

BUREAU OF INDIAN STANDARDS

(MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT)

MINUTES

Eleventh Meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15

Chairperson:

Dr. V. R. Singh (*In personal capacity*)
Former Director-Grade-Scientist,
National Physical Laboratory(NPL), New Delhi

Member Secretary:

Chandan Kumar Scientist-C/Deputy Director, Bureau of Indian Standards

Meeting Date and Time: 28 June 2023 (Wednesday), 11:00 am

ITEM 0 General

The list of participants is attached as Annex-1.

ITEM 0.1 Welcome Address by Head(MHD)

Sh. A. R. Unnikrishnan, Head (MHD) extended a warm welcome to the Chairperson and the members present in the Eleventh meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15. He appreciated the members for their active contributions in supporting the national standardization activity.

He solicited the cooperation of the members while discussing the agenda.

ITEM 0.2 Opening Remarks by the Chairperson

Dr. V. R. Singh, Chairperson, MHD 15 welcomed all the members present in the Eleventh meeting of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15.

In his opening remarks, he mentioned that we are living in the age of Artificial Intelligence (AI) and Internet of Things (IoT) and medical devices have been truly transformed with the ever-increasing use of these technologies. He pointed out that with the growth of such technologies, issues related to data quality and storage are of prime concern. He also referred to the advancement in Point-of-care-testing (PoCT) devices and use of nanotechnology in medical devices in the context of modern healthcare delivery systems. He stressed on the need to develop standards for such medical devices and called upon members to focus on these priority areas.



He requested for active cooperation of the members to make the meeting successful.

ITEM 0.3 Presentation on Process Reforms in Standardization Activity of BIS

A presentation was made by the Member Secretary to apprise the members about several process reforms in the standardization activity of BIS. A brief summary covering the important points is attached as Annex-2.

ITEM 1 Formal Confirmation of Minutes of the Previous Meeting

1.1 The Committee approved the minutes of previous (Tenth) meeting circulated vide BIS DG letter No. MHD 15/A-2.10 without any change.

ITEM 2 Action Taken Report on the minutes of last meeting

2.1 The committee noted the information about the actions taken on the minutes of the last meeting as given at *Annex 1 to the Agenda*.

ITEM 2 Scope and Composition of the Sectional Committee

2.1 The Committee reviewed its scope and recommended to revise it as given below:

Scope: To prepare Standards for Medical Electrical equipment, software and systems concerning diagnostic, radiotherapy, nuclear medicine, radiation dosimetry, surgical, therapeutic and monitoring used for various specialties.

• Liaisons:

- a) IEC TC 62 Medical equipment, software, and systems [P-Member]
- b) IEC SC 62A Common aspects of medical equipment, software, and systems [P-Member]
- c) IEC SC 62B Medical imaging equipment, software, and systems [P-Member]
- d) IEC SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry [P-Member]
- e) IEC SC 62D Particular medical equipment, software, and systems [P-Member]
- **2.2** The Committee reviewed its composition and the attendance of the members in the last three meetings. It was reiterated that if an organization does not participate in three meetings consecutively without giving any justification, it indicates lack of interest in the committee work and the committee will consider withdrawal of such organizations from its composition.

It was also stressed that as per BIS Guidelines, as far as possible, non-industry representation should not be less than two-third of the committee composition. The Committee observed that the industry representation has gone beyond the prescribed limit and suggested that the industry



representatives which are not/less relevant to the scope of the committee and are already represented on the other sectional committees directly relevant to their field may be considered for removal. It was decided to send a letter to the following members from the industry requesting them to share details about their range of products which come under the scope of MHD 15 and how they can support the national/international standardization work:

- (a) Abbott India Limited, New Delhi
- (b) Boston Scientific India Private Limited, Gurugram
- (c) India Medtronic Private Limited, Gurugram
- (d) Johnson & Johnson Private Limited, Mumbai
- (e) Stryker India Private Limited, Gurugram

It was decided that decision regarding the withdrawal/retention of the above organizations would be taken based on the responses received in consultation with the Chairperson.

ITEM 3 Draft Indian Standards for Finalization

The Committee noted the documents under wide circulation and decided that in case no comments are received during the wide circulation stage before the last date of comments, these may be finalized in consultation with the Chairperson. However, if comments are received during the wide circulation stage, these may first be resolved in the next committee meeting before finalization. The list of the documents under wide circulation is given below:

- **1. MHD 15 (22648) (Modified/Technically Equivalent to IEC 60601-1:2020)** Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (Third Revision)
- **2.** MHD 15(22651) (Modified/Technically Equivalent to IEC 60601-1-2:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 2 Electromagnetic disturbances Requirements and tests (Second Revision)
- **3.** MHD 15(22652) (Modified/Technically Equivalent to IEC 60601-1-3:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 3 Radiation protection in diagnostic X-ray equipment (First Revision)
- **4.** MHD 15(22653) (Modified/Technically Equivalent to IEC 60601-1-6:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 6 Usability (First Revision)
- **5.** MHD 15(22654) (Modified/Technically Equivalent to IEC 60601-1-8:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 8 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (First Revision)



- **6.** MHD 15(22655) (Modified/Technically Equivalent to IEC 60601-1-9:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 9 Requirements for environmentally conscious design
- **7.** MHD 15(22656) (Modified/Technically Equivalent to IEC 60601-1-10:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 10 Requirements for the development of physiologic closed-loop controllers (First Revision)
- **8.** MHD 15(22657) (Modified/Technically Equivalent to IEC 60601-1-11:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (First Revison)
- **9.** MHD 15(22658) (Modified/Technically Equivalent to IEC 60601-1-12:2020) Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 12 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- **10.** MHD **15**(**22659**) (Modified/Technically Equivalent to IEC **60336:2020**) Medical electrical equipment X-ray tube assemblies for medical diagnosis Focal spot dimensions and related characteristics
- **11.** MHD **15(22660)** (Modified/Technically Equivalent to IEC 60522-1:2020) Medical electrical equipment Diagnostic X-rays: Part 1 Determination of quality equivalent filtration and permanent filtration
- **12.** MHD **15(22661)** (Modified/Technically Equivalent to IEC 60522-2:2020) Medical electrical equipment Diagnostic X-rays: Part 2 Guidance and rationale on quality equivalent filtration and permanent filtration
- **13. MHD 15(22662) (Modified/Technically Equivalent to IEC 61675-1:2022)** Radionuclide imaging devices Characteristics and test conditions: Part 1 Positron emission tomographs (First Revision)
- **14.** MHD 15(22663) (Modified/Technically Equivalent to IEC 61689:2022) Ultrasonics Physiotherapy Systems Field Specifications and Methods of Measurement in the Frequency Range 05 MHz to 5 MHz
- **15.** MHD **15(22664)** (Modified/Technically Equivalent to IEC 60601-2-2:2023) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 2 High frequency surgical equipment and high frequency surgical accessories (First revision)



- **16.** MHD **15(22665)** (Modified/Technically Equivalent to IEC 60601-2-3:2022) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 3 Short-wave therapy equipment (First revision)
- **17.** MHD **15**(**22666**) (Modified/Technically Equivalent to IEC **60601-2-10:2023**) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 10 Nerve and muscle stimulators (First revision)
- **18.** MHD **15**(22667) (Modified/Technically Equivalent to IEC 60601-2-43:2022) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 43 X-ray equipment for interventional procedures (First revision)
- **19.** MHD **15**(**22668**) (Modified/Technically Equivalent to IEC **60601-2-45:2022**) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 45 Mammographic X-ray equipment and mammographic stereotactic devices (First revision)
- **20.** MHD 15(22669) (Modified/Technically Equivalent to IEC 60601-2-54:2022) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 54 X-ray equipment for radiography and radioscopy (First revision)
- **21.** MHD 15(22670) (Modified/Technically Equivalent to IEC 60601-2-63:2021) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 63 Dental extra-oral X-ray equipment (First revision)
- **22.** MHD 15(22671) (Modified/Technically Equivalent to IEC 60601-2-65:2021) Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance Section 65 Dental intra-oral X-ray equipment (First revision)
- **23.** MHD 15(22679) (Modified/Technically Equivalent to IEC 60806:2022) Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis (First revision)

ITEM 4 Draft Indian Standards for Approval for Wide Circulation

- **4.1** The Committee to initiate the adoption of the following IEC documents to revise/amend the corresponding Indian Standards and approved the wide circulation of these IEC documents for a period of one month:
 - 1. **IEC 60601-2-6:2022 [IEC 60601-2-6:2012+AMD1:2016+AMD2:2022 CSV]** Medical electrical equipment Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment



- 2. Corrigendum 1 to IEC 80601-2-26:2019 [IEC 80601-2-26:2019/COR1:2021] Medical electrical equipment Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- 3. **IEC 60601-2-33:2022** Medical electrical equipment Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- IEC 60601-2-41:2021 Medical electrical equipment Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- 5. **IEC 60601-2-46:2023** Medical electrical equipment Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
- 6. **IEC 80601-2-59:2023 [IEC 80601-2-59:2017+AMD1:2023 CSV]** Medical electrical equipment Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
- 7. **IEC 62653-1:2021 [IEC 62563-1:2009+AMD1:2016+AMD2:2021 CSV]** Medical electrical equipment Medical image display systems Part 1: Evaluation methods
- **4.2** The Committee decided to circulate the list of standards published by IEC/TC 62 and its SC 62A, 62B, 62C and 62D along with their status of adoption among the members for 15 days requesting them to suggest the IEC standards to be considered for adoption as Indian Standards.

ITEM 5 New Subjects

5.1 The Committee was informed that any New Work Item Proposal (NWIP) may be submitted through the BIS website www.bis.gov.in.

ITEM 6 Technical Issues

6.1 Review of IS 7620 Series of Indian Standards on X-ray Equipment viz-a-viz IS 13450 Series of Standards

CMD-III representative informed that a meeting is being planned with AERB in the month of July 2023 to discuss the review of IS 7620 Series of Indian Standards on X-ray Equipment viz-a-viz IS 13450 Series of Standards and MHD will be informed once the schedule is finalized.

ITEM 7 International Electrotechnical Commission (IEC)

7.1 The Committee noted the information regarding the P-membership of India on IEC/TC 62 and SC 62A, 62 B, 62C & 62D subcommittees.

The Committee also noted the information regarding obligatory voting for BIS(India) on all the ballot documents circulated by the Secretariat of IEC/TC 62 and SC 62A, 62 B, 62C & 62D subcommittees.



The Committee also discussed regarding the nomination of experts from other sectional committees on the Working Groups of IEC/TC 62 and its SCs wherever specific domain expertise is required. It was agreed to consider such proposals as per BIS guidelines.

7.2 The Committee noted the information about the next Plenary/Working Group meetings of IEC/TC 62 and its SCs scheduled from 11-22 Sept 2023 in Seoul, South Korea in Face-to-face mode. The nominations received for participation in the meetings were recommended along with the participation of Chairman, MHD 15 and Member Secretary, MHD 15 in the Plenary Meetings of IEC TC 62 and SC 62A, 62B, 62C and 62D. The complete list of delegates recommended for participation in the meetings along with the source of funding is given below:

| S.No. | Member & organization | Meetings to be attended | Date | Funding |
|-------|-----------------------------|-------------------------|-----------------|------------|
| 1. | Dr. V. R. Singh, | SC 62 A Plenary | 19 Sept 2023 | |
| | Chairperson, MHD 15 | SC 62 B Plenary | 20 Sept 2023 | Funding by |
| | (In personal capacity) | SC 62 C Plenary | 21 Sept 2023 | BIS |
| | | SC 62 D Plenary | 21 Sept 2023 | |
| | | TC 62 Plenary | 22 Sept 2023 | |
| 2. | Dr. Pratik Kumar, | SC 62C/WG 1 | 15-19 Sept 2023 | Funding by |
| | AIIMS, New Delhi | SC 62 B Plenary | 20 Sept 2023 | BIS |
| | | SC 62 C Plenary | 21 Sept 2023 | |
| 3. | Prof. S. Ramakrishnan, | SC 62 A Plenary | 19 Sept 2023 | |
| | IIT Madras, Chennai | SC 62 D Plenary | 21 Sept 2023 | Funding by |
| | | TC 62 Plenary | 22 Sept 2023 | IIT Madras |
| 4. | Dr. Ratnesh Singh | SC 62 A Plenary | 19 Sept 2023 | Funding by |
| | Kanwar, INMAS, New Delhi | SC 62 D Plenary | 21 Sept 2023 | INMAS |
| 5. | Mr. Chandan Kumar, | SC 62 A Plenary | 19 Sept 2023 | |
| | Member Secretary, | SC 62 B Plenary | 20 Sept 2023 | Funding by |
| | MHD 15 | SC 62 C Plenary | 21 Sept 2023 | BIS |
| | BIS, New Delhi | SC 62 D Plenary | 21 Sept 2023 | |
| | | TC 62 Plenary | 22 Sept 2023 | |

ITEM 8 Programme of Work

8.1 The Committee noted the Programme of Work of Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 as available on the BIS portal https://www.services.bis.gov.in/php/BIS 2.0/bisconnect/pow new.



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

The Committee noted the Indian Standards which are due for review in the July-Sept 2023 Quarter and based on the review analysis report submitted by the Secretariat on the portal, decided as follows:

| Sl. No. | IS No. | Due date | Decision of the Committee |
|---------|-------------------------------|-----------|--|
| 1. | IS/ISO 4090 : 2001 | July 2023 | |
| 2. | IS 11478:2018/ | Aug 2023 | |
| | IEC/TR 60930:2008 | | |
| 3. | IS 13450 (Part 1/Sec 2):2018/ | June 2023 | Reaffirm - As the base ISO standard |
| | IEC 60601-1-2 : 2014 | | remains valid on date, it was decided to |
| 4. | IS 13450 (Part 2/Sec 4):2018/ | Aug 2023 | reaffirm the standard w.e.f due date for a |
| | IEC 60601-2-4 : 2010 | | period of five years. |
| 5. | IS 13450 (Part 2/Sec 5):2018/ | Aug 2023 | |
| | IEC 60601-2-5 : 2009 | | |
| 6. | IS 13450 (Part 2/Sec 6):2018/ | Aug 2023 | Reaffirm and revise – As the base IEC |
| | IEC 60601-2-6 : 2012 | | standard has been revised, the Committee |
| 7. | IS 13450 (Part 2/Sec | July 2023 | decided to reaffirm the standard w.e.f and |
| | 10):2018/ | | take up its revision simultaneously through |
| | IEC 60601-2-10 : 2012 | | adoption of the latest IEC edition. |
| 8. | IS 13450 (Part 2/Sec | Aug 2023 | |
| | 11):2018/ | | |
| | IEC 60601-2-11 : 2013 | | |
| 9. | IS 13450 (Part 2/Sec | Aug 2023 | |
| | 17):2018/ | | Reaffirm - As the base ISO standard |
| | IEC 60601-2-17 : 2013 | | remains valid on date, it was decided to |
| 10. | IS 13450 (Part 2/Sec | Aug 2023 | reaffirm the standard w.e.f due date for a |
| | 23):2018/ | | period of five years. |
| | IEC 60601-2-23 : 2011 | | |
| 11. | IS 13450 (Part 2/Sec | June 2023 | |
| | 47):2018/ | | |
| 1.0 | IEC 60601-2-47 : 2012 | | - |
| 12. | IS/IEC 61331-1 : 2014 | July 2023 | |
| 13. | IS/IEC 61675-1 : 2013 | Aug 2023 | Reaffirm and revise – As the base IEC |
| 14. | IS/IEC 61689 : 2013 | June 2023 | standard has been revised, the Committee |
| | | | decided to reaffirm the standard w.e.f and |
| | | | take up its revision simultaneously through |
| | | | adoption of the latest IEC edition. |

8.3 Review of Indian Standards published before year 2000

The Committee reviewed the status of progress of review of the following three pre-2000 standards under MHD 15 as follows:



| S.No. | Indian Standard | Status | |
|-------|----------------------------------|---|--|
| 1. | IS 11393 : 1985 Specification | The Committee noted the comments received from Dr. | |
| | for scintillation counters | P. S. Sarkar, BARC on IS 11393 and decided to | |
| | | circulate the comments among other members for their | |
| | | feedback. It was also decided to identify and contact a | |
| | | manufacturer of the product for inputs. Dr. Sarkar | |
| | | volunteered to share the contact details of the | |
| | | manufacturer of the product. | |
| 2. | IS 11753 : 1986 Specification | R&D project has been proposed by Sh. Sushil Rana, | |
| | for electrical impedance | Recorders and Medicare Systems Pvt Ltd, Panchkula for | |
| | plethysmograph | which he has sought support from PGIMER, Chandigarh, | |
| | | BARC and AIIMS, New Delhi. Center for Innovation and | |
| | | BioDesign (CIBioD), ICMR housed in PGIMER, | |
| | | Chandigarh has offered support for the R&D Project. The | |
| | | Committee decided to contact Dept. of Physiology, | |
| | | AIIMS, New Delhi and BARC for supporting the project. | |
| 3. | IS 11789 : 1986 | IEC 60806:2022 is being adopted to revise IS | |
| | Determination of the | 11789:1986 [Doc No. MHD 15(22679)]. | |
| | maximum symmetrical | | |
| | radiation field in the radiation | | |
| | beam from a rotating anode | | |
| | X-ray tube for medical | | |
| | diagnosis | | |

ITEM 9 Action taken report on the Minutes of Previous Meeting/Issue arising out of the previous meetings

The Committee noted the action taken report on the minutes of the previous meeting given at *Annex 3 to the Agenda*.

ITEM 10 Date and Place for the Next Meeting

The next meeting will be scheduled as per the Annual Meeting Calendar of MHD 15 for 2023-24 given below:

| Quarter | Meeting Date |
|-----------------------------|--------------------------|
| April-June (Q1) | 28 June 2023 (Conducted) |
| July-September (Q2) | 27 September 2023 |
| October-December (Q3) | 20 December 2023 |
| January 2024-March 2024(Q4) | 20 March 2024 |



ITEM 11 Any Other Business

Prof. S. Ramakrishnan proposed to conduct the Q4 meeting of MHD 15 at IIT Madras, Chennai campus along with a Seminar/Workshop focused on standardization of Medical Devices being dealt under the Committee. The Committee appreciated and agreed in principle to the proposal.

There being no other business to discuss, the meeting ended with a hearty vote of thanks to the Chairperson and all the members.



Annex-1

Members Present:

(Member Secretary)

| | Member | Organization |
|------|---------------------------------|---|
| 1. | Dr. V. R. Singh (Chairperson) | In personal capacity |
| 2. | Sh. Asok Kumar Raghavan Nair | Asia Pacific Medical Technology Association |
| ۷. | 511. 7 ISOK Rumai Rughavan Ivan | (APACMed), Gurugram |
| 2 | Do Dord'lle Wesser | · · · · · · · · · · · · · · · · · · · |
| 3. | Dr. Pratik Kumar | All India Institute of Medical Sciences, New Delhi |
| 4. | Sh. Yoginder Nath | Allie d Medical Systems Limited, Chandigarh |
| 5. | Dr. Ranajit Bandopadhayay | Allied Medical Limited, Gurugram |
| 6. | Sh. R. K. Chaturvedi | Atomic Energy Regulatory Board, Mumbai |
| 7. | Dr. Rajesh Kumar | Bhabha Atomic Research Centre, Mumbai |
| 8. | Dr. P. S. Sarkar | Bhabha Atomic Research Centre, Mumbai |
| 9. | Sh. Aseem Sahu | Central Drugs Standard Control Organization, New Delhi |
| 10. | Sh. Arvind Hiwale | Central Drugs Standard Control Organization, New Delhi |
| 11. | Sh. Manmohan Singh | Clarity Medical Pvt. Ltd., Mohali |
| 12. | Dr. K. Mohanavelu | Defence Bio-Engineering & Electromedical Laboratory |
| 12 | Sh. Zakaria Khan Yusufzai | (DEBEL), Bangalore |
| 13. | Sii. Zakaria Kiiaii Tusuizai | Department of Industrial Policy & Promotion (DIPP), New Delhi |
| 14. | Sh. Rajaram B | Elekta Medical Systems India Private Limited, Chennai |
| 15. | Prof. Ramakrishnan S | Indian Institute of Technology Madras, Chennai |
| 16. | Ms. Indira Narayan Murthy | Intuitive Surgical India Pvt. Limited, Bengaluru |
| 17. | Ms. Sushmita Roy Chowdhury | Kalam Institute of Health Technology, Vishakhapatnam |
| 18. | Sh. Santosh Balivada | Kalam Institute of Health Technology, Vishakhapatnam |
| 19. | Sh. Syed Mustafiz | Kalam Institute of Health Technology, Vishakhapatnam |
| 20. | Dr. Ranjan Kumar Choudhury | National Health Systems Resource Centre, New Delhi |
| 21. | Ms. Manisha Sharma | National Health Systems Resource Centre, New Delhi |
| 22. | Dr. Vikas K. Jagtap | North Eastern Indira Gandhi Regional Institute of Health and |
| | <u> </u> | Medical Sciences, Shillong |
| 23. | Ms. Dhivya T. | Panacea Medical Technologies Private Limited, Bengaluru |
| 24. | Sh. Rajendra Prasad | Philips Electronics India Limited, Gurugram |
| 25. | Sh. Sushil Rana | Recorders and Medicare Systems Private Limited, Panchkula |
| 26. | Sh. A. Ganesh Kumar | Siemens Healthcare Private Limited, Gurugram |
| 27. | Dr. Abhay Deshpande | Society for Applied Microwave Electronics |
| | | Engineering & Research (SAMEER), Mumbai |
| 28. | Sh. Basavaraj Angadi | TUV Rheinland (India) Private Limited, Bangalore |
| 29. | Ms. Pooja Sharma | Varian Medical Systems International Private Limited, Mumbai |
| 30. | Sh. Dorai Subramaniam | Wipro G E Healthcare Private Limited, Bengaluru |
| 31. | | Bureau of Indian Standards, New Delhi |
| C 1. | (M. 1 C | |



BIS Directorate General:

32. Sh. A. R. Unnikrishnan Head(MHD), BIS, New Delhi

33. Sh. Peeyush Prakash Scientist-D, CMD-III, BIS, New Delhi



Annex-2

PROCESS REFORMS IN STANDARDIZATION ACTIVITY

It was informed to the committee that BIS has instituted several process reforms in respect of formulation of Indian Standards and it is essential that the committee members are fully aware of these reform measures. The presentation of these measures before the committee would give the members an excellent bird's-eye view of the new reforms in Standardization activity.

STANDARDS NATIONAL ACTION PLAN (SNAP)

Standards National Action Plan (SNAP) 2022-2027 is one of the major transformational initiatives launched by BIS and the document has been developed after a series of consultations with various stakeholders and interested parties. SNAP would serve as a roadmap for standardization and will play an important role in steering the national standardization efforts.

The committee noted that the SNAP document is available in BIS website under the link https://www.bis.gov.in/wp-content/uploads/2023/05/SNPbookBilingual.pdf. The committee also noted the subject areas in the health/ healthcare sector that are to be taken up for standardization by 2027 as per the assigned priorities.

STANDARDIZATION PORTAL

The committee noted the functioning of revamped standards portal and appreciated the efforts taken by BIS in digitization of various stages of Standardization activity and encouraged the members to enhance the use of IT tools and to effectively utilize the services of the portal in the best possible manner so as to increase the efficiency of operations.

ROLLING ANNUAL ACTION PLAN FOR 2023-24

The importance of rolling annual action plan which is an annual strategic roadmap document that helps in monitoring the progress of standards development at various stages was discussed.

IDENTIFICATION OF NEW AREAS FOR STANDARDIZATION

The relevance and strategic significance of BIS as the National Standards Body needs to be augmented. This would require identification of new emerging areas where standardization could benefit the society at large.

The committee noted that this can be achieved through the annual programme for standardization for Central/State Ministries/ Departments & Industry Associations, effective utilization of Standardization Cells, interaction with the faculty of Prominent Technical Institutes, subscription of important Scientific Journals & Magazines etc. The members were requested to suggest the



details of scientific journals and periodicals that are relevant to the work of the committee which can be subscribed by BIS.

CREATION OF POOL OF EXPERTS

Considering the diverse and specialized nature of standardization, there is a need to create a pool of experts in committees so that they can contribute towards standards formulation in various areas.

The committee noted that this would include experts in individual capacity as well as specialist organizations who can contribute and urged the members to volunteer as well as suggest the names of organizations that can be included as experts so as to assist BIS in increasing its network of experts. The committee also noted the various committee management strategies and the standards promotion activities adopted by BIS to fulfil its various objectives.

STAKEHOLDER MANAGEMENT

The technical committees form the backbone of the standardization infrastructure of BIS. The committee noted that the increased participation of various stakeholders in standard formulation process needs to be sustained which would strengthen the standardization activities of BIS.

ANNUAL CALENDAR OF SECTIONAL COMMITTEE MEETINGS

The meetings of sectional committees are normally convened once in three months in consultation with the Chairperson. For effective planning of the meeting, an Annual Meeting Calendar need to be prepared in advance.

The committee noted that the advance information on meeting dates would help the members to plan their meeting schedule among other commitments.

RESEARCH PROJECTS

It was discussed that the formulation/ review/ revision of the standards is primarily based on the technical inputs provided by the committee members. However, it would be prudent to ensure that adequate research inputs from various sources in the form of authentic data are available to BIS which would strengthen the standards setting process. The various R & D schemes available in this context were briefed to the committee members.

PARTICIPATION AT INTERNATIONAL MEETINGS AT ISO/IEC LEVEL AND NEW WORK ITEM PROPOSALS RECEIVED FROM ISO/IEC

It is important for BIS, as the National Standards Body and the founder member of ISO and IEC, to contribute effectively on the international front. The committee noted that the strategic participation and effective contribution to international standardisation activities would result in high visibility of the country in the international forum.



Further, as a part of the national standards strategy, it is also expected that the committee members give a closer examination of the New Work Item Proposals received from ISO/IEC from the Indian industry perspective as well.

PARTICIPATION IN NATIONAL AND INTERNATIONAL EVENTS

The need and importance of participation in national and international events that are relevant to the area of scope of the committee was discussed. The members were requested to inform BIS about any such events so that BIS officers as well as the committee members can ensure effective participation in these events.