ANNUAL REPORT 2023

NSAI TECHNICAL COMMITTEES
NSAI/TC 5 - HEALTHCARE STANDARDS

Contents

1 Chair's Statement

Mr. Conor Murray is the current chair of NSAI TC 5 and is a subject matter expert in cleanroom and contamination control technology and has been involved in the Life Science industry for over 3 decades. He takes an active role in this sector as chair of the Irish Clean Room Society (ICS) and currently chair of the international confederation of contamination control societies (ICCCS). Conor is active in ASHRAE, a professional organization in the area of heating, ventilation, air conditioning and refrigeration with over 53,000 members globally and is a past president of the Irish Chapter. He is now active at European and international level on technical standards ad research as part of climate rebalancing.

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.

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

"As chair of NSAI/TC 5 I am a keen supporter of experts getting involved in standard development and encouraging users of standards to contribute, in order to improve standards in our work and daily lives.

Standards have moved from being viewed as barriers and trade restrictions to encouraging and enabling trade on a harmonised basis.

The 2 great challenges of our day are the safety and well-being of the people in our nation, and how to move to a circular economy as custodians on our fragile planet, and not the wanton consumers we have been for generations.

We are now part of ageing populations where we expect to live longer and better through medical innovation, lifesaving treatments but increasingly life-style drugs and services. Standards have a role to play and can ensure the safety and quality of our products and services, the environment, our health, and overall wellbeing.

The HealthCare Standards Committee (HCSC) plays a vital role in the overall preparation and ongoing review of standards and associated documents in CEN & ISO. Apart from supporting the Irish Healthcare industry as a nearly €10b contribution to the Irish economy our public healthcare system is a benefactor of the quality of our efforts. Good healthcare standards foster consumer confidence and opens markets with compatible and comparable products and services.

Many Healthcare devices are manufactured in Cleanrooms and associate controlled environments. These facilities consume very large amounts of energy and the capital investment (CAPEX), coupled with running costs (OPEX) feed into the end user costs of medical and healthcare services. On a purely personal note I spend half of my life in *ProBono* volunteer work in local community and international organisations on energy efficiency, or on mentorship and giving our youth a voice in the future as part of Climate Change.

While there are ongoing challenges with MDR in the European Commission, NSAI through its active participation in the ABHS (Advisory Board for Healthcare Standards) we expect further progress in the availability of harmonised in 2024 and 2025.

I would like to thank the staff of NSAI and in particular, Linda Hendy as secretary of NSAI/TC 5, for all their support in keeping this committee actively engaged in the ISO and CEN standardisation process.

Finally, I will repeat the oft used phrase "If you're not in you can't win!" If we want to make a difference in Healthcare standards then we must sign up to the NSAI portal and get involved as volunteers. I am delighted to say that we regularly over 30 experts at our quarterly TC5 HCSC web-based meetings and up to 20 in our annual face to face get togethers. You know your names and I want to thank every one of you for your invaluable contributions and volunteer services. Make no mistake – you do make a difference in our daily lives".

2 Introduction

The MedTec 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. Software and AI developments in medical devices is an area where new standards are being developed along with continued developments of standards in support of MDR & IVDR. 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** • **SC 9**	Dentistry Filling & restorative materials Prosthodontic materials Terminology Dental implants Dental CAD/CAM Systems
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
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	NSAI/TC 5 Healthcare Standards Committee
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 10	Horizontal Standards
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
Aerogen
Abbott
Amcor
Bausch & Lomb
Boston Scientific
Clearsphere
Creganna Medical
Cook Medical
Decontamination Technical Services
Ecolabs
Embecta
Expleo Group
Hollister
HPRA
HSE Estates
HSE
INAB
Irish Clean room society
Johnston & Johnston
Kersia Group
Lifelet Medical
Lime Hill Quality
Medical Bureau of Road Safety - UCD
Medline
Medtronic
Merit Medical
Micro Matters
Moore environmental
Nanosonics
NSAI Certification
Osteopathic Council of Ireland
Pallaire
Specialist Orthodontic Practices
Steris
Stryker
TCD
Teleflex
Transitions
TU Dublin
UCD
Viatris
Wassenburg Medical
West Pharmaceutical Services

5 Summary of 2023 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	202-03-08	N1128
2	2023-06-14	N1136
3	2023-09-27	N1144
4	2023-11-29	N1147

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 standard providing feedback and comments through the national balloting platform. Several experts are leading in some new standard developments at the international level and have taken a convenor role see 5.2 for more details.

A review of membership was carried out and changes to membership of relevant groups implemented in early 2023. This is to better reflect members interests, and to ensure active contribution at the national level. This resulted in the loss of some members. However, over 2023 there was good interest in participation at the national level with over 27 new member applying to get involved. Some experienced members also stepped down from the committee, following retirement. R. O'Kelly, who represented the Association of Clinical Biochemists in Ireland, stepped down in 2023 after 9 years as a member of NSAI/TC 5. NSAI expressed its gratitude to experts who volunteered to contribute to standard over their time as a member of NSAI/TC 5. The experience and knowledge of all national experts is key in order for NSAI to provide feedback on international medical device standard developments.

5.2 International

5.2.1 International Work

Members of NSAI/TC 5 are actively contributing to standard 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. This work item was initiated in 2022, based on a proposal submitted by NSAI & C. Murray.

Work on another new standard started in 2023 and comes under 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, with S. Maguire taking the role of convenor. This work was also initiated based on a proposal put forward by S. Maguire and NSAI.

Irish expert S. Butler was involved in the initiation of the development ISO 11717-3 – *Sterilisation of healthcare products – microbiological methods Pt 3: Bacterial endotoxin testing*. Irish experts provided comments over the different stages of development of this standard with the standard finally published in 2023.

Dr. Gearóid McGauran – Medical Officer, HPRA continued his participation in ISO TC 150/WG8 attending several meetings and contributing to the development of ISO 14607 – *Non-active surgical implants – Mammary implants –*

Particular requirements. The development of the Annex Z in support of the MDR was a key focus this year with the standard getting through the draft standard stge. The final publication is now expected in 2024.

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. P. Dunne also contributed an article outlining planned revisoins and timelines for the ISO 80369 series of standards in the NSAI Ezine for the April 2023 edition.

R. Cowman (Medline Industries) was secretary of ISO/TC 198/WG 1 EO Sterilization, however during 2023 has taken on the role of convenor. This group is currently working on a revision of ISO 11135. – *Sterlization of healthcare products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.*

It was a busy year in terms of hosting international meetings in NSAI. Two international groups were hosted in NSAI during 2023, providing national experts the opportunity to attend international meetings in NSAI offices.

Groups hosted by NSAI IN 2023 included:

- CEN/TC 102 – Sterilizers and associated equipment for processing of medical devices
- CEN/TC 102/WG4 – Packaging.
- ISO/TC 121/SC2- Anaesthetic and respiratory equipment – airway devices and related equipment
- ISO/TC 121/SC6 - Anaesthetic and respiratory equipment – Medical gas supply systems.

See pictures 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 80369-3:2016 (Systematic Review)	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications
prEN 17180	Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing
ISO FDIS 11737-3	Sterilisation of healthcare products – Microbiological methods – Part 3: Bacterial endotoxin testing
EN 15964 (Systematic Review)	Breath alcohol test devices other than single use devices - Requirements and test methods
ISO DIS 11137-1	Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO EN 1422 (NWIP)	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
EN 868-2 (Systematic Review)	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
ISO/DIS 10993-17	Biological evaluation of medical devices Pt 17: Toxicological risk assessment of medical device constituents

ISO DIS 80369-1	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements.
ISO FDIS 17665	Sterilization of healthcare products – Moist heat – Part 3: Guidance on the designation of a medica device to a product family and processing category for steam sterilization
ISO 9394	Ophthalmic optics – Contact lenses and contact lens care products – Determination of biocompatible by ocular study with rabbit eyes
ISO CD 14155	Clinical investigation of medical devices for human subjects – Good clinical practice
ISO DIS 11135	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO DIS 80369-20	Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
ISO FDIS 10993-17	Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents
ISO DIS 18562-1	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO DIS 18562-4	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
ISO FDIS 5367	Anaesthetic and respiratory equipment – Breathing sets and connectors
ISO FDIS 27427	Anaesthetic and respiratory equipment – Nebulizing systems and components
ISO 11137-1	Sterilization of healthcare products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
EN 1422 (NWIP)	Steriliers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods.
ISO DIS 80369-1	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements.
ISO FDIS 17665	Sterilization of healthcare products – Moist heat
ISO 9394 (Systematic Review)	Ophthalmic optics- Contact lenses and contact lens care products
EN 17180	Sterilizers for medical purposes – Low temperature vapourised hydrogen peroxide sterilizers – Requirements and testing.
ISO CD 14155	Clinical investigation of medical devices for human subjects – Good clinical practice.
ISO 20696 ((Systematic Review)	Sterile urethral catheters for single use.
ISO CD TS 6838	Ophthalmic optics – contact lenses
ISO CD 14644-5	Cleanrooms and associated controlled environments – Part 5: Operations
ISO CD 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

ISO DTR 14644-21	Cleanrooms and associated controlled environments – Part 21: Airborne particle sampling techniques.
ISO CD 8250	Cleanliness of medical devices – Process design and test methods.
ISO DIS 18190	Anaesthetic and respiratory equipment – General requirements for airways and related equipment.
prEN 556-2	Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 2: Requirements for aseptically processed medical devices.
ISO CD 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
ISO WD TS 24172	Alternative test method for heat and moisture exchangers.
Iso 11737-1 (Systematic Review)	Sterilization of healthcare products – Microbiological methods – Part 1: Determination of a population of microorganisms on products.

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. The delays experienced in getting standards harmonised by the Commission in 2022 was resolved with the awarding of a new contract for the HAS or Harmonised Standards Consultancy process. The HAS review process for draft standard has been restarted in 2023 with a focus on getting the backlog of standards addressed. A little progress was made during 2023 with 18 standards now harmonised for the MDR and 11 for the IVDR. To address concerns about delays the Commission has now extended the transitional period for the MDR for legacy devices up to Dec 2028, to ensure continuity of supply for medical devices. A second revision of Mandate M575 is currently in progress to extend the deadline for adoption of mandated standards in line with this proposed extension. Many of the Technical Committees involved in the preparation of the harmonised standards welcomed the extension of the deadline for standard development.

It is hoped that the list of Harmonised standards will increase further in 2024 with CEN/CENELEC putting forward over 30 additional standards to the Commission for publication in the OJEU following successful HAS review in Dec 2023.

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

6 Work programme for 2024 onwards

ISO 13485 – *Medical devices - Quality management systems – Requirements for regulatory purposes* is a key standard for manufacturers of medical devices. This standard is up for review in early 2025 but work is starting on identifying possible changes needed for any revision. A survey was issued to seek input from users of the standard in late 2023, which was promoted by NSAI/TC 5 with a news article on the NSAI Website. Planned revisions of this important standard will be a focus of the work of NSAI & TC 4 in 2024.

NSAI/TC 5 has no national work items but is continuing to focus on contributing to development of European and international standard to support safety and performance of medical devices, with a particular focus on those used to support the MDR and IVDR.

S. Butler (NSAI/TC 5/SC 9) & L. Hendy (middle) with organizers of the IBEC Sterility Assurance Forum – May 2023, where both presented on sterility standards.

L. Hendy (far right) attending the CEN/TC 102 Plenary meeting with other international experts – NSAI Offices June 2023.

CEN/TC 102 – Sterilizers and associated equipment for processing of medical devices.

National expert N. Gibbons (far left) & other experts of CEN/TC 102/WG4 – Packaging, meeting in NSAI offices – June 2023.

Experts attending ISO.TC 121/SC2 Meeting, held in NSAI offices, Nov 2023.

ISO/TC 121 - Anaesthetic and respiratory equipment /SC2 – Airway devices and related equipment.

S. Maguire (Medtronic) & L. Hendy (NSAI TC 5 Secretary) in attendance at the ISO/TC 121/SC2 meeting, NSAI Offices, Nov 2023.