ANNUAL REPORT 2022

NSAI TECHNICAL COMMITTEES
NSAI/TC 5 - HEALTHCARE STANDARDS

Contents

1 Chairman of NSAI/TC 5

Mr. Conor Murray is the current chair of NSAI TC 5 and is an expert in cleanroom technology. In addition, he takes an active role in this sector as chair of the Irish Clean Room Society (ICS). In 2022 Conor also took on the role of President in ASHRAE Ireland, a professional organization in the area of heating, ventilation, air conditioning and refrigeration. Conor is active in contributing to standard development for cleanrooms and is Head of Delegation for ISO/TC 209 – *Cleanrooms and associated controlled environments*. He is also a convenor of ISO/TC 209 WG2 – *Microbiological contamination control in cleanrooms* and is convenor for the development of a new proposal ISO 14644-20 – *Cleanrooms and associated controlled environments – Pt 20: Microbiological contamination control*, which was added to the work programme of ISO/TC 209 in 2022. He is a keen supporter of experts getting involved in standards development and encourages users of standards to contribute in order to improve standards.

2 Introduction

There is active participation in international standard development with up 35 experts involved in international work

The MedTech sector continues to be a key contributor to the Irish economy, accounting for 8% of exports from Ireland. This equates to over €13 billion annual exports. There are over 40,000 employed by the Irish MedTech industry making it the largest employer of MedTech professions in Europe per capita. Ireland is home to 14 of the top 15 MedTech companies and over 300 companies (source IDA). The sector continues to evolve, expanding capabilities to include innovation, digitization and next generation technologies. The impact of the COVID-19 Pandemic has driven developments in the area of telemedicine, connected/digital health and home care. Standards continue to evolve to support new technologies in the healthcare sector and NSAI continues to support the sector through NSAI/TC 5 Healthcare Standards Committee (HCSC).

3 Scope of TC

Having regard to the protection of the health and safety of patients and users of healthcare products and to assist manufacturers and all involved in the supply of healthcare products, the Healthcare Standards Committee (HCSC) provides the national forum for review of standard developments for healthcare and medical devices.

As a consultative committee under NSAI, TC 5 fulfils the following roles:

- Provide inputs and recommendations as necessary in relation to medical device standardization
- Monitor and participate as appropriate in the development of standards generally with particular focus on the European harmonization programme which supports European regulations for the sector;
- Consult and disseminate information to national stakeholders on healthcare standard developments that might impact the sector nationally; &
- Advise and assist NSAI as necessary with related developments e.g. EC Directives, Mandates, GMP Guidelines etc.

The Committee monitors the work of the following international technical committees.

Committee Name	Committee Title
CEN/CLC JTC 3	Quality management and general aspects for medical devices
ISO/TC 210	Quality management and general aspects for Medical Devices
CEN/TC 55	Dentistry
ISO/TC 106 • **SC 1** • **SC 2** • **SC 3** • **SC 8**	Dentistry Filling & restorative materials Prosthodontic materials Terminology Dental implants
CEN/TC 140	In-vitro diagnostic medical device
ISO/TC 212	Clinical laboratory testing and in-vitro diagnostic test systems
CEN/TC 170	Ophthalmics optics
ISO/TC 172 • **SC 7**	Optics and phonics Ophthalmics optics and instruments
CEN/TC 205	Non-active medical devices
ISO/TC 76	Transfusion, infusion and injection & blood processing equipment for medical & pharmaceutical use
ISO/TC 84	Devices for administration of medicinal products and catheters
ISO/TC 157	STI Barrier prophylactics
ISO/TC 173/SC3	Aids for ostomy & incontinence
CEN/TC 367	Breath-alcohol testers
ISO/TC 168	Prosthetics and orthotics
CEN/TC 215	Respiratory and anaesthetic equipment
ISO/TC 121 • **SC 1** • **SC 2** • **SC 3** • **SC 4** • **SC 6** • **SC 8**	Anaesthetic and respiratory equipment Breathing attachments and anaesthetic machines Airways and related equipment Respiratory devices and related equipment used for patient care Vocabulary and semantics Medical gas supply systems Suction devices
CEN/CLC JTC 16	Active implantable medical devices
CEN/TC 285	Non active surgical implants
ISO/TC 150 • **SC1** • **SC2** • **SC4** • **SC5** • **SC6** • **SC7**	Implants for surgery Materials Cardiovascular implants and extracorporeal systems Bone and joint replacements Osteosynthesis and spinal devices Active implants Tissue engineered medical products
CEN/TC 206	Biological and clinical evaluation of medical devices
ISO/TC 194	Biological and clinical evaluation of medical devices
CEN/TC 102	Sterilizers and associated equipment
CEN/TC 204	Sterilization of medical devices
CEN/TC 216	Chemical disinfectants and antiseptics
ISO/TC 198	Sterilization of healthcare products
CEN/TC 239	Rescue system
CEN/TC 243	Cleanroom technology
ISO/TC 209	Cleanroom and associated controlled environments
ISO/TC 330	Surfaces with biocidal and antimicrobial properties
CEN/TC 414	Services in osteopathy
ISO/TC 338	Menstrual products

4 Structure and Membership

4.1 Structure

The Figure below illustrates the structure of the Committee:

NSAI/TC 5	Committee Title
NSAI/TC 5	Healthcare horizontal issues
SC 1	Dentistry
SC 2	In-vitro diagnostics
SC 3	Ophthalmics
SC 4	Non-active medical devices
SC 5	Respiratory and anaesthesia
SC 6	Implantable
SC 7	Biological and clinical evaluation
SC 9	Sterilizers, sterilization, and cleaning
SC 11	Ambulances
SC 13	Cleanrooms
SC 16	Osteopathic services
SC 19	Miscellaneous

4.2 Members

The following organisations are members of NSAI/TC 5 and the subcommittees:

Member Organisations
Irish Clean room society
Hollister
Bausch & Lomb
Medtronic
Viatris
Abbott
Amcor
Nanosonics
NSAI
Boston Scientific
Stryker
Merit Medical
Oxygen-Care
Medical Bureau of Road Safety - UCD
North Ridge Quality
Kersia Group
HPRA
TCD
Lime Hill Quality
Expleo Group
HSE Estates
HSE
Steris

Specialist Orthodontic Practices
INAB
Micro Matters
Transitions
Embecta
Medline
Teleflex
Baxter
Johnston & Johnston
Wassenburg Medical
Nanosonics
Decontamination Technical Services
Aerogen
TU Dublin
Clearsphere
Osteopathic Council of Ireland
Amcor

5 Summary of 2022 Activities

5.1 National

5.1.1 Meetings

Committee members attended the following national meetings in NSAI as follows:

Meeting No.	Date	Minutes Reference ** optional**
1	2022-03-09	N1111
2	2022-06-15	N1113
3	2022-09-14	N1119
4	2022-12-14	N1124

5.1.2 National Work

The focus of NSAI/TC 5 is contribution to international standards for the medical device sector. Currently there are no national projects under NSAI TC 5.

Experts contributed to several international standards, providing feedback and comments through the national balloting platform. Several experts took the lead in some new standard developments at the international level. See section 5.2 for more details.

Towards the end of 2022 a review of the structure and international committees monitored by NSAI/TC 5 was carried out. A survey of members was carried out to check international areas of interests and national groups under TC 5. The feedback of the survey is being review with any necessary changes to be implemented in 2023.

5.2 International

5.2.1 International Work

Members of NSAI/TC 5 are actively contributing to standards development work at the international level. C. Murray is convenor to ISO/TC 209/WG2 biocontamination control and is working on a new standard ISO/AWI 14644-20 –

Cleanroom and associated environments – Part 20: Microbiological contamination control, which was added to the work program in 2022. This new work item was accepted based on a proposal submitted by NSAI & C. Murray.

NSAI submitted a new work proposal to ISO TC 121 for a new project on video laryngoscopes. This submission was prepared in conjunction with S. Maguire of Medtronic. The proposal was approved and was registered to the work programme of ISO/TC 121/SC2. The new standard is ISO/AWI 7376-2 – Aesthetic and respiratory equipment Part 2: Video Laryngoscopes and this is being developed by ISO/TC 121/SC2/WG17, where S. Maguire has taken on the role of convenor.

Work continued the development of ISO 11717-3 – Sterilisation of healthcare products – microbiological methods Pt 3: Bacterial endotoxin testing. Irish experts have contributed to the development of this standard with S. Butler of Medtronic key to ensuring Irish experts comments were submitted and considered at the international level. The standard is reaching the final stages of development with publication expected in 2023.

Dr. Gearóid McGauran – Medical Officer, HPRA participated in ISO TC 150/WG8 attending several meetings and contributed to the development of ISO 14607 – Non-active surgical implants – Mammary implants – Particular requirements. This standard is expected to reach final draft in 2023.

Work continued on the revision of ISO 80369-1 – Small bore connectors for liquids and gases in healthcare applications Pt 1: General requirements with several meetings of the working group occuring in 2022. P. Dunne from Boston Scientific is actively participating in the development of this standard and provided several meeting reports on international meetings attended. Work is expected to continue on this revision into 2023.

L. Cameron of Embecta participated in ISO/TC 83/WG6 Sharps containers which is working on a revison of ISO 23908 – Sharps injury protection - Requirements and test methods – Sharps protection features for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance adminstration.

G. Daly of Nanosonics attended ISO/TC 198 WG 13 – Washer disfector meeting where the ISO 15883 series of standards on Washer Disinfectors was under review.

N. Pardy participated in a meeting of ISO/TC 198 WG2 – Radiation sterilization. During this meeting results of ballots of ISO/CD 11137-1 & ISO/FDIS 13004 were reviewed.

R. Cowman (Medline Industries) attended the ISO/TC 198 plenary meeting as Head of Delegation and provided a report of the progress made at the meeting.

The work of sterilization experts was recognised at the NSAI Standards Forum and awards cermony which was held on World Standards Day on October 13. R. Cowman (Medline Industries Ltd) and S. Butler (Medtronic) were both awarded for their work in contributing to international standards and also in engaging other national experts in standard development work through the IBEC Sterility Assurance Forum. See pictures from the award cermony at the end of this report.

5.2.2 International Standards Reviewed

Experts reviewed and contributed to many drafts and ballots that came up under NSAI/TC 5 during the year. Inputs were provided on the following standards:

Standard	Title
ISO/DIS 15189	Medical Laboratories – Requirements for quality &competence
ISO/CD 11137	Sterilisation of healthcare products – Radiation Pt 2 Establishing the sterilization dose.
ISO/DIS 24395	Dentistry – Classification of tooth restorations preparations

ISO/CD 80369-20	Small bore connectors for liquids and gases in healthcare applications – Pt 1-: Common test methods
ISO/CD 14607	Non-active surgical implants – Mammary implants – Particular requirements
ISO 18369-3 (Systematic review)	Ophthalmic optics – Contact lenses – Pt 3 – Measurement methods
EN 868-2 (Systematic Review)	
ISO/DIS 10993-17	Biological evaluation of medical devices Pt 17: Toxicological risk assessment of medical device constituents
ISO 10993-5 (Systematic review)	Biological evaluation of medical devices Pt 5: Test for in-vitro cytotoxicity
ISO 10993-6 (Systematic Review)	Biological evaluation of medical devices Pt 6: Test for local effects after implantation.
ISO/CD 10993-20	Biological evaluation of medical devices Pt 20: Principles and methods for immunotoxicology testing of medical devices.
ISO/CD 5362	Anaesthetic reservoir bags.
ISO/DIS 11737-3	Sterilization of healthcare products – Microbiological methods Pt 3: Bacterial endotoxin testing.
ISO/DIS 17256	Anaesthetic and respiratory equipment – Respiratory therapy tubing and connectors.
ISO/DIS 17665	Sterilization of healthcare products – Moist heat – Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO/FDIS 23368	Anaesthetic and respiratory equipment – low flow nasal cannulae for oxygen therapy
ISO 10685-1 (Systematic Review)	Ophthalmic optics - Spectacle frames and sunglasses electronic catalogue and identification Pt1: Product identification and electronic catalogue product hierarchy
ISO 10685-2(Systematic Review)	Ophthalmic optics – spectacle frames and sunglasses electronic catalogue and identification Pt 2 – Commercial information
ISO 10685-3(Systematic Review)	Ophthalmic optics – spectacle frames and sunglasses electronic catalogue and identification Pt3 – Technical information
ISO 14889 (Systematic Review)	Ophthalmic optics – Spectacle lenses – Fundamental requirements for uncut finished lenses
EN 878-3	
ISO 10322-1 (Systematic Review)	Ophthalmic optics – Semi finished spectacle lens banks Pt 1 Specification for single vision and multifocal lens blanks.
ISO 18190 (Systematic Review)	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
ISO 18369-1 (Systematic Review)	Ophthalmic optics – Contact lenses – Pt 1 Vocabulary, classification system and recommendations for labelling specifications.

ISO 8980-1 (Systematic Review)	Ophthalmic optics – Uncut finished spectacle lenses – Pt 1 Specifications for single vision and multifocal lenses
ISO/CD 10555-4	Intravascular catheters – Sterile and single use catheters Pt 4 Balloon dilation catheters.
ISO 10993-4 (Systematic Review)	Biological evaluation of medical devices Pt 4: Selection of tests for interactions with blood.
ISO/CD 6028	Healthcare organization management – Pandemic response – Function requirements for self-symptom checker app.
ISO/CD 6763	Pandemic response – social distancing and source control
ISO/CD 14607	Non active surgical implants – Mammary implants – Particular requirements.
ISO/TIS 7581	Evaluation of bactericidal activity of a non-porous antimicrobial surface used in a dry environment.
ISO/DIS 10993-17	Biological evaluation of medical devices Pt 17: Toxicological risk assessment of medical device constituents
ISO/FDIS 3107	Dentistry – Zinc oxide-eugenol cements and non-eugenol zinc oxide cements
ISO/CD 10555-1	Intravascular catheters – sterile and single-use catheters Pt 1: General requirements
ISO 18189 (Systematic Review)	Ophthalmic optics – contact lenses and contact lens care products – cytotoxicity testing of contact lenses in combination with lens care solutions to evaluate lens/solution interactions.
ISO/CD 80369-1	Small bore connectors for liquid and gasses in healthcare applications Pt 1: General requirements.
ISO 8980-2 (Systematic Review)	Ophthalmic optics – Uncut finished spectacle lenses Pt 2: Specifications for power variation lenses
ISO/CD 11135	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

5.3 Regulatory Development/Update

Work to develop standards in support the Medical Device Regulation (MDR) and In-Vitro medical Device Regulation (IVDR) is continuing. However, there were delays experienced in getting standards harmonised by the Commission. This was due to the issuing and appointment of a new contract for the HAS or Harmonised Standards Consultancy process. The tendering process and reappointment of new consultants took up most of 2022. Some progress was made during 2022 with 16 standards harmonised for the MDR and 10 for the IVDR. However due to the delays with HAS Consultants reappointments the Commission proposed to extend the limit date of 2024 as listed in the Mandate to 2025. HAS assessments of mandated standards restarted in November and it is hoped this will result in more additions to the list of Harmonised standards in the OJEU in 2023.

There are no national work items allocated to NSAI/TC 5 and the committee.

6 Work programme for 2023 onwards

NSAI/TC 5 has no national work items but is continuing to focus on contributing to development of European and international standard to support the MDR and IVDR.

S. Butler (Medtronic) accepting her award from NSAI CEO, G. Larkin at the NSAI Standards Forum 2022.

R. Cowman (Medline Industries Ltd) receiving his award from NSAI CEO G. Larkin at the NSAI Standard Forum 2022.