



NSAI

ANNUAL REPORT 2025

NSAI TECHNICAL COMMITTEES
NSAI/TC 5 - HEALTHCARE STANDARDS

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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 4 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. In 2025 he resumed his role of convenor of ISO/TC 209 WG2 – Microbiological contamination control in cleanrooms and is also convenor of WG 5 in CEN/TC 243 working on a new revision of EN 17141 on microbiological contamination control in cleanrooms.

“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. This work supports the Irish healthcare industry and contributes in a practical way, to the effectiveness and safety of our public healthcare system. High quality healthcare standards build confidence among patients and the public, and they enable access to wider markets by underpinning compatibility and trust in products and services.

I would like to thank the staff of NSAI and in particular Linda Hendy, as Healthcare Standards Manager, for their ongoing support in keeping this committee actively engaged in the ISO and CEN standardisation programmes.

As we look ahead, the importance of standards continues to grow, particularly as healthcare systems increase their reliance on digital health solutions, interoperability, data governance, cybersecurity, and new technologies such as AI-enabled tools and diagnostics. The Committee will continue to focus on ensuring that emerging standards are practical, aligned with Irish needs, and supportive of safe innovation and improved patient outcomes.

Those involved in standard development also have get more familiar with the new collaborative platform for standard development called the OSD or On-line standard development. So a new but welcome challenge that should facilitate greater collaboration during standard development.

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 participate. I am delighted to report increased engagement with up to forty attending national meetings (up from thirty in 2024). NSAI/TC 5 meetings are generally web based and held every quarter and are a good way to keep up to date in standard developments. You know your names and I want to thank each 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 MedTech sector continues to be a key contributor to the Irish economy, with approximately €15 billion in 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 the EU Medical Device Regulation (MDR) & the In-Vitro Diagnostic Medical Device Regulation (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 standardisation

- Monitor and participate as appropriate in the development of standards generally with particular focus on the European harmonisation 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. EU 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	Dentistry
• SC 1	Filling & restorative materials
• SC 2	Prosthetic materials
• SC 3	Terminology
• SC 8	Dental implants
• SC 9	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	Optics and phonics
• SC 7	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	Anaesthetic and respiratory equipment
• SC 1	Breathing attachments and anaesthetic machines
• SC 2	Airways and related equipment
• SC 3	Respiratory devices and related equipment used for patient care
• SC 4	Vocabulary and semantics
• SC 6	Medical gas supply systems
• SC 8	Suction devices
CEN/CLC JTC 16	Active implantable medical devices
CEN/TC 285	Non active surgical implants
ISO/TC 150	Implants for surgery
• SC1	Materials
• SC2	Cardiovascular implants and extracorporeal systems
• SC4	Bone and joint replacements
	Osteosynthesis and spinal devices

<ul style="list-style-type: none"> • SC5 • SC6 • SC7 	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
Airmid Health group
Alcon
Amcor
Aztec Medical

Azurity Pharmaceuticals
Bausch & Lomb
Becton Dickinson
Boston Scientific
Clearsphere
Cardinal Health
Cook Medical
Cosmo pharmaceuticals
Creganna Medical
CroíValve
Croom Medical
Decontamination Technical Services
DKIT
Emergent BioSolutions
Ecolabs
Ellab
Embecta
Endo International
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)
Solventum
Steris
Steripack Ireland
Stryker
SymPhysis Medical
TCD
TCD Dental
TE Connectivity
Transitions
TU Dublin
UCC
UCD
Viatrix

Vitalograph
Zimmer Biomet

5 Summary of 2025 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	2025-02-26	N1185
2	2025-06-11	N1190
3	2025-09-17	N1194
4	2025-12-03	N1200

5.1.2 National Work

The focus of NSAI/TC 5 is its 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 2025 there was good interest in participation at the national level with over thirty new members applying to get involved. This included representatives of many medical device organisations such as Aerogen, Airmid Healthgroup, Becton Dickinson, Boston Scientific, Cook medical, Ellab, Homecare medical, Medtronic, NSAI Certification, Solventum, Steris, SymPhysis, TU Dublin, UCC, Medical Bureau of Road Safety (MBRS) – UCD, and Vitalograph.

The secretary of NSAI/TC 5, Linda Hendy welcomed an invitation to present at the Irish MedTech Sterility Assurance Forum held in Athlone on 20th of November and provided an update on sterilization standards to the group. Members were encouraged to get involved in standard development work. A picture from the event is provided at the end of this report.

NSAI is grateful to experts who volunteer to contribute to standard development. 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. Some key areas of national engagement are listed below:

- a revision of EN 17141 – *Cleanrooms and associated controlled environments – microbiological contamination control*, is under way under CEN/TC 243/WG5, with the Chair of NSAI/TC 5 convening this group.
- ISO 7376-2:2025 – *Aesthetic and respiratory equipment Part 2: Video Laryngoscopes*, was published in June. And was developed by ISO/TC 121/SC2/WG17 which was led by an Irish expert.

- National expert appointed as convener of CEN/TC 215/WG4 -Airway devices, related equipment and suction devices
- The revision of ISO 80369-1 – *Small bore connectors for liquids and gases in healthcare applications Pt 1: General requirements*, was published in October with the revision initiated based on a submission from Ireland and an Irish expert taking the lead in the revision under ISO/TC 210/JWG4 – Small bore connectors.
- ISO/TC 210/JWG4 continues the revision of the ISO 80369 series of standard for Small-bore connectors for liquid and gases in healthcare applications to align the structure and terminology of all parts with the recently revised part 1 and part 6, national experts continue to engage in this work, including a proposal for a revision of ISO 80369-2 for connectors for respiratory applications based on an submission from NSAI.
- ISO/TC 198/WG 1 EO Sterilization, continued work on a revision of ISO 11135. – *Sterilization of healthcare products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*, with an Irish expert convening the work and other experts participating in the Working Group.
- ISO/TC 194/WG1 - Systematic approach to biological evaluation and terminology completed the revision of ISO 10993-1 – *Biological evaluation of medical devices – Pt 1 Requirements and general principles for the evaluation of biological safety within a risk management process*, and the standard was published late 2025, thanks to two experts attending meetings and contributing to the development of the standard. Both experts are continuing their involvement in ISO/TC 194/WG1 –, as this group is working on several guidance documents to support users of the new revision.
- Through the Irish MedTech Sterility Assurance Forum there is great interest and contributions to sterility and sterilization standards developed by ISO TC 198, CEN TC 102, & CEN TC 204, with over 12 national experts engaging in international standards work.
- A revision of the EN 868 Series of standards for Packaging of terminally sterilised medical devices is underway under CEN/TC 102/WG 4, with an Irish expert engaged in this work.
- NSAI in conjunction with Medical Bureau of Road Safety, hosted a meeting of CEN/CLC BTF 116-1 – *Alcohol interlocks in September*. This group is working on a revision of EN 50436-3 – *Alcohol interlocks – Test methods and performance requirements – Part 3: Guidance for authorities, decision makers, purchasers and users*, see a picture of delegates attending this meeting 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
- Dentistry
- Ophthalmic optics
- Quality and risk management
- Breath alcohol testers

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 45 standards now harmonised for the MDR (up from 27 in 2025) and 23 for the IVDR. It is hoped further progress on this will be made in 2026.

During 2025 the Commission carried out a review both the MDR & IVDR seeking feedback from the sector. As a result, the Commission is proposing a target revision to reduce and simplify the rules for medical devices to make them easier, faster and more effective and to promote competitiveness while ensuring patient safety.

These proposed changes and possible impact for the sector will be something to watch for 2026.

6 Work programme for 2026 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 safety and performance of medical devices, with a particular focus on those used to support the MDR and IVDR.

Photos from 2025



Delegates attending CEN/CLC BTTF 116-2 – Alcohol interlocks meeting – hosted by NSAI & MBRS in UCD, Sept 23-24th, 2025.



**Irish Sterility Assurance Forum
Speakers – November 2025 –
Linda Hendy, secretary of
NSAI/TC 5 is second from the
right,**