



**NSAI**

F-ST-25 – Rev 0

Pgs 1-5

# ANNUAL REPORT 2020

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

## Contents

1	Introduction .....	3
2	Scope of TC.....	3
3	Structure and Membership .....	4
3.1	Members .....	4
4	Summary of 2020 Activities .....	4
4.1	National .....	4
4.1.1	Meetings .....	5
4.1.2	National Work .....	5
4.2	International/Regional .....	5
4.2.1	Meetings .....	5
4.2.2	International/Regional Work .....	5
4.2.3	International/Regional Standards Reviewed .....	6
4.3	Regulatory Development/Update .....	7
5	Irish Publications/Reviews.....	7
5.1	Publications .....	7
6	Work programme for 2020 onwards .....	7
7	Additional Information .....	7

## 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. Many of the European standards developed by CENELEC/TC 62 are used to support the Medical Device Directive (MDD) and the new Medical Device Regulation (MDR), which is now due to come into force in May 2021.



The industry currently has 2 experts involved in international work

A total of 24 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.

TC 10 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.

Wiring rules for medical applications also fall under the NSAI/ETC/TC 10 scope with experts engaged in the development of HD 60364-7-710 – Low-voltage electrical installations – Part 7-710 – Requirements for special installations or locations – medical locations. This work is carried out by IEC/TC 64 & CENELEC/TC 64. European HD draft standards on Low-voltage electrical installations form inputs for national wiring rules. NSAI/ETC/TC 10 contributed to the revision of the national wiring rules which is carried out in conjunction with NSAI/ETC/TC 02 – Electrical Installations. The revision of the national working rules was a key project and a main focus for 2019. The new wiring rules – I.S. 10101 were published in March 2020.

The committee mirrors the following international committees:

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

<b>CLC/TC 64 WG 6</b>	Medical locations
-----------------------	-------------------

## 3 Structure and Membership

There are 4 sub-committees were set up under NSAI/ETC/TC 10 to mirror the established 4 sub-committees under IEC/TC 62 and to give access to SC documents.

There is one active working group that focuses on contributions to international standards on electrical installations and advises on revisions to national wiring rules.

### 3.1 Members

The list below are the members for the year:

Organisation	Role
<b>Naas General Hospital – HSE</b>	3 expert members (Chair & 2 members)
<b>Beaumont Hospital - HSE</b>	2 Expert members
<b>Tallaght Hospital - HSE</b>	1 Expert member
<b>IMSTA &amp; Oxygen-Care</b>	1 Expert member
<b>Tullamore Hospital - HSE</b>	1 Expert member
<b>Crumlin Children’s Hospital</b>	1 Expert member
<b>National Maternity Hospital</b>	1 Expert member
<b>Independent Expert</b>	1 Expert member
<b>St. Luke’s Hospital</b>	1 Expert member
<b>Letterkenny Hospital</b>	1 Expert member
<b>Cork University Hospital</b>	1 Expert member
<b>St. Vincents University Hospital</b>	1 Expert member
<b>HSE Estates</b>	1 Expert member
<b>O’Hara engineering</b>	1 Expert member
<b>HSE</b>	1 Expert member
<b>Mercury Engineering</b>	1 Expert member
<b>NSAI Certification</b>	1 Expert member
<b>Medtronic</b>	1 Expert member
<b>Boston Scientific</b>	1 Expert member
<b>Independent expert</b>	1 Expert member
<b>NSAI</b>	Committee secretary

Three new members joined the committee in 2020.

## 4 Summary of 2020 Activities

### 4.1 National

#### Covid 19 Pandemic:

The pandemic, which spread across all of Europe and the rest of the world in 2020, impacted on standards work. Most technical committees moved to use of virtual or on-line. While this has worked quite well it is hoped that some form of physical meetings will return in 2021. The use of virtual meetings has some advantages in that it facilitated greater national participation in international meetings, without the need for international travel.

The pandemic also had a big impact on the work of members of NSAI/ETC/TC 10, as many are front line workers in healthcare service providers. As a result, some meetings were postponed, however the committee did continue to meet in 2020.

### 4.1.1 Meetings

Committee members participated in the following national meetings which were held virtually or on-line as follows:

Meeting No.	Date	Minutes Reference ** optional**
1	03 <sup>rd</sup> Mar	N1101
2	26 <sup>th</sup> May	N1105
3	29 <sup>th</sup> Sept	N1121
4	24 <sup>th</sup> Nov	N1142
Wiring SC	5 Meetings finalising input on IEC CDV 60363-7-710 Contributed to final editing of National wiring rules I.S. 10101.	See NSAI/ETC/TC 10 Wiring SC documents

### 4.1.2 National Work

The new edition (5<sup>th</sup>) of the wiring rules – I.S. 10101 was published in March. ETC TC 10 contributed to the finalization of this new revision in conjunction with NSAI/ETC/TC 2 – Electrical installations. Part 7-710 addresses the safety of electrical equipment in medical locations and was the focus of the revision work that comes under the remit of NSAI/ETC/TC 10.

## 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 IEC/SC 62A Plenary IEC/SC 62B Plenary IEC/SC 62C Plenary IEC/SC 62D Plenary	No meeting scheduled in 2020 – planned for early 2021 in Frankfurt		
CLC TC 62	Virtual	12 <sup>th</sup> June 2020	4

### 4.2.2 International/Regional Work

Most of the international contributions of NSAI/ETC/TC 10 is focused at the European level. With the new MDR or Medical Device Regulation coming into force in May 2020, standards that support medical device regulations or Harmonised Standards require updating. The EN 60601 series form the bulk of standards under CENELEC/TC 62 that will require updating for the new MDR.

Other standards 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 NSAI/ETC/TC 10 over the next few years. Most standards have until May 2024 to be revised.

At IEC/TC 62 and SC 62A, SC 62B, SC 62C and SC 62D develops many of the standards that are adopted at the European level to support the Medical device regulations. Artificial intelligence and health software are some of the topics under review by IEC/TC 62 with respect to new areas for standardization. NSAI/ETC/TC 10 continues to monitor international standard work programmes.

NSAI/ETC/TC 10 members also participate in IEC/TC 64 MT40 - Maintenance of IEC 60364-7-710 - Medical locations and CENELEC/TC 64 WG 6 Medical locations. There were two meetings of MT 40 and one meeting of WG 6 in 2019 where members of NSAI/ETC/TC 10 participated.

### 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 2020.

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 SC 62 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](#)

## 4.3 Regulatory Development/Update

The new Medical Device Regulation (MDR) was due to come into force on the 27<sup>th</sup> of May 2020. As a result, many harmonised standards will require updating. Much of the work programme of CENELEC TC 62 will focus on adopting many international standards and drafting supporting annexes for the new regulation. In April the European Commission proposed a one-year delay to the date of application for the MDR to May 26<sup>th</sup> 2021. This was decided due to the effect of the pandemic which impacted the supply of some devices. There were some shortages or disruption in continuity of supply of certain devices during the pandemic (masks, gloves, ventilators etc). The ability of Notified bodies to do on site audits was also an issue, as a result virtual auditing became the norm. There was no change to the deadline for standards revision for the MDR which is still May 27<sup>th</sup> 2024.

## 5 Irish Publications/Reviews

### 5.1 Publications

NSAI/ETC/TC 10 finalised its contribution to the finalisation of the national wiring rules, I.S. 10101, which were published in March 2020.

Currently there is no other national work under way.

## 6 Work programme for 2020 onwards

NSAI/ETC/TC 10 plans to continue to monitor the work of CENELEC/TC 62 and IEC /TC 62, SC 62A, SC 62B, SC 62C, SC 62D. National experts nominated to IEC/TC 64 MT40 will continue to contribute to the Final revision of IEC 60363-7-710 and the European HD 60363-7-710.

## 7 Additional Information

None