC 62/SC 62C)	**Adopted**	**Under Development**	**Not adopted**
31	**15**	**1**	**15**
Published standards (IEC/TC 62/SC 62D)	**Adopted**	**Under Development**	**Not adopted**
50	**37**	**5**	**8**

IEC/TC 62 Medical equipment, software, and systems

S. No.	IEC Standard	Title	Existing IS	Status of adoption
1.	IEC/TR 60788: 2004	Medical electrical equipment – Glossary of defined terms	IEC/TR 60788:2004	Adopted

IEC/TC 62/SC 62A Common aspects of medical equipment, software, and systems

S. No.	IEC Standard	Title	Existing IS	Status of adoption
1.	IEC 60601-1: 2005 +AMD1: 2012 + AMD2: 2020 CSV	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance	IS 13450 (Part 1): 2024	Adopted
2.	IEC 60601-1-2: 2014+ AMD1: 2020 CSV	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	IS 13450 (Part 1/Sec 2): 2024	Adopted

3.	IEC 60601-1-6: 2010+ AMD1: 2013 + AMD2: 2020 CSV	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	IS 13450 (Part 1/Sec 6): 2024	Adopted
4.	IEC 60601-1-8: 2006+ AMD1: 2012 + AMD2: 2020 CSV	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IS 13450 (Part 1/Sec 8): 2024	Adopted
5.	IEC 60601-1-9: 2007+ AMD1: 2013 + AMD2: 2020 CSV	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design	IS 13450 (Part 1/Sec 9) : 2024	Adopted
6.	IEC 60601-1-10: 2007 + AMD1: 2013+ AMD2: 2020 CSV	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	IS 13450 (Part 1/Sec 10) : 2023	Adopted
7.	IEC 60601-1-11: 2015 + AMD1: 2020 CSV	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IS 13450 (Part 1/Sec 11) : 2023	Adopted
8.	IEC 60601-1-12: 2014 + AMD1: 2020 CSV	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 intended for use in the emergency medical services environment	IS 13450 (Part 2/Sec 12) : 2024	Adopted
9.	IEC/TR 60601-4-1: 2017	Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy	IS 13450 (Part 4/Sec 1): 2020	Adopted
10.	IEC/TR 60601-4-2: 2016	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems		Not adopted

11.	IEC/TR 60601-4-3:2018	Medical electrical equipment - Part 4-3: Guidance and interpretation - Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements		Not adopted
12.	IEC/TR 60601-4-4:2017	Medical electrical equipment - Part 4-4: Guidance and interpretation - Guidance for writers of particular standards when creating alarm system-related requirements		Not adopted
13.	IEC/TR 60601-4-5:2021	Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety-related technical security specifications		Not adopted
14.	IEC TS 60601-4-6:2024	Medical electrical equipment - Part 4-6: Guidance and interpretation - Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances		Not adopted
15.	**IEC/TR 60878: 2022+ COR1: 2023**	**Graphical symbols for electrical equipment in medical practice**	**IS 14180: 2019**	**Old edition Adopted**
16.	IEC/TR 60930: 2008	Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems	IS 11478: 2018	Adopted
17.	IEC/TR 61258: 2008	Guidelines for the development and use of medical electrical equipment educational materials		Not adopted
18.	IEC/TR 62296: 2009	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements		Not Adopted
19.	IEC 62304: 2006 +AMD1: 2015 CSV	Medical device software - Software life cycle processes	IS/ISO 62304: 2015	Adopted
20.	IEC 62353: 2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment	IS/IEC 62353: 2014	Adopted
21.	IEC/TR 62354: 2014	General testing procedures for medical electrical equipment		Approved for adoption in last meeting
22.	IEC 62366-1: 2015 + AMD1: 2020 CSV	Medical devices - Part 1: Application of usability engineering to medical devices	IS/IEC 62366-1: 2015	Adopted

23.	IEC/TR 62366-2: 2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	IS/IEC/TR 62366-2: 2016	Adopted
24.	IEC 80001-1: 2021	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
25.	IEC/TR 80001-2-1: 2012	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
26.	IEC/TR 80001-2-2:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	IS/IEC/TR 80001-2-2: 2012	Adopted
27.	IEC/TR 80001-2-3:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks		Not Adopted
28.	IEC/TR 80001-2-4:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-4: Application guidance - General implementation guidance for healthcare delivery organizations		Not Adopted
29.	IEC/TR 80001-2-5:2014	Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application guidance - Guidance on distributed alarm systems		Not Adopted
30.	IEC/TR 80001-2-8:2016	Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2		Not Adopted
31.	IEC/TR 80001-2-9:2017	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

32.	IEC TR 80002-1:2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software		Not Adopted
33.	IEC TR 80002-3:2014	Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)		Not Adopted
34.	IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle		Not Adopted
35.	IEC 82304-1:2016	Health software - Part 1: General requirements for product safety	IS/IEC 82304-1 : 2016	Adopted
36.	ISO 14971:2019	Medical devices- Application of risk management to medical devices	IS/ISO 14971 : 2019	Adopted (MHD14)
37.	ISO TR 17791:2013	Health informatics -- Guidance on standards for enabling safety in health software	IS/ISO/TR 17791 : 2013	Adopted
38.	ISO TR 24971:2020	Medical devices - Guidance on the application of ISO 14971	IS/ISO/TR 24971 : 2020	Old edition Adopted (MHD14)
39.	ISO TR 80001-2-6:2014	Application of risk management for IT-networks incorporating medical devices -- Part 2-6: Application guidance -- Guidance for responsibility agreements		Not Adopted
40.	ISO TR 80001-2-7:2015	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
41.	ISO TR 80002-2:2017	Medical device software - Part 2: Validation of software for medical device quality systems	IS/ISO/TR 80002-2 : 2017	Adopted
42.	ISO 81001-1:2021	Health software and health IT systems safety, effectiveness and security - Part 1: Principles and concepts		Not Adopted
43.	ISO TS 82304-2:2021	Health software - Part 2: Health and wellness apps - Quality and reliability	IS/ISO/TS 82304-2 : 2021	Adopted

IEC/TC 62/SC 62B Medical imaging equipment, software, and systems

S. No.	IEC Standard	Title	Existing IS	Status of adoption
1.	IEC 60336: 2020 + COR1: 2022	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	IS 18443: 2024	Under Print
2.	IEC 60522-1: 2020	Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration	IS 18448 (Part 1) : 2024	Adopted
3.	IEC TR 60522-2: 2020	Medical electrical equipment - Diagnostics X-rays - Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration	IS 18448 (Part 2) : 2024	Adopted
4.	IEC 60526: 1978 + COR1: 2010	High-voltage cable plug and socket connections for medical X-ray equipment		Approved for adoption in last meeting
5.	IEC 60601-1-3: 2008 + AMD1: 2013 + AMD2: 2021 CSV	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	IS 13450 (Part 1/Sec 3) : 2024	Adopted
6.	IEC 60601-2-28: 2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	IS 13450 (Part 2/Sec 2) : 2019	Adopted
7.	IEC 60601-2-33: 2022	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	MHD/15/24688	Finalized in last meeting
8.	IEC 60601-2-37: 2007 + AMD1: 2015 CSV	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	IS 13450 (Part 2/Sec 37) : 2019	Adopted
9.	IEC 60601-2-43: 2022	Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	IS 13450 (Part 2/Sec 43) : 2024	Adopted
10.	IEC 60601-2-44: 2009 + AMD1: 2012 + AMD2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	IS 13450 (Part 2/Sec 44) : 2016	Adopted

	CSV			
11.	IEC 60601-2-45: 2011 + AMD1: 2015 + AMD2: 2022 CSV	Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	IS 13450 (Part 2/Sec 45) : 2024	Adopted
12.	IEC 60601-2-54: 2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	IS 13450 (Part 2/Sec 54) : 2023	Adopted
13.	IEC 60601-2-63: 2012 + AMD1: 2017 + AMD2: 2021 CSV	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra- oral X-ray equipment	IS 13450 (Part 2/Sec 63) : 2024	Under Print
14.	IEC 60601-2-65: 2012 + AMD1: 2017 + AMD2: 2021 CSV	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra- oral X-ray equipment	IS 13450 (Part 2/Sec 65) : 2023	Adopted
15.	IEC 60613: 2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis		Approved for adoption in last meeting
16.	IEC 60627: 2013	Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids		Approved for adoption in last meeting
17.	IEC 60806: 2022	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis	IS 11789: 1986	Adopted
18.	IEC TS 61223-1: 1993	Evaluation and routine testing in medical imaging departments - Part 1: General aspects		Approved for adoption in last meeting

19.	IEC TS 61223-2-1: 1993	Evaluation and routing testing in medical imaging departments - Part 2-1: Constancy tests - Film processors		Approved for adoption in last meeting
20.	IEC 61223-3-2: 2007	Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment		Approved for adoption in last meeting
21.	IEC 61223-3-4: 2000	Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment		Approved for adoption in last meeting
22.	IEC 61223-3-5: 2019 + COR1: 2022	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment		Approved for adoption in last meeting
23.	IEC 61223-3-6: 2020	Evaluation and routine testing in medical imaging departments - Part 3-6: Acceptance and constancy tests - Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation		Approved for adoption in last meeting
24.	IEC 61223-3-7: 2021	Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography		Approved for adoption in last meeting
25.	IEC 61223-3-8:2024	Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy		Not adopted
26.	IEC 61262-1: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 1: Determination of the entrance field size	IS/IEC 61262-1 : 1994	Adopted
27.	IEC 61262-2: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 2: Determination of the conversion factor	IS/IEC 61262-2 : 1994	Adopted

28.	IEC 61262-3: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 3: Determination of the luminance distribution and luminance non-uniformity	IS/IEC 61262-3 : 1994	Adopted
29.	IEC 61262-4: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 4: Determination of the image distortion	IS/IEC 61262-3 : 1994	Adopted
30.	IEC 61262-5: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 5: Determination of the detective quantum efficiency		Approved for adoption in last meeting
31.	IEC 61262-6: 1994	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 6: Determination of the contrast ratio and veiling glare index		Approved for adoption in last meeting
32.	IEC 61262-7: 1995	Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 7: Determination of the modulation transfer function		Approved for adoption in last meeting
33.	IEC 61331-1: 2014	Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials	IS/IEC 61331-1 : 2014	Adopted
34.	IEC 61331-2: 2014	Protective devices against diagnostic medical X-radiation - Part 2: Translucent protective plates	IS/IEC 61331-2 : 2014	Adopted
35.	IEC 61331-3: 2014	Protective devices against diagnostic medical X-radiation - Part 3: Protective clothing, eyewear and protective patient shields	IS/IEC 61331-3 : 2014	Adopted
36.	IEC 61910-1: 2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy		Not Adopted

37.	IEC 62220-1-1: 2015	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging	IS/IEC 62220-1-1 : 2015	Adopted
38.	IEC 62220-1-2: 2007	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography	IS/IEC 62220-1- 2 : 2007	Adopted
39.	IEC 62220-1-3: 2008	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging	IS/IEC 62220-1- 3 : 2008	Adopted
40.	IEC 62464-1: 2018	Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters		Approved for adoption in last meeting
41.	IEC 62494-1: 2008	Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography		Approved for adoption in last meeting
42.	IEC 62563-1: 2009 + AMD1: 2016 + AMD2: 2021 CSV	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	MHD/15/24734	Finalized in last meeting
43.	IEC 62563-2: 2021	Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for medical image displays		Approved for adoption in last meeting
44.	IEC 62570: 2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment		Not Adopted
45.	IEC 62985: 2019 + COR1: 2022	Methods for calculating size specific dose estimates (SSDE) for computed tomography		Not Adopted

46.	IEC 63077: 2019	Good refurbishment practices for medical imaging equipment		Not Adopted
47.	ISO TS 10974: 2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	IS/ISO/TS 10974 : 2018	Adopted

IEC/TC 62/SC 62C Equipment for radiotherapy, nuclear medicine, and radiation dosimetry

S. No.	IEC Standard	Title	Existing IS	Status of adoption
1.	IEC 60580: 2019	Medical electrical equipment - Dose area product meters	IS/IEC 60580 : 2019	Adopted
2.	IEC 60601-2-1: 2020	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV		Not Adopted
3.	IEC 60601-2-8: 2010 + AMD1: 2015 CSV	Medical electrical equipment - Part 2-8: Particular requirements forthe basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	IS 13450 (Part 2/Sec 8) : 2019	Adopted
4.	IEC 60601-2-11: 2013	Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	IS 13450 (Part 2/Sec 11) : 2018	Adopted
5.	IEC 60601-2-17: 2013	Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment	IS 13450 (Part 2/Sec 17) : 2018	Adopted
6.	IEC 60601-2-29: 2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	IS 13450 (Part 2/Sec 29) : 2018	Adopted
7.	IEC 60601-2-64: 2014	Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment		Adopted

8.	IEC 60601-2-68: 2014	Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	IS 13450 (Part 2/Sec 68) : 2020	Adopted
9.	IEC 60731: 2011 + AMD1: 2016 CSV	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	MHD/15/25328	To be finalized
10.	IEC 60976: 2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics		Not Adopted
11.	IEC TR 60977: 2008	Medical electrical equipment - Medical electron accelerators - Guidelines for functional performance characteristics		Not Adopted
12.	IEC 61168: 1993	Radiotherapy simulators - Functional performance characteristics	IS/IEC 61168 : 1993	Adopted
13.	IEC TS 61170: 1993	Radiotherapy simulators - Guidelines for functional performance characteristics	IS/IEC 61170 : 1993	Adopted
14.	IEC 61217: 2011	Radiotherapy equipment - Coordinates, movements and scales	IS/IEC 61217 : 2011	Adopted
15.	IEC 61267: 2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics		Not Adopted
16.	IEC 61303: 1994 + COR1: 2016	Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance		Not Adopted
17.	IEC 61674: 2012	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging		Not Adopted
18.	**IEC 61675-1: 2022**	**Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs**	**IS/IEC 61675-1 : 2013**	**Old edition Adopted**

19.	IEC 61675-2: 2015	Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging	IS/IEC 61675-2 : 2015	Adopted
20.	**IEC 61676: 2023**	**Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology**	**IS/IEC 61676 : 2002**	**Old edition Adopted**
21.	IEC TR 61948-1: 2016	Nuclear medicine instrumentation - Routine tests - Part 1: Gamma radiation counting systems		Not Adopted
22.	IEC TR 61948-2: 2019	Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging		Not Adopted
23.	IEC TR 61948-3: 2018	Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs	IS/IEC/TR 61948-3 : 2018	Adopted
24.	IEC TR 61948-4: 2019	Nuclear medicine instrumentation - Routine tests - Part 4: Radionuclide calibrators		Not Adopted
25.	IEC 62083: 2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	IS/IEC 62083 : 2009	Adopted
26.	IEC 62274: 2005	Medical electrical equipment - Safety of radiotherapy record and verify systems		Not Adopted
27.	IEC 62467-1: 2009	Medical electrical equipment - Dosimetric instruments as used in brachytherapy - Part 1: Instruments based on well-type ionization chambers		Not Adopted
28.	IEC 62667: 2017	Medical electrical equipment - Medical light ion beam equipment - Performance characteristics		Not Adopted
29.	IEC TR 62926: 2019	Medical electrical system - Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy		Not Adopted

30.	IEC 63073-1: 2020	Dedicated radionuclide imaging devices - Characteristics and test conditions - Part 1: Cardiac SPECT		Not Adopted
31.	IEC TR 63183: 2019	Guidance on error and warning messages for software used in radiotherapy		Not Adopted

IEC/TC 62/SC 62D Particular medical equipment, software, and systems

S. No.	IEC Standard	Title	Existing IS	Status of adoption
1.	IEC 60601-2-2: 2017 + AMD1: 2023 CSV	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	IS 13450 (Part 2/Sec 2) : 2019	Adopted
2.	IEC 60601-2-3: 2012 + AMD1: 2016 + AMD2: 2022 CSV	Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	IS 13450 (Part 2/Sec 3) : 2022	Adopted
3.	IEC 60601-2-4: 2010 + AMD1: 2018 CSV	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	IS 13450 (Part 2/Sec 4) : 2018	Adopted
4.	IEC 60601-2-5: 2009	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	IS 13450 (Part 2/Sec 5) : 2018	Adopted
5.	IEC 60601-2-6: 2012 + AMD1: 2016 + AMD2: 2022 CSV	Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	MHD/15/24732	Finalized in last meeting
6.	IEC 60601-2-10: 2012 + AMD1: 2016 + AMD2: 2023 CSV	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	IS/ISO 13450-2-10 : 2018	Adopted
7.	IEC 60601-2-16: 2018	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	IS 13450 (Part 2/Sec 16) : 2019	Adopted

8.	IEC 60601-2-18: 2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	IS 13450 (Part 2/Sec 18) : 2014	Adopted
9.	IEC 60601-2-19: 2020	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	IS 13450 (Part 2/Sec 19) : 2023	Adopted
10.	IEC 60601-2-20: 2020	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	IS 13450 (Part 2/Sec 20) : 2023	Adopted
11.	IEC 60601-2-21: 2020	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	IS 13450 (Part 2/Sec 21) : 2023	Adopted
12.	IEC 60601-2-23: 2011	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	IS 13450 (Part 2/Sec 23) : 2018	Adopted
13.	IEC 60601-2-24: 2012	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	IS 13450 (Part 2/Sec 24) : 2019	Adopted
14.	IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	IS 13450 (Part 2/Sec 25) : 2018	Adopted
15.	IEC 60601-2-27: 2011 + COR1: 2012	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	IS 13450 (Part 2/Sec 27) : 2018	Adopted
16.	IEC 60601-2-31: 2020	Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	IS 13450 (Part 2/Sec 31) : 2021	Adopted
17.	IEC 60601-2-34: 2011	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	IS 13450 (Part 2/Sec 34) : 2019	Adopted

18.	IEC 60601-2-35: 2020	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	IS 13450 (Part 2/Sec 35) : 2023	Adopted
19.	IEC 60601-2-36: 2014	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	IS 13450 (Part 2/Sec 36) : 2019	Adopted
20.	IEC 60601-2-39: 2018	Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	IS 13450 (Part 2/Sec 39) : 2019	Adopted
21.	IEC 60601-2-40: 2016	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	IS 13450 (Part 2/Sec 40) : 2020	Adopted
22.	IEC 60601-2-41: 2021	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis	MHD/15/24715	Finalized in last meeting
23.	IEC 60601-2-46: 2023	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	MHD/15/24718	Finalized in last meeting
24.	IEC 60601-2-47: 2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems		Not Adopted
25.	IEC 60601-2-50: 2020	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	IS 13450 (Part 2/Sec 50) : 2022	Adopted
26.	IEC 60601-2-52: 2009 + AMD1: 2015 CSV	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	IS 13450 (Part 2/Sec 52) : 2020	Adopted
27.	IEC 60601-2-62: 2013	Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	IS 13450 (Part 2/Sec 62) : 2018	Adopted

28.	IEC 60601-2-75: 2017 + AMD1: 2023 CSV	Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment	MHD/15/25315	Finalized in last meeting
29.	IEC 60601-2-76: 2018	Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment	IS 13450 (Part 2/Sec 76) : 2019	Adopted
30.	IEC 60601-2-83: 2019 + AMD1: 2022 CSV	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	MHD/15/25327	Finalized in last meeting
31.	IEC TR 61289: 2019	High frequency surgical equipment and high frequency surgical accessories - Operation and maintenance		Not Adopted
32.	IEC TR 62653: 2020	Guideline for safe operation of medical equipment used for haemodialysis treatments		Not Adopted
33.	IEC 80369-5: 2016 + COR1: 2017 + COR2: 2021	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications	IS/IEC 80369-5 : 2016	Adopted
34.	**IEC 80601-2-26:2019+AMD1:2024 CSV**	**Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs**	**IS 13450 (Part 2/Sec 26) : 2021**	**Old Edition Adopted**
35.	IEC 80601-2-49: 2018	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors	IS/IEC 80601-2-49): 2018	Adopted
36.	IEC 80601-2-58: 2014 + AMD1: 2016 CSV	Medical electrical equipment - Part 2-58: Particular requirementsfor the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery	IS/IEC 80601-2-58 :2016	Adopted
37.	IEC 80601-2-59: 2017 + AMD1: 2023 CSV	Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	IS/IEC 80601-2-59 : 2017	Adopted
38.	IEC 80601-2-60: 2019	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment		Not Adopted

39.	IEC 80601-2-77: 2019	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment		Not Adopted
40.	IEC 80601-2-78: 2019	Medical electrical equipment - Part 2-78: Particular requirements for basic safety andessential performance of medical robots for rehabilitation, assessment, compensation or alleviation		Not Adopted
41.	ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	IS/ISO 80369-1 : 2018	Adopted
42.	ISO 80369-3: 2016 + AMD1:2019	Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications		Not Adopted
43.	ISO 80369-6: 2016	Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	IS/IEC 80369-6 : 2016	Adopted
44.	ISO 80369-7: 2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016	Old Edition Adopted
45.	ISO 80369-20: 2015	Small-bore connectors for liquids and gases in healthcare applications -- Part 20: Common test methods	IS 17964 (Part 20) : 2023	Adopted
46.	ISO 80601-2-56: 2017 + AMD1: 2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	IS 80601 (Part 2/Sec 56) : 2017	Adopted
47.	ISO 80601-2-61: 2017	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	IS/ISO 80601-2-61 : 2017	Adopted
48.	ISO 81060-2:2018	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type	IS/ISO 81060-2 : 2018	Adopted (Under MHD 11)
49.	IEC 80601-2-26:2019+AMD1:2024 CSV	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	IS 13450 (Part 2/Sec 26) : 2021	Old Edition Adopted
50.	ISO 5363:2024	Robotics - Test methods for exoskeleton-type walking RACA robot		Not Adopted

ANNEXURE-C

(Item 9.4.2)

Summary of ballots closed since last meeting

IEC/TC 62

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Vote casted
62/506/Q	Questionnaire on the appointment of TC 62 Liaison Representatives to IEC/TC 111 Environmental standardization for electrical and electronic products and systems and ISO/TC 194 Biological and clinical evaluation of medical devices	2024-02-23	2024-04-05	In favour of the appointment of Liaison Representatives
62/509/Q	Questionnaire on the establishment of a Preliminary Work Item (PWI): "Establishing the credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification	2024-03-15	2024-04-26	In favour of establishment of the Preliminary Work Item
62/513/Q	Questionnaire regarding the 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" and call for experts	2024-06-14	2024-07-26	In favour of setting up of Ad hoc group and the appointment of mentioned convener, no experts nominated
62/515/Q	Questionnaire on Supporting document listing the standards suitable to be used for development of AI/ML standards in the medical area (confirmed by IEC TC 62 “Medical equipment, software and systems	2024-07-12	2024-08-23	In favour of the supporting documents

IEC/TC 62A

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Vote casted
62A/1556/NP	PNW TS 62A-1556 ED1: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	2024-01-12	2024-04-05	In favour of the document, sent as Committee Draft for vote
62A/1558/DC	Document for Comment National Committee review of: ISO/TR 80001-2-6:2014, Application of risk management for IT-networks	2024-01-26	2024-04-19	Reconfirmation of the technical report

	incorporating medical devices - Part 2-6: Application guidance - Guidance for responsibility agreements and ISO/TR 80001-2-7, 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			
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	2024-02-02	2024-04-26	No comments sent
62A/1577/DC	Document for Comment - IEC 60447: Basic and safety principles for man-machine interface, marking and identification - Actuating principles	2024-03-01	2024-04-12	No comments sent
62A/1581/Q	Nomination of a Co-convenor for SC62A/WG 46: Ionizing radiation hazards	2024-03-08	2024-04-05	Yes
62A/1585/Q	Document for Comment National Committee review of: IEC TR 60601-4-1:2017, Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy	2024-03-29	2024-05-10	Yes
62A/1595/Q	Questionnaire - National Committee approval to: Convert project PWI TR 62A-1, IEC 60601-4-7, Medical electrical equipment - Part 4-7: Guidance and interpretation - Essential performance fault safety to IEC PAS 60601-4-7, Medical electrical equipment - Part 4-7: Guidance and interpretation - Essential performance fault safety and convert PT 62A-1 into a PT 60601-4-7, keeping its members and project leader	2024-04-26	2024-06-07	Disapproved and Comments attached, Initially, it was agreed to provide general guidance and examples without altering essential performance requirements. Now, they propose changing it from a Technical

				Report (non-binding) to a Publicly Available Specification (almost a standard).
62A/1596/Q	Nomination of the Convenor for SC62A/WG 40: Material hazards	2024-05-10	2024-06-21	Yes
62A/1604/Q	Appointment of a Vice-Chair of SC 62A	2024-06-28	2024-08-09	Yes

IEC/TC 62B

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Vote casted
62B/1352/Q	Questionnaire regarding a Convenor of Maintenance Team SC 62B/MT 47, Protective devices against diagnostic medical X-radiation and starting the revision of the IEC 61331 series	2024-05-17	2024-06-28	Yes
62B/1353/Q	Questionnaire on the Establishment of a Category A liaison with the American Society for Testing and Materials (ASTM)	2024-05-31	2024-07-12	Yes

IEC/TC 62C

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Vote casted
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 performance of light ion beam medical electrical equipment	2024-02-09	2024-05-03	In favour
62C/909/FDIS	IEC 61674 ED3: Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	2024-02-23	2024-04-05	In favour
62C/907/CDV	IEC 63322 ED1: Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources	2024-03-08	2024-05-31	In favour
62C/911/CD	IEC 63465 ED1: Calibration and quality control in the use of radionuclide calibrators	2024-04-05	2024-06-28	No comments sent
62C/912/CDV	IEC 61675-2 ED 3: Radionuclide imaging devices - Characteristics and	2024-05-31	2024-08-23	In favour

	test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging			
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	2024-06-14	2024-08-09	No comments sent

IEC/TC 62D

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Vote casted
62D/2113/CDV	IEC 80601-2-89 ED1: Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children	2024-03-01	2024-05-24	In favour
62D/2114/CDV	IEC 80601-2-52 ED1: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	2024-03-01	2024-05-24	In favour
62D/2121/Q	Nomination of Convenor for IEC/SC 62D/MT16, Electro-optical equipment	2024-03-01	2024-04-12	Yes
62D/2125/FDIS	ISO 80369-2 ED1: Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases	2024-03-08	2024-04-19	In favour
62D/2122/CD	ISO 80601-2-69 ED3: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	2024-03-08	2024-05-03	No Comments sent
62D/2123/CD	ISO 80601-2-67 ED3: Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	2024-03-08	2024-05-03	No comments sent
62D/2124/CD	ISO 80601-2-70 ED3: Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment	2024-03-08	2024-05-03	No comments sent
62D/2126/CD	ISO 80601-2-90 ED2: Medical electrical equipment - Part 2-90: Particular requirements for basic	2024-03-15	2024-05-10	No comments sent

	safety and essential performance of respiratory high-flow therapy equipment			
62D/2127/CD	ISO 80601-2-74 ED3: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	2024-03-15	2024-05-10	No comments sent
62D/2129/CD	IEC 60601-2-4/AMD2 ED3: Amendment 2 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	2024-03-29	2024-05-24	No comments sent
62D/2132/CD	IEC TR 63577 ED1: Design principles and validation methods for the maintenance of microbial control for non-disposable fluid paths of dialysis equipment	2024-04-19	2024-07-12	No comments sent
62D/2134/FDIS	ISO 80601-2-79 ED2: Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment	2024-05-10	2024-06-21	In favour, no comments
62D/2135/FDIS	ISO 80601-2-80 ED2: Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency	2024-05-10	2024-06-21	In favour
62D/2140/Q	Nomination of convenor for IEC/SC 62D/JWG 22, Electromedical diagnostic and patient monitoring equipment	2024-05-24	2024-07-05	Yes
62D/2144/Q	Nomination of co-convenor of SC 62D/JWG 1, Critical Care Ventilators (joint with ISO/TC 121/SC 3) for a term of 3 years	2024-06-07	2024-07-19	Yes
62D/2145/FDIS	ISO 80369-20 ED2: Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	2024-06-14	2024-07-26	In favour
62D/2146/FDIS	IEC 80601-2-49/AMD1 ED1: Amendment 1 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors	2024-06-21	2024-08-02	In favour
62D/2150/CD	IEC 80601-2-60/AMD1 ED2:	2024-06-21	2024-08-16	No comments

	Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment			sent
62D/2155/FDIS	IEC 60601-2-34 ED4: Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	2024-07-12	2024-08-23	In favour

ANNEXURE-D

(Item 9.4.2)

Open ballots during Q2 and Q3

IEC/TC 62

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Questions	Response
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	2024-08-09	2024-09-20	(Comments to be provided)	
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	2024-08-09	2024-09-20	Do you approve the nomination of Mr Gurvinder Virk as TC 62 representative in SC 65A/JWG 21? or Would you like to nominate another candidate as TC 62 representative in SC 65A/JWG 21?	Yes or No
62/517/DC	Document for Comments - Guidance on use of AI by IEC Technical Committees	2024-08-09	2024-09-27	(Comments to be provided)	
62/520/CD	**IEC 63450 ED1: Testing of Artificial Intelligence / Machine Learning-enabled Medical Devices**	**2024-08-16**	**2024-11-08**	**(Comments to be provided in OSD)**	

IEC/TC 62A

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Questions	Response
62A/1606/NP	**PNW 62A-1606 ED1: Packaging for non-sterile medical devices – Requirements for**	2024-07-05	2024-09-27	1. Vote	a. In Favor b. Against c. Abstain

	packaging systems			2. If approved, should the next stage be a (Any additional comments to be provided)	a. Committee draft b. Committee draft for vote
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**	2024-08-09	2024-11-01	1. Vote	a. In Favor b. Against c. Abstain
				2. If approved, should the next stage be a (Any additional comments to be provided)	a. Committee draft b. Committee draft for vote

IEC/TC 62B

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Questions	Response
62B/1357/Q	Questionnaire: Convenor of Working Group 31, Mammographic X-ray equipment	2024-07-26	2024-09-06	Do you approve the nomination of Mr Stefan Veitenhansl as Convenor of WG 31?	a. Yes b. No c. Abstention

IEC/TC 62C

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Questions	Response
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	2024-07-05	2024-09-20	(Comments to be provided)	
62C/922/Q	**Questionnaire on the revision of IEC 60976:2007, Medical electrical equipment – Medical electron accelerators –**	2024-08-09	2024-09-20	**Do you agree to revise IEC 60976?**	a. Yes b. No c. Abstain

	Functional performance characteristics				
62C/923/CD	**IEC 63321 ED1: Medical electrical equipment - Functional performance characteristics for X-ray-based image-guided radiotherapy equipment**	**2024-08-16**	**2024-10-11**	**(Comments to be provided in <u>OSD</u>)**	
62C/926/AC	Call for nominations for the Chair of SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry	2024-08-23	2024-11-15	The Secretariat of SC 62C has proposed the nomination of Mr Jeffrey Vincent Siebers (US National Committee) as Chair of SC 62C.	Yes Or Would you like to nominate another candidate as Chair of SC 62C

IEC/TC 62D

Ballot Reference	Ballot title	Ballot starts date	Ballot end date	Questions	Response
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	2024-06-07	2024-08-30	Vote (Any additional comments to be provided)	a. In Favor b. Against c. Abstain
62D/2136/CDV	IEC 80601-2-60 AMD1 ED2: Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	2024-06-28	2024-09-20	Vote (Any additional comments to be provided)	a. In Favor b. Against c. Abstain
62D/2160/DC	ISO/TC 210/WG2 IMDRF Survey *(This survey has been developed by ISO TC 210/WG 2, General*	2024-07-26	2024-09-06	A survey to be taken by the experts at the following	

	aspects stemming from the application of quality principles to medical devices.)			link: https://www.aami.org/standards/participating-in-standards-development/iso-tc210-wg2-essential-principles-survey	
62D/2162/FDIS	IEC 60601-2-39 ED4: Medical electrical equipment - Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment	2024-08-09	2024-09-20	Vote (Any additional comments to be provided)	a. In Favor b. Against c. Abstain
62D/2163/FDIS	IEC 60601-2-16 ED6: Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	2024-08-09	2024-09-20	Vote (Any additional comments to be provided)	a. In Favor b. Against c. Abstain

ANNEXURE-E

(Items 11.1.2)

Review of Indian Standards (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)**	**Item 8**
2	**IS 7620 (Part 2): 1986**	**Specification for diagnostic medical X-ray equipment: Part 2 Performance requirements (First Revision)**	**Item 8**
3	**IS 7620 (Part 3): 1991**	**Medical electrical equipment - Diagnostic X-ray equipmbnts: Part 3 radiation safety requirements**	**Item 8**
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	The following standards are also adopted under MHD15: **1.** IEC 60601-2-65: 2012 Medical electrical equipment: Part 2 Particular requirements for the basic safety and essential performance: Sec 65 Dental intra-oral X-ray equipment **2.** IEC 60601-2-63: 2012 Medical electrical equipment: Part 2 Particular requirements for the basic safety and essential performance: Sec 63 dental extra-oral X-ray equipment. The Committee may consider withdrawal of this IS.

ANNEXURE-F

(Item 11.2.3)

Review of Indian Standards (5 year per cycle)

S.No.	IS No.	IS Title	Due date
1.	*IS 7620 (Part 1): 1986*	*Specification for diagnostic medical X-ray equipment: Part 1 general and safety requirements (First Revision)*	*December, 2024*
2.	*IS 7620 (Part 2): 1986*	*Specification for diagnostic medical X-ray equipment: Part 2 performance requirements (First Revision)*	*December, 2024*
3.	IS/IEC 61262-2: 1994	Medical electrical equipment characteristics of electro - Optical X-ray image intensifiers: Part 2 determination of the conversion factor	December, 2024
4.	IS/IEC 61262-1: 1994	Medical Electrical Equipment - Characteristics of Electro-Optical X-Ray Image Intensifiers	February, 2025
5.	IS 13450 (Part 2/Sec 46): 2020 IEC 60601-2-46: 2016	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 46 Operating tables	March, 2025
6.	IS 13450 (Part 2/Sec 52): 2020 IEC 60601-2-52: 2018	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 52 Medical beds	March, 2025
7.	IS 13450 (Part 2/Sec 68): 2020 IEC 60601-2-68: 2014	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 68 X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	March, 2025
8.	IS 13450 (Part 2/Sec 40): 2020 IEC 60601-2-40:2016	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 40 Electromyographs and evoked response equipment	March, 2025
9.	IS 13450 (Part 2/Sec 41): 2020 IEC 60601-2-41:2009	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 41 Surgical luminaires and luminaires for diagnosis	March, 2025
10.	IS 13450 (Part 2/Sec 18): 2014 IEC 60601-2-18: 2009	Medical electrical equipment: Part 2 Particular requirements for the basic safety and essential performance: Sec 18 endoscopic equipment	November, 2024