BUREAU OF INDIAN STANDARDS

Program of Work

MHD 14 : Hospital Planning

Scope: a) To prepare codes, guides and standards (physical, staff and equipment planning), quality management systems and operational systems for health care services; b) Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance;

Liaison: **ISO TC-304 (P):** *Healthcare organization management* **ISO TC-210 (P):** *Quality management and corresponding general aspects for products with a health purpose including medical devices* **ISO TC-212 (P):** *Clinical laboratory testing and in vitro diagnostic test systems*

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS 10905 (Part 1) : 1984 Reviewed In : 2018 Reaffirmed but not taken up for revision	Recommendations for basic requirements of general hospital buildings: Part 1 Administrative and hospital services department buildings		-	Indigenous
2	IS 10905 (Part 2) : 1984 Reviewed In : 2018 Reaffirmed but not taken up for revision	Recommendations for basic requirements of general hospital buildings: Part 2 medical services department buildings		-	Indigenous
3	IS 10905 (Part 3) : 1984 Reviewed In : 2018 Reaffirmed but not taken up for revision	Recommendations for basic requirements of general hospital buildings: Part 3 engineering services department buildings		-	Indigenous
4	IS 12377 : 2016	Classification and matrix for various categories of hospitals (First Revision)		-	Indigenous
5	IS 12433 (Part 1) : 1988 Reviewed In : 2018 Reaffirmed but not taken up for revision	Basic requirements for hospital planning: Part 1 up to 30 bedded hospital		2	Indigenous
6	IS 12433 (Part 2) : 2001 Reviewed In : 2018	Basic requirements for hospital planning: Part 2 up to 100 bedded hospital		-	Indigenous
7	IS/ISO 13485 : 2016	Medical Devices — Quality Management Systems —		-	Identical under single numbering

	ISO 13485:2016	Requirements for Regulatory Purposes (First Revision)			
8	IS 13808 (Part 1) : 1993 Reviewed In : 2018 Reaffirmed but not taken up for revision	Quality management procedures for out - Patient department (OPD) and emergency services - Guidelines: Part 1 upto 30 bedded hospitals		1	Indigenous
9	IS 13808 (Part 2) : 1993 Reviewed In : 2018 Reaffirmed but not taken up for revision	Quality management procedures for diagnostic and blood transfusion services - Guidelines: Part 1 up to 30 - Bedded hospitals		1	Indigenous
10	IS 13808 (Part 3) : 1995 Reviewed In : 2021 Reaffirmed but not taken up for revision	Quality management for hospital services (Upto 30 - Bedded Hospitals) - Guidelines: Part 3 wards, nursing services and operation theatre	December, 2021	-	Indigenous
11	IS 13808 (Part 4) : 1996 Reviewed In : 2021 Reaffirmed but not taken up for revision	Quality management for hospital services (For 30 - Bedded Hospital) - Guidelines: Part 4 hospital support services	December, 2021	-	Indigenous
12	IS 13808 (Part 5) : 1996 Reviewed In : 2021 Reaffirmed but not taken up for revision	Quality management for hospital services (For 30 - Bedded Hospital) - Guidelines: Part 5 hospital equipment management	December, 2021	-	Indigenous
13	IS/ISO 14971 : 2019 ISO 14971:2019 ISO 14971 : 2019	Medical devices - Application of risk management to medical devices First Revision		-	Identical under single numbering
14	IS/ISO 15189 : 2022 ISO 15189 : 2022 ISO 15189 : 2022	Medical Laboratories Requirements for Quality and Competence Third Revision		-	Identical under single numbering
15	IS/ISO 15190 : 2003 ISO 15190 : 2003 ISO 15190:2003	Medical Laboratories - Requirements for Safety		-	Identical under single numbering
16	IS 15195 : 2002 Reviewed In : 2017	Performance guidelines for quality assurance in hospital services up to 30 - Bedded hospitals	October, 2017	-	Indigenous
17	IS/ISO 15195 : 2018 ISO 15195 : 2018 Reviewed In : 2024 ISO 15195:2018	Laboratory Medicine - Requirements for the Competence of Calibration Laboratories Using Reference Measurement Procedures	July, 2024	-	Identical under single numbering
18	IS/ISO 15223-1 : 2016 ISO 15223-1 : 2016 ISO 15223-1:2016	Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)	-	-	Identical under single numbering
19	IS/ISO 15223-2 : 2010 ISO 15223-2 : 2010 ISO 15223-2 : 2010	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied: Part 2 symbol development, selection and		-	Identical under single numbering

		validation			
20	IS 15461 : 2004 Reviewed In : 2019	Performance guidelines for quality assurance in hospital services up to 100 - Bedded hospitals	July, 2019	-	Indigenous
21	IS 15551 : 2003 Reviewed In : 2019	Quality management systems - Guidelines for process improvements in health service organizations	December, 2019	-	Indigenous
22	IS 15784 : 2007 Reviewed In : 2017	Healthcare facilities - Particular requirements	September, 2017	-	Indigenous
23	IS 15902 : 2011 Reviewed In : 2020	Guidelines For Nursing Home	November, 2020	-	Indigenous
24	IS 15903 : 2010 Reviewed In : 2020	Guidelines For Maternity Nursing Home	November, 2020	-	Indigenous
25	IS 15904 : 2011 Reviewed In : 2020	Guidelines For Single Doctor Clinic--Including Dental Clinic	November, 2020	-	Indigenous
26	IS/ISO 16142-1 : 2016 ISO 16142-1 : 2016 ISO 16142-1 : 2016	Medical Devices - Recognized Essential Principles of Safety and Performance of Medical Devices Part 1 General Essential Principles and Additional Specific Essential Principles for all Non-IVD Medical Devices and Guidance on the Selection of Standards		-	Identical under single numbering
27	IS/ISO 16142-2 : 2017 ISO 16142-2 : 2017 IS/ISO 16142-2: 2017	Medical devices - Recognized essential principles of safety and performance of medical devices: Part 2 General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards		-	Identical under single numbering
28	IS 17722 : 2021 ISO/TS 22583:2019 ISO/TS 22583:2019	Guidance for supervisors and operators of point-of-care testing POCT devices		-	Identical under dual numbering
29	IS/ISO 17822-1 : 2014 ISO 17822-1 : 2014 ISO 17822-1 : 2014	In vitro diagnostic test systems - Qualitative nucleic acid - Based in vitro examination procedures for detection and identification of microbial pathogens: Part 1 general requirements, terms and definitions		-	Identical under single numbering
30	IS 17898 : 2023 ISO 15190:2020 ISO 15190:2020	Medical laboratories Requirements for safety (First Revision)		-	Identical under dual numbering
31	IS 17922 (Part 1) : 2023 IEC 62366-1: 2015 CSV IEC 62366-1: 2015 CSV	Medical Devices Part 1: Application of Usability Engineering		-	Identical under dual numbering
32	IS 17964 (Part 20) : 2023 ISO 80369-20: 2015 ISO 80369-20: 2015	Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods		-	Identical under dual numbering
33	IS 18105 (Part 1) : 2023 ISO 15223-1:2021 ISO 15223-1:2021	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements		-	Identical under dual numbering

34	IS 18131 : 2023 ISO 17822:2020 ISO 17822:2020	In vitro diagnostic test systems Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens Laboratory quality practice guide (First Revision)		-	Identical under dual numbering
35	IS 18132 : 2023 ISO 22367 : 2020 ISO 22367 : 2020	Medical laboratories - Application of risk management		-	Identical under dual numbering
36	IS/ISO 18250-1 : 2018 ISO 18250-1:2018 ISO 18250-1:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 1 General requirements and common test methods		-	Identical under single numbering
37	IS/ISO 18250-3 : 2018 ISO 18250-3:2018 ISO 18250-3:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3 Enteral Applications		1	Identical under single numbering
38	IS/ISO 18250-6 : 2019 ISO 18250-6:2019 ISO 18250-6:2019	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 6 Neural Applications		-	Identical under single numbering
39	IS/ISO 18250-7 : 2018 ISO 18250-7:2018 ISO 18250-7:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7 Connectors for intravascular infusion		-	Identical under single numbering
40	IS/ISO 18250-8 : 2018 ISO 18250-8:2018 ISO 18250-8:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 8 Citrate-based anticoagulant solution for apheresis applications		-	Identical under single numbering
41	IS 18325 : 2023 ISO/TS 20914:2019 ISO/TS 20914:2019	Medical laboratories Practical guidance for the estimation of measurement uncertainty		-	Identical under dual numbering
42	IS 18374 : 2023 ISO 23162:2021 ISO 23162:2021	Basic semen examination Specification and test methods		-	Identical under dual numbering
43	IS 18376 : 2023 ISO/TR 20416: 2020 ISO/TR 20416: 2020	Medical devices Post-market surveillance for manufacturers		-	Identical under dual numbering
44	IS/ISO 20417 : 2021 ISO 20417:2021 ISO 20417:2021	Medical devices Information to be supplied by the manufacturer		-	Identical under single numbering
45	IS/ISO/TS 20658 : 2023 ISO 20658: 2023 ISO 20658: 2023	Requirements for the collection and transport of samples for medical laboratory examinations (First Revision)		-	Identical under single numbering
46	IS/ISO/TS 20658 : 2017 ISO/TS 20658 : 2017 ISO 20658: 2023	Medical Laboratories - Requirements for Collection, Transport, Receipt, and Handling of Samples		-	Identical under single numbering
47	IS/ISO 20776-1 : 2019 ISO 20776-1 : 2019 ISO 20776-1:2019	Susceptibility Testing of Infectious Agents and Evaluation of Performance of Antimicrobial Susceptibility Test Devices Part 1		-	Identical under single numbering

		Broth Micro-Dilution Reference Method for Testing the in vitro Activity of Antimicrobial Agents Against Rapidly Growing Aerobic Bacteria Involved in Infectious Diseases			
48	IS/ISO 20776-2 : 2021 ISO 20776-2: 2021 ISO 20776-2: 2021	Clinical Laboratory Testing and In Vitro Diagnostic Test Systems â€" Susceptibility Testing of Infectious Agents and Evaluation of Performance of Antimicrobial Susceptibility Test Devices Part 2 Evaluation of Performance of Antimicrobial Susceptibility Test Devices Against Reference Broth Micro-Dilution (First Revision)		-	Identical under single numbering
49	IS/ISO 20776-2 : 2007 ISO 20776-2 : 2007 ISO 20776-2: 2021	Clinical Laboratory Testing and In-vitro Diagnostic Test Systems - Susceptibility Testing of Infectious Agents and Evaluation of Performance of Antimicrobial Susceptibility Test Devices Part 2 Evaluation of Performance of Antimicrobial Susceptibility Test Devices		-	Identical under single numbering
50	IS/ISO/TS 22367 : 2008 ISO/TS 22367 : 2008 ISO/TS 22367:2008	Medical Laboratories - Reduction of Error through Risk Management and Continual Improvement		-	Identical under single numbering
51	IS 23485 : 2019	Medical devices - Quality management system requirements and essential principles of safety and performance for medical devices		-	Indigenous
52	IS/ISO/TR 24971 : 2020 ISO/TR 24971:2020 ISO/TR 24971:2020	Medical Devices Guidance on the Application of ISO 14971 (First Revision)		-	Identical under dual numbering
53	IS/ISO 35001 : 2019 ISO 35001:2019 ISO 35001:2019	Biorisk management for laboratories and other related organisations		-	Identical under single numbering
54	IS/ISO 62304 : 2015 ISO 62304 : 2015 ISO 62304 : 2015	Medical device software - Software life cycle processes		-	Identical under single numbering
55	IS/IEC/TR 62366-2 : 2016 IEC 62366-2 : 2016 IEC/TR 62366-2:2016	Medical devices Part 2 Guidance on the Application of Usability Engineering to Medical Devices		-	Identical under single numbering
56	IS/ISO/TR 80002-2 : 2017 ISO/TR 80002-2 : 2017 ISO/TR 80002-2:2017	Medical Device Software Part 2 Validation of Software for Medical Device Quality Systems		-	Identical under single numbering
57	IS/IEC/TR 80002-3 : 2014 IEC/TR 80002-3:	Medical device software Part 3: Process reference model of medical device software life cycle		-	Identical under single numbering

	2014 IEC/TR 80002-3: 2014	processes IEC 62304			
58	IS/ISO 80369-1 : 2018 ISO 80369-1 : 2018 Reviewed In : 2024 ISO 80369-1:2018	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements	July, 2024	-	Identical under single numbering
59	IS/IEC 80369-5 : 2016 IEC 80369-5:2016 IEC 80369-5:2016	Small-bore connectors for liquids and gases in healthcare applications Part 5 Connectors for limb cuff inflation applications		-	Identical under single numbering
60	IS/IEC 80369-6 : 2016 ISO 80369-6:2016 ISO 80369-6:2016	Small bore connectors for liquids and gases in healthcare applications Part 6 Connectors for neuraxial applications		-	Identical under single numbering

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
No Records Found		

Preliminary Draft Standards

SI. No.	Doc No.	Title
No Records Found		

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
No Records Found		

Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
1	MHD 14 (26217)	Healthcare Organization Management Pandemic Response Temporary Medical Facility
2	MHD 14 (26222)	Medical Device Software Part 1 Guidance on the Application of ISO 14971 to Medical Device Software
3	MHD 14 (26224)	Small-bore connectors for liquids and gases in healthcare applications Part 3 Connectors for enteral applications

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
No Records Found		

Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
No Records Found		

Total Published Standards:53 Total Standards Under development:3

Aspect Wise Report

Product : 8
Code of Practices : 26
Methods of Test : 5
Terminology : 1
Dimensions : 0
System Standard : 14
Safety Standard : 2
Others : 0
Service Specification : 0
Process Specification : 2
Unclassified : 0

Annexure-I :List of Indian Standards Withdrawn/Superseded

SI. No.	IS No. & Year	Title
1	IS 10578 : 1983 Reviewed In : 2006	Surgical Spring Trusses
2	IS 10764 : 1983	Boiling Pan Non-Pressure Type
3	IS 11882 : 1987	Frying Pan Tilting Type Electrically Operated
4	IS 11971 : 1987	Jacketed Cooking Vessel tilting Type electrically Operated
5	IS 15579 : 2005	Medical devices -Quality management systems-Requirements for regulatory purposes
6	IS 17723 : 2021 ISO 22870:2016 ISO 8655-7:2022	Point-of-care testing POCT Requirements for quality and competence
7	IS 3991 : 1993	Bowls Lotion
8	IS 3995 : 1980	Mugs
9	IS 3996 : 1982	Spittoons
10	IS/IEC 62366-1 : 2015 IEC 62366-1 : 2015 â€˜ IEC 62366-1:2015	Medical Devices Part 1 Application of Usability Engineering to Medical Devices
11	IS 9310 : 1979	Water Purifier Potable
12	IS B9310 : 1979	Water Purifier Potable BI-LINGUAL

Annexure-II :List of Indian Product Standards

SI. No.	IS No. & Year	Title
1	IS/ISO 18250-1 : 2018 ISO 18250-1:2018 ISO 11416 :1995	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 1 General requirements and common test methods
2	IS/ISO 18250-3 : 2018 ISO 18250-3:2018 BS EN 12546-1:2000	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3 Enteral Applications
3	IS/ISO 18250-6 : 2019 ISO 18250-6:2019 IEC 61196-8:2012	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 6 Neural Applications
4	IS/ISO 18250-7 : 2018 ISO 18250-7:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7 Connectors for intravascular infusion
5	IS/ISO 18250-8 : 2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 8

	ISO 18250-8:2018 19036	Citrate-based anticoagulant solution for apheresis applications
6	IS/ISO 80369-1 : 2018 ISO 80369-1 : 2018 Reviewed In : 2024 ISO 80369-1:2018	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements
7	IS/IEC 80369-5 : 2016 IEC 80369-5:2016	Small-bore connectors for liquids and gases in healthcare applications Part 5 Connectors for limb cuff inflation applications
8	IS/IEC 80369-6 : 2016 ISO 80369-6:2016	Small bore connectors for liquids and gases in healthcare applications Part 6 Connectors for neuraxial applications