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NSAI TECHNICAL COMMITTEES (TC5) HEALTHCARE STANDARDS

Contents

1 Introduction

The medical technology sector in Ireland is recognised as an emerging hub supplying medical devices to the global market.. The sector employs over 38,000 people in Ireland and is the second largest employer of medtech professionals in Europe, per capita. Ireland is one of the largest exported of medical products in Europe with annual exports of €12.6 billion and companies here directly export to over 100 countries worldwide. As many as 9 of the world's top 10 medical technology companies have a base in Ireland and 60% of the 450 medtech companies based here are indigenous. Ireland also has a strong services and contract research and manufacturing in this sector with many supplier organizations supporting this sector.

2 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 those involved in the supply of healthcare products, the Health Care Standards Committee (HCSC) as a consultative committee to NSAI, will

Make recommendations as necessary, in relation to healthcare standardisation

Monitor and participate in, as appropriate, the development of healthcare standards generally, with particular emphasis on the European healthcare harmonisation programme

Consult with and disseminate information to interested parties on healthcare standards and on the development of new standards and contribute to public awareness of standardisation work and its benefits, via appropriate media

Advise and assist NSAI in connection with related developments, as the committee deems appropriate (e.g. EC Directives, domestic legislation, GMP Guidelines etc.)

The committee mirrors the following international committees:

Committee Name	Committee Title

3 Structure and Membership

3.1 Structure

The Figure below illustrates the structure of the Committee:

NSAI Healthcare Standards committee structure	Title	International committees monitored

NSAI TC 5	Healthcare standards (Horizontal issues)	ISO TC 210 – Quality management and general aspects for medical devices CEN/CENELEC/JTC 3 - Quality management and general aspects for medical devices CEN TC 206 - Biological & clinical evaluation of medical devices ISO TC 194 - Biological & clinical evaluation of medical devices CEN TC 316 – Medical products utilizing cells, tissues and/or their derivatives CEN ABHS
SC1	Dentistry	ISO TC 106 – Dentistry CEN TC 55 - Dentistry
SC2	In-vitro diagnostic	CEN TC 140 ISO TC 212
SC3	Ophthalmics	CEN TC 140 ISO TC 212
SC4	Non-active medical devices	CEN TC 205 ISO TC 76 ISO TC 84 ISO TC 157
SC5	Respiratory and anaesthesia	CEN TC 215 ISO TC 121
SC6	Implantables	CEN TC 285 ISO TC 150
SC7	Orthopaedic implants	CEN TC 285 ISO TC 168
SC9	Sterilizers, sterilization and cleaning	CEN TC 102 CEN TC 195 CEN TC 204 CEN TC 216 CEN TC 243

		ISO TC 198
SC11	Ambulances and rescue systems	CEN TC 239 ISO TC 121
SC12	Healthcare services	CEN TC 362 CEN TC 449 CEN TC 450 ISO TC 304
SC13	Cleanrooms	CEN TC 243 ISO TC 209
SC14	Ostomy and incontinence	ISO TC 173/SC3
SC15	Aesthetic surgery services	CEN TC 403
SC 16	Osteopathic services	CEN TC 414
SC 19	Miscellaneous (alcohol breath testers)	CEN TC 367

3.2 Members

The list below are the members for the year:

Organisation	Name	Role
Independent expert	Wilfrid Higgins	Chairman
Medtronic	Suzanne Butler	member
Boston Scientific	Paul Cahalan	member
Boston Scientific	Garrett Casserly	member
Abbott	Gerry Conlon	member
HPRA	Mairead Finucane	member
Celestica	Leo Flemming-Farrell	member
Oxygen-care	Karl Goulding	member
Merit Medical	James Hoade	member
Medtronic	Aislinn Keogh	member
Trinzo	Noel Kinneen	member
Mylan	Christopher Kinsella	member
Medtronic	Cathal Lucey	member
NSAI Certification	Niamh Lynch	member
Medtronic	Seamus Maguire	member
BSCI	Susan McMonagle	member
NSF Health Science	Robyn Meurant	member
NSAI Certification	Mary Murphy	member
Abbott	Fiona Murphy	member
Irish Cleanroom Society	Conor Murray	member

Micromatters	Kevina O'Donoghue	member
BSCI	Stephanie O'Donoghue-Fahy	member
Coomb Hospital	Ruth O'Kelly	member
Rotunda hospital	John O'Loughlin	member
Teleflex	Agnieszka Piaskowska	member
AMBER - TCD	Adriele Prina-Mello	member
Becton- Dickenson	Andrew Roche	member
	Sabine Rowland	member
Boston Scientific	Elaine Ruddle	member
Mylan	Paul Scannell	member
Neomed	Hilary Sherman	member
Boston Scientific	Noel Smith	member
Neomed	Melinda Smith	member
Boston Scientific	Aoife Tobin	member
Trinzo	Liam Turley	member
Neurent Medical	Kenny Walsh	member
NSAI Standards	Linda Hendy	Secretary

Sub-committees 1 to 19 review specific subject matter standards and subject matter experts are assigned to different NSAI TC 5 SC's in line with their areas of interest.

4 Summary of 2018 Activities

4.1 National

4.1.1 Meetings

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

Meeting No.	Date	Minutes Reference ** optional**
No 118	2018-03-13	See N1021
No. 119	2018-09-25	See N1022

4.1.2 National Work

There is no national project work underway for this committee during 2018

4.2 International/Regional

4.2.1 Meetings

Committee members attended international meetings as follows:

Committee Name	Location	Date	No. of Attendees

CEN ABHS 1st Meeting	Lübeck, Germany	May	1
CEN ABHS 2nd Meeting	Brussels	Oct	1
ISO TC 198	London	Sept	4

4.2.2 International/Regional Work

CEN TC 243 Cleanroom Technology WG5 Biocontamination control.

Conor Murray from the Irish Clean Room Society is the convenor of this WG. This group is working on developing prEN 17141 – *Cleanrooms and associated controlled environments – biocontamination control.* This standard went for 2nd enquiry ballot in 2018. The WG are working on preparing the Formal vote draft which is planned for early 2019.

4.3 Regulatory Development/Update

The new Medical Device Regulation 2017/745 is coming into force in May 2020. The new IVD regulation 2017/746 will come into force May 2022. This impacts on many standards that apply to the medical device sector. To date the European Commission has to issue a new Standards Mandate to the European Standard Development organizations for revision of Harmonized standards to support the new regulations.

5 Irish Publications/Reviews

5.1 Publications

The Committee did not publish any national deliverables this year.

6 Work programme for 2019 onwards

NSAI TC 5 has no national work but is focusing on contributing to the development of CEN standards to support the MDD and the New Medical Device Regulation and In-vitro diagnostic medical devices

7 Additional Information

In September ISO TC 198 held a plenary meeting hosted by BSI in London. There were several national delegates in attendance – Richard Cowman (Steris), Suzanne Butler (Medtronic), Brigid Keenan (Teleflex), Linda Hendy (NSAI).

Richard Cowman and Linda Hendy attending the plenary meeting of ISO TC 198 in BSI offices – Chiswick Tower, London.

The secretary attended a medical device conference organized by BSI & AAMI. This meeting was held in London in June 2018 and provided updates on regulatory developments in Europe and USA and the possible impact of the new regulation that are coming into force in Europe from 2020.