ANNUAL REPORT 2024

NSAI TECHNICAL COMMITTEES
NSAI/TC 5 - HEALTHCARE STANDARDS

Contents

1 Chairman'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. He takes an active role in this sector as chair of the Irish Cleanroom Society (ICS) and outgoing chair of the international confederation of contamination control societies (ICCCS). Conor has been involved in the Life Science industry for over four decades. Conor is active in ASHRAE a global grass roots organisation, with over 53,000 members, in the engineering of commercial and industrial buildings and facilities. Conor is a past president of the Irish chapter and is now active in the European region and at a global level on technical standards and 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 past convenor of ISO/TC 209 WG2 – Microbiological contamination control in cleanrooms and is currently convenor of WG 5 in CEN/TC 243 working on the revision of EN 17414 on microbiological contamination control in cleanrooms. With six grandchildren Conor has a passion for giving our youth a voice in their future, and mentors a number of young professionals from different European and international countries. ISO standards form a critical part of international harmonisation, fostering global collaboration and promoting best practice. We are on a shared journey towards a circular economy as custodians of our fragile planet and not wanton consumers of our natural resources.

"The HealthCare Standards Committee (HCSC) play a vital role in the overall preparation and ongoing review of standards and associated documents in CEN and ISO. Apart from supporting the Irish Healthcare industry our public healthcare system is a benefactor of the quality of our efforts. Good healthcare standards foster consumer confidence and opens up markets with compatible and comparable products and services.

I would like to thank the staff of NSAI and in particular Linda Hendy, as Healthcare Standards Officer, 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 in and 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, with approximately €15 billion annual exports, accounting for 8% of exports from Ireland. There are over 50,000 employed by the Irish MedTech industry making it the largest employer of MedTech professions in Europe per Capita. There are over 300 companies based here which includes 14 of the top 15 MedTech 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).

There is active participation in international standard development with over 50 experts involved in international work

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/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	Medical laboratories and in-vitro diagnostic 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	Non-systemic contraceptives and 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 for processing of medical devices
CEN/TC 204	Sterilization of medical devices
CEN/TC 216	Chemical disinfectants and antiseptics
ISO/TC 198	Sterilization of healthcare products
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 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 19	Miscellaneous

4.2 Members

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

Member Organisations
Aerogen
Abbott
Alcon
Amcor
Aztec Medical
Bausch & Lomb
Boston Scientific
Clearsphere
Cardinal Health

Cook Medical
Creganna Medical
CroíValve
Decontamination Technical Services
DKIT
Ecolabs
Embecta
Expleo Group
GK Medtech
Hollister
Homecare Medical
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
Nelipack
NSAI Certification
Pallaire
Specialist Orthodontic Practices (SOP Dental)
Steris
Steripack Ireland
Stryker
TCD
TE Connectivity
Transitions
TU Dublin
UCD
Viatris
Vitalograph
West Pharmaceutical Services

5 Summary of 2024 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	2024-03-13	N1156
2	2024-06-12	N1163
3	2024-09-18	N1168
4	2024-11-27	N1177

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 are leading in some new standard developments at the international level and have taken a convenor role see 5.2 for more details.

Over 2024 there was good interest in participation at the national level with over 19 new members applying to get involved. This included representatives of many medical device organisations such as Abbott, Alcon, CroíValve, Cook Medical, Cardinal Health, Boston Scientific, Homecare medical and Vitalograph. Representatives from the education sector also joined with a representative from DKIT also joining in 2024.

A couple of members changed role and therefore stepped down from the group. NSAI is grateful to experts who volunteer to contribute to standard development and give of their time over and above their own role and responsibilities. The experience and knowledge of all national experts is key 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 continued his role as convenor to ISO/TC 209/WG2 biocontamination control which was working on a new standard ISO/PWI 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. International experts did meet to develop content, but consensus was not reached, and the project may be put on hold for the moment. This work may transfer to CEN/TC 243 – Cleanroom technology, during 2025.

Work progressed on another new standard started in 2023 and comes under the work programme of ISO/TC 121/SC2. The new standard is ISO 7376-2 – *Aesthetic and respiratory equipment Part 2: Video Laryngoscopes*, is being developed by ISO/TC 121/SC2/WG17, with S.Maguire (Medtronic Ireland)) taking the role of convenor. This project reached the DIS or Draft standard stage during 2024 and work will continue to develop the standard based on feedback received during the balloting stage.

S.Maguire and his work in standard development was recognised at the NSAI Standards Forum in October, where he was awarded the NSAI 1996 award for contribution to standards. This was in recognition of his contribution to standard

development since he joined the committee back in 2012. It is also for recognition of his role in taking the lead in the development of a new standard in video laryngoscopes. See pictures of this award at the end of this report.

Dr. G. McGauran – Medical Officer, HPRA continued his participation in ISO TC 150/WG8 and contributing to the development of ISO 14607 – *Non-active surgical implants – Mammary implants – Particular requirements.* This standard was published MID 2024 and contains an Annex Z in support of the MDR. Many thanks to Dr McGauran for this committement in seeing this project through to publication.

Work continued on the revision of ISO 80369-1 – *Small bore connectors for liquids and gases in healthcare applications Pt 1: General requirements,* which reached Final draft or FDIS Stage during 2024. P.Dunne from Boston Scientific is actively participating in the development of this standard and provided regular meeting reports to members of NSAI/TC 5 on international meetings attended. The publication of this standard is expected in 2025. P.Dunne is the national expert reporting on developments on all parts of the ISO 80369 series.

R.Cowman (Medline Industries) continued his role as convenor of ISO/TC 198/WG 1 EO Sterilization, and continued the 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.* This standard has reached the DIS or Draft stage during 2024 however the standard is not expected for publication until 2026. Work on this standard will continue during 2025.

The revision of ISO 10993-1 – *Biological evauation of medical devices – Pt 1 Requirements and general principles for the evauation of biological safety within a risk management process* is well underway with the final draft and final publication expected in 2025. Two experts C.Lucy of Medtronic and M.NíDhomhnaill of Cook Medical attending meetings and contributing to the development of the standard. Many thanks to M.NíDomhnaill for contributing to an news article on the changes which is available on the NSAI website – see link Medical Devices: Planned Revision of Key Biocompatibility Standard – ISO 10993-1 | NSAI

It was a busy year in terms of hosting international meetings. The plenary meeting of ISO TC 198 Sterilization of Health Care products was hosted by NSAI in June. The venue for the meeting was ATU Galway where up to 10 Working Groups and over 160 international experts who participate in the work of ISO TC 198 met from June 24th to 28th, 2024. By hosting the meeting in Ireland, NSAI facilitated the participation of up to 20 national experts in the meeting. This included active participation of national experts as well as observing members. Attending as an observing member gave national experts an idea of the work and as a result a number decided to join international working group. Many thanks to ATY Galway for allowing the use of their facilities and support during the meeting.

Many thanks also to N.Gibbons (Steris), a member of NSAI TC 5, for organising a very interesting tour of the Steris testing facilities in Galway for ISO TC 198 delegates. See photos at the end of this report

The meeting also offered an opportunity to show case the new Masters in Science in End-to-End sterility assurance developed by Irish Medtech Skillnet which was also launched in ATU Galway during that week – see article on NSAI Website for more information NSAI to Host Key Plenary Meeting on Sterilization in Health Care | NSAI

Many thanks to MedTech Skillnet for co-ordinating with NSAI regarding the launch of their new masters qualification during the meeting of ISO TC 198.

See pictures from the ISO TC 198meeting in ATU Galway 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. Key areas of focus included:

- Sterilization and sterile methods,
- Biocompatibility standards.
- Luer connector standards
- Packaging standards

- Vascular implants
- Anaesthetic and Respiratory equipment
- Cleanroom and associated controlled environments
- Clinical investigation of medical devices
- Breath alcohol testers
- Breast implants

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. Further progress was made during 2025 with 27 standards now harmonised for the MDR (up from 11 in 2024) and 16 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, in order to ensure continuity of supply for medical devices. A 2nd amendment to the Commission Mandate M575 was accepted and adopted in May to add further standards for harmonization. This also extended the deadline for having the standards available for harmonisation which will facilitate the CEN/CENELEC Technical Committees in the preparation of the standards Mandated by the Commission.

It is hoped that the list of Harmonised standards will increase further in 2025 with CEN/CENELEC putting forward up to 30 additional standards for the Commission and the HAS review process in Oct 2024.

There is no national work items allocated to NSAI/TC 5 and sub-committees.

6 Work programme for 2025 onwards

The systematic review of ISO 13485:2016 – *Medical devices – Quality management systems – requirements for regulatory purposes,* is due to occur in early 2025. This is an important standard for the sector so members of NSAI TC 5 plan to focus on gathering national inputs on the need for change in this standard.

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.

Photos from 2024

Members of ISO/TC 198 at the plenary meeting held by NSAI in ATU Galway June 2024

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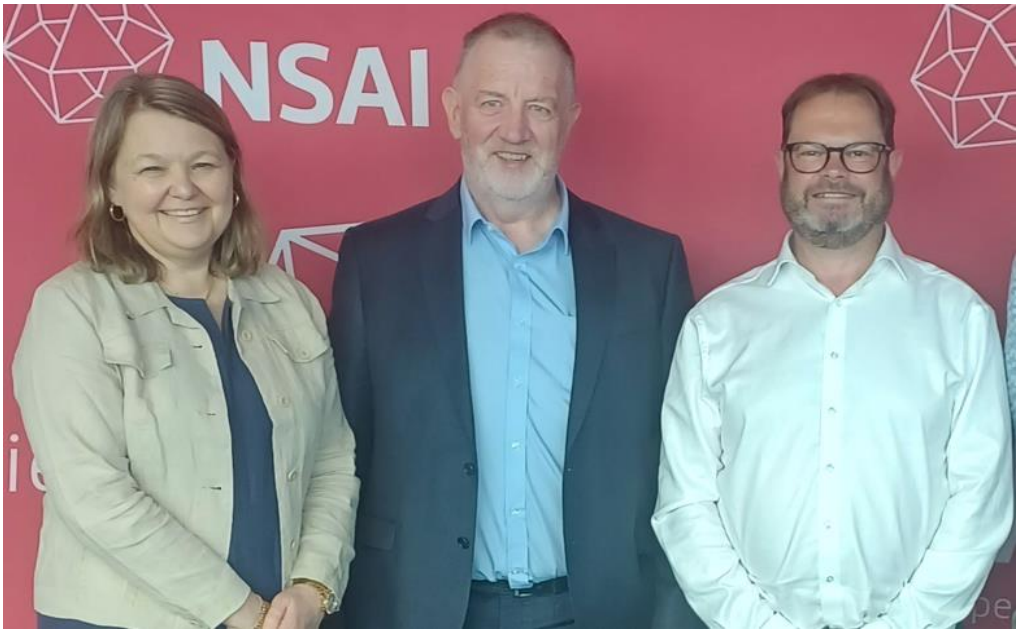
Delegates from ISO TC 198 meeting visiting the Steris Facilities in Galway organised by Noel Gibbons (centre in orange high visibility jacket)



L.Hendy, (NSAI/TC 5 Secretary) N.Gibbons (Steris), R Bancroft (Chair of ISO TC 198 &) in Galway

Members of ISO/TC 198/WG1 Industrial ethylene oxide sterilisation, meeting in Galway, Convenor R.Cowman (Medline) front row 4rd from left & S.Butler (Medtronic) 3rd from right.

S.Maguire receiving the NSAI 1996 award for contribution to standard development at the NSAI Standards Forum, Oct 2024

L to R: Dara Calleary (TD), S.Maguire (Medtronic), G.Larkin (NSAI CEO), L.Hendy (NSAI/TC 5 Secretary)