STRATEGIC ROAD MAP

MEDICAL EQUIPMENT & HOSPITAL PLANNING DIVISION COUNCIL

1 INTRODUCTION

1.1 Medical equipment and Hospital Planning Division Council (MHDC) of Bureau of Indian Standards (BIS) deals with standardization in the field of medical equipment, surgical dressings, artificial limbs, rehabilitation equipment, diagnostic kits, veterinary surgery instruments, dental equipment, laboratory instruments and equipment, hospital biomedical waste management and infection, control, medical biotechnology and medical nano-technology, hospital planning and health care service, biological and clinical evolution of medical device, Immuno-biological diagnostic kits and medical electrical equipment.

1.2 The Strategic Roadmap of the MHDC has been developed as a document that would reflect its vision of National Standardization for medical devices and equipment and provide a broad standardization roadmap with a five-year perspective. The aim is to align the standardization work with the needs of the healthcare sector, the technology requirements and allow sectional committees to prioritize amongst different projects, identify the benefits expected from the availability of Indian Standards and to support the national regulatory framework in field of medical devices.

1.3 The Roadmap covers the following main strategic objectives of Division Council:

a) to provide a framework for the development of Indian standards to support the regulatory framework in the country for medical devices;
b) to review the standards for their robustness and relevance to keep pace with the fast evolving technology in the field of medical devices and healthcare;
c) to provide a platform for enabling the domestic industry to be able to compete at international levels through harmonization with International Standards and adoption of best standardization practices;
d) to emphasize on safeguard of health, safety, environment and preventing bio-hazards through standardization; and
e) to promote innovation through standardization of evolving / new technologies in field of medical devices, healthcare technology and digital health.

2. Current Scenario:

2.1 MHDC has published over 1400 standards through 20 Sectional Committees, 484 of which are harmonized with the International Standards brought out by International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). The scope and area of work of each sectional Committee are given in **Annex A** of this document.

2.2 Medical Equipment and Hospital Planning Department **(**MHD), as on date has "Participating Member" status in 20 Technical Committees/ Sub-Committees of ISO/IEC. India holds convenership of 04 Working Group of ISO Technical Committees.

2.3 Regulatory Framework: The Clause 7 "Product standards for medical device" of the Medical Devices Rules, 2017 provides for the following regarding conformance of medical devices to Standards:

"*(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.*

(2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeia standards.

(3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

Accordingly, the availability of Indian Standards becomes crucial for regulation of Medical Devices by the concerned Regulator.

3. Identified strategies to achieve the defined objectives

MHDC will employ the following strategies to accomplish the preceding objectives:

a) continuous monitoring of the structure of MHD to accurately reflect the dynamic work programme, needs of the industries, consumers and other stakeholders;
b) establishing the priority of work items within Sectional Committees and Panels in the MHD;
c) according priority to the timely circulation of documents and adherence to target dates;
d) limiting the physical meetings and encouraging virtual meetings;

e) continuing to work in close liaison with ISO/IEC and other standards formulation bodies and liaison committees to garner consensus, avoid duplication and conflict;
f) expediting the publication of Indian standards;
g) improving the level of engagement at ISO/IEC forums by presenting India's viewpoint during the meetings;
h) maintaining close liaison with stakeholders including industry associations, regulatory bodies, Research organizations, Academic Institutions, Start-ups and consumer forums.

4. IMPLEMENTATIONS OF THE STRATEGIC ROADMAP

4.1 The strategic roadmap of MHDC will be implemented in the next five years and the progress to be monitored periodically. Focused approach towards development of action plans, key milestones, defined tasks, and timelines will be adopted.

4.2 Implementation of standards is the spirit behind their formulation. MHDC envisages to continue organizing webinars, seminars, orientation programmes and virtual meets to effectively engage with the stakeholders. Participation in networking forums and conclaves organized by likeminded organizations both at National and International level is to be encouraged for dissemination of Indian Standards as well as foster exchange of knowledge with other Standards Developing Organizations (SDOs). Special emphasis is envisaged on organization of such programmes in educational institutions with a view to sensitize the students regarding the science and sanctity of Standards.

4.3 Harmonization of Standards: It shall be the endeavor of MHDC to promote harmonization with ISO/IEC Standards, wherever feasible and implementable in the National Scenario. The mapping of Indigenous Standard with corresponding ISO/ IEC Standards will be undertaken for harmonization, wherever International Standard is existing or feasible.

4.4 Participation in International Standardization: Expert members associated with MHD sectional committees have been actively contributing in the formulation of standards in ISO Technical Committees. With a view to engage in formulation of international standards in the prioritized areas especially the emerging technologies, MHDC envisages to encourage more rigorous participation of its officers and experts in the ISO activities.

Formulation of ISO standards in the area of AYUSH informatics has been initiated at the behest of BIS under the ISO TC 215. Similar unique initiatives are likely to be explored in other areas of National interest and International relevance as well.

4.5 New Subjects: Recent pandemic has been challenging not only for the medical fraternity but also for standard setting organizations. MHDC played a pivotal role in mitigation of the morbidity by expeditious formulation of Indian Standards for

critical care equipment *inter-alia* Ventilators and Oxygen concentrators. The MHDC is committed to respond promptly during such National exigencies in future also.

It is intended to identify the broad areas of priority in which standardization work need to take place, keeping into consideration the technologies, innovations, Government policies, regulatory requirements, environmental and social aspects. Importance of keeping pace with the upcoming technological innovations in the field of medical devices and related domains is well understood and MHDC looks forward to working in collaboration with experts and stakeholders in the identified areas including but not limited to health informatics, Electronic Health records (EHRs), block chain, 3D printing, forensic sciences, Nano-technology, *In-vitro* Diagnostics, etc.

4.6 Priority Areas: The MHDC intends to assign priority to standardization in the following areas:

a) **Medical biotechnology and Nanotechnology:** They are emerging and fast evolving areas which have tremendous influence on medicine and healthcare technology.

b) **Health informatics**: The application of Health Informatics (Digital Health/e-Health) technologies has become an influencing factor in healthcare industry. Such technologies help to improve quality of healthcare, reduce medical errors, reduce healthcare costs, increase administrative efficiency, and expand access to affordable healthcare. Patients using digital networks to communicate with doctors are enjoying the benefits of innovative healthcare experience. It provides them the power to manage their health by providing access to their health data from different sources such as doctor's clinics, hospitals, laboratories, pharmacist and even old medical records.

c) **Ayush Informatics**: Owing to the complexities involved in identification of Prakriti which forms the pivotal aspect of personalized medicine by identifying a patients' susceptibility to diseases, drug responsiveness, prognosis as well as the suitability of diet and life-style and overall responsiveness to the environment, it becomes imperative to utilize artificial intelligence and data mining techniques to get the precise information in the easiest way and to deliver effective healthcare to the patients. Application of standardized informatics tools in Ayurveda is poised to bring robustness in clinical decision support systems, electronic health records, telemedicine, processing and storage of data, automation of time consuming, subjective and labor-intensive clinical examination involving multi-layered parameters, personalized medication, identification of herbs, processing of formulations, pharmacovigilance and even drug re-positioning. Health related data

is complex, multidimensional, variable and above all personalized especially in reference to Ayurveda.

d) **Anatomy and Forensic Sciences:** The development of National standards for forensic science is important to enhance the reliability, transparency and confidence in forensic evidence. It will also facilitate the exchange of forensic results, information and intelligence, including the sharing of databases, to ensure forensic services are fit for purpose.

e) **Anaesthetic and Resuscitation technology and equipment:** The instruments and equipment used for anaesthesing and ventilating a patient, including diagnostic instruments is important in care of patients during routine palliative treatment, emergencies as well as during pandemics.

f) **Biomedical Waste Management**:: The safe disposal of biomedical waste is an important concern in hospitals and diagnostic centre. The quantity of such waste is poised to increase with advanced use of medical/ health care facilities and rise in population. Thus standardization for Equipment and instruments for infection control and Equipment/containers required under Biomedical Waste Management and handling rules 1998 will help in preventing health hazards due to biological waste.

4.7 Review of Standards: The existing number of over 1400 standards under the MHDC and its Sectional Committees needs regular review/ confirmation/ amendment/ revision, to ensure their relevance and to meet pace with evolving technology. A time bound action plan will be devised for each sectional committees for in depth review of each standard which are more than 5 years old.

4.8 In addition to already identified priority area, MHDC is committed towards formulating standards for medical devices commensurate to the evolving needs of Indian consumers and medical device industry.

ANNEX -A

Sectional Committees under Medical Equipment and Hospital Planning Department (MHD)	**Scope of Sectional Committee**
MHD 1 : Surgical Instruments Sectional Committee	To formulate Indian Standards for general, pediatric, urological and plastic surgery instruments, B.P. blades, endoscopic instruments with fibre optics pertaining to Gastroenterology & Urology, haemostatic forceps, etc.
MHD 2 : Orthopaedic Instruments, Implants And Accessories Sectional Committee	To formulate Indian Standards for instruments used in orthopaedic surgery and orthopaedic implants (Excluding cardio-vascular and neuro-surgical implants) such as bone holding forceps, bone nail, bone cutting saws and bone drills, etc.
MHD 3 : Obstetric And Gynaecological Instruments Sectional Committee And	To formulate Indian Standards for instruments, appliances and medical devices, used in obstetrics and gynaecology and for contraception
MHD 4 : Ear, Nose And Throat Surgery Instruments Sectional Committee	To formulate Indian Standards for instruments used in ear, nose and throat surgery including ENT microsurgery instruments, ENT implants, vibrators, audiometers, hearing-aids tuning forks, hooks and elevators, diagnostic instrument, etc.
MHD 5 : Ophthalmic Instruments And Appliances Sectional Committee	To formulate Indian Standards for surgical instrument, Occular implants and equipment used in eye surgery
MHD 6 : Thoracic And Cardiovascular Surgery Instruments Sectional Committee	To formulate Indian Standards for thoracic and cardiovascular surgery instruments, implants and accessories
MHD 7 : Neurosurgery Instruments Implants And Accessories Sectional Committee	To formulate Indian Standards for Neurosurgery instruments, implants and accessories (cranial & spinal) and monitoring devices

MHD 8 : Dentistry Sectional Committee	To formulate Indian Standards for all types of dental instruments, equipments, filling and restorative materials, prosthodontic materials, dental implants, terminology, methods of tests.
MHD 9 : Artificial Limbs, Rehabilitation Appliances and Equipment for the Disabled Sectional Committee	To formulate Indian Standards for artificial limbs, prosthetic and orthotic appliances and rehabilitation equipment
MHD 10 : Medical Laboratory Instruments Sectional Committee	To formulate Indian Standards for medical instruments and glass wares in all in-vitro diagnostic medical laboratories including clinical-pathology, hematology, histopathology, cytopathology, bio chemistry, microbiology and molecular biology.
MHD 11 : Anaesthetic, Resuscitation And Allied Equipment Sectional Committee	To formulate Indian Standards for instruments and equipment used for anaesthesing and ventilating a patient, including diagnostic instruments such as sphygmomanometers, suction apparatus and anaesthetic face mask.
MHD 12 : Hospital Equipment and Surgical Disposal Sectional Committee	To formulate Indian Standards for: i) Hospital equipment used in OPD wards and operation theaters such as Sterilizers, Incubators, hospital furniture, and operation tables etc. ii) Surgical disposable products like Transfusion, infusion and injection equipment etc., and devices for administration of medical product and intravascular catheters
MHD 13 : Veterinary Hospital Planning And Surgical Instruments Sectional Committee	To formulate Indian Standards for Veterinary Hospital Planning and Veterinary Hospital Instruments including instruments pertaining to Veterinary Surgery, gynaecology and medicine for diagnosis and therapeutic management of diseased/healthy animal
MHD 14 : Hospital Planning Sectional Committee	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;

MHD 15 : Electromedical Diagnostic Imaging and Radiotherapy equipment Sectional Committee	To prepare Standards for: i) Electrical equipment concerning diagnostic, surgical, therapeutic and monitoring equipment for various specialties ; ii) Ionizing radiation imaging and radiotherapy, dentistry, equipment for radiotherapy, nuclear medicine and radiation dosimetry
MHD 17 : Health Informatics Sectional Committee	Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between Independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications) and to reduce duplication of effort and redundancies
MHD 19 : Immuno-biological Diagnostic Kits Sectional Committee	To formulate Indian Standards on: i) Biological tests, biological stains, immuno-biological and diagnostic kits. ii) Biological and clinical evaluation of medical and dental materials, devices, implants together with standardization of biological test methods applicable to those materials and devices, and iii) Good clinical practice principles to clinical investigations in humans of those devices" iv) To co-ordinate with the work of : ISO/TC 194 - Biological and Clinical Evaluation of Medical Devices : (P Member)
MHD 20 : Medical Biotechnology And Nanotechnology Sectional Committee	To formulate Indian Standards for Equipment used in Medical bio-technology and Medical Nanotechnology.
MHD 21 : Hospital Bio Medical Waste Management And Infection Control Sectional Committee	To formulate Indian Standards for: i) Equipment and instruments for infection control ii) Equipment/containers required under Biomedical Waste Management and handling rules 1998.
MHD 23: Anatomy and Forensic Sciences Sectional Committee	1. To formulate Indian Standards for medical instruments and equipment used in anatomy including genetics, histology, storage of body and body parts, embalming, plastination of human parts/sections for teaching, museum preservation, study of virtual anatomy etc. 2. To formulate Indian Standards for medical instruments and equipment used in forensic medicine including storage of human body and viscera at different temperatures, preservatives, study of toxicology,

	forensic biology and study of biological tissues, firearm evaluations, DNA analysis etc.