



**NSAI**

# ANNUAL REPORT 2023

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

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## 1 Chairperson's Statement

2023 proved to be a year of greater activity and return to many norms of previous years, although the time people can devote to committee work competes with their own work and participations. As a result all meetings in 2023 were held virtually including the AGM. We expect this to be a feature of the coming year's meeting schedule.

It was also another successful year for membership with numbers continuing to increase as the year progressed and greater interaction on committee activities throughout. Additionally meeting attendances were up and consistent.

CENELEC continued to ramp up activities throughout the year and thanks to the committee, even distribution of documentation and review became more interactive, with a great body of work being completed by all. We expect an even greater challenge in 2024 for the committee and their valued support.

Last year we noted the use of community prescribed patient medical devices and systems in use in acute clinical and medical environments. This will continue to pose new challenges as trends in software as a medical device and Internet of Things (IoT) continues to grow.

The continued development of standards to support software as a medical device will have greater importance for patients, clinic staff and support staff. It is important that these standards clearly define the roles and responsibilities for the effective management, governance and security of such systems.

Progress on wiring rules in medical installations is a body of work that continues in other TC's, we hope that committee members who reside on both groups will be in a position to update over the next year.

We hope that the dedicated respective subgroups will be able to progress these matters over the course of 2024. TC10 remain committed to assist and advise wherever relevant.

Finally, I would like to thank the support of all the members of TC10 for their continued dedication and support and we look forward to achieving even more in the coming twelve months in ETC/TC 10.

## 2 Introduction

NSAI/ETC/TC 10 is the national mirror committee to IEC/TC 62 and its subcommittees, and CLC/TC 62, with responsibility for coordinating the development of standards for electrical equipment used in medical practice, in particular the IEC 60601 series of standards.

IEC 60601 standards improve safety in the use of medical electrical equipment by providing a body of standards that assist:

- Manufacturers in designing & assembling safe medical electrical equipment & systems;
- Manufacturers, test houses & regulatory authorities in assessing compliance with requirements set forth in the standard; and
- Health care professionals in managing the risks associated with use of these products.

## 3 Scope of TC

NSAI TC ETC 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.

ETC TC 10 is responsible for co-ordinating national participation in the work of IEC TC 62 and its 4 sub-committees and CLC TC 62.

Another function of ETC TC 10 is to provide expertise and assist in developments of IEC 60364 Part 7-710 - Requirements for special installations or locations - Medical locations and developments of National rules for electrical installations

The committee mirrors the following international committees:

Committee Name	Committee Title	Membership
<b>IEC/TC 62</b>	Medical equipment, software, and systems	P-Member
<b>IEC/TC 62A</b>	Common aspects of medical equipment, software, and systems	P-Member
<b>IEC/TC 62B</b>	Medical imaging equipment, software, and systems	O-Member
<b>IEC/TC 62C</b>	Equipment for radiotherapy, nuclear medicine and radiation dosimetry	o-Member
<b>IEC/TC 62D</b>	Particular medical equipment, software, and systems	P-Member
<b>CENELEC TC62</b>	Electrical equipment in medical practice	N/A

Additionally, the committee mirrors the following;

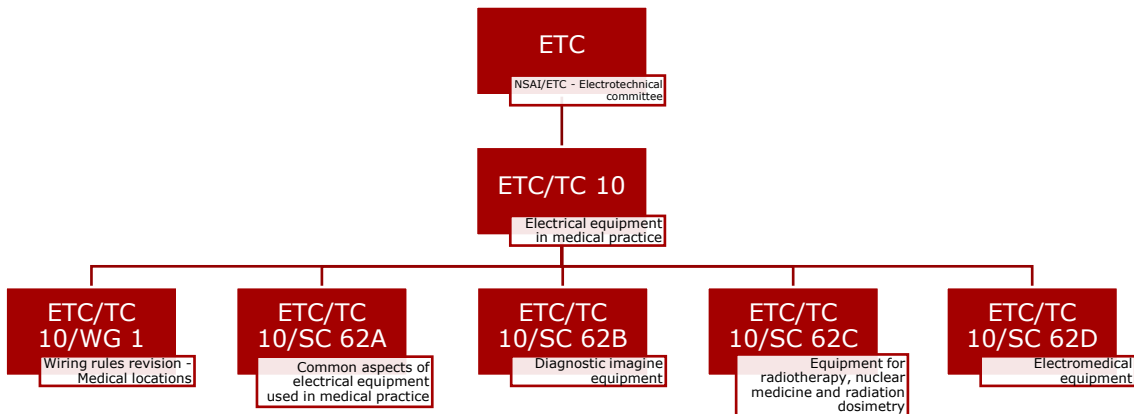
Committee Name	Committee Title
<b>IEC/TC 64/MT40</b>	Electrical installations and protection against electric shock - Maintenance of IEC 60364-7-710 - Medical locations
<b>CLC/TC 64/WG6</b>	Medical locations

Members of NSAI/ETC/TC 10 are also participants on the above.

## 4 Structure and Membership

### 4.1 Structure

The Figure below illustrates the structure of the Committee:



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

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

### 4.2 Members

The list below are the organizations represented on NSAI ETC/TC 10 in 2023:

Organisation	Role
<b>Tallaght University Hospital</b>	Chairperson
<b>NSAI</b>	Secretary
<b>Midlands Regional Hospital Tullamore</b>	Committee member
<b>Bender</b>	Committee member
<b>Beaumont Hospital</b>	Committee members (x2)
<b>Naas General Hospital</b>	Committee member
<b>Our Lady's Childrens Hospital Crumlin</b>	Committee member
<b>National Maternity Hospital</b>	Committee member
<b>NSAI</b>	Secretary Support Team
<b>Mercury Engineering</b>	Committee member
<b>NSAI Certification</b>	Committee member

<b>Tyndall Institute</b>	Committee member
<b>St. Lukes Hospital</b>	Committee member
<b>BD</b>	Committee member
<b>St. James' Hospital</b>	Committee member
<b>HSE Estates</b>	Committee member
<b>Compliance Engineering Ireland</b>	Committee member
<b>Cork University Hospital</b>	Committee member
<b>Resmed</b>	Committee member
<b>Independent Experts</b>	Committee members (x4)

## 5 Summary of 2023 Activities

### 5.1 National

#### 5.1.1 Meetings

Committee members participated in following national meetings;

Meeting No.	Date	Minutes Reference
1	31st January	N1180
2	18 <sup>th</sup> April	N1182
3	25 <sup>th</sup> July	N1184
4	7 <sup>th</sup> November	N1186

#### 5.1.2 National Work

NSAI/ETC/TC 10 had no national deliverables in 2023. The committee's focus is on participation in International Standards development.

### 5.2 International/Regional

#### 5.2.1 Meetings

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

Committee Name	Location	Date	No. of Attendees
CLC TC 62	Virtual	2023-05-24	1

Most of the international contributions of ETC/TC 10 is focused at the European level. The EN 60601 series form the bulk of standards under CLC/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 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. 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.

ETC/TC 10 members also participate in IEC TC 64 MT40 - Maintenance of IEC 60364-7-710 - Medical locations and CENELEC TC 64 WG6 Medical locations.

## 5.2.2 International/Regional Work

ETC TC10 monitors and advises in relation to NSAI's position on the work being undertaken by CENELEC and IEC in the areas of Medical equipment, software and systems.

ETC/ TC 10 members contributed to the development of international and regional standards in 2023 by advising NSAI on voting positions.

## 5.2.3 International/Regional Voting

IEC/TC 62: Ireland voted on all documents closed in 2023 with a 100% overall voting record.

IEC/SC 62A: Ireland voted on all documents closed in 2023 with a 100% overall voting record.

IEC/SC 62D: Ireland voted on all documents closed in 2023 with a 100% overall voting record.

CLC/TC 62: Ireland voted on all documents closed in 2023 with a 100% overall voting record.

The committee actively voted on 5 items in 2023.

Body	Vote reference	Comments submitted	WIID	Decision
IEC	<b>62D/1988/CDV</b>	<b>No</b>	-	<b>Approve</b>
IEC	<b>62D/1990/CDV</b>	<b>No</b>	-	<b>Approve</b>
IEC	<b>62D/1992/CDV</b>	<b>No</b>	-	<b>Approve</b>
IEC	<b>62A/1511/Q</b>	<b>Yes</b>	-	<b>Comment only</b>
IEC	<b>62A/1528/Q</b>	<b>Yes</b>	-	<b>Approve</b>

## 5.2.4 International/Regional Standards Reviewed

The work programme of both CLC/TC 62 and IEC/TC 62, SC 62A, 62B, 62C & 62D were monitored during 2023

## 5.3 Regulatory Development/Update

AI in standards

Software as a medical device

IVDR

Delays to implementation of MDR

Standards supporting the Medical Device Regulation (MDR) are a key focus of the work programme for CLC/TC 62. The HAS Consultant approval process was renewed in 2023, however was paused for a period leading to a backlog of appraisals and therefore delays in the citation of standards under the MDR and IVDR.

A total of 12 standards were cited in the OJ EU under the MDR, and 7 under the IVDR in 2023.

## 6 Irish Publications/Reviews

### 6.1 Publications

The committee did not publish any deliverables this year.

### 6.2 Reviews

The committee did not review any national documents.

## 7 Work programme for 2024 onwards

In 2024, ETC/TC 10 plans to continue to monitor the work of CLC/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 work on IEC 60363-7-710 and the European HD 60363-7-710.