BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Medical Biotechnology and Medical Nanotechnology Sectional Committee, MHD 20	18	04 December 2024, Wednesday 11:00 AM
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=m9c447d34e0c54e56adcbed8b55447714 **Meeting Number**: 2518 126 9506 **Password**: MHD20@18		
Chairperson	Prof. Nirmal Kumar Ganguly (In Personal Capacity) Ex-Director General, Indian Council of Medical Research (ICMR)	
Member Secretary	Mr. Karthik Reddy Katipally Scientist-B, BIS.	

ITEM 0 GENERAL

0.1 Welcome Address by BIS

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 17th meeting of Medical Biotechnology and Medical Nanotechnology Sectional Committee (MHD 20) held on 02 September 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no: MHD20/A2.17 dated 12-09-2024.

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 Medical Biotechnology and Medical Nanotechnology Sectional

Committee (MHD 20) is as follows:

a) Standardization in the field of medical biotechnology, including but not limited to Biobanks and Bioresources, analytical methods (including Chemical and Biological), products (including tissue-engineered medical products), delivery systems, etc.

b) Standardization in the field of medical nanotechnology, including but not limited to products, processes and test methods.

c) To coordinate with the work of:

1. ISO/TC 276 "Biotechnology"
2. ISO/TC 276/SC 1 "Analytical Methods"
3. ISO/TC 229/WG 3 "Health, Safety & Environmental Aspects of Nanotechnologies"

The Committee may please note.
2.1.1 Details of Working Panels and working groups under MHD20 are given in ***Annexure-A.***

2.2 The present composition of Medical Biotechnology and Medical Nanotechnology Sectional Committee (MHD 20) along with participation status of members is enclosed at ***Annexure-B***.

2.3 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, any member remaining absent from two consecutive meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become automatically disqualified to continue as the member of the Sectional Committee.

2.4 The following organizations were requested for their co-option and the status is given below:

Sl. No.	Organisation	Nomination
1.	Indian Institute of Technology Bombay	*No response received*
2.	Translational Health Science and Technology Institute	*No response received*
3.	CSIR-Centre for Cellular & Molecular Biology (CCMB).	Dr. Md. Idris, Senior Principal Scientist
4.	National Institute of Immunology	*No response received*
5.	Institute of Life Sciences	*No response received*
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'
9	Institute for Stem Cell Science and Regenerative Medicine (inStem)	*No response received*
10	Institute Of Liver & Biliary Sciences	*No response received*
11	Karkinos Healthcare Pvt. Ltd.	*No response received*
12	Sapien Biosciences	*No response received*
13	National Cancer Tissue Biobank (Nctb)	*No response received*
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 An expression of interest was sent to all relevant subject matter experts in the field of biotechnology. The following organizations have requested BIS for representation in the Committee:

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

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

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

2.6 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

There are No documents for finalization

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are no standards for wide circulation.

The Committee may kindly note.

4.2 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The following indigenous subject drafts are under preparation.

Sl. No.	Project Title.
1.	Additive manufacturing in healthcare. (MHD 20/WG 1)
2.	Isolation, Characterization and General Requirements for Handling of Extracellular Vesicles (MHD 20/ WG 2)
3	DNA sequencer system (Draft is given in ***Annexure-C***)

The Committee may please note.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.

5.2.2 The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

(a) Agree
(b) Agree (with comments*)
(c) Don’t agree (with comments*)

(d) No Comments, as it is not related to my area of expertise.

5.2.3 The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

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 Standards formulation on following subjects was recommended by Department of Pharmaceuticals (DoP) under the directions of NITI aayog as part of implementation of NMDP,2023.

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

The Committee may kindly deliberate and decide.

ITEM 8 TECHNICAL ISSUES

There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical Committees/Subcommittees of ISO are given below:

Sl. No.	**Liaison Committee of ISO**	**Type of Membership**	**Last Meeting**
1.	ISO TC 276 “Biotechnology”	Participating Member	17- 22 June 2024
2.	ISO/TC 276/SC 1 “Analytical Methods”	Participating Member	17- 22 June 2024
3	ISO TC 229 “Nanotechnologies” [1]	Participating Member	NA

9.1.2 The establishment of a new subcommittee (SC 2) on Microphysiological Systems and Organ-on-Chip under ISO/TC 276 was notified to MHD20 via ballot under ISO/TC 276 "Resolution 48/2024/01 - Establishment of ISO/TC 276/SC 2." As the NMC, we agreed to the formation of this subcommittee and committed to actively participating in all related meetings and ballots whenever notified. The Scope and structure of the committee is as follows;

Scope: Standardization in the field of Microphysiological Systems (MPS) and Organ-on-Chip (OoC) that includes the following topics:
• Terminology, ecosystem, interdepencies
• Biological inputs in MPS and OoC
• Engineering, including manufacturing and designing
• Hardware parameters, experimental design, and data management
• Characterisation of materials and processes
ISO/TC 276/SC 2 MPS and OoC has a specific focus for OoC as a hybrid system consisting of biological cells and technical components and the interaction between the two.

Structure:
Subcommittee 2 Microphysiological systems and Organ-on-Chip
• WG 1 – Terminology
• WG 2 – Biological inputs in MPS and OoC
• WG 3 – Experimental design and data management MPS and OoC
• JWG 4 – Engineering, Joint Working Group with ISO/TC 48 (WG3)
• CAG – Chair Advisory Group

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation’s interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

[1] MHD20 Coordinates with ISO TC 229/WG 3 ‘Health, Safety and Environmental Aspects of Nanotechnologies’

The Committee may kindly note.

9.2 The committee may kindly note that BIS has launched a international relations portal which is integrated with Existing Standards portal with single sign on, this portal will be used to process the Ballots, NWIP proposals and delegation proposals. The concept of assigning priority to ISO projects is enabled in the portal, A ballot can be accorded any of three priorities i.e, High priority, Medium Priority and Low Priority with a proper justification. The priority of the Project will be decided in consultation with Chairperson and if necessary, the whole sectional committee. After the priority is assigned, an expert will be designated for the projects for Medium and High priority. This has been introduced to increase the ownness of the document and international contribution. The designated experts will be the face of India for respective projects. A document on how to access IR portal and how to vote on notified ballots is prepared.(Click here to access the document)

9.3 Given that BIS holds a Participating membership in these technical committees, it is crucial for its members to vote on the notified ballots. An updated list of ballots received since the previous meeting, along with the votes cast by us as the national mirror committee, can be found in ***Annexure-D.*** Committee may consider assigning experts to the open ballots.

The Committee may kindly deliberate and decide.

ITEM 10. PROGRAMME OF WORK

The present Programme of Work of Medical Biotechnology and Medical Nanotechnology Sectional Committee (MHD 20) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

ITEM 11. REVIEW OF INDIAN STANDARDS

There are currently no standards due for review.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

There are currently no issues related to the previous meeting.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 20 is scheduled on 6th March 2025.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

Annexure-A

Working Panels

1. **MHD20/ P1 Biobanking;** including human, animal, plant and microorganism resources for Research & Development aspects, but excluding clinical diagnosis, therapeutics, food production and agriculture.
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.
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
4. **MHD20/ P4 Nanotechnology Applications in Healthcare:** Products, processes, test methods and delivery systems derived from nanotechnology for healthcare applications.

Working Groups

1. **MHD 20/WG 1** Additive manufacturing in healthcare. (Agreed Timeline was 6 months, i.e, till 6th December 2024)

2. **MHD 20/ WG 2** Isolation, Characterization and General Requirements for Handling of Extracellular Vesicles. (Agreed Timeline was 6 months, i.e, till 6th December 2024)

Annexure-B

Sl. No	Organization	Member Name	15th meeting 06/03/2024	16th meeting 06/06/2024	17th meeting 02/09/2024	Attendance (x/3)
1.	In Personal Capacity, Noida	Prof. Nirmal Kumar Ganguly	P	P	p	3/3
2.	Akrivis Health Care Private Limited, Visakhapatnam	Dr. Vamshi Krishna Irlapati	A	P	P	2/3
3.	Akrivis Health Care Private Limited, Visakhapatnam	Dr. Yadidya Mandalapu	A	P	P	2/3
4.	Amrita Vishwa Vidyapeetham, Coimbatore	Dr. Prof. Amit Kumar Dinda	P	A	A	1/3
5.	Amrita Vishwa Vidyapeetham, Coimbatore	Dr. Prof. Shanit Kumar Nair	A	A	A	0/3
6.	Amrita Vishwa Vidyapeetham, Coimbatore	Dr. Binulal Nelson Sathy	A	A	P	1/3
7.	CSIR - National Physical Laboratory, New Delhi	Dr. Rajesh	A	P	P	2/3
8.	CSIR - National Physical Laboratory, New Delhi	Dr. Ved Varun Agrawal	P	A	A	1/3
9.	CSIR - Central Drug Research Institute, Lucknow	Dr Amit Misra	P	P	P	3/3
10.	CSIR - Central Drug Research Institute, Lucknow	Dr. Prabhat Ranjan Mishra	A	A	P	1/3
11.	CSIR - Central Drug Research Institute, Lucknow	Dr. Namrata Singh	A	A	A	0/3
12.	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Vijay Kumar Meena	P	P	P	3/3
13.	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Ranjan Kumar Jha	P	A	P	2/3
14.	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	P	A	A	1/3
15.	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan	A	P	P	2/3

16.	Central Drugs Standard Control Organization, New Delhi	Shri Pradeep	A	A	A	0/3
17.	Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	Dr. Jayant Daniel	P	A	A	1/3
18.	Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	S.N. Kartik	A	P	A	1/3
19.	Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	Smt. A.Hemalatha	A	P	A	1/3
20.	ICMR - National Institute of Nutrition, Hyderabad	Dr. M. Raghunath	A	A	A	0/3
21.	ICMR - National Institute of Nutrition, Hyderabad	Dr. Sudip Ghosh	P	P	P	3/3
22.	Indian Institute of Technology Madras, Chennai	Prof. Smita Srivastava	P	A	P	2/3
23.	Indian Institute of Technology Madras, Chennai	Prof. Vignesh Muthuvijayan	P	P	P	3/3
24.	Indian Institute of Technology Madras, Chennai	Dr. Greeshma Thrivikraman	P	A	P	2/3
25.	Indian Institute of Technology Roorkee, Roorkee	Prof. Gopinath Packirisamy	P	A	A	1/3
26.	Indian Institute of Technology Roorkee, Roorkee	Prof. Krishna Mohan Poluri	P	A	P	2/3
27.	Institute of Chemical Technology, Mumbai	Prof. Padma V. Devarajan	P	P	P	3/3
28.	Institute of Chemical Technology, Mumbai	Prof. Sadhana Sathaye	P	A	A	1/3
29.	Institute of Nano Science and Technology, Mohali	Dr. Surajit Karmakar	P	P	P	3/3
30.	Institute of Nano Science and Technology, Mohali	Dr. Rahul Kumar Verma	A	A	P	1/3
31.	Institute of Nano Science and Technology, Mohali	Dr. Kiran Shankar Hazra	A	A	A	0/3

32.	Kalam Institute of Health Technology, Vishakhapatnam	Shri Ravi Vital	A	P	A	1/3
33.	Kalam Institute of Health Technology, Vishakhapatnam	Ms. Mohini Mehta	P	A	A	1/3
34.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Tanmay	A	A	A	0/3
35.	National Institute of Biologicals, Noida	Dr. Gauri Misra	P	P	A	2/3
36.	National Institute of Biologicals, Noida	Smt Shalini Tewari	P	P	A	2/3
37.	National Mineral Development Corporation, Hyderabad	Shri Rajan Kumar	P	A	P	2/3
38.	National Mineral Development Corporation, Hyderabad	Dr. C Kesava Rao	P	P	A	2/3
39.	Office of Development Commissioner (MSME), New Delhi	Shri K. Socrates	A	A	A	0/3
40.	Office of Development Commissioner (MSME), New Delhi	Shri G. Nagaraja	P	P	P	3/3
41.	Siemens Healthcare Private Limited, Bengaluru	Dr. Manohar Kollegal	P	A	P	2/3
42.	Siemens Healthcare Private Limited, Bengaluru	Shri A. Ganesh Kumar	P	P	P	3/3
43.	Siemens Healthcare Private Limited, Bengaluru	Ms. Sudipa Bhattacharya	P	P	P	3/3
44.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr Anil Kumar PR	P	P	P	3/3
45.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr Shiny Velayudhan	A	P	P	2/3
46.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Dr Naresh Kasoju	P	P	P	3/3
47.	IN PERSONAL CAPACITY	Dr Madhu Bala	P	A	P	2/3
48.	IN PERSONAL CAPACITY	Dr. Suneel Rallapalli	A	P	P	2/3
49.	IN PERSONAL CAPACITY	Mr. Dhanasekaran Muthusamy	A	P	A	1/3

Annexure-C

DNA SEQUENCER SYSTEM - REQUIREMENTS

(Working draft)

Foreword

The ever growing demand for high-quality genomic data across diverse fields such as clinical diagnostics, biomedical research, agriculture, and environmental studies has driven the continuous evolution of DNA sequencing technologies. As these technologies advance, understanding the capabilities, performance, and limitations of sequencing platforms becomes essential for ensuring the reliability and reproducibility of results. This standard aims to provide a comprehensive framework for evaluating DNA sequencing systems, emphasizing throughput requirements, performance metrics, and design considerations critical to the intended functioning of sequencing technologies.

DNA sequencing plays a pivotal role in a wide range of applications, from whole-genome sequencing (WGS) and RNA sequencing (RNA-Seq) to targeted gene analysis and metagenomics. However, each application has its own set of throughput, accuracy, sensitivity, and data quality demands. Therefore, it is essential to categorize sequencing systems based on their throughput capabilities, design considerations, and intended usage.

DNA Sequencer System subject was taken up for standard formulation under the directions of Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India as part of implementation of National medical device policy,2023.

DNA Sequencer System - Requirements

1. Scope

This standard specifies the requirements for ensuring the proper functioning and performance of DNA sequencing systems. It includes the criteria for accuracy, sensitivity, throughput, read quality, reproducibility. It also outlines the required test methods and manufacturer documentation.

2. Terminology

2.1 Definitions

DNA sequencing system

Base call accuracy : precision with which the nucleotides (A, T, G, C) are identified during DNA or RNA sequencing.

2.2 Abbreviations

- **BWA**: Burrows-Wheeler Aligner, a tool used for aligning sequencing reads to reference genomes.
- **GATK**: Genome Analysis Toolkit, a toolkit for variant discovery and analysis.
- **FASTQC**: A quality control tool for high throughput sequence data.
- **RIN**: RNA Integrity Number, a score that measures RNA quality.

2. System Requirements

2.1. Accuracy

2.1.1 The DNA sequencer shall achieve a base call accuracy with ≥85% of bases having a Phred quality score 30 (Q30).

$Q = -10\log_{10}(e)$

where e is the estimated probability of the base call being wrong.

Note: Higher Q scores indicate a smaller probability of error. Lower Q scores can result in a significant portion of the reads being unusable. They may also lead to increased false-positive variant calls, resulting in inaccurate conclusions.

Relationship Between Sequencing Quality Score and Base Call Accuracy		
Quality Score	**Probability of Incorrect Base Call**	**Inferred Base Call Accuracy**
10 (Q10)	1 in 10	90%
20 (Q20)	1 in 100	99%
30 (Q30)	1 in 1000	99.9%

2.1.2 Base-calling accuracy shall be validated using known reference genomes.

2.3The sequencer shall detect true variants with a sensitivity of ≥95%.

2.4 The sequencer shall exhibit a false-positive rate of <2%, achieving specificity ≥98%.

2.5 Throughput

2.5.1. The sequencer shall meet throughput requirements as advertised. The general and widely accepted categorization is given below;

Sequencer Type	**Typical Data Output**	**Application**
Low Throughput	10-50 Gb/run	Targeted sequencing, amplicon sequencing, small RNA sequencing
Medium Throughput	50-300 Gb/run	Whole-genome sequencing, RNA-Seq, Epigenomics, Metagenomics
High Throughput	300 Gb - 1 Tb/run	High-depth WGS, large-scale transcriptomics, population genomics
Ultra-High Throughput	1 Tb to 10 Tb/run	Large-scale sequencing (thousands of genomes), clinical genomics, deep sequencing

2.5.2 The system's runtime shall be within the manufacturer's advertised range.

2.6. Read Quality

2.6.1 The sequencer shall achieve Q30 for ≥85% of bases.

2.6.2 The system shall provide read lengths suitable for the intended applications, such as paired-end reads of 150 bp for whole-genome sequencing.

2.7 Reproducibility

2.7.1 The system shall demonstrate ≥95% variant concordance across multiple runs with identical samples.

2.7.2 Coverage depth variation across runs shall be minimal.

3. Test Methods for Ensuring Proper Functioning

3.1 Accuracy Testing

3.1.1 To ensure the base-calling accuracy and variant identification are in alignment with truth sets. Sequence a well-characterized reference genome (e.g., NA12878). Align the reads using BWA (Burrows-Wheeler Aligner). Call variants using GATK HaplotypeCaller or a similar tool. Compare the sequenced variants with the truth set using RTG Tools or equivalent software.

3.1.2 Phred quality score ≥30 for ≥85% of bases.

3.1.3 Variant concordance ≥95% compared to the reference truth set.

3.3 Sensitivity and Specificity Testing

3.3.1.To evaluate the system's ability to detect true variants (sensitivity) and avoid false variants (specificity). Use synthetic DNA/RNA samples with known variants. Sequence the sample and align reads using Bowtie2. Perform variant calling using FreeBayes or GATK. Compare detected variants with known truth sets using BCFtools for variant analysis.

3.3.2 Sensitivity shall be ≥95%.

3.3.3 Specificity shall be ≥98%.

3.4 Throughput Testing

3.4.1 To assess the data yield and processing speed of the sequencer. Sequence a pooled library optimized for maximum throughput. Record data yield and runtime. Compare the results with manufacturer specifications.

3.4.2 Data yield shall be within the range for different categories of throughput (see 2.2.1).

3.4.3 Sequencing time within the manufacturer's specified range.

3.4 Read Quality Testing

3.4.1 To evaluate the quality of raw sequencing reads. Sequence a standard control library and assess quality using FASTQC. Analyse parameters such as GC content, base quality scores, and adapter contamination.

3.4.2 Read quality shall be as given in **2.3.**

3.4.3 Adapter contamination <2%.

3.5 Reproducibility Testing

3.5.1 To ensure consistency across sequencing runs. Sequence multiple replicates of the same sample. Compare the results across runs using BCFtools isec or similar tools.

3.5.2 Variant concordance shall be ≥95%.

3.5.3 There shall be Minimal variation in coverage depth across runs.

4. Documentation Requirements

4.1 System Setup and Calibration Documents

4.1.1. The manufacturer shall provide a comprehensive user manual, including instructions for system assembly, installation, and calibration procedures.

4.1.2. Calibration protocols shall include the use of control samples (e.g., PhiX) and recommended tools for verification.

4.2 Maintenance Documentation

4.2.1 The manufacturer shall provide a maintenance schedule outlining routine checks and calibrations.

4.2.2 The manufacturer shall provide troubleshooting guides for common issues, including error handling and recovery procedures.

4.3 The manufacturer shall specify the operational temperature, humidity, and environmental conditions for optimal system performance.

Annexure-D

Received Ballots ISO/TC 276

Sl. No	Type	Reference	Title	Questions	Decisions	Start date	End date
1.	CIB	Resolution 48/2024/01 - Establishment of ISO/TC 276/SC 2	ISO/TC 276 approves the establishment of a new Subcommittee with the following title: ISO/TC 276/SC 2 ""Microphysiological systems and Organ-on-Chip"". ISO/TC 276 approves the following scope of ISO/TC 276/SC 2: ""Standardization in the field of Microphysiological Systems (MPS) and Organ-on-Chip (OoC) that includes the following topics: • Terminology, stakeholder environment, interdepencies in MPS and OoC • Biological components in MPS and OoC • Engineering in MPS and OoC, including manufacturing and designing • Experimental design, data processing and integration of MPS and OoC studies • Characterisation of materials and processes ISO/TC 276/SC 2 MPS and OoC has a specific focus for MPS and OoC as a hybrid system consisting of biological components and technical components and the interaction between the two. ISO/TC 276/SC 2 will work closely with related working groups within ISO/TC 276 and related (technical) committees, e.g. ISO/TC 48 and ISO/TC 212, in order to identify standardization needs and gaps, and collaborate with other organisations to avoid duplications and	Do you agree to the establishment of ISO/TC 276/SC 2 "Microphysiological systems and Organ-on-Chip"?	Yes	2024-09-14	2024-10-12

			overlapping standardization activities."" ISO/TC 276 approves Prof. Andries Van der Meer (https://people.utwente.nl/andries.vandermeer; Chairman of the CEN/CENELEC Focusgroup on Organ-On-Chip) as the Chairperson. The ISO/TC 276/SC 2 Secretariat will be held by the Netherlands (NEN).				
2.	CIB	Resolution 49/2024/01 - Liaison with MICROBE	ISO/TC 276 decides to establish a Category C liaison between ISO/TC 276/WG 2 and MICROBE. ISO/TC 276 decides to establish a Category C liaison between ISO/TC 276/WG 5 and MICROBE. The liaison representatives for WG 2 will be Dr. Ian Probert and Cornelia Stumptner. The liaison representatives for WG 5 will be Dr. Rob Finn, Dr Matthew Ryan and Prof. Dr. Jörg Overmann.	Do you agree to the Category C liaison establishment between ISO/TC 276/WG 2 and MICROBE?	Abstain	2024-09-25	2024-10-23
3.	FDIS	ISO/FDIS 24480	Biotechnology — Validation of database used for nucleotide sequence evaluation	Do you approve the technical content of the final draft?	Yes	2024-09-02	2024-10-28
4.	CIB	Feedback+Call for Experts - Organoid Manufacturing and QC	With this consultation ISO/TC 276 intends to collect feedback and comments as well as interested experts for an active involvement in the development of the following project organoid project proposal: Biotechnology — Bioprocessing for cells and related entities — General requirements for organoids manufacturing and quality control The feedback will be used to align the the scope and content of the draft with the other organoid-related project proposals in WG4, WG2 and SC1.	Do you wish to actively participate in the project development of this organoid manufacturing & QC proposal?	No	2024-09-12	2024-11-06

5.	CIB	Feedback+Call for Experts - Quality Assessment of Organoids	With this consultation ISO/TC 276 intends to collect feedback and comments as well as interested experts for an active involvement in the development of the following project organoid project proposal: Biotechnology — Bioprocessing for cells and related entities — Requirements for endpoint quality assessment of intestinal organoidsThe feedback will be used to align the the scope and content of the draft with the other organoid-related project proposals in WG4, WG2 and SC1.	Do you wish to actively participate in the project development of this intestinal organoid assessment proposal?	No	2024-09-12	2024-11-06
6.	FDIS	ISO/FDIS 18162	Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells	Do you approve the technical content of the final draft?	Abstain	2024-09-13	2024-11-08
7.	CIB	Resolution 50/2024/01 - SC2 Chairman	ISO/TC 276 approves Prof. Massimo Mastrangeli as the Chairperson of ISO/TC 276/SC2 ""Microphysiological systems and Organ-on-Chip"".	Do you agree with Prof. Massimo Mastrangeli as the Chairperson of ISO/TC 276/SC 2?	Yes	2024-10-16	2024-11-12
8.	CIB	Feedback on ISO/CD 25184 - Verified New Generation Sequences	Dear ISO/TC 276 members, Enclosed you find ISO/CD 25184, Requirements for Reference New Generation Nucleotide Sequences: Verified New Generation Sequences (VNGS) which is currently developped and balloted within ISO/TC 34/SC 16. Reviewing the broard topic and scope of the document that are NOT limited to the scope of ISO/TC 34 ""Food products"", but are rather inclusive of applications within Biotechnology and Diagnostics, feedback and input is requested from ISO/TC 276. Thank you!	Do you have comments on ISO/CD 25184?		2024-11-14	2024-12-02

9.	CIB	ISO/FDIS 16677-1 - Editorial Commenting	Biobanking — Germplasm — Part 1: Agricultural animal species	Do you have editorial comments on ISO/FDIS 16677-1?		2024-11-06	2024-12-02
10.	NP	ISO/PWI 25383	Biotechnology — Single cell sequencing — Requirements for data processing of RNA-sequencing	Do you approve, disapprove or abstain on this NWIP?		2024-09-11	2024-12-04
11.	NP	ISO/NP 25430-1	Biotechnology — Organoids — Part 1: Vocabulary	1a. Do you approve, disapprove or abstain on this NWIP?		2024-09-14	2024-12-07
12.	NP	ISO/NP 25448	Microphysiological systems and Organ-on-Chip systems — Vocabulary	1a. Do you approve, disapprove or abstain on this NWIP?		2024-09-25	2024-12-18
13.	CIB	Resolution 51/2024/01 - PWIP databases design+construction	ISO/TC 276 approves the registration of a new ISO/PWI for Biotechnology — General requirements for bioinformatics databases design and construction. The project will be developed by ISO/TC 276/WG 5. The project leader will be Xiaofeng Wei.	Do you agree to the PWI registration for this proposal on general requirements for design and construction of bioinformatics databases?		2024-11-12	2024-12-18
14.	DIS	ISO/DIS 20070	Biotechnology — Biobanking — Requirements for sample containers for storing biological materials in biobanks	Do you approve the technical content of the draft?		2024-10-14	2025-01-06
15.	DIS	ISO/DIS 20309	Biotechnology — Biobanking — Requirements for deep-sea biological materials	Do you approve the technical content of the draft?		2024-10-14	2025-01-06
16.	NP	ISO/NP 25530	Microphysiological System (MPS) and Organ-on-Chip (OoC) systems — Quality control and documentation requirements for biological components	1a. Do you approve, disapprove or abstain on this NWIP?		2024-10-23	2025-01-15

17.	NP	ISO/NP 25591	Microphysiological systems and Organ-on-Chip systems — Digital twins and computational modelling	1a. Do you approve, disapprove or abstain on this NWIP?		2024-11-06	2025-01-29
18.	NP	ISO/NP 25630	Biotechnology — Biobanking — General requirements for human intestinal organoids and human intestinal cancer organoids	1a. Do you approve, disapprove or abstain on this NWIP?		2024-11-21	2025-02-13
19.	CIB	Feedback on ISO 24651:2022	In preparation for the parallel revision that will be discussed during the next meeing in Cairns (June 2025), we invite all ISO/TC 276 members to give their feedback on the need for a revision of ISO 24651:2022. Please provide comments, if you deem a revision necessary, and indicate your availability for an active participation in a revision.	Recommended action		2024-11-23	2025-03-01
20.	SR	ISO/TS 20388:2021	Biotechnology — Biobanking — Requirements for animal biological material	Recommended action		2024-10-15	2025-03-04
21.	SR	ISO/TS 23105:2021	Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development	Recommended action		2024-10-15	2025-03-04

Received Ballots ISO/TC 276 SC 1

Sl. No	Type	Reference	Title	Questions	Decisions	Start date	End date
1.	CIB	PWI Ballot PWI 8934 Cell Viability Pt 2	ISO 8934-2 Biotechnology —Cell viability analytical methods – Part 2: Experimental Designs and Statistical Analysis for Quality of Direct Viability Methods	Do you approve the initiation of this draft as a PWI?	Yes	2024-09-30	2024-10-28
2.	CIB	SC1 Feedback on CD 25184 - Verified New Generation Sequences	CD 25184 - Verified New Generation Sequences	Do you have comments on ISO/CD 25184?		2024-11-14	2024-12-02
3.	DIS	ISO/DIS 20397-3	Biotechnology — Massively parallel sequencing — Part 3: General requirements and guidance for metagenomics	Do you approve the technical content of the draft?		2024-09-16	2024-12-09
4.	DIS	ISO/DIS 16921-1	Biotechnology — Gene delivery systems — Part 1: Vocabulary	Do you approve the technical content of the draft?		2024-11-18	2025-02-10

Ending Ballots ISO/TC 276

Sl. No	Type	Reference	Title	Questions	Decisions	Start date	End date
1.	NP	ISO/NP 25347	Biotechnology — Bioprocessing — General requirements for purification of extracellular vesicles	Did you consult with the range of relevant stakeholders identified in the proposal in the development of this voting position and related comments?	Yes	2024-07-03	2024-09-25
2.	NP	ISO/PWI 8472-3.2.3	Biotechnology — Data interoperability for stem cell data — Part 3: Schema of the database structure	We are committed to participating actively in the development of the project, at least by commenting on working drafts (P-members voting "Disapprove" in Qu. 1a may nevertheless nominate experts):	Yes	2024-07-13	2024-10-05
3.	CIB	Resolution 48/2024/01 - Establishment of ISO/TC 276/SC 2	ISO/TC 276 approves the establishment of a new Subcommittee with the following title: ISO/TC 276/SC 2 ""Microphysiological systems and Organ-on-Chip"". ISO/TC 276 approves the following scope of ISO/TC 276/SC 2: ""Standardization in the field of Microphysiological Systems (MPS) and Organ-on-Chip (OoC) that includes the following topics: • Terminology, stakeholder environment, interdepencies in MPS and OoC • Biological components in MPS and OoC • Engineering in MPS and OoC, including manufacturing and	Do you agree to the establishment of ISO/TC 276/SC 2 "Microphysiological systems and Organ-on-Chip"?	Yes	2024-09-14	2024-10-12

			designing • Experimental design, data processing and integration of MPS and OoC studies • Characterisation of materials and processes				
4.	DIS	ISO/DIS 8472-2	Biotechnology — Data interoperability for stem cell data — Part 2: Key characteristics of stem cell data	Do you approve the technical content of the draft?	Yes	2024-07-23	2024-10-15
5.	FDIS	ISO/FDIS 24480	Biotechnology — Validation of database used for nucleotide sequence evaluation	Do you approve the technical content of the final draft?	Yes	2024-09-02	2024-10-28
6.	CIB	Call for Experts for Genetic Diversity Assessment	Dear ISO/TC 276 members, Based on Resolution 20/2024/01 taken by ISO/TC276/SC1 on 2024-06-22 we are searching for interested experts who would like to participate in the active development of a project on Biotechnology - Whole genome sequencing - Genetic diversity assessment within ISO/TC 276/SC 1/WG 3. Please indicate your active participation in this ballot. Thank you!	Would you like to participate actively in the development of the project?	No	2024-08-16	2024-10-31
7.	CIB	Feedback+Call for Experts - Organoid Manufacturing and QC	With this consultation ISO/TC 276 intends to collect feedback and comments as well as interested experts for an active involvement in the development of the following project organoid project proposal: Biotechnology — Bioprocessing for cells and related entities — General requirements for organoids manufacturing and quality control The feedback will be used to align the the scope and content of the draft with the other organoid-related project proposals in WG4, WG2 and SC1.	Do you wish to actively participate in the project development of this organoid manufacturing & QC proposal?	No	2024-09-12	2024-11-06

8.	CIB	Feedback+Call for Experts - Quality Assessment of Organoids	With this consultation ISO/TC 276 intends to collect feedback and comments as well as interested experts for an active involvement in the development of the following project organoid project proposal: Biotechnology — Bioprocessing for cells and related entities — Requirements for endpoint quality assessment of intestinal organoidsThe feedback will be used to align the the scope and content of the draft with the other organoid-related project proposals in WG4, WG2 and SC1.	Do you wish to actively participate in the project development of this intestinal organoid assessment proposal?	No	2024-09-12	2024-11-06
9.	FDIS	ISO/FDIS 18162	Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells	Do you approve the technical content of the final draft?	Yes	2024-09-13	2024-11-08

Ending Ballots ISO/TC 276 SC 1

Sl. No	Type	Reference	Title	Questions	Decisions	Start date	End date
1	FDIS	ISO/FDIS 24479	Biotechnology — Cellular morphological analysis — General requirements and considerations for cell morphometry to quantify cell morphological features	Do you approve the technical content of the final draft?	Yes	2024-07-23	2024-09-17
2	NP	ISO/PWI 12833	Biotechnology — Requirements for RNA quantification methods for gene expression analysis of biological systems	Did you consult with the range of relevant stakeholders identified in the proposal in the development of this	Yes	2024-07-19	2024-10-11

				voting position and related comments?			
3	NP	ISO/PWI 16944	Biotechnology — Guidance and requirements for assays used in the detection of anti-adeno-associated viruses (AAV) antibodies when evaluating preexisting immunity to AAV	Did you consult with the range of relevant stakeholders identified in the proposal in the development of this voting position and related comments?	Yes	2024-07-19	2024-10-11
4	CIB	PWI Ballot PWI 8934 Cell Viability Pt 2	ISO 8934-2 Biotechnology —Cell viability analytical methods – Part 2: Experimental Designs and Statistical Analysis for Quality of Direct Viability Methods	Do you approve the initiation of this draft as a PWI?	Yes	2024-09-30	2024-10-28
5	CIB	PWI Ballot Genetic Diversity Assessment	Biotechnology- Whole genome sequencing - Genetic diversity assessment	Do you have one or more experts to identify to contribute to this project as it develops? If yes, please provide the name(s) and e-mails in your comments.	No	2024-08-08	2024-10-31