BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

MINUTES

Sectional Committee		Meeting No:	Date, Day & Time
Medical Biotechnology and Medical Nanotechnology Sectional Committee, (MHD -20)		18	04 December 2024, Wednesday 11:00 AM
Chairperson	Prof. Nirmal Kumar Ganguly (In Personal Capacity) Former Director General, Indian Council of Medical Research (ICMR).		
Member Secretary	Mr. Karthik Reddy Katipally Scientist B/Assistant Director, Bureau of Indian Standards.		

The list of participants is given in ***Annexure-A.***

ITEM 0. GENERAL

0.1 Welcome address by BIS.

Member Secretary greeted a warm welcome to the Chairperson, Prof. Nirmal Kumar Ganguly and all the members for the 18th Meeting of Medical Biotechnology and Medical Nanotechnology Sectional Committee.

0.2 Opening remarks by Chairperson

Prof. Nirmal Kumar Ganguly, Chairperson, extended a warm welcome to all the Committee Members and expressed his delight at the active participation shown by everyone. He Recommended member to actively participate in meetings and provide valuable inputs on all the under-development documents (nationally and internationally) and urged all members to engage actively in deliberations to ensure the success of the meeting.

ITEM 1. CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The Committee confirmed the minutes of the Previous (17th) meeting of Medical Biotechnology and Medical Nanotechnology Sectional Committee, MHD20.

1.2 The Committee noted the contents of Item 1.2 of the agenda.

ITEM 2. SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The Committee noted the contents of Item 2.1 of the agenda and adopted the scope (last changed in 17th Meeting) as it is without any changes.

2.1.1 Committee members were requested to join one or more working panels based on their interests. It was also communicated that they may nominate other experts from their organization. The committee recommended that the Member Secretary reach out to established biobanks (such as Tata Memorial Centre and NIMHANS) for nominations to the Biobanking panel and approach academic and research institutions such as the IITs, IISERs, institutes under DBT (such as NIBMG), ICMR, and CSIR (such as IMTECH) for adequate representation in other working panels.

The Chairperson recommended approaching Prof. Tapas K. Kundu for the Nanotechnology Working Panel, Prof. Anurag, former Director of the Institute of Genomics and Integrative Biology, for the Analytical Methods in Biotechnology Panel, and Dr. Vinod Scaria from Karkinos Healthcare for the Biobanking and Analytical Methods in Biotechnology Panels.

The Committee recommended convening the first meeting of all working panels by January 2025. The scope and subjects under development nationally and internationally are provided in ***Annexure-B***. This was recommended to be part of the agenda for first meeting of all working panels

2.2 The Committee noted the participation of members in the committee and recommended that the Member Secretary write to experts who have not attended the last two meetings. In cases where no response is received, it was recommended to seek new nominations.

2.3 The Committee noted the contents of Item 2.3 of the agenda

2.4 The Committee approved the following nominations and recommended that the Member Secretary follow up with organizations where nominations are yet to be received. The Committee also recommended Dr. T.R. Santhosh Kumar, Scientist G, for the convenorship of the Biobanking panel.

Sl. No.	Organisation	Nomination
3.	CSIR-Centre for Cellular & Molecular Biology (CCMB).	Dr. Md. Idris, Senior Principal Scientist
6.	Rajiv Gandhi Centre for Biotechnology	**MHD20/P1** 1. Dr. T.R. Santhosh Kumar, Scientist G 2. Dr. Karthika Rajeeve Scientist E1 **MHD20/P2** Dr Debasree Dutta Scientist EII **MHD 20/ P3** Devasena Anantharaman, Scientist F
7.	CSIR- Institute Of Genomics And Integrative Biology (CSIR–IGIB)	Dr. Viren Sardana, Principal Scientist Dr. Aastha Mishra, Sr. Scientist
8.	The National Center For Cell Science (Nccs)	1. MHD20/ P1, Dr. Rahul Patil, Scientist 'D', 2. MHD20/ P2, Dr. Punam

		Nagvenkar, Scientist 'E' 3. MHD20/ P3, Dr. Dhiraj Dhotre, Scientist 'D'
14	ICMR-National Institute of Cancer Prevention and Research	Dr. Anuj Kumar, Scientist D Dr. Pramod Kumar, Scientist D (for P1,P2 and P3)

2.5 The Committee approved the nomination of following experts.

2.5.1 MHD20/ P1, Biobanking Panel

Sl. No.	Organisation	Nomination
1.	Acharya Nagarjuna University	Dr. D. Srinivasa Rao Assistant Professor Dr. G. Giridhar, Assistant Professor, Dr. D. Ravi Sankara Reddy, Assistant Professor
2.	Amity Institute of Biotechnology	Dr. Subhasha Nigam Associate Professor
3.	Maharani Lakshmi Ammanni College for Women	Dr. Jolitha A B Associate Professor Dr. Sushil kumar middha Associate Professor
4.	Regenerative Cell Research Institute Pvt. Ltd.	Dr Deepika Arora, Laboratory Director Mr. Aditya Banerjee, Scientist
5.	CSIR-Central Food Technological Research Institute	Dr. N.Vinod Kumar, Scientist

2.5.2 MHD20/ P2, Bioprocessing Panel

Sl. No.	Organisation	Nomination
1.	Acharya Nagarjuna University	Dr. D. Srinivasa Rao, Assistant Professor Dr. D. Ravi Sankara Reddy
2.	CMS College, Kerala	Dr. Jinu John, Head & Assistant Professor, Department of Biotechnology
3.	Regenerative Cell Research Institute Pvt. Ltd.	Dr Deepika Arora, Laboratory Director Mr. Aditya Banerjee, Scientist
4.	Amity Institute of Biotechnology	Dr Smriti Shrivastava, Assistant Professor

2.5.3 MHD20/ P3, Analytical methods in Biotechnology Panel

Sl. No.	Organisation	Nomination
1.	Acharya Nagarjuna University	Dr. D. Srinivasa Rao Assistant Professor
2.	CMS College, Kerala	Dr. Jinu John, Head & Assistant Professor, Department of Biotechnology
3.	Regenerative Cell Research Institute Pvt. Ltd.	Dr Deepika Arora, Laboratory Director Mr. Aditya Banerjee, Scientist
4.	CSIR-Central Food Technological Research Institute	Dr. N.Vinod Kumar, Scientist
5.	Amity Institute of Biotechnology	Dr Smriti Shrivastava, Assistant Professor

2.5.4 MHD20/ P4, Nanotechnology Applications in Healthcare Panel

Sl. No.	Organisation	Nomination
1.	Acharya Nagarjuna University	Dr. D. Srinivasa Rao Assistant Professor Dr. G. Giridhar, Assistant Professor,
2.	Amity Institute of Nanotechnology	Dr. Monika Joshi
3.	Regenerative Cell Research Institute Pvt. Ltd.	Dr Deepika Arora, Laboratory Director Mr. Aditya Banerjee, Scientist

ITEM 3. DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

The Committee noted the contents of Item 3 of the agenda.

ITEM 4. DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The Committee noted the contents of Item 4.1 of the agenda.

4.2 The Committee noted the contents of Item 4.2 of the agenda.

ITEM 5. DRAFT UNDER PREPARATION

5.1 The Committee extended the timeline for MHD 20/WG 1 and MHD 20/WG 2 until 6th February 2025 and recommended that the Working Groups adhere to the revised timelines.

The Committee recommended appointing an expert from CSIR-IGIB as the convenor of the Working Group on the DNA Sequencer System. It also recommended according high priority to this subject, as it is included in the list shared by the DoP under the directions of NITI Aayog.

5.2 The Committee noted the contents of Item 5.2 of the agenda.

ITEM 6. COMMENTS ON PUBLISHED STANDARDS

The Committee noted the contents of Item 6 of the agenda.

ITEM 7. NEW SUBJECTS

7.1 The Committee deliberated on antimicrobial activity of silver nanoparticles and recommended that Dr Amit Mishra to look into standard formulation of this subject.

7.2 The Committee recommended taking up the following subjects for standards formulation. These subjects will be addressed by specific working groups (to be formed) under MHD 20/P3. The Committee also recommended co-opting subject experts from the industry, such as Thermo Fisher Scientific and Analytical Technologies Limited.

1. Double Beam UV Spectrophotometer
2. GC-MS SQD with Liquid Autosampler and Headspace
3. Quaternary FHPLC
4. PCR/Thermal Cycler (Digital PCR, DDPR)

ITEM 8. TECHNICAL ISSUES

The Committee noted the contents of Item 8 of the agenda.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 The Committee noted the contents of Item 9.1 of the agenda. Considering the scope of MHD 20 and the scope of ISO/TC 276/SC 2, the Committee recommended that the Member Secretary take the necessary steps to establish liaison (as NMC) with ISO/TC 276/SC 2, Microphysiological Systems and Organ-on-Chip. The Committee also recommended ensuring the inclusion of subject experts in the committee to contribute to ISO activities and to ensure that India's views are adequately represented.

9.2 The Committee noted the contents of Item 9.2 of the agenda and requested members to provide their inputs and comments.

9.3 The Committee acknowledged and appreciated the inputs provided by Dr. Amit Misra, Dr. Naresh Kasoju, and Dr. Madhu Bala on notified ISO ballots. Chairperson recommended that all committee members provide comments and inputs on national and international standards under development that fall within their areas of expertise.

ITEM 10. PROGRAMME OF WORK

The Committee noted the contents of Item 10 of the agenda.

ITEM 11. REVIEW OF INDIAN STANDARDS

The Committee noted the contents of Item 11 of the agenda.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

The Committee noted the contents of Item 12 of the agenda.

ITEM 13 DATE AND PLACE OF NEXT MEETING

The Committee agreed to schedule the next meeting on 6th March 2025 in Face to Face mode.

ITEM 14 ANY OTHER BUSINESS

Dr. Madhu Bala has appraised the committee on the developments and deliberations in ISO/TC 276/WG 2 on Biobanking on NK cells.

Annexure-A

Sl. No.	Organization	Member Name
1.	In Personal Capacity, Noida	Prof. Nirmal Kumar Ganguly
2.	Akrivis Health Care Private Limited, Visakhapatnam	Dr. Vamshi Krishna Irlapati
3.	CSIR - National Physical Laboratory, New Delhi	Dr. Rajesh
4.	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Vijay Kumar Meena
5.	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Ranjan Kumar Jha
6.	CSIR - Central Drug Research Institute, Lucknow	Dr Amit Misra
7.	CSIR-Institute of Genomics and Integrative Biology (CSIR-IGIB)	Dr. Aastha Mishra
8.	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan
9.	CSIR - National Physical Laboratory, New Delhi	Dr. Ved Varun Agrawal
10.	Indian Institute of Technology Madras, Chennai	Prof. Smita Srivastava
11.	Indian Institute of Technology Madras, Chennai	Prof. Vignesh Muthuvijayan
12.	Indian Institute of Technology Roorkee, Roorkee	Prof. Krishna Mohan Poluri
13.	Institute of Chemical Technology, Mumbai	Prof. Padma V. Devarajan
14.	Institute of Nano Science and Technology, Mohali	Dr. Surajit Karmakar
15.	National Institute of Biologicals, Noida	Dr. Gauri Misra
16.	National Institute of Biologicals, Noida	Smt Shalini Tewari
17.	Office of Development Commissioner (MSME), New Delhi	Dr. G. Nagaraja
18.	Siemens Healthcare Private Limited, Bengaluru	Dr. Manohar Kollegal
19.	Siemens Healthcare Private Limited, Bengaluru	Ms. Sudipa Bhattacharya
20.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr Anil Kumar PR
21.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr Shiny Velayudhan
22.	IN PERSONAL CAPACITY	Dr Madhu Bala

Annexure-B

1) MHD20/ P1 Biobanking; including human, animal, plant and microorganism resources for Research & Development aspects, but excluding clinical diagnosis, therapeutics, food production and agriculture.

S No	ISO TC/SC/WG	Reference No	Title
1.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/DIS 18162	Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells.
2.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/CD 20012	Biotechnology — Biobanking — Requirements for human natural killer cells derived from pluripotent stem cells.
3.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/CD 20309,	Biotechnology — Biobanking — Requirements for deep-sea biological materials.
4.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/CD 20070,	Biotechnology — Biobanking — Requirements for sample containers for storing biological materials in biobanks.
5.	ISO/TC 276/WG 2 Biobanks and bioresources	Feedback CIB for the proposal on Biotechnology	Biobanking — General requirements for human intestinal organoids and human intestinal cancer organoids together with a call for experts
6.	ISO/TC 276/WG 2 Biobanks and bioresources	Feedback CIB for the proposal on Biotechnology	Biotechnology — General requirements and considerations for organoids manufacturing and quality control together with a call for experts
7.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/AWI 24952	Biotechnology — Biobanking — General requirements for (semi-)automated storage and retrieval systems to the following:
8.	ISO/TC 276/WG 2 Biobanks and bioresources	ISO/CD 20387	Biotechnology — Biobanking — General requirements for biobanking

2) MHD20/ P2 Bioprocessing: manufacturing and related processes for cells, for cells used for therapeutic purposes, cells used in in-vitro evaluation systems for pharmaceuticals. develops standards regarding manufacturing and related processes for cell-related entities, including exosomes, bacteriophages, and so forth.

Indigenous:

1. **MHD 20/WG 1** Additive manufacturing in healthcare.
2. **MHD 20/ WG 2** Isolation, Characterization and General Requirements for Handling of Extracellular Vesicles.

S No	ISO TC/SC/WG	Reference No	Title
1.	ISO/TC 276/WG 6 Nucleic acid- and protein-based devices	ISO/WD 24031	Biotechnology — General requirements for nucleic acid- and protein-based bio-devices.
2.	ISO/TC 276/WG 6 Nucleic acid- and protein-based devices	PWI for the project proposal	Biotechnology — Data distribution of human mesenchymal stromal cells.
3.	ISO/TC 276/WG 6 Nucleic acid- and protein-based devices	PWI for the project proposal	Biotechnology — Metadata specifications for human mesenchymal stromal cells
4.	ISO/TC 276/WG 6 Nucleic acid- and protein-based devices	SO/CD TS 9491-2	Biotechnology — Predictive computational models in personalized medicine research — Part 2: Guidelines for implementing computational models in clinical integrated decision support systems.
5.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	8 -week Feedback CIB for the proposal on	Biotechnology — Bioprocessing — General requirements for endpoint quality assessment of intestinal organoids together with a call for experts.
6.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	NP ballot for the proposal on	Biotechnology – Bioprocessing – General requirements for purification of extracellular vesicles.
7.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	ISO/WD TS 20853	Biotechnology — Bioprocessing — General requirements for the bacteriophage preparation for therapeutic use
8.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	Consultation for proposal on processing decellularized ECM	Biotechnology – Bioprocessing – Guideline for processing decellularized extracellular matrix of soft tissues
9.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	Consultation for proposal on development process of MPS	Biotechnology — Bioprocessing — Developing process of microphysiological systems for evaluation of substances

10.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	Consultation for proposal on CoA and CoO for AMs	Biotechnology - Ancillary materials present during the production of cell and gene therapy product manufacturing - Part 2: guidelines for certificate of analysis and certificate of origin
11.	ISO/TC 276/WG 4 Bioprocessing for cells and related entities	ISO/AWI 25347	Biotechnology — Bioprocessing — General requirements for purification of extracellular vesicles

3) MHD20/ P3 Analytical methods in Biotechnology: standardization for accurate, reproducible and robust measurements and analyses in support of biotechnologies relevant molecules and entities, including nucleic acids, proteins, and cells

Indigenous(working groups are yet to be formed)

1. DNA sequencer system
2. Double Beam UV Spectrophotometer
3. GC-MS SQD with Liquid Autosampler and Headspace
4. Quaternary FHPLC
5. PCR/Thermal Cycler (Digital PCR, DDPR)

Sl No	**TC/SC/WG**	**Reference No**	**Title**
1	ISO/TC276/SC1/WG3 Nucleic acids	ISO/AWI 20397-3	Biotechnology - Massively parallel sequencing - Part 3: General requirements and guidance for metagenomics NGS Pt 3 Metagenomics
2	ISO/TC276/SC1/WG3 Nucleic acids	ISO/CD 21085	Biotechnology — General requirements for the measurement of ultra-low concentration samples of target nucleic acid sequences
3	ISO/TC276/SC1/WG3 Nucleic acids	ISO/PWI 12833	Biotechnology — Requirements for RNA quantification methods for gene expression analysis of biological systems
4	ISO/TC276/SC1/WG2 Cell characterization	ISO/CD 24479	Biotechnology — Cellular morphological analysis — General requirements and considerations for cell morphometry to quantify cell morphological features
5	ISO/TC276/SC1/WG2 Cell characterization	ISO/CD 20391-1	Ed. 2 Biotechnology — Cell counting — Part 1: General guidance on cell counting methods

6	ISO/TC276/SC1/WG2 Cell characterization	SO/FDIS 24479	Biotechnology — Cellular morphological analysis — General requirements and considerations for cell morphometry to quantify cell morphological features
7	ISO/TC276/SC1/WG2 Cell characterization	ISO/AWI 8934	Biotechnology — General requirements and considerations for cell viability measurements – Part 1: Mammalian cells
8	ISO/TC276/SC1/WG2 Cell characterization	ISO/AWI TR 4752	Biotechnology — Inventory of methods for detection of microbiological contamination in mammalian cell culture
9	ISO/TC276/SC1/WG2 Cell characterization	ISO/TS 23511:2023,	Biotechnology — General requirements and considerations for cell line authentication ◊ to IS
10	ISO/TC276/SC1/WG1 Gene delivery	ISO/AWI 16921-1	Biotechnology – Gene delivery systems – Part 1: Vocabulary
11	ISO/TC276/SC1/WG1 Gene delivery	ISO/AWI 16291-2	Biotechnology – Gene delivery systems – Part 2: Viral vector titer
12	ISO/TC276/SC1/WG1 Gene delivery	ISO 5058-1:2021	Biotechnology — Genome editing — Part 1: Vocabulary
13	ISO/TC276/SC1/WG1 Gene delivery	ISO 5058-1:2021/Amd 1:2022	Biotechnology — Genome editing — Part 1: Vocabulary — Amendment 1
14	ISO/TC276/SC1/WG1 Gene delivery	ISO/PWI 16921-3	Biotechnology — Gene delivery systems — Part 3: Lipid nanoparticles
15	ISO/TC276/SC1/WG1 Gene delivery	ISO/PWI 16944	Biotechnology - Considerations and minimum requirements for assays used in the detection of anti-adeno-associated viruses (AAV) antibodies when evaluating pre-existing immunity to AAV
20	ISO/TC 276/WG 5 Data processing and integration	ISO/PWI 8472-3	Biotechnology — Data interoperability for stem cell data — Part 3: Schema of database structure.
21	ISO/TC 276/WG 5 Data processing and integration	NP ballot for ISO/PWI,	Biotechnology — Single cell sequencing — Requirements for data processing of RNA-sequencing.
22	ISO/TC 276/WG 5 Data processing and integration	ISO/DIS 24480	Biotechnology — Validation of database used for nucleotide sequence evaluation

4) MHD20/ P4 Nanotechnology Applications in Healthcare: Products, processes, test methods and delivery systems derived from nanotechnology for healthcare applications.

Indigenous(working groups are yet to be formed)
1) antimicrobial activity of silver nanoparticles

S No	ISO TC/SC/WG	Reference No	Title
1.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/Dis 4962 : 2024	Nanotechnologies — In vitro acute nanoparticle phototoxicity assay
2.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 4963	Nanotechnologies — Radiotelemetry-spectral-echocardiography based real-time surveillance protocol for in vivo toxicity detection and monitoring of engineered nanomaterials (ENM)
3.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 5265	Nanotechnologies — Method for characterizing and quantifying nanomaterials released from wood products
4.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 7666	evaluation method for chronic inhalation toxicity based on long burden of nanomaterials
5.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/TS 7833 : 2024	Nanotechnologies — Extraction method of nanomaterials from organs by the proteinase K digestion
6.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/TS 11353	Nanotechnologies — A test method for detection of nano-object release from respiratory mask media under different working conditions
7.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 12769	Nanotechnologies — Toxicity assessment of manufactured nanomaterials in soils using plant Arabidopsis thaliana

8.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 21497	Nanotechnologies — Method for the removal of carbon nanomaterials from wastewater using hypochlorite
9.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 21523	Nanotechnologies — Characterization of biotransformed metal oxide nanomaterials in organs
10.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/PWI 24864	Safety assessment of nanomaterials for use as fertilizers in agriculture
11.	ISO/TC 229/WG 3 Health, Safety and Environmental Aspects of Nanotechnologies	ISO/NP TS 25648	Nanotechnologies ---- Radiolabeling method to detect the distribution of nanomaterials in laboratory animals
12.	ISO/TC 229/WG 5 Products and Applications	ISO/NP 23653	Nanotechnologies – Experimental considerations when evaluating nanoparticle performance of intracellular uptake