

ANNEX F

(Item 7)

Program of Work

Scope of the Hospital Planning Sectional Committee (MHD14):

- 1) To prepare codes, guide and standard (Physical, Staff and Equipment Planning), Quality management system and operational system for health care services.
- 2) Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test system. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference system and quality assurance; and
- 3) To coordinate with the work of:
 - a) ISO/TC 210 “Quality managements and Corresponding general aspects for Medical devices: (P Member)
 - b) ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic test system”: (P Member)
 - c) ISO/TC 304 “Healthcare organization management” (P Member)

Published Standards

Sl. No.	IS No.	TITLE
1)	IS 10905 : Part 1 : 1984	Recommendations for basic requirements of general hospital buildings Part 1 Administrative and hospital services department buildings
2)	IS 10905 : Part 2 : 1984	Recommendations for basic requirements of general hospital buildings Part 2 medical services department buildings
3)	IS 10905 : Part 3 : 1984	Recommendations for basic requirements of general hospital buildings Part 3 engineering services department buildings
4)	IS 12377 : 2016	Classification and matrix for various categories of hospitals First Revision
5)	IS 12433 : Part 1 : 1988	Basic requirements for hospital planning Part 1 up to 30 bedded hospital
6)	IS 12433 : Part 2 : 2001	Basic requirements for hospital planning Part 2 up to 100 bedded hospital
7)	IS/ISO 13485 : 2016	Medical Devices Quality Management Systems Requirements for Regulatory Purposes First Revision
8)	IS 13808 : Part 1 : 1993	Quality management procedures for out - Patient department OPD and emergency services - Guidelines Part 1 upto 30 bedded hospitals
9)	IS 13808 : Part 2 : 1993	Quality management procedures for diagnostic and blood transfusion services - Guidelines Part 1 up to 30 - Bedded hospitals
10)	IS 13808 : Part 3 : 1995	Quality management for hospital services Upto 30 - Bedded Hospitals - Guidelines Part 3 wards nursing services and operation theatre

11)	IS 13808 : Part 4 : 1996	Quality management for hospital services For 30 - Bedded Hospital - Guidelines Part 4 hospital support services
12)	IS 13808 : Part 5 : 1996	Quality management for hospital services For 30 - Bedded Hospital - Guidelines Part 5 hospital equipment management
13)	IS/ISO 14971 : 2019	Medical devices - Application of risk management to medical devices First Revision
14)	IS/ISO 15189 : 2012	Medical laboratories - Requirements for quality and competence Second Revision
15)	IS/ISO 15190 : 2003	Medical Laboratories Requirements for Safety
16)	IS 15195 : 2002	Performance guidelines for quality assurance in hospital services up to 30 - Bedded hospitals
17)	IS/ISO 15195 : 2018	Laboratory Medicine Requirements for the Competence of Calibration Laboratories Using Reference Measurement Procedures
18)	IS/ISO 15197 : 2013 ISO 15197 : 2013	In vitro Diagnostic Test Systems Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus
19)	IS/ISO 15198 : 2004	Clinical Laboratory Medicine In vitro Diagnostic Medical Devices Validation of User Quality Control Procedures by the Manufacturer
20)	IS/ISO 15223 : Part 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
21)	IS/ISO 15223 : Part 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 validation
22)	IS 15461 : 2004	Performance guidelines for quality assurance in hospital services up to 100 - Bedded hospitals
23)	IS 15551 : 2003	Quality management systems - Guidelines for process improvements in health service organizations
24)	IS 15784 : 2007	Healthcare facilities - Particular requirements
25)	IS 15902 : 2011	Guidelines For Nursing Home
26)	IS 15903 : 2010	Guidelines For Maternity Nursing Home
27)	IS 15904 : 2011	Guidelines For Single Doctor Clinic--Including Dental Clinic
28)	IS/ISO 16142 : Part 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

29)	IS/ISO 16142 : Part 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
30)	IS/ISO 17511 : 2020	In Vitro Diagnostic Medical Devices - Requirements for Establishing Metrological Traceability of Values Assigned to Calibrators Trueness Control Materials and Human Samples
31)	IS 17722: 2021 (ISO/TS 22583: 2019)	Guidance for Supervisors and Operators of Point-of-care Testing (POCT) Devices
32)	IS 17723: 2021 ISO 22870:2016	Point-of-care testing POCT Requirements for quality and competence
33)	IS/ISO 17822 : Part 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
34)	IS/ISO 18250 : Part 1 : 2018 ISO 18250-1:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 1 General requirements and common test methods
35)	IS/ISO 18250 : Part 3 : 2018 ISO 18250-3:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3 Enteral Applications
36)	IS/ISO 18250 : Part 6 : 2019 ISO 18250-6:2019	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 6 Neural Applications
37)	IS/ISO 18250 : Part 7 : 2018 ISO 18250-7:2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7 Connectors for intravascular infusion
38)	IS/ISO 18250-8 : 2018	Medical Devices — Connectors for Reservoir Delivery Systems for Healthcare Applications Part 8 Citrate-based Anticoagulant Solution for Apheresis Applications
39)	IS/ISO/TS 20658 : 2017	Medical Laboratories - Requirements for Collection Transport Receipt and Handling of Samples
40)	IS/ISO 20776 : Part 1 : 2019	Susceptibility Testing of Infectious Agents and Evaluation of Performance of Antimicrobial Susceptibility Test Devices Part 1 Broth Micro-Dilution Reference Method for Testing the in vitro Activity of Antimicrobial Agents Against Rapidly Growing Aerobic Bacteria Involved in Infectious Diseases
41)	IS/ISO 20776 : Part 2 : 2007	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

42)	IS/ISO/TS 22367 : 2008	Medical Laboratories - Reduction of Error through Risk Management and Continual Improvement
43)	IS 23485 : 2019	Medical devices - Quality management system requirements and essential principles of safety and performance for medical devices
44)	IS/ISO 23640 : 2011 ISO 23640 : 2011	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
45)	IS/ISO/TR 24971 : 2013 ISO/TR 24971 : 2013	Medical devices - Guidance on the application of ISO 14971
46)	IS/ISO 35001: 2019	Biorisk Management for Laboratories and Other Related Organisations
47)	IS/ISO 62304 : 2015 ISO 62304 : 2015	Medical device software - Software life cycle processes
48)	IS/IEC 62366 : Part 1 : 2015	Medical Devices Part 1 Application of Usability Engineering to Medical Devices
49)	IS/IEC/TR 62366 : Part 2 : 2016	Medical devices Part 2 Guidance on the Application of Usability Engineering to Medical Devices
50)	IS/ISO/TR 80002 : Part 2 : 2017	Medical Device Software Part 2 Validation of Software for Medical Device Quality Systems
51)	IS/ISO 80369 : Part 1 : 2018	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements
52)	IS/IEC 80369-5 : 2016	Small-bore connectors for liquids and gases in healthcare applications Part 5 Connectors for limb cuff inflation applications
53)	IS/IEC 80369-6 : 2016	Small bore connectors for liquids and gases in healthcare applications Part 6 Connectors for neuraxial applications

Standards Under Development

Projects Approved

SI. No.	Doc No	TITLE
NIL		

Preliminary Draft Standards

SI. No.	Doc No	TITLE
NIL		

Drafts Standards in WC Stage

SI. No.	Doc No	TITLE
1)	MHD 14 (18414)	Medical Devices Guidance on the Application of ISO 14971 First Revision
2)	MHD 14 (20106) (IEC 62366-1: 2015 CSV)	Medical Devices Part 1 Application of Usability Engineering to Medical Devices First Revision

Draft Standards Completed WC Stage

SI. No.	Doc No	TITLE
1)	MHD 14 (12096) Revision of: IS 12433:1988	BASIC REQUIREMENTS FOR HOSPITAL PLANNING PART 1 UP TO 30 BEDDED HOSPITAL
2)	MHD 14 (12097) Revision of: IS 12433:2001	BASIC REQUIREMENTS FOR HOSPITAL PLANNING PART 2 UP TO 100 BEDDED HOSPITAL
3)	MHD 14 (20111)	Medical devices Post-market surveillance for manufacturers
4)	MHD 14 (20126)	Medical laboratories Practical guidance for the estimation of measurement uncertainty
5)	MHD 14 (20130)	Basic semen examination Specification and test methods

Finalized Draft Indian Standard

SI. No.	Doc No	TITLE
1)	MHD 14 (18421)	Medical devices - Quality management system requirements and essential principles of safety and performance for medical devices Amendment - 1

Finalized Draft Indian Standards under Print

SI. No.	Doc No	TITLE
1)	MHD 14 (16960) (ISO 80369-20: 2015)	Small-bore connectors for liquids and gases in healthcare applications Part 20 Common test methods
2)	MHD 14 (18395) (ISO 15190:2020)	Medical laboratories Requirements for safety First Revision

3)	MHD 14 (18400)	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1 General requirements
4)	MHD 14 (18408)	In vitro diagnostic test systems Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens Laboratory quality practice guide First Revision
5)	MHD 14 (18413)	Medical laboratories - Application of risk management

Total Published Standards: 53
Total Standards Under development: 13

Aspect Wise Report

Product:	8
Code of Practices :	18
Methods of Test :	8
Terminology :	1
Dimensions :	0
System Standard :	14
Safety Standard :	2
Others :	2
Service Specification :	0
Process Specification :	0
Unclassified :	0