BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Hospital Planning Sectional Committee (MHD 14)	21	07 May 2024, Tuesday 11 AM

via Webex platform

Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m14dc553a43e116513bef57399b6b50b2

Meeting Number: 2514 932 9530

Password: Mhd14@21

Chairperson	Member Secretary
Dr. Anil Kumar Additional Deputy Director General, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India	Vinit Vidyadhar Bansod Scientist-C/Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES BY HEAD (MHD)

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 20th meeting of the Hospital Planning Sectional Committee (MHD 14) held on 13/10/2023 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD14/A2.20 dated 19/04/2024.

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 Hospital Planning Sectional Committee (MHD 14) is as follows:

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;

c) Liaison with the ISO Technical and Sub-committees:
i) *ISO/TC 210 – 'Quality management and corresponding general aspects for products with a health purpose including medical devices' - (P-member)*
ii) *ISO/TC 212 – 'Medical laboratories and in vitro diagnostic systems' (P-member)*
iii) *ISO/TC 304 – 'Healthcare organization management' (P-member)*

The Committee may please note.

2.2 The present composition of the Hospital Planning Sectional Committee (MHD 14) is enclosed at ***Annexure A.***

The Committee may please note.

2.3 Requests have been received from the following for representation on the Committee:

Sl. No.	**Organisation**	**Nomination**
1)	Individual Capicity	Mr. ChandraSR K (*Refer* ***Annexure B***)
2)	DuPont Specialty Products India Pvt. Ltd.	Mr. Vishnu Shankar Vyas Role: Regional Leader- AP, Regulatory & Standards (*Refer* ***Annexure C***)

The Committee may deliberate and decide.

2.4 Philips India Limited, Gurugram, may consider nominating an Alternate Members and a Young Professional (*below 37 years of age*) on the TC.

2.5 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 There are no draft standards/amendments pending for finalization.

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are no draft standards/amendments pending for approval for wide circulation.

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.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The Committee may kindly note.

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 A new subject for formulation of Indian Standard on '**Sustainability on Healthcare'** has been received from **Consortium of Accredited Health Care Organizations (CAHO),** and was circulated to all members for comments/observations vide our MHD email, dated **18 April 2024**.

The working draft submitted by the proposer is enclosed at ***Annexure D***.

The comments received on the document are enclosed at ***Annexure E***.

The Committee may kindly deliberate and decide.

ITEM 8 TECHNICAL ISSUES

8.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 The MHD 14 'Hospital Planning Sectional Committee' is a Participating Member and the National Mirror Committee (NMC) for the following ISO TCs.

TC No.	WG No	WG Title
ISO/TC 210 Quality Management and Corresponding General Aspects for Products with a Health Purpose Including Medical Devices	ISO/TC 210/WG 1	Application of Quality Systems to Medical Devices ***Nominated Members:*** ***1) Dr Anil Kumar*** ***2) Dr Y. P. Bhatia***
	ISO/TC 210/WG 2	General Aspects Stemming from the Application of Quality Principles to Medical Devices ***Nominated Members:*** ***1) Dr Anil Kumar***
	ISO/TC 210/WG 3	Symbols and Nomenclature for Medical Devices
	ISO/TC 210/WG 5	Connectors for Reservoir Delivery Systems
	ISO/TC 210/WG 7	Good Engineering Maintenance Management ***Nominated Members:*** ***1) Dr Anil Dewan***
ISO/TC 212 Medical Laboratories and In Vitro Diagnostic Systems	ISO/TC 212/WG 1	Quality and Competence in the Medical Laboratory ***Nominated Members:*** ***1) Dr Anil Kumar*** ***2) Mr N. Venkateswaran*** ***3) Mr Pankaj Johri*** ***4) Ms Gayathri S***
	ISO/TC 212/WG 2	Reference Systems ***Nominated Members:*** ***1) Dr Anil Kumar***

TC No.	WG No	WG Title
		2) Mr N. Venkateswaran ***3) Mr Pankaj Johri*** ***4) Ms Gayathri S***
	ISO/TC 212/WG 3	In vitro diagnostic products
	ISO/TC 212/WG 4	Microbiology and molecular diagnostics
	ISO/TC 212/WG 5	Laboratory Biorisk Management ***Nominated Members:*** ***1) Dr Anil Kumar*** ***2) Mr N. Venkateswaran*** ***3) Mr Pankaj Johri*** ***4) Ms Gayathri S***
ISO/TC 304 Healthcare Organization Management	ISO/TC 304/WG 1	Vocabulary
	ISO/TC 304/WG 4	Pandemic Preparation and Response

9.2 Appointed Working Group Experts are obliged to inform the National Mirror Committee of their contribution and progress of technical work carried out by them at the ISO level.

The Committee may kindly note.

9.3 The 11th Plenary meeting of ISO/TC 304 'Healthcare organization management' is scheduled to be held on **28 May 2024** in Virtual Mode. Nominations were sought from the MHD14 Committee members vide our email dated 23 April 2024. The last date for submitting nominations was **29 April 2024**.

The nominations received are enclosed at ***Annexure F*** and are submitted for the note of the TC and for kind consideration of Hon'ble Chair, MHD14.

9.4 The list of standards published by ISO/TC 210, ISO/TC 212, and ISO/TC 304 and their status of harmonization are given at ***Annexure G.***

ITEM 10 PROGRAMME OF WORK

10.1 The present Programme of Work of Hospital Planning Sectional Committee (MHD 14) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 Review of Indian Standards (as per 5-year cycle)

10.2.1 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.

10.2.2 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.

10.3.3 The list of such Indian Standards which are due for review in FY 2024-25 are as follows.

Sl. No.	Indian Standard No. & Title	Proposed Action
1)	**IS/ISO 15195 : 2018 '**Laboratory Medicine - Requirements for the Competence of Calibration Laboratories Using Reference Measurement Procedures**'**	Reaffirmation
2)	**IS/ISO 80369-1 : 2018 '**Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements**'**	Reaffirmation
3)	**IS 15461 : 2004 '**Performance guidelines for quality assurance in hospital services up to 100 - Bedded hospitals**'**	Archive
4)	**IS 15551 : 2003 '**Quality management systems - Guidelines for process improvements in health service organizations**'**	Take up for review

ITEM 11 DATE AND PLACE OF NEXT MEETING

11.1 As per the approved meeting calendar for **FY 2024-25,** the next meeting of the Hospital Planning Sectional Committee is tentatively scheduled for August 08, 2024, Thursday

The Committee may kindly note.

Annexure A

(*Item 2.2*)

Composition of the Committee

Sl No.	Organization	Member Name
1)	Directorate General of Health Services, New Delhi	Dr. Anil Kumar
2)	Association of Indian Medical Device Industry, New Delhi	Ms. Shanmugapriya
		Dr. H S Ratti
3)	Boston Scientific India Private Limited, Gurugram	Mr. Prashanth Prabhakar
		Mr. Dev Chopra
4)	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu
		Ms. Shyamni Sasidharan
		Mr. Aniruddh Singh Negi
5)	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Nandini Duggal
		Dr. M. P. S. Chawla
		Dr. Sharad Pandey
6)	Federation of Indian Chambers of Commerce and Industry, New Delhi	Dr. Yash Paul Bhatia
		Dr. Vikas Malhotra
		Dr. Prachi Pal
7)	HLL Infra Tech Services Limited,Noida	Mr. Devender Pratap Singh
		Mr. Prem Prakash
8)	Hindu Rao Hospital, Delhi	Dr. Harsh Vardhan Singh
		Dr. Dinesh Yadav
9)	ICMR - National Institute of Virology, Pune	Dr. Jayati Mullick
		Dr. Shailesh Dattatraya Pawar
10)	India Medtronic Private Limited, Gurugram	Mr. Kailash Khathod
		Ms. Latika Vats
		Mr. Amit Kumar
11)	Indian Institute of Technology Madras, Chennai	Dr. S. Ramakrishnan
		Dr. N. Arunachalam
		Dr. Swathi Sudhakar
12)	Indian Medical Association, New Delhi	Dr. J A Jayalal
		Dr. Jayesh M. Lele
13)	Kalam Institute of Health Technology, Vishakhapatnam	Ms. Deepti
		Dr. Arjun Thimmaiah
		Mr. Satyan Sharma
14)	Lady Hardinge Medical College, New Delhi	Dr. Anup Mohta
		Dr. Preeti Chauhan
		Dr. Shivraj Meena
	National Accreditation Board for Hospitals	Dr. Atul Mohan Kochhar

Sl No.	Organization	Member Name
15)	and Healthcare Providers, New Delhi	Dr. Punam Bajaj
16)	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Mr. N. Venkateswaran
		Mr. Pankaj Johri
		Ms. Gayathri S
		Ms. Rozina
17)	National Health Systems Resource Centre, New Delhi	Dr. Ranjan Choudhury
		Ms. Manisha Sharma
		Ms. Charu
18)	Philips India Limited, Gurugram	Mr. A V A Rajendra Prasad
19)	School of Planning and Architecture, New Delhi	Dr. Shri Anil Dewan
		Ms. Chitrarekha Kabre
		Ms. Niyati Gupta
20)	Stryker India Private Limited, Gurugram	Mr. Deepak Sharma
		Ms. Ishani Mondal

Annexure B

Chandrasekhara Reddy K

Mobile: +91 9500040802 ~ E-Mail: chandureddyk@gmail.com

AN OVERVIEW

- Development Engineering Manager with 22+ years of overall experience in Product engineering of Consumer Electronic Devices (5 Years), Medical Devices (14+ Years), Industrial devices (2) and Automotive (1 Years).
- Expertise in end-to-end design, development and enhancement of embedded software system that comply with secure development life cycle practices to meet cyber security requirements.
- Expertise in managing cross functional teams, Stakeholders and Project(s).

SKILL SET

- Customer-centric professional, driving/motivating team to meet customer expectations.
- Functional and Cross functional team management. Technology/Project/People Management.
- Defining suitable methodology and best practices for product development, project execution.
- Experience in handling NPD, enhancement and Sustenance Projects.
- Expertise in RTOS, Non RTOS based system design. Firmware (Efficient C, CPP& Assembly Coding).
- Expertise in new Technology Adaption in new/existing Products.
- Proposing and driving team to realize use cases for new features based on functionality/Technologies.
- Expertise in reviewing multi-dimensional review of product artefacts: Product use cases, Product/Software Requirements, System architecture, Software Architecture, Module Design and Code.

ORGANISATIONAL SCAN

Engineering Manager / Healthcare Technology Innovation Centre, IIT Madras / Jan 22 –

- Managing endoscopy system product development
- Setting up Verification Team, Quality Team
- Setting up Quality Management System and Process Adaption

Consultant / Aug 20 – Dec 21

- Managing Medical Device Software development
- Estimation and Planning for Wearable device prototype based on Nordic semiconductor Platform (Zephyr OS).
- Contributed towards Process improvement.

Principal Project Officer / IIT Madras, Chennai / Jun19 – Jul20

- Development Manager for productizing Ultrasound based Research outcome to address safety critical industrial needs.
- Responsible for Realizing first stage Proof of Concept Demo kits.
- Responsible for Lab infrastructure management, Calibration and procurement.
- Improving ultrasound echo signal
- Contributed towards Process improvement.
- Supporting Staff, students for their day-to-day research requirement.

Development Manager /KONE Elevator India Private Limited, Chennai / Aug18 – Apr19

- Product/Team/Technical/Project management of safety critical Industrial product.
- Requirement Preparation, Requirement/Scope management; Long term Roadmap definition for Connectivity.
- Team formation/ skill building/ product owner for Cloud based Application.
- Responsible to drive Technical Discussion, Lab setup/infrastructure.

- Contributed towards Process improvement.

Innovation Consultant / Apr17 – Jul18

- Responsible for Strategy and Planning for healthcare wearable (multi-vital sign parameter monitor).
- Working with other start-ups to explore developing less complex affordable NPD for Indian market.
- Clinical Study in Hospital environment.
- Vendor selection and management.

Senior Technical Manager/ HCL Technologies Ltd, Chennai / Jun'12 – Mar'17

- uNabto solution integration with solar inverter to enable connectivity.
- Managed (Technical/Project) software team in developing insulin infusion pump using SafeRTOS/FreeRTOS.
- Managed Medical Grade IoT Gateway with Could Connectivity Requirements and Verification team.
- Technical/Project management of Regulatory Assessment for Wi-Fi Adaptation in Endoscopy Products to enable IoT/Connectivity; Responsible for Cyber Security Assessment
- Managed Cloud based Defibrillator Wi-Fi Accessory Product sustenance.
- *IEC 62304:2006+AMD1:2015* Gap Analysis and QMS update to incorporate IEC 62304 amd#1, Voice Over Text Learning module preparation for IEC62304 standard.
- Driving team in design and Development of AUTOSAR based driver modules.
- Resource recruitment, Vendor interfacing, customer interface, Infrastructure Procurement.

Quality improvement/Team Mentoring:

- Driving design/code review of Medical Products Defibrillator, Myocardial infarction system and IVF Incubator.
- Driving design/code review of High-end Industrial Water pumps UI Subsystems.

Technology adaption:

- Wi-Fi Security for Medical products.
- NFC use case definition for Infusion Pump, Insulin Patch Pump.

Manager / CMC Ltd, Hyderabad / May' 10 – Feb'12

- Defining Consumer domain CoE strategy.
- DLNA based Apps development.
- Study the trends in Medical Domain and exploring new business opportunities.
- Proposed value-added patient care Medical echo system to improve the lives of the patients and Health care providers.

Project Lead / WIPRO Technologies, Hyderabad / Jul' 04 – Mar '10

Project Management/Technology adaption:

- Interactive DTV Solution Project for Brazilian Market.
- Porting DTV platform to PC Environment Project.

Design and Development/Technical Management/Customer Management:

- Developing Software for Quadra Core Mobile Chipset.
- Porting Music Player Middleware. Integrating Bluetooth Solution and realizing use cases.
- Brew based Media Player Application development

Member Technical Staff / HCL Technologies, Chennai / Mar' 01 – Jun'04

Design and Development: Sterilization System

- Involved in design and development of modules: Temperature control and Sterilization Process application.
- Contributed in the Designing of the Cycle Control Configuration File (CCF).

- Analysing the Requirements, Change Request. Maintenance support for Sterilization Process Application.
- Power Loss Management.

Design and Development: Handheld device to control Implantable device

- Nucleus PLUS RTOS Porting/Customization for S3C2400/10.
- RTC, PWM Timer, Parallel EEPROM Driver Development.
- System control module development.

Design and Development: Automotive dashboard application

- Dash board application to display various indications: engine temperature, oil pressure, engine warning, battery status, fuel indicator, Fog lamp indicator.

EDUCATION & CERTIFICATIONS

1998 **Bachelor of Technology in Computer Science and Engineering** from Acharya Nagarjuna University, Guntur, Andhra Pradesh, India. Secured Distinction (76%)

2000 **Master of Technology in Computer Science and Engineering** from Pondicherry University, Pondicherry, India. 7.2 CGPA.

2011 Certified Project Management Professional (PMP) since 2011, **PMP®** Number: 1457479

2020 Computer Vision Courses from opencv.org (in progress)

2021 Technology Based Entrepreneurship Development Programme (TEDP) – 6 Week Training from Department of Science and Technology (DST) and IIT Madras

2021 Certificate Course on Deeptech Entrepreneurship- 1 Week Training from IIT Hyderabad

ANNEXURE: SKILL SET

Programming Languages	C, CPP and ARM assembly
Operating Systems	RT Linux, Linux, QNX, Nucleus Plus, Rex, C-Executive, embOS, SafeRTOS, FreeRTOS, Zephyr OS
BSP/RTOS Porting	Nucleus Plus, C-Executive, FreeRTOS, SafeRTOS
Multimedia Knowledge	Good understanding of Qualcomm's audio sub-system architecture on MSM7500 chipset. Hands on exposure to Mobile concurrent operations. Audio Formats: WAV, AAC-LC, SBC Basic knowledge on gstreamer, ffmpeg.
Version control	CVS, PVCS, Perforce, SVN, GIT
Defect Reporting/Tracking	PVCS Tracker, CRMDB, Bugzilla, Redmine, Quality center
Technical Trainings Undergone	Linux Device Drivers, Linux kernel programming, embedded Linux Machine Learning
Project Management Skills	Certified Project Management Professional (PMP) Undergone 10 days training on project Management MS Project Exposure, project planning, tracking, monitoring and control.
Quality/Process: **Medical Quality:** **Life Cycle Model:** **CyberSecurity:**	Familiar with ISO 9001, CMMI, ISO/IES 27001, Undergone training on Six Sigma, Process Performance Model ISO 13485, ISO 14971, IEC 62304, IEC/TR 80002-1, *IEC 60601-1-8:2006+AMD1:2012* Alarms standard, FDA Design Controls -21 CFR 820.30 Waterfall and Agile Scrum *NIST security standards,* Basic familiarity on IHE, DICOM, HL7

Vishnu Shankar Vyas

SYNOPSIS

Seasoned healthcare professional with 18 yrs of progressive experience into Medical Devices Regulatory Affairs & Compliance, Corporate Quality, Regulatory Project Management, Crisis Management, Legal, Planning, Developing Regulatory Strategy for new product launches, Driving Regulatory Engagements with internal and external stakeholders, Standards Advocacy and Government Relationship.

PROFESSIONAL EXPERIENCES

S. No.	Name of the Company/ Institute	Nature of Industry	Position	Work Duration
01	DuPont Healthcare Packaging	Science & Technology company with Healthcare segment	AP Regional Leader, Regulatory & Standards	Currently working Since Aug 2017
02	B. Braun Medical	Healthcare Company with Medical Devices and Pharmaceuticals	Head of Regulatory Affairs/QA and Public Policies	Sept 16- July 17
03	Edward Lifesciences	Medical Device Technology Company	Head- Regulatory Affairs/QA and GA APEC	Oct 12- Sept 16
04	Medtronic Inc.	Medical Device Technology Company	Deputy Manager- Regulatory Affairs	April 12- Sept 12
05	Becton Dickinson & Company	Medical Device Technology Company	Executive- Regulatory Affairs	March 09- March 12
06	Max Neeman Medical International Ltd.	Clinical Research Organization	Sr. Executive- Regulatory Affairs	July 06- Feb 09

DuPont Healthcare
(Regional Leader AP Regulatory & Standards)

- Member of the global Healthcare Regulatory & Standards core team.
- Responsible for the regulatory & standards strategy for DuPont Healthcare Packaging in AP region including India, ASEAN, South Korea and Japan.
- Featured speaker at International conferences and seminars on medical and pharmaceutical packaging regulatory aspects, including new EU MDR/ Global MD regulations evolution.
- Responsible for effective relationship management with targeted Regulators, professional influencers and thought leaders in the broader industry and its stakeholders.
- DuPont representative at Medical Devices industry associations in India and ASEAN, holding leadership positions.
- Active in developing a regulatory roadmap & knowledge base to identify key regulatory issues, stakeholders, activities and events for AP.

Standards Development Contribution:

- Member of MHD 12, represents BIS at ISO/ TC 198/WG7 & WG9 'Sterilization of Healthcare products' since 2017.
- Member of global GS1 Healthcare team.

ACADEMIC PROFILE

M. Tech in Pharmaceutical Operations and Management from BITS, Pillani

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Sustainability in Healthcare

Contents

1.0 About the standard:

This is an Indian standard established by the CAPS division, a dedicated unit within the Consortium of Accredited Healthcare Organizations (CAHO) for its action program on healthcare sustainability. The International framework on CSR ISO 26000, Sustainable procurement guidance ISO 20400, UNGC principles, GRI standards, WHO guidance document on Climate Change and SHIPP, are some of the reference materials used in conceptualizing these Indian standards on sustainability relating to the healthcare and its value chain.

The standard aims at enabling the journey of Sustainability in Healthcare organizations by comprehensively addressing the elements of responsible operations while respecting cultural, societal, environmental, and legal differences and conditions of economic development between the various states and territories. Therefore, the aims include:

- Providing practical guidance related to conducting responsible healthcare operations
- Assist in stakeholder mapping, stakeholder engagement, and responsible public disclosures for a healthcare entity on sustainability related practices
- Assist in process of identifying material topics in relation to sustainability
- Aid in providing performance management and improvement guidance on sustainability related topics
- Enhance transparency, improve confidence and satisfaction in organizational practices amongst their patients and other stakeholders.

Standard Outline

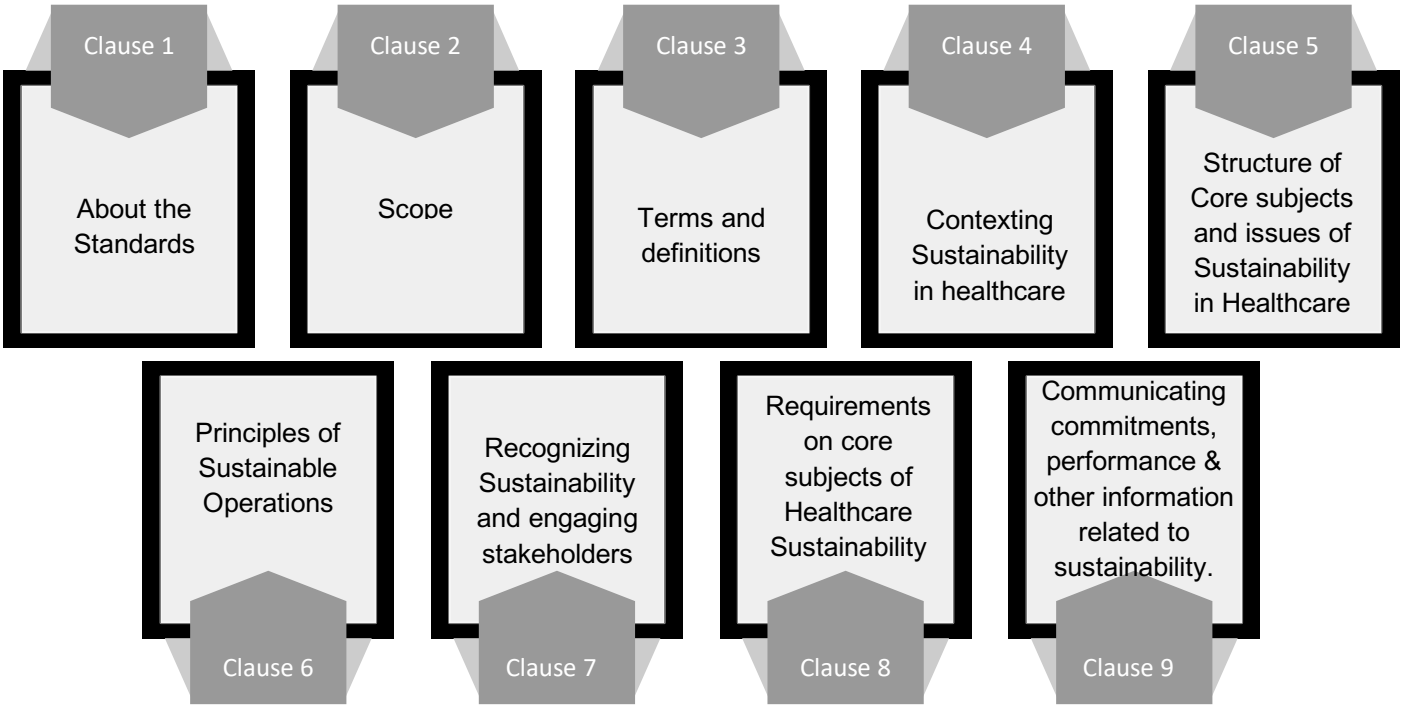

Figure 1: Coverage of Sustainability in Healthcare standard

Clause number	Clause title	Description
1	About the standard	Describes the background, references made in the development of the current standard
2	Scope	Defines the scope of this Standard
3	Terms and definitions	Identifies and provides the definition of key terms that are of fundamental importance for understanding Sustainability in Healthcare and for using this Standard.
4	Contexting Sustainability in healthcare	Describes the important factors and conditions that have influenced the establishment of this standard within an organisation and that continue to affect its nature and practice. It also describes the concept of Sustainability in the Healthcare value chain – what it means and how it applies to organizations. The clause includes guidance for

		small and medium-sized organizations on the use of this standard.
5	Structure of Core subjects and issues of Sustainability in Healthcare	Introduces and explains the structure of the standard and its coverage through subclauses. It outlines material topics that are relevant and critical to sustainability within the healthcare setting.
6	Principles of Sustainable Operations	Details the principles of Sustainable operations
7	Recognizing Sustainability and engaging stakeholders	Defines the mapping of stakeholder, and importance of connecting with stakeholders for their inputs in establishing the sustainability journey within the organization
8	Requirements on core subjects of Healthcare Sustainability	Explains the structure defined in clause no. 5 by detailing the requirements within it
9	Communicating commitments, performance and other information related to sustainability	Importance of communicating sustainability information to various stakeholders

2.0 Scope

This standard provides guidance to all types of healthcare organizations, regardless of their size or location, on:

a) Concepts, terms and definitions
b) Principles and practices
c) The structure of the core subjects, material topics and issues
d) Identifying and engaging with stakeholders
e) Identifying requirements of the core subjects
f) Communicating commitments, performance and other information related to sustainability
g) Outlining disclosure methodologies on sustainability performance to all stakeholders

3.0 Terms and definitions

KEY DEFINITIONS		
1	accountability	state of being answerable for decisions and activities to the organization's governing bodies, legal authorities and, more broadly, its stakeholders
2	consumer	individual member of the general public purchasing or using property, products or services for private purposes
3	customer	organization or individual member of the general public purchasing property, products or services for commercial, private or public purposes
4	due diligence	comprehensive, proactive process to identify the actual and potential negative social, environmental and economic impacts of an organization's decisions and activities over the entire life cycle of a project or organizational activity, with the aim of avoiding and mitigating negative impacts
5	employee	individual in a relationship recognized as an “employment relationship” in national law or practice
6	environment	natural surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, people, outer space and their interrelationships
7	ethical behavior	behavior that is in accordance with accepted principles of right or good conduct in the context of a particular situation and is consistent with international norms of behavior
8	gender equality	equitable treatment for women and men
9	impact of an organization	positive or negative change to society, economy or the environment, wholly or partially resulting from an organization's past and present decisions and activities
10	initiative for social responsibility	programme or activity expressly devoted to meeting a particular aim related to social responsibility
11	international norms of behavior	expectations of socially responsible organizational behavior derived from customary international law, generally accepted principles of international law, or intergovernmental agreements that are universally or nearly universally recognized

12	organization	entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives
13	organizational governance	system by which an organization makes and implements decisions in pursuit of its objectives
14	principle	fundamental basis for decision making or behavior
15	product	article or substance that is offered for sale or is part of a service delivered by an organization
16	Patient	A person with a specific disease or condition who receives or is registered to receive treatment from a healthcare provider or any registrable birth
17	Patient Safety	the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum
18	service	action of an organization to meet a demand or need
19	social dialogue	negotiation, consultation or simply exchange of information between or among representatives of governments, employers and workers, on matters of common interest relating to economic and social policy
20	social responsibility	responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behavior that ● contributes to sustainable development, including health and the welfare of society; ● takes into account the expectations of stakeholders; ● is in compliance with applicable law and consistent with international norms of behavior ; and ● is integrated throughout the organization and practiced in its relationships
21	sphere of influence	range/extent of political, contractual, economic or other relationships through which an organization has the ability to affect the decisions or activities of individuals or organizations

22	stakeholder	individual or group that has an interest in any decision or activity of an organization
23	stakeholder engagement	activity undertaken to create opportunities for dialogue between an organization and one or more of its stakeholders, with the aim of providing an informed basis for the organization's decisions
24	supply chain	sequence of activities or parties that provides products or services to the organization
25	sustainable development	development that meets the needs of the present without compromising the ability of future generations to meet their own needs
26	transparency	openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner
27	value chain	entire sequence of activities or parties that provide or receive value in the form of products or services
28	vulnerable group	group of individuals who share one or several characteristics that are the basis of discrimination or adverse social, economic, cultural, political or health circumstances, and that cause them to lack the means to achieve their rights or otherwise enjoy equal opportunities worker person who performs work, whether an employee or someone who is self-employed

4. Contexting Sustainability in healthcare:

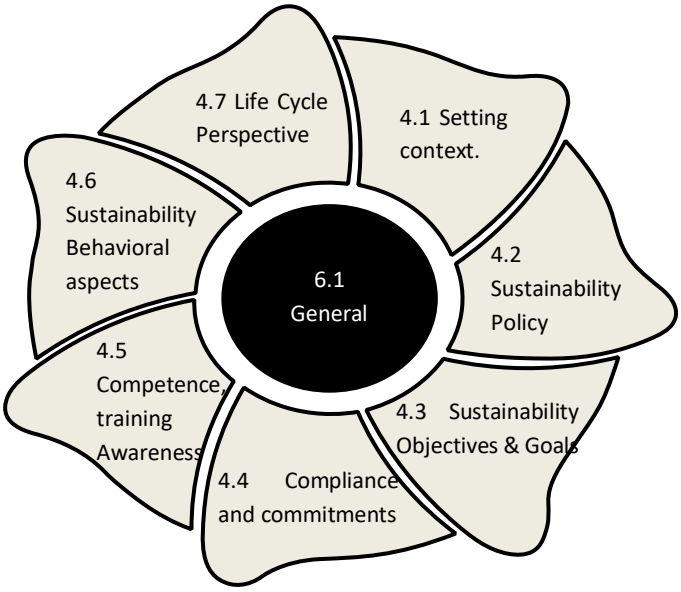

Figure 1: Requirements of Contexting

4.1 Setting context: Sustainability in a healthcare organization requires considering three key dimensions depicted in the diagram below:

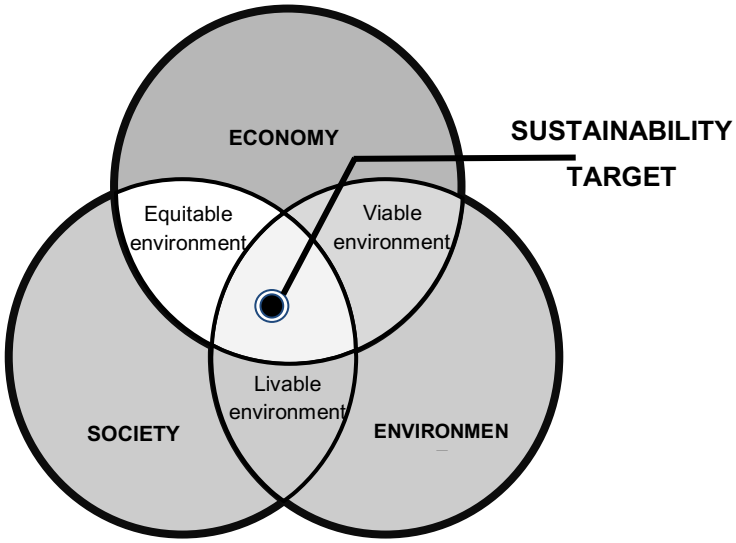

Figure 2: Triple bottom principle of Sustainability

Environmental: Healthcare facilities consume significant resources (energy, water, etc.) and generate substantial waste (pharmaceuticals, medical equipment, etc.). This contributes to greenhouse gas emissions, pollution, and resource depletion. Implementing sustainable practices like energy-efficient equipment, renewable energy sources, waste reduction and recycling, and green procurement can mitigate these impacts.

Social: Healthcare disparities, accessibility issues, and ethical concerns regarding drug development and patient data privacy are social sustainability challenges. Promoting equitable access to healthcare, engaging diverse communities, upholding ethical practices in research and data handling, and fostering a culture of safety and well-being for patients and staff contribute to social sustainability.

Economic: Rising healthcare costs and inefficient resource management put financial sustainability at risk. Optimizing resource allocation, adopting cost-effective technologies, and promoting preventive care can lead to financial sustainability and improved health outcomes.

Therefore, Contexting sustainability in a healthcare organization involves:

- Understanding the environmental, social, and economic impacts of its operations.
- Developing and implementing strategies to reduce negative impacts and create positive benefits across these three dimensions.
- Integrating sustainability into its core values, mission, and decision-making processes.
- Collaborating with stakeholders like government, communities, suppliers and value chain to advance sustainable healthcare practices.

By proactively addressing sustainability, healthcare organizations can contribute to a healthier planet,healthier communities, and a more resilient healthcare system.

4.2 Sustainability Policy: Organisation top management shall in consultation with the Board establish the sustainability policy, this shall act as a framework to arrive at the objectives and goals

4.3 Sustainability Objectives & Goals: Organisation shall identify the objectives & goals related to sustainability, and fulfill the policy commitments. While establishing the objectives and goals action plans to support the implementation shall be made.

4.4 Compliance and commitments: Organisation shall identify all applicable legal requirements and other requirements including the declaration of commitment towards compliance to National and International frameworks of Sustainability or those related with it.

4.5 Competence, training & Awareness: Organization shall identify the competencies of people who are directly involved in establishment, implmentation and maintenance of the Sustainability in healthcare standards

4.6 Sustainability Behavioral aspects: Organization shall identify the programs and opportunities to intervene on the behavior of people they can directly control and try to influence over those it can exercise indirectly control. This shall be mapped considering the influence the people could have on the achievement of the sustainability goals identified.

4.7 Life Cycle Perspective: Organisation shall adopt lice cycle approach while reviewing the sustainability claims on the products or services they offer. Declare the phase of the life cycle in which the particular element of sustainability is being considered for its performance

5. Structure of Core subjects and issues of Sustainability in Healthcare

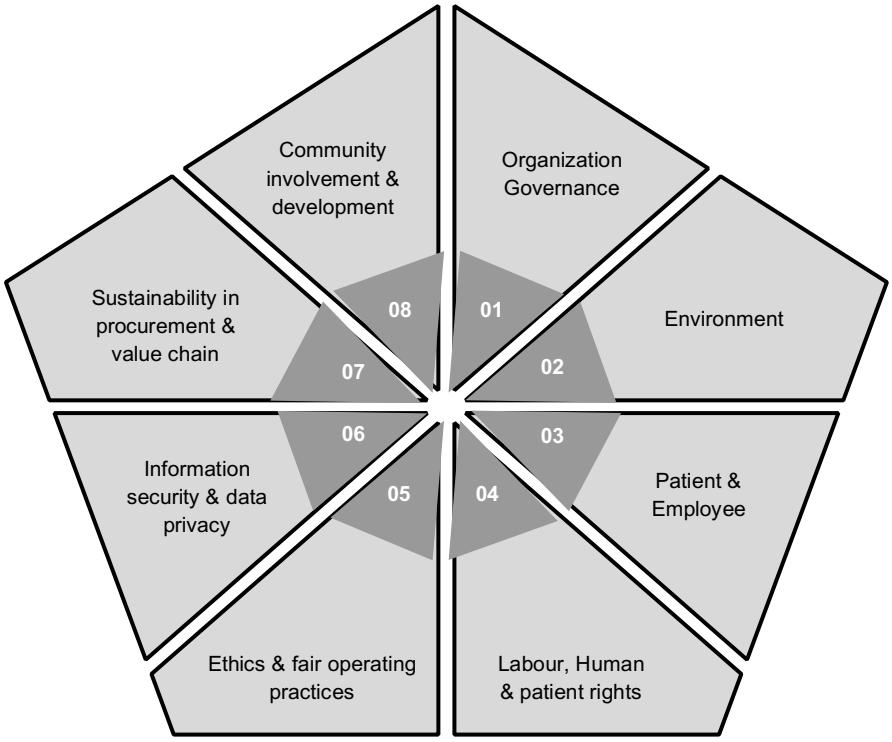

Figure 3: Core elements of healthcare value chain Sustainability

1. **Organization Governance**
2. **Environment**
3. **Patient & Employee Safety**
4. **Labour, Human & patient rights**
5. **Ethics & fair operating practices**
6. **Information security & data privacy**
7. **Sustainability in procurement & value chain**
8. **Community involvement & development**

6. Principles of Sustainable Operations

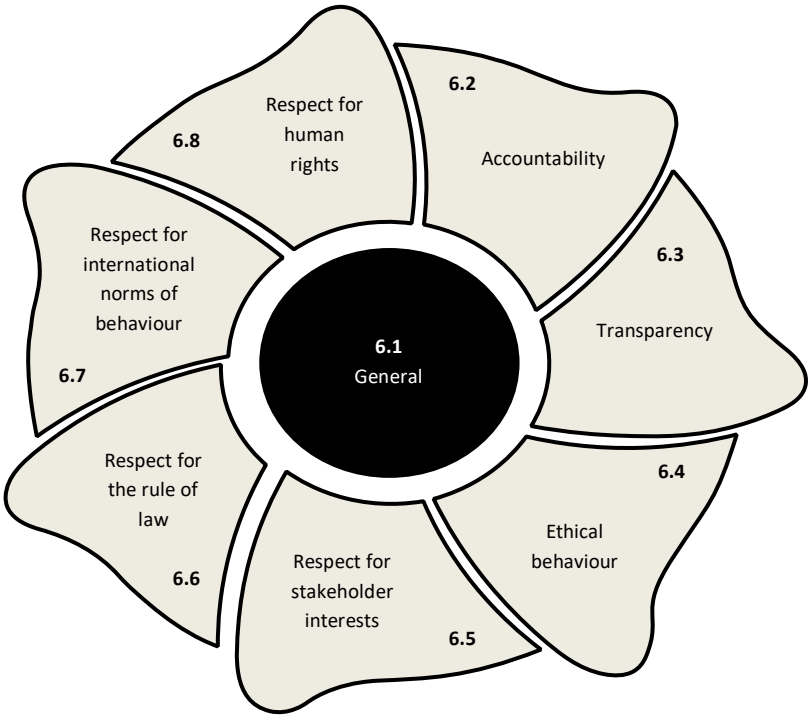

Figure 4: Diagram on Principles of Sustainable operations

6.1 General

This section provides guidance on seven principles of Sustainable operations that an organisation needs to consider for establishing the goals of Sustainable development.

Organisation shall societal, environmental, legal, cultural, political and organizational diversity, differences in economic conditions, local conditions while being consistent with international norms of behaviour

6.2 Accountability

Organization is accountable for its impacts on society, the economy, and the environment. Organization conducts frequent meetings (MRMs) that include issues related to these areas. The organization identifies all legal norms, communicates with legal authorities about laws and regulations, and prepares an action plan for non-compliances.

6.3 Transparency

Organization shall be transparent in its decisions and activities that impact society and the environment. Policies, decisions, and activities are discussed in MRMs and presented objectively to stakeholders.

6.4 Ethical behaviour

Organization shall behave ethically. Its functional chart and roles of each function promote ethical behaviour in decision-making and interactions with others.

6.5 Respect for stakeholder interests

Organization shall respect, consider, and respond to the interests of its stakeholders. The organization recognizes that stakeholders can affect or significantly affect its activities.

6.6 Respect for the law of the land

Organizations shall commit to identifying all applicable legal and other requirements to which the organisation subscribes while relating to sustainability establishment, implementation and maintenance. It takes steps to be aware of applicable legal requirements and periodically evaluates its compliance.

6.7 Respect for international norms of behaviour

Organizations shall respect national norms of behaviour while adhering to the principle of respect for the rule of law. The organization strives to respect norms as much as possible.

6.8 Respect for human rights

Organizations shall respect human rights and recognize their importance and universality. The organization promotes human rights where possible and takes steps to respect them in situations where they are not protected.

7. Recognizing Sustainability and engaging stakeholders

7.1 General

Organization considers its social responsibility towards its stakeholders and society, which may have different objectives and perspectives.

7.2 Recognizing Sustainability

Organization studies social responsibility in seven core subjects: organizational governance, human rights, labor practices, the environment, fair operating practices, consumer issues, and community involvement. It's responsible for the impacts of its decisions and activities, within and beyond its value chain.

7.3 Stakeholder identification and engagement

Stakeholders are individuals or groups with an interest in a decision and its effects. They can influence the decision-making process and be affected by the outcome. Stakeholder engagement involves dialogue through various formats such as meetings, conferences, and web-based forums as outlined in the procedure for stakeholder identification and engagement.

There are various reasons for an organization to engage with its stakeholders. Stakeholder engagement can be used to: –

1. Increase understanding of consequences on stakeholders
2. Maximize beneficial impact, minimize adverse impact
3. Ensure credible claims of social responsibility
4. Review performance for improvement
5. Reconcile conflicts between interests
6. Address link between stakeholder interests and social responsibility
7. Contribute to continuous learning
8. Address conflicting interests
9. Provide diverse perspectives
10. Increase transparency
11. Form partnerships for mutual benefit

8. Requirements on core subjects of Healthcare Sustainability

8.1.0 Organization Governance : This core subject focuses on the structures, processes, and systems by which an organization is directed and controlled. It includes ensuring the accountability, transparency, and integrity of the organization to its stakeholders. Organizations Governance is a framework of organizational controls outlined in the Organizational Structure; along with the policies and procedures ensuring sustainable growth in the presence of fair and ethical corporate practices thereby striking a balance with the Stakeholders.

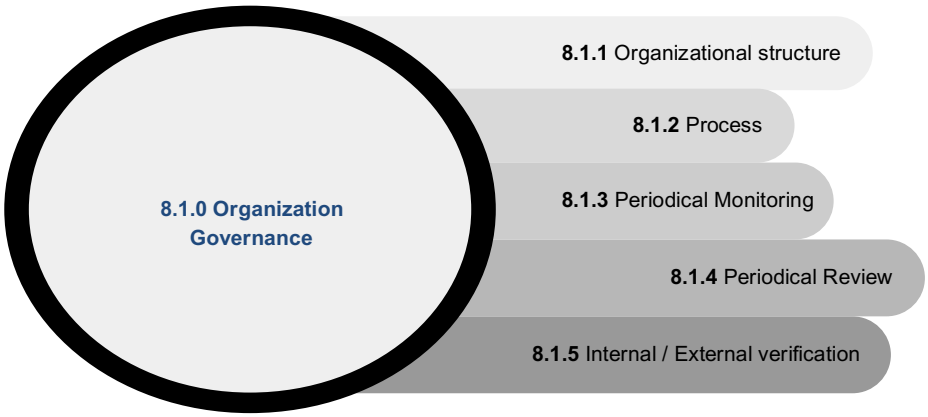

Figure 5: Organizational Governance subclause

8.1.1 Organizational structure: Sustainability Governance refers to the way in which hospitals govern their Sustainability Initiatives. It identifies who has power and accountability, and who makes decisions. It is, in essence, a toolkit that enables management and the board to deal more effectively with the challenges of running the hospital Sustainably.

8.1.2 Process: Sustainability shall be a process in the organization, ensuring that Hospitals have appropriate decision-making processes and controls in place so that the interests of all stakeholders (shareholders, employees, suppliers, Patients and the community) and the future generation are considered. Ensure clear alignment between identified material issues and established sustainability goals. Link specific actions to these goals with a demonstrably impactful relationship. Develop detailed action plans for each initiative, outlining roles, responsibilities,and timeframes for execution. Clearly assign responsible parties within the organization. Define realistic timeframes for accomplishment.

8.1.3 Periodical Monitoring: Establish measurable KPIs based on relevant sustainability parameters. Ensure KPIs align with identified material issues and program goals. Select KPIs that track progress and effectiveness of implemented actions. Regularly monitor and track KPI performance. Analyze and report findings to board and senior management, including instances of deviation from targets. Implement corrective actions or adjustments based on observed deviations.

8.1.4 Periodical Review: Secure formal approval of the sustainability program and action plans from relevant management levels.This ensures commitment and resources for implementation.

8.1.5 Internal / External verification : Organisation shall enhance the confidence of the established system through external verification system. Ensure this is carried out periodically.

8.2.0 Environment: This core subject is about the impact of an organization's activities on the environment. The term Environment includes water, air, land and their inter-relationship with human beings, other living creatures, plants, microorganisms, and property. Society is facing environmental challenges like depletion of natural resources, pollution, climate change, habitat destruction, species loss, and ecosystem collapse. Our organization has a procedure Environmental Procedure to identify and control any environmental issues.

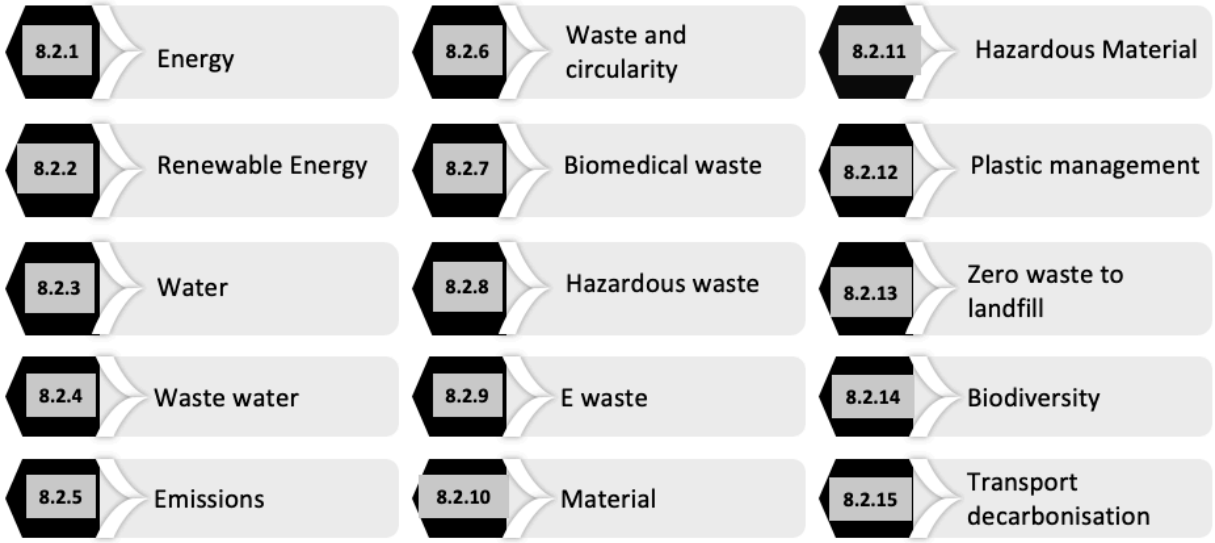

Figure 6: Environmental attributes

The issues include:

8.2.1 Energy: Healthcare Energy Management Expectations:

Energy Mapping & Review: Organisation shall ensure all types of energy are identified, consumption monitored through metering systems, Energy audits are conducted and action plans are established for energy efficiency and conservation. Benchmarking of energy performance related systems, equipment in the facility shall be arrived at with local, national and international best.

Training is organized for capacity building on matters related to energy, behavioral changes are brought in so employees are able to exhibit energy conserving behavior. Overall, these expectations assess the hospital's commitment to continuous energy efficiency improvement through data-driven decision making, employee engagement, and targeted action.

8.2.2 Renewable Energy: Organisation shall Ensure the system incorporates the usage of renewable energy sources by identifying specific categories of renewables considered by the organization's policies. Evaluate if policies support a positive and progressive energy transition. The policy shall include measurable methods for demonstrating a progressive approach to using renewable energy. Assess the organization's policies for monitoring and reducing wastage of energy from renewables. Identify the methods used for monitoring

energy produced from renewable sources, including the use of IT monitoring tools. Determine if the system includes remote monitoring stations for measuring energy produced from renewable sources.

8.2.3 Water: Organisation shall establish a policy for water conservation. Confirm the organization's water management strategy and its sources for daily usage. Assess policies for ensuring good quality water and methods for treating water based on quality reports. Explore the organization's plans to reduce water consumption and reuse treated water from ETP or STP on its premises. Ensure the system includes water meters at intake and end-user locations, along with benchmarking for water quantity usage.Evaluate water measuring methods for treated water generated on the premises and the organization's water footprint source. Assess if the organization has water intensity monitoring methods in place.

8.2.4 Waste water Organisation shall Confirm the presence of a wastewater treatment plant (STP or ETP) and its formal approval from the concerned statutory body, along with the organization's consent to operate from the local Pollution Control Board. Assess the system's regular waste water quality monitoring for treated waste water and the presence of a metering system for the treated water. Determine if the hospital maintains a dedicated team for ensuring reliable operation and maintenance of the wastewater treatment plant, including proper sludge treatment to ensure treated water quality and compliance with regulations. Explore if the wastewater system includes a distribution system enabling reuse of treated water for irrigation, cooling tower make-up, etc., and if the organization utilizes the treated wastewater.

8.2.5 Emissions: Organisation shall define a system to inventorise the emissions. The direct emissions covered under scope 1, indirect emissions covered in Scope 2, indirect emissions from upstream and downstream in scope 3 and other than GHG emissions suh as ODS, NOx, SOx, etc.. Organisation shall work on having intensity reduction targets

8.2.6 Waste and circularity: Organisation shall Identify and segregate various types of waste across the hospital, Use of designated colour bags, Weighing/measuring/quantifying waste on a daily/weekly basis, Centralized collection of all general waste prior to disposal to authorised vendor. Explore options for circularity.

8.2.7 Biomedical waste: Orgaisation shall Identify and segregation of Biomedical Waste (BMW) across the hospital according to categories for BMW use of designated bags, Weighing/measuring/quantifying BMW waste on a daily/weekly basis, Centralized collection of all BMW waste prior to disposal, Disposal of waste in accordance with CPCB/local waste management rules/laws

8.2.8 Hazardous waste Organisation shall Identify and categorize hazardous waste, Weighing/measuring/quantifying hazardous waste on a daily/weekly basis, Implementation of appropriate precautions for handling hazardous waste with evidence, Training of all staff on hazardous waste management. Disposal of waste in accordance with CPCB/local waste management rules/laws

8.2.9 E waste organization shall Establish an e-waste management program, including disposal mechanism for Defined categories for e-waste within the hospital, Quantification/measurement of e-waste on a periodic basis, Engagement with a CPCB or Local PCB approved e-waste vendor. Collection of a certificate of use/reuse/refurbish/recycle/safe disposal from the vendor

8.2.10 Material: Organisation shall establish the method for identification of the materials used as hazardous and non hazardous and maintain the material safety data sheet for all hazardous material. The consumption shall be monitored and focus towards reduction and where possible replacement with eco friendly material shall be made.

8.2.11 Hazardous Material organization shall establish existence of a hazardous materials management, its Identification and regular updating of hazardous materials used in the hospital, Maintenance of inventory and consumption records for hazardous materials. Training and awareness sessions for all staff members on hazardous materials. Implementation of spill/leak management response procedures for hazardous materials

8.2.12 Plastic management: Organisation shall establish a policy towards plastic management. Do mapping of plastic usage within the hospital. Efforts to assess reuse, reduction, or alternatives to single-use plastics (SUPs), Implementation of a monitoring system to track the percentage reduction of SUPs and reporting of the program to management Organization shall define methodology to categorize clinic and non-clinical plastics, Measurement of consumption on a monthly/half-yearly/annual basis, Program to create staff awareness for reducing consumption, Implementation of reduction/reuse/recycle strategy or plan. Structured recycling program and vendor for plastics

8.2.13 Zero waste to landfill: Organisation shall Implementation waste reduction strategy for general and other waste. Measurement of landfill reduction on a periodic basis (monthly, half-yearly, annual). Development of a waste reuse plan in collaboration with vendors (e.g., waste to energy, repurposing for road/construction), Quantification of waste diverted for reuse purposes, Application and acquisition of zero waste to landfill certification

8.2.14 Biodiversity: organization shall establish a biodiversity conservation policy, the impacts and pressures on Ecosystem due to the activities, products and services are identified, evaluated and controlled. A Biodiversity management plan may be drawn that includes the process of enumeration

of carbon sequestration due to green cover and soil, deriving the biodiversity index by assessing the number of tree species within the hospital premises. Plans shall be made to prioritize local species in green cover planning and management. Implement protection measures for any threatened species.

8.2.15 Transport decarbonisation: Organisation shall have commitment to encourage electric vehicles and provide E-charging stations in the premises, provide preferential parking for electric vehicles/cycles. Create awareness on drives on low/no emission travel to encourage the adoption of low/no emission travel methods, shared mobility, and public transport by employees. Finalize vehicles or contracted vehicles with Low-emissions fuel like CNG or biodiesel for the hospital fleet. Ensure Pedestrian access for walking across the facility to encourage walking as a means of transportation.

8.3.0 Patient & Employee Safety: This involves ensuring that products and services are safe and do not pose a risk to Patient and Employee health or safety.

Figure 7:Patient & Employee safety

8.3.1 Health Safety: Organizations should take measures to prevent accidents and injuries in the workplace and provide a safe and healthy work environment for all employees. Towards achieving this, the organization may set up health & safety policy, conduct hazard identification, risk assessment and establish controls to ensure operations are carried out to reduce illness or injury.

8.3.2 Life and Fire safety : Organizations should take measures to prevent accidents and injuries in the workplace and provide a safe and healthy work environment for all employees. Comply to all the legal and other requirements it subscribes to.

8.3.3 Protecting patients health and safety: Organisation shall define the ways and strategic approach, goals set and measure the performance of patient health & safety

8.4.0 **Labour, Human & patient rights:** At an organization, we value our people and believe in empowering them to achieve challenging goals while fulfilling our social responsibilities. We have set procedures in place to govern employee rights and actions, including recruitment, appraisals, compensation, leaves, training, and more. Our supplier code of conduct requires safe and healthy working conditions, fair hiring practices, and ethical behavior. Labor practices encompass all policies and practices relating to work performed within an organization, including recruitment, promotion, disciplinary and grievance procedures, transfer and relocation of workers, termination of employment, training and development, health and safety, and working conditions.

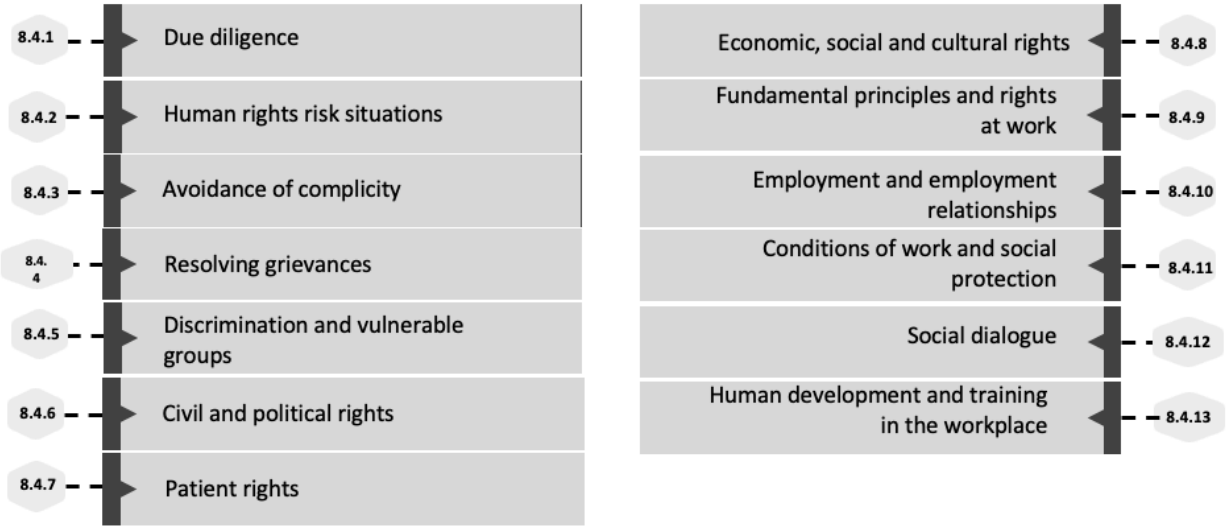

Figure 8: Labour & Human rights requirements

8.4.1 Due diligence : This refers to the process of identifying, assessing, and taking appropriate action to address human rights risks and impacts related to an organization's activities.

8.4.2 Human rights risk situations : This involves identifying and mitigating potential risks to human rights that may arise from an organization's operations or business relationships.

8.4.3 Avoidance of complicity : Organizations should take steps to ensure that they are not complicit in human rights abuses, either directly or through their business relationships or supply chains.

8.4.4 Resolving grievances : This involves establishing mechanisms for effectively addressing and resolving complaints or grievances from individuals or groups who believe their human rights have been affected by the organization's activities.

8.4.5 Discrimination and vulnerable groups: Organizations should ensure that their practices do not discriminate against individuals or groups and should take steps to protect and support vulnerable groups.

8.4.6 Civil and political rights: This includes respecting and promoting rights such as freedom of expression, association, and assembly, which are essential for an open and democratic society.

8.4.7 Patient rights: This includes all rights that need to be made available at all times - prior, during and after treatment - to a person who is receiving or is registered to receive care in a healthcare setting. This includes respect and adherence to all rights relating to but not limited to bodily autonomy, decision making, consent, human rights, privacy, ethical and moral rights, social rights etc. Patient's rights are linked to concurrent responsibilities that a patient has with the care provider, healthcare

organization and towards compliance with all laws and regulations enforceable in the territory/s where care is being provided.

8.4.8 Economic, social and cultural rights : This includes the rights to work, to form and join trade u unions, to social security, and to a standard of living that allows for the realization of other human rights

8.4.9 Fundamental principles and rights at work: This refers to the International Labour Organization's core labor standards, which include freedom of association, the right to collective bargaining, the elimination of forced labor, the abolition of child labor, and the elimination of discrimination in employment

8.4.10 Employment and employment relationships: This involves ensuring that employment relationships are based on fair terms and conditions, including the right to a living wage, safe working hours, and freedom from harassment and abuse.

8.4.11 Conditions of work and social protection : This includes providing safe and healthy working conditions, adequate social protection for workers, and respect for workers' rights to organize and bargain collectively.

8.4.12 Social dialogue: This refers to the tripartite dialogue between governments, employers, and workers to promote decent work and social justice.

8.4.13 Human development and training in the workplace : This involves investing in the skills and capabilities of workers through training and development programs to enhance their employability and contribution to the organization.

8.5.0 **Ethics & fair operating practices:** Fair operating practices refer to ethical conduct in organizational dealings with government agencies, partners, suppliers, contractors, customers, competitors, and associations.

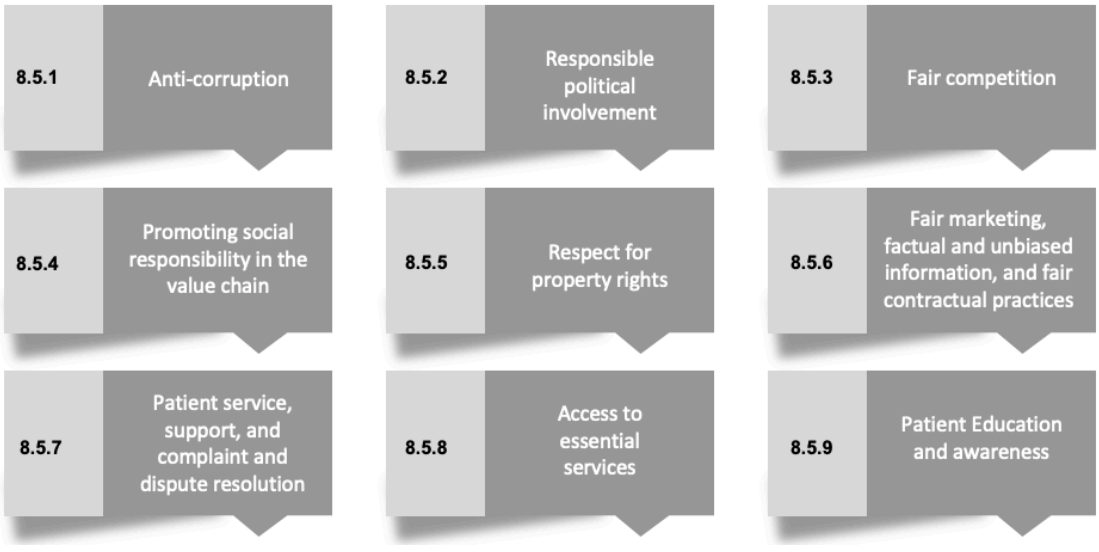

Figure 9: Ethics & fair operating practices

8.5.1 Anti-corruption : Organizations should have measures in place to prevent, detect, and address corruption, bribery, and fraud.

8.5.2 Responsible political involvement: This involves engaging in political activities in a transparent and responsible manner that does not unduly influence political processes or decisions.
8.5.3 Fair competition: Organizations should compete fairly, avoiding deceptive practices, price-fixing, and other anti-competitive behaviors.
8.5.4 Promoting social responsibility in the value chain: This includes encouraging suppliers, contractors, and other business partners to adopt responsible social and environmental practices.
8.5.5 Respect for property rights: Organizations should respect the intellectual property rights of others and ensure that their own property rights are not misused to the detriment of others.
8.5.6 Fair marketing, factual and unbiased information, and fair contractual practices: Organizations should provide accurate and transparent information about their products and services, avoiding deceptive marketing practices and unfair contract terms.
8.5.7 Patient service, support, and complaint and dispute resolution : This includes providing good-quality patient service, support for products and services, and effective mechanisms for handling and resolving complaints and disputes.
8.5.8 Access to essential services : This involves ensuring that essential services, such as water, energy, and telecommunications, are accessible and affordable to all consumers.
8.5.9 Patient Education and awareness: Education and awareness of patients, next of kin and caregivers is a critical aspect of ethical conduct by a healthcare provider. This includes open, transparent, coherent and comprehensive education on clinical procedures, patient rights & responsibilities, clinical risks, assumed reasonable outcomes, financial and/or payor details, billing transparency and consents. The process of education and awareness of the above is not limited to patients, but also the next of kin, care-givers and any other person or persons that are directly related to the outcome and progress of any clinical intervention.

8.6.0 Information security & data privacy: Organizations should protect the privacy and personal data of consumers, ensuring that data is collected, used, and shared ethically and in compliance with relevant data protection laws and regulations.

Figure 9: Information security and data privacy

8.6.1 Information security controls: Organization shall establish, implement, and maintain the organizational, administrative, technological controls that's essential to ensure or bring the confidence of adequate physical and soft security measures related to information security by conducting the following regularly.

- Implement strong authentication: Utilize multi-factor authentication (MFA) for all user access, including logins to electronic health records (EHRs), workstations, and administrative systems.
- Enforce least privilege: Grant users access only to the information and systems they need to perform their job duties. Regularly review and update access privileges.
- Monitor user activity: Implement a system to monitor user access and activity to detect suspicious behavior.
- Regular vulnerability assessments and penetration testing: Identify and address vulnerabilities in your IT systems and network.
- Employee training and awareness: Provide regular training for employees on information security policies and procedures.
- Physical security: Implement physical security controls to protect IT infrastructure and data, including access controls, security cameras, and environmental controls.

8.6.2 Consumer data protection and privacy: organization shall plan to

- Encrypt sensitive data: Encrypt patient data at rest and in transit, including emails, files, and backups.
- Data classification: Classify data based on its sensitivity and implement appropriate security controls for each level.
- Data loss prevention (DLP): Implement DLP solutions to prevent unauthorized data exfiltration through various channels like email, USB drives, and cloud storage.

8.6.3 Infosec Incident reporting, investigation, and action

- Implement HIPAA compliance: Ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) by implementing appropriate safeguards for protected health information (PHI).
- Patient education: Educate patients about their privacy rights and how their data is protected.
- Data breach notification: Have a plan in place to notify patients and authorities in case of a data breach.
- Incident response plan: Develop and implement a comprehensive incident response plan to identify, contain, and recover from security incidents.
- Incident reporting: Establish clear procedures for reporting security incidents to the appropriate personnel.
- Incident investigation: Conduct thorough investigations into security incidents to determine the root cause and implement corrective actions.

8.7.0 Sustainability in procurement & value chain

8.7.1 Identification of value chain and its level of influence on the sustainability goals: Organization shall ensure the upstream and downstream is mapped and identify critical partners and their level of influence.

8.7.2 Creating ESG awareness in the value chain: Organization shall ensure those partners in the upstream and downstream having medium and high influence are considered for programs of handholding in creating the essential awareness on how they contribute to the value chain sustainability Impact reduction on ESG matters.

8.7.3 Baselining the ESG performance of the supply chain / Value chain: The organization shall conduct baselining exercises to know the current performance of partners in the value chain in each of the elements of ESG that are material to the partners and to the organization.

8.7.4 Targets and goal setting for the supply chain / Value chain: The organization shall conduct baselining exercises to know the current performance of partners in the value chain in each of the elements of ESG that are material to the partners and to the organization.

8.7.5 Action plan for the risks and opportunities enumerated: Organisation shall identify the risks correlated with the value chain after doing the baselining and enumerate action plans for mitigating risks and planning the actions for opportunities implementation if any.

8.7.6 Verification of validation of supply chain / Value chain implementation: Periodically the achievement of the goals and targets by the value chain partners shall be verified and validated by independent verification and validation bodies to establish the confidence on the data and achievements.

8.8.0 Community involvement & development: A community refers to a geographic area or social settlement in close proximity to an organization's sites or impact areas. The organization should ensure safety and environmental precautions for the area and its members.

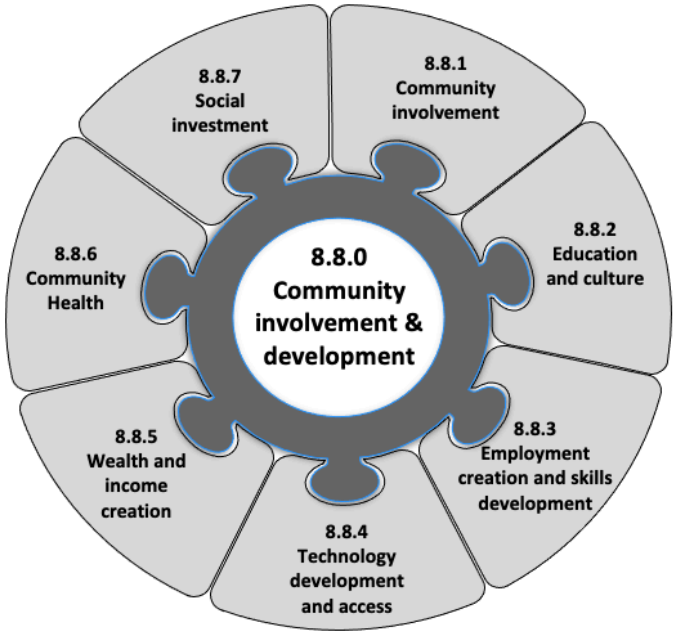

Figure 10: Community development

8.8.1 Community involvement: Organizations should engage with local communities, understanding their needs and concerns, and supporting community initiatives.
8.8.2 Education and culture : Organizations should contribute to consumer education and awareness, helping consumers make informed choices and understand their rights.
8.8.3 Employment creation and skills development : Organizations can contribute to local employment by creating job opportunities and investing in skills development programs.
8.8.4 Technology development and access : This includes promoting equitable access to technology and supporting the development of technologies that can benefit local communities.
8.8.5 Wealth and income creation: Organizations can contribute to local economic development by generating wealth and creating opportunities for income generation.
8.8.6 Community Health : Supporting community health initiatives, including access to healthcare and promotion of healthy lifestyle
8.8.7 Social investment : Making strategic investments in social projects and programs that align with the organization's values and contribute to the well-being of the community.

9.0 Communicating commitments, performance and other information related to sustainability

9.1 Internal / External Communication: Organisation shall communicate the sustainability policy internally and externally to the value chain who can have influence on its performance.
The organization shall decide on the communication of sustainability performance internally / externally through the Sustainability reports that may have been assured through the external verification and validation bodies.
9.2 Disclosures: Organisation shall review the various disclosures that it subscribes and relates to in accordance with the policy and commitment and decide the disclosures it would implement.
9.3 Claims, Public declarations: Organisation shall identify the opportunities for sustainability claims and any public declaration related to their products or services or community engagement projects and ensure confidence through external verification prior to such claims and comply to any applicable legal or other requirements.

Authors:

Dr. Lallu Joseph, General Secretary CAHO
Dr. Karan, Chair of CAHO’s program on Sustainability
Ms. Keerthi D Souza, CoChair of CAHO’s program on Sustainability
Mr. Vinodh, Chair of Engineers Forum of CAHO
Mr. Arul Prakash, Cochair of Engineers Forum of CAHO

Annexure E

(*Item 7.2*)

Comments received on NWIP – Sustainability in Healthcare

Comment 1:
Commenter: Indian Medical Association, New Delhi

"the objective mentioned in the letter and the contents of the drafts do not explicitly match. The objectives mentioned were:

- **Protecting India's environment** and ensuring a healthy future for generations to come.
- **Optimizing resource allocation** and **reducing the financial burden** on the healthcare system.
- **Promoting social consciousness of patient safety and caregiver wellness while promising access to quality healthcare** for all citizens.

Additionally, there are not many differences between the documents that the BIS already has and this one.
However, as it has been prepared and submitted by highly appreciable people, it is worth discussing fully.**"**

Comment 2:
Commenter: Lady Hardinge Medical College, New Delhi

"The subject is very relevant for the HCOs to consider and shall have a great impact.

It needs to be discussed in a core group/subcommittee with experts with knowhow in the field.**"**

Annexure F

(*Item 9.3*)

Nomination and Justification of NHSRC for participation in the Plenary meeting of ISO/TC 304

Format for Sending Nominations for Participation in 'ISO/TC 304 'Healthcare Organization Management' 11th Plenary Meeting

1) Meeting Details

Name, Organization and Contact details	**Details of the meetings to be attended (on which date the meeting is to be attended)**
1. Dr. Ranjan Kumar Choudhury, Advisor, Healthcare Technology Division, NHSRC, New Delhi. E-mail: ranjan.choudhury@nhsrcindia.org Contact No. +91-7752987502 2. Dr. Manisha Sharma, Consultant, Healthcare Technology Division, NHSRC, New Delhi E-mail: manisha.sharma@nhsrcindia.org Contact No. +91-9779455973	28 May 2024 ISO/TC 304 'Healthcare Organization Management' 11th Plenary Meeting

2) Technical Justification for Participation:

Dr. Ranjan Kumar Choudhury and Dr. Manisha Sharma are working in the field of priority medical devices and for health system strengthening. Participation in the BIS MHD 14 Meeting can be justified as a means to enhance expertise, network with peers, and stay current in the rapidly evolving field of healthcare technology. It will provide a platform for knowledge exchange and for exploring new fields in standard development for medical devices.

3) Contribution to MHD14 and ISO/TC 304 activities (e.g. Comments submitted on ISO ballots, draft document circulated):

- Regular comments are submitted on ISO Ballots, draft documents by the HCT team members.
- Active members in the MHD 14 sectional committee meetings.

Annexure G

(*Item 9.4*)

List of ISO Standards Published by ISO/TC 210, ISO/TC 212 & ISO/TC 304 Secretariat

ISO/TC 210 'Quality Management and Corresponding General Aspects for Products with a Health Purpose Including Medical Devices'

ISO/TC 210		**MHD14**		
Published standards	30	**Adopted**	**Under Development**	**Not adopted**
Under Development	13	21	2	7

Standards published under ISO/TC 210

S.no	**ISO**	**Title**	**Existing IS**	**Status of adoption**
1)	ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes	IS/ISO 13485:2016	Published Aug-2017
2)	ISO 14971:2019	Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019	Published March- 2021
3)	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS/ISO 15223-1 : 2016	Published Dec 2019 (Revision needed)
4)	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	IS/ISO 15223-2 : 2010	Published Nov-2018
5)	ISO 18250-1:2018	Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods	IS/ISO 18250-1 : 2018	Published Aug-2021
6)	ISO 18250-3:2018	Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications	IS/ISO 18250-3 : 2018	Published Aug-2021

7)	ISO 18250-6:2019	Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 6: Neural applications	IS/ISO 18250-6 : 2019	Published Aug-2021
8)	ISO 18250-7:2018	Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 7: Connectors for intravascular infusion	IS/ISO 18250-7 : 2018	Published Aug-2021
9)	ISO 18250-8:2018	Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 8: Citrate-based anticoagulant solution for apheresis applications	IS/ISO 18250-8 : 2018	Published Sep-2021
10)	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	IS 18376 : 2023	Published Nov-2023
11)	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	MHD/14/23491	Under Print
12)	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971	IS/ISO/TR 24971 : 2020	Published Aug-2023
13)	IEC 62304:2006	Medical device software — Software life cycle processes	IS/ISO 62304 : 2015	Published Nov-2018
14)	IEC 62304:2006/Amd 1:2015	Medical device software — Software life cycle processes — Amendment 1		Not adopted
15)	IEC 62366-1:2015 (Withdrawn)	Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023	Published Nov-2023
16)	IEC 62366-1:2015/Amd 1:2020	Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1	IS 17922 (Part 1) : 2023 IEC 62366-1 : 2015 + AMD 1 : 2020	Published Nov-2023
17)	IEC 62366-1:2015/Cor 1:2016	Medical devices — Part 1: Application of usability engineering to medical devices — Technical Corrigendum 1		Not Adopted
18)	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	Published Nov-2019
19)	IEC/TR 80002-1:2009	Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software		Not Adopted

20)	ISO/TR 80002-2:2017	Medical device software — Part 2: Validation of software for medical device quality systems	IS/ISO/TR 80002-2 : 2017	Published Nov-2019
21)	IEC/TR 80002-3:2014	Medical device software — Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	MHD/14/24698	Under Print
22)	ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	IS/ISO 80369-1 : 2018	Published Nov-2019
23)	ISO 80369-3:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications		Not adopted
24)	ISO 80369-3:2016/Amd 1:2019	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications — Amendment 1		Not adopted
25)	IEC 80369-5:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications	IS/IEC 80369-5 : 2016	Published Sep-2021
26)	IEC 80369-5:2016/Cor 1:2017	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications — Technical Corrigendum 1		Not Adopted
27)	IEC 80369-5:2016/Cor 2:2021	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications — Technical Corrigendum 2		Not Adopted
28)	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	Published Sep-2021
29)	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	Published Oct-2019
30)	ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods	IS 17964 (Part 20) : 2023	Published Jul-2023

ISO/TC 212 'Medical Laboratories and In Vitro Diagnostic Systems'

ISO/TC 212		**MHD14**		
Published standards	47	**Adopted**	**Under Development**	**Not adopted**
Under Development	23	15	2	30

Standards published under ISO/TC 212

S.no	**ISO**	**Title**	**Existing IS**	**Status of adoption**
1)	ISO 4307:2021	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA		Not adopted
2)	ISO/TS 5798:2022	In vitro diagnostic test systems — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods		Not adopted
3)	ISO 15189:2022	Medical laboratories Requirements for quality and competence	IS/ISO 15189 : 2022	Published March 2023
4)	ISO 15190:2020	Medical laboratories — Requirements for safety	IS 17898 : 2023	Published July 2023
5)	ISO 15193:2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures		Not adopted
6)	ISO 15194:2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation		Not adopted
7)	ISO 15195:2018	Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures	IS/ISO 15195 : 2018	Published Nov 2019
8)	ISO 15197:2013	In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing	IS/ISO 15197 : 2013	Published Aug 2014 **(MHD 19)**

		in managing diabetes mellitus		
9)	ISO 15198:2004	Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer	IS/ISO 15198 : 2004	Published Nov 2019 **(MHD 19)**
10)	ISO 16256:2021	Clinical laboratory testing and in vitro diagnostic test systems — Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases		Not adopted
11)	ISO/TS 16782:2016	Clinical laboratory testing — Criteria for acceptable lots of dehydrated Mueller-Hinton agar and broth for antimicrobial susceptibility testing		Not adopted
12)	ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	IS/ISO 17511 : 2020	Published Nov 2020 **(MHD 19)**
13)	ISO/TS 17518:2015	Medical laboratories — Reagents for staining biological material — Guidance for users		Not adopted
14)	ISO 17593:2022	Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy	IS 18298 : 2023	Published Nov 2023 **(MHD 10)**
15)	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	IS 18131 : 2023	Published July 2023
16)	ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements		Not adopted
17)	ISO 18113-2:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2:		Not adopted

		In vitro diagnostic reagents for professional use		
18)	ISO 18113-3:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use		Not adopted
19)	ISO 18113-4:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing		Not adopted
20)	ISO 18113-5:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing		Not adopted
21)	ISO 18153:2003	In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials		Not adopted
22)	ISO 19001:2013	In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology		Not adopted
23)	ISO 20166-1:2018	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 1: Isolated RNA		Not adopted
24)	ISO 20166-2:2018	Molecular in vitro diagnostic examinations — Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 2: Isolated proteins		Not adopted
25)	ISO 20166-3:2018	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 3: Isolated DNA		Not adopted

26)	ISO 20166-4:2021	Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: In situ detection techniques		Not adopted
27)	ISO 20184-1:2018	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 1: Isolated RNA		Not adopted
28)	ISO 20184-2:2018	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 2: Isolated proteins		Not adopted
29)	ISO 20184-3:2021	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 3: Isolated DNA		Not adopted
30)	ISO 20186-1:2019	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 1: Isolated cellular RNA		Not adopted
31)	ISO 20186-2:2019	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 2: Isolated genomic DNA		Not adopted
32)	ISO 20186-3:2019	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma		Not adopted
33)	ISO 20658:2023	Requirements for the collection and transport of samples for medical laboratory examinations	MHD/14/24687 (Rev.)	Under Print
34)	ISO 20776-1:2019	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	IS/ISO 20776-1 : 2019	Published Nov 2019

		activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases		
35)	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 against reference broth micro-dilution	MHD/14/24695 (Rev.)	Under Print
36)	ISO/TS 20914:2019	Medical laboratories — Practical guidance for the estimation of measurement uncertainty	IS 18325 : 2023	Published Aug 2023
37)	ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice		Not adopted
38)	ISO 21151:2020	In vitro diagnostic medical devices — Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples		Not adopted
39)	ISO 21474-1:2020	In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 1: Terminology and general requirements for nucleic acid quality evaluation		Not adopted
40)	ISO 21474-2:2022	In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 2: Validation and verification		Not adopted
41)	ISO 22367:2020	Medical laboratories — Application of risk management to medical laboratories	IS 18132: 2023	Published July 2023
42)	ISO/TS 22583:2019	Guidance for supervisors and operators of point-of-care testing (POCT) devices	IS 17722 : 2021	Published Dec 2021
43)	ISO 23118:2021	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes in		Not adopted

		metabolomics in urine, venous blood serum and plasma		
44)	ISO 23162:2021	Basic semen examination — Specification and test methods	IS 18374 : 2023	Published Nov 2023
45)	ISO 23640:2011	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	IS/ISO 23640 : 2011	Published Nov 2018 **(MHD 19)**
46)	ISO 35001:2019	Biorisk management for laboratories and other related organisations	IS/ISO 35001 : 2019	Published Dec 2021
47)	ISO 35001:2019/Amd 1:2024	Biorisk management for laboratories and other related organisations — Amendment 1: Climate action changes		Not adopted

ISO TC 304 'Healthcare Organization management'

ISO/TC 304		**MHD14**		
Published standards	10	**Adopted**	**Under Development**	**Not adopted**
Under Development	7	1	0	9

Standards published under ISO/TC 304

S.no	ISO	Title	Existing IS	Status of adoption
1)	ISO 5258:2022	Healthcare organization management — Pandemic response (respiratory) — Drive-through screening station		Not adopted
2)	ISO 5472:2022	Healthcare organization management — Pandemic response (respiratory) — Walk-through screening station		Not adopted
3)	ISO 5741:2023	Healthcare organization management — Pandemic response — Temporary medical facility		Not adopted
4)	ISO 6028:2023	Healthcare organization management — Pandemic response — Functional requirements for self-symptom checker app		Not adopted
5)	ISO 7101:2023	Healthcare organization management — Management		Not adopted

		systems for quality in healthcare organizations — Requirements		
6)	ISO/TS 17371:2023	Healthcare organization management — Infection prevention and control (IPC) measures for cross-border workers		Not adopted
7)	ISO/PAS 18999:2024	Healthcare organization management — Pandemic response —Guidelines for respiratory infection prevention and control in hospitals		Not adopted
8)	ISO 22886:2020	Healthcare organization management — Vocabulary		Not adopted
9)	ISO 22956:2021	Healthcare organization management — Requirements for patient-centred staffing	IS/ISO 22956 : 2021	Published Mar 2022 **(SSD)**
10)	ISO 23447:2023	Healthcare organization management — Hand hygiene performance		Not adopted