BUREAU OF INDIAN STANDARDS

Program of Work

MHD 14 : Hospital Planning

Published Standards

- 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

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		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			-	Identical under single numbering
15	IS/ISO 15190 : 2003 ISO 15190 : 2003 ISO 15190:2003	*		-	Identical under single numbering
16	IS 15195 : 2002	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		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,	-	-	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		-	Identical under single numbering

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

34	IS 18131 : 2023	In vitro diagnostic test systems		-	Identical under dual
	ISO 17822:2020	Nucleic acid amplification-based			numbering
	ISO 17822:2020	examination procedures for			
		detection and identification of			
		microbial pathogens Laboratory			
		quality practice guide (First			
		Revision)			
35	IS 18132 : 2023	Medical laboratories - Application		-	Identical under dual
	ISO 22367 : 2020	of risk management			numbering
	ISO 22367 : 2020				
36	IS/ISO 18250-1 :	Medical devices - Connectors for		-	Identical under single
	2018	reservoir delivery systems for			numbering
	ISO 18250-1:2018	healthcare applications - Part 1			
	ISO 18250-1:2018	General requirements and common			
		test methods			
37	IS/ISO 18250-3 :	Medical devices - Connectors for		1	Identical under single
	2018	reservoir delivery systems for			numbering
	ISO 18250-3:2018	healthcare applications - Part 3			
	ISO 18250-3:2018	Enteral Applications			
38	IS/ISO 18250-6 :	Medical devices - Connectors for		-	Identical under single
	2019	reservoir delivery systems for			numbering
	ISO 18250-6:2019	healthcare applications - Part 6			-
	ISO 18250-6:2019	Neural Applications			
39	IS/ISO 18250-7 :	Medical devices - Connectors for		-	Identical under single
	2018	reservoir delivery systems for			numbering
	ISO 18250-7:2018	healthcare applications - Part 7			
	ISO 18250-7:2018	Connectors for intravascular			
		infusion			
40	IS/ISO 18250-8 :	Medical devices - Connectors for		-	Identical under single
	2018	reservoir delivery systems for			numbering
	ISO 18250-8:2018	healthcare applications - Part 8			U
	ISO 18250-8:2018	Citrate-based anticoagulant			
		solution for apheresis applications			
41	IS 18325 : 2023	Medical laboratories Practical		-	Identical under dual
	ISO/TS 20914:2019	guidance for the estimation of			numbering
	ISO/TS 20914:2019	measurement uncertainty			C
42	IS 18374 : 2023	Basic semen examination		-	Identical under dual
	ISO 23162:2021	Specification and test methods			numbering
	ISO 23162:2021	1			U
43	IS 18376 : 2023	Medical devices Post-market		-	Identical under dual
	ISO/TR 20416: 2020				numbering
	ISO/TR 20416:				6
	2020				
44		Medical devices Information to be		-	Identical under single
	ISO 20417:2021	supplied by the manufacturer			numbering
	ISO 20417:2021	11 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
45	IS/ISO/TS 20658 :	Requirements for the collection		-	Identical under single
	2023	and transport of samples for			numbering
	ISO 20658: 2023	medical laboratory examinations			C
1	ISO 20658: 2023	(First Revision)			
46	IS/ISO/TS 20658 :	Medical Laboratories -		-	Identical under single
	2017	Requirements for Collection,			numbering
1	ISO/TS 20658 :	Transport, Receipt, and Handling			C
1	2017	of Samples			
	ISO 20658: 2023	rr			
47		Susceptibility Testing of Infectious		-	Identical under single
	2019	Agents and Evaluation of			numbering
1	ISO 20776-1 : 2019	5			
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49 IS/ISO 20776-2: 207 Clinical Laboratory Testing and Invitro Diagnostic Test Systems - Interview System Continuer Diagnostic Test System Continuer Diagnostic Test System Continuer Diagnostic Test Systems - Interview System Continuer Diagnostic Test Systems - I						
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58	IS/ISO 80369-1 : 2018 ISO 80369-1 : 2018 Reviewed In : 2024 ISO 80369-1:2018	11	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	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 1		
	ISO 18250-1:2018	General requirements and common test methods		
	ISO 11416 :1995			
2	IS/ISO 18250-3 : 2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3		
	ISO 18250-3:2018	Enteral Applications		
	BS EN 12546-1:2000			
3	IS/ISO 18250-6 : 2019	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 6		
	ISO 18250-6:2019	Neural Applications		
	IEC 61196-8:2012			
4	IS/ISO 18250-7 : 2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7		
	ISO 18250-7:2018	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