



NSAI

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ANNUAL REPORT 2018

**NSAI TECHNICAL COMMITTEES
(ETC TC 10 ELECTRICAL
EQUIPMENT IN MEDICAL
PRACTICE)**

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1 Introduction

This TC serves the manufacture, supply and operation of electrical medical equipment sectors in Ireland. The monitoring and development of standards in this area contribute to the safety of equipment in the field. The overall aim is to ensure the safety of patients and operators of equipment in the health care sector. The safety of electrical installations (or national wiring rules) in medical locations also comes under the remit of this committee

The main activity for this committee is to monitor and provide input on the IEC and CENELEC documents. The standards produced are important as several are listed in the OJEU as harmonized standards under the Medical Device Directive (MDD) and the new Medical Device Regulation Radio (MDR), which is due to come into force May 2020.



The industry currently has 3 experts involved in international work

A total of 16 active national members

2 Scope of TC

NSAI TC 10 provides a national focal point for the development of the IEC 60601 series of standards. The goal of the IEC 60601 standards is to improve safety in the use of Medical equipment by providing a body of standards to assist manufacturers, users and patients alike.

TC10 is also responsible for co-ordinating the participation of Irish experts in the work of IEC TC 62 and its four subcommittees and CENELEC TC 62.

Another function of TC 10 is to provide expertise and assist in any development of "Section 710 – Medical Locations Part 7: Requirements for Special Installations or Locations - of the National Rules for Electrical Installations; ET 101". To this end TC10 has members on the IEC TC64 SC – IEC 60364-7-710.

The committee mirrors the following international committees:

Committee Name	Committee Title
IEC TC 62	Electrical Equipment in medical locations
IEC TC 62A	Common aspects of electrical equipment used in medical practice
IEC TC 62B	Diagnostic imaging equipment
IEC TC 62C	Equipment for radiotherapy, nuclear medicine and radiation dosimetry
IEC TC 62D	Electromedical equipment
CENELEC TC62	Electrical equipment in medical practice
IEC TC 64 MT40	Electrical installations and protection against electric shock - Maintenance of IEC 60364-7-710 - Medical locations

3 Structure and Membership

In 2018 4 sub-committees were set up under ETC TC 10 to mirror the established 4 sub-committees under IEC TC 62. Four national leads were appointed to each of these national sub-committees and further work is planned in 2019 to recruit additional experts for these national sub-committees. With the revision of national wiring rules initiated in 2018 a national wiring rules group was also established in 2018 – ETC TC 10 SC5 – Wiring Rules – Medical locations. See the list of members below in 4.1.

3.1 Members

The list below are the members for the year:

Organisation	Name	Role
Independent Expert	Peter Grainger	Chairman
Beaumont Hospital - HSE	Pat Cooney	Expert member
Tallaght Hospital - HSE	Leighton Curry	Expert member
IMSTA & Oxygen-Care	Karl Goulding	Expert member
Tullamore Hospital - HSE	Liam Hackett	Expert member
Crumlin Children's Hospital	Harnett, Philip	Expert member
National Maternity Hospital	Eoghan Hayden	Expert member
Independent Expert	Jonathan Kidd	Expert member
St. Luke's Hospital	McGivney, John	Expert member
Letterkenny Hospital	Paddy McGowan	Expert member
Naas Hospital	Colm McGrath	Expert member
Cork University Hospital	Bernard Murphy	Expert member
St. Vincents University Hospital	Aidan O'Connor	Expert member
HSE Estates	Brendan Redington	Expert member
Beaumont	David Sheedy	Expert member
BSCI	Noel Smith	Expert member
NSAI	Linda Hendy	Committee secretary

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**
1	13 th Feb 2018	N1050
2	29 th May 2018	N1061
3	28 th Sept 2018	N1067
4	6 th Nov 2018	N1069
Wiring SC	8 Meetings to draft I.S. 10101.	See ETC TC 10 Wiring SC documents

	1 Meeting to review CDV IEC 60363-7-710	
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4.1.2 National Work

In 2018 work started on the revision of the national wiring rules – ET101 4th Edition. The bulk of this work is carried out under ETC TC 2 – Electrical Installations. However, part 7-710 addresses the safety of electrical equipment in medical locations and comes under the remit of NSAI ETC TC 10. In 2018 a Sub-Committee or SC was set up under ETC TC 10 to specifically work on the revision of part 7-710. Members of ETC TC 10 volunteered to contribute to this group with Jonathan Kidd taking the lead in drafting the revision. Participants from organizations such as Bender and Siemens were invited to participate in the wiring rules revision. These organizations are knowledgeable in the application of the wiring rules.

4.2 International/Regional

4.2.1 Meetings

Committee members attended international CENELEC (CLC) and IEC meetings as follows:

Committee Name	Location	Date	No. of Attendees
IEC TC 62 Plenary	London, UK	17 to 20 th April 2018	1
IEC SC62A Plenary			1
IEC SC62B Plenary			1
IEC SC62C Plenary			1
IEC SC62D Plenary			1
CLC TC 62	Budapest, Hungary	12 & 13 th June	2

4.2.2 International/Regional Work

Most of the international contributions of ETC TC 10 is focused at the European level. With the new MDR or Medical Device Regulation, standards that support medical device regulations or Harmonised Standards require updating. The EN 60601 series form the main standards that will require updating. Other include EN 62304 – Medical device software – Software life cycle processes and EN 62366-1 – Medical devices – application of usability engineering to medical devices. This will be the main focus of the ETC TC 10 over the next few years. Most standards have until May 2024 to be revised.

At IEC TC 62 and SC62A, SC62B, SC62C and 62D develops many of the standard that are adopted at the European level to support the Medical device regulations. NSAI ETC TC 10 also continues to monitor international standard work programmes.

ETC TC 10 members also participate in IEC TC 64 MT40 - Electrical installations and protection against electric shock - Maintenance of IEC 60364-7-710 - Medical locations. Brendan Redington and Jonathan Kidd are the nominated national experts participating in MT40.

4.2.3 International/Regional Standards Reviewed

The work programme of both CENELEC TC 62 and IEC TC 62, SC 62A, 62B, 62C & 62D were monitored during 2018.

For CENELEC TC 62 see the links below for the full work programme.

List of [Published standards](#)

List of [revisions and new standards](#)

For IEC TC 62 the standards work programme are found under SC62 A-D – see below:

SC 62A – Common aspects of electrical equipment used in medical practice

List of [Published standards](#)

List of [revision and new standards](#)

SC62B – Diagnostic imaging equipment

List of [Published standards](#)

List of [revision and new standards](#)

SC62C – Diagnostic imaging equipment

List of [Published standards](#)

List of [revision and new standards](#)

SC62D – Electromedical equipment

List of [Published standards](#)

List of [revision and new standards](#)

Members of ETC TC 10 monitored the work of IEC TC 64 MT 40 which developed IEC 60363-7-710 – Low voltage electrical installation – Part 7-710: Requirements for special installations or locations – Medical locations. In 2018 the CDV or committee draft was circulated for ballot and comment. This was reviewed by the newly established Wiring SC under ETC TC10.

4.3 Regulatory Development/Update

The new Medical Device Regulation comes into force on the 27th of May 2020. As a result, many harmonised standards will require updating. CENELEC TC 62 will have responsibility for adopting many international standards as necessary. The deadline for many of these updates is May 27th 2024.

5 Irish Publications/Reviews

5.1 Publications

In 2018 work started on the revision of ET 101 (4th edition). Members of ETC TC 10 volunteered to contribute to the wiring rules revision and joined the newly set up sub-committee or Wiring SC under ETC TC 10. Jonathan Kidd took a lead in drafting the revision. Participants from organizations such as Bender and Siemens were invited to participate in the

wiring rules revision. These organizations are knowledgeable in the application of the wiring rules. This group also monitored the work of IEC TC 64 MT40 as this is the international group that is currently working on the next revision of IEC 60363-7-710.

6 Work programme for 2019 onwards

ETC TC 10 plans to continue to monitor the work of CENELEC TC 62 and IEC TC 62, SC62A, SC62B, SC62C, SC62D. National experts nominated to IEC TC 64MT40 will contribute to the next revision of IEC 60363-7-710.

7 Additional Information

In January 2018 NSAI marked the transition of ETCI committees to NSAI by hosting an event in the Helix. This was an interesting evening where the work and contribution of ETCI and the national committees to international standards work over many years was highlighted. Peter Grainger and Linda Hendy attended the event as representatives of ETC TC 15.



Attendees at the CENELEC TC 62 Meeting, Budapest – June 2018, including ETC TC 10 Chair – Peter Grainger (seated front row, 2nd from Right) and ETC TC 10 Secretary, Linda Hendy (behind Peter).