



**NSAI**

# ANNUAL REPORT 2024

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

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## 1 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.

2024 was a busy year for NSAI/ETC/TC 10 which saw a net increase in membership and Irish experts contributing extensively to numerous significant projects beginning in IEC/TC 62, including the next edition of IEC 60601-1, IEC 62304, and a number of new standards relating to Artificial intelligence.

2024 also saw the committee Chairperson stepping down. NSAI expresses its gratitude to the Chair for their work in steering the committee over the past number of years.

## 2 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;

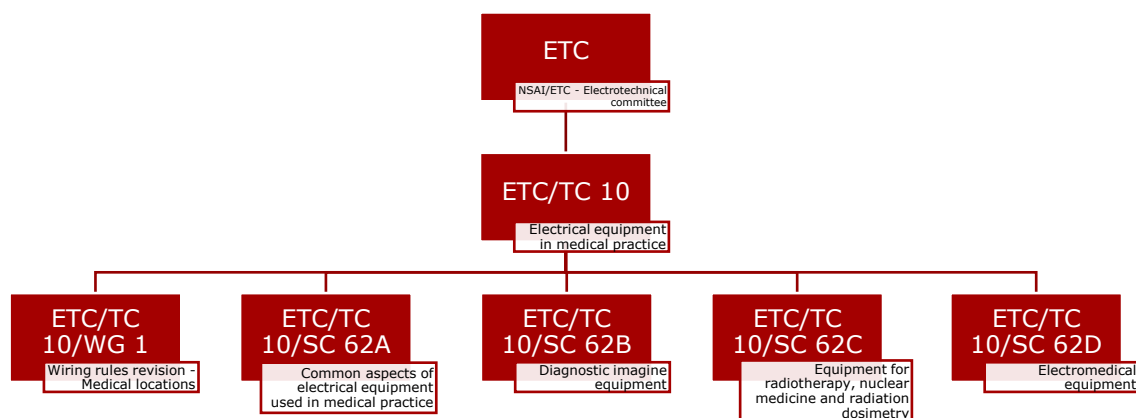
Committee Name	Committee Title
<b>IEC/TC 64/MT40</b>	Electrical installations and protection against electric shock - Maintenance of IEC 60364-7-710 - Medical locations
<b>CLC/TC 64/WG6</b>	Medical locations

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

## 3 Structure and Membership

### 3.1 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.

## 3.2 Members

The list below are the organizations represented on NSAI ETC/TC 10 in 2024:

Organisation
<b>Tallaght University Hospital – Chairperson*</b>
<b>NSAI - Secretary</b>
<b>Midlands Regional Hospital Tullamore</b>
<b>Bender</b>
<b>Beaumont Hospital</b>
<b>Naas General Hospital</b>
<b>Our Lady’s Childrens Hospital Crumlin</b>
<b>National Maternity Hospital</b>
<b>NSAI</b>
<b>Mercury Engineering</b>
<b>NSAI Certification</b>
<b>Tyndall Institute</b>
<b>St. Lukes Hospital</b>
<b>BD</b>
<b>St. James’ Hospital</b>
<b>HSE Estates</b>
<b>Compliance Engineering Ireland</b>
<b>Cork University Hospital</b>
<b>Resmed</b>
<b>Dundalk IT</b>
<b>Stryker</b>
<b>Boston Scientific</b>
<b>Independent Experts</b>

\*NOTE: Chairperson stepped down during 2024

## 4 Summary of 2024 Activities

### 4.1 National

#### 4.1.1 Meetings

Committee members participated in following national meetings;

Meeting No.	Date	Minutes Reference
1	30 <sup>th</sup> January	N1187
2	9 <sup>th</sup> April	N1191
3	24 <sup>th</sup> September	N1193
4	28 <sup>th</sup> November	N1196

## 4.1.2 National Work

NSAI/ETC/TC 10 had no national deliverables in 2024. The committee's focus is on participation in International Standards development.

## 4.2 International/Regional

### 4.2.1 Meetings

NSAI/ETC/TC 10 members contributed significantly in 2024 to IEC/TC 62 projects, and attended the following meetings;

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

Committee Name	Date	No. of Attendees
IEC/TC 62	2024-10-26	3
IEC/TC 62/SC 62A	2024-10-25	3
IEC/TC 62/SC 62A/MT 49	2024-05-06	1
IEC/TC 62/SC 62A/MT 49	2024-10-14	1
IEC/TC 62/SC62D	2024-10-24	3
IEC/TC 62/SC 62A/WG 48	2024-04-29	1
IEC/TC 62/SC 62A/WG 48	2024-09-17	1
IEC/TC 62/AG 1	2024-10-24	1
IEC/TC 62/PT 63450	2024-12-09	1
IEC/TC 62/SC 62A/AG 33	2024-10-21	1
IEC/TC 62/SC 62A/WG 39	2024-10-14	1
IEC/TC 62/SC 62A/WG 41	2024-04-29	1
IEC/TC 62/SC 62B	2024-10-21	1
IEC/TC 62/SC 62B/AG 49	2024-10-24	1
IEC/TC 62/SC 62C	2024-10-21	1
IEC/TC 62/SC 62C	2024-10-21	1
IEC/TC 62/SC 62D/AG 32	2024-10-21	1
IEC/TC 62/SC 62D/MT 23	2024-04-22	1

### 4.2.2 International/Regional Work

In addition to participating on the drafting of standards, as indicated in 4.2.1, 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 2024 by advising NSAI on voting positions.

### 4.2.3 International/Regional Voting

IEC/TC 62: Ireland voted on all documents closed in 2024 with a 100% overall voting record.

IEC/SC 62A: Ireland voted on all documents closed in 2024 with a 100% overall voting record.

IEC/SC 62D: Ireland voted on all documents closed in 2024 with a 100% overall voting record.

CLC/TC 62: Ireland voted on all documents closed in 2024 with a 100% overall voting record.

The committee actively voted on 8 items in 2024.

Body	Vote reference	Comments submitted	WIID	Decision
IEC	62A/1538/DTS	No	-	Approve
IEC	62/509/Q	No	-	Approve
IEC	62A/1623/Q	Yes	-	Comments Only
IEC	62/513/Q	Yes	-	Approve
IEC	62/531/NP	No	-	Approve
IEC	62A/1595/Q	Yes		Approve
IEC	62A/1559/CD	Yes		Comments Only
CEN	Inclusion of CEN/TC 62 standards in M/595	No		Abstain

### 4.2.4 International/Regional Standards Reviewed

The work programme of both CLC/TC 62 and IEC/TC 62, SC 62A, 62B, 62C & 62D were monitored during 2024

## 4.3 Regulatory Development/Update

Standards supporting the Medical Device Regulation (MDR) are a key focus of the work programme for CLC/TC 62. A backlog of appraisals and therefore delays in the citation of standards continues under the MDR and IVDR.

A total of 27 standards were cited in the OJ EU under the MDR, and 16 under the IVDR by the end of 2024.

## 5 Irish Publications/Reviews

### 5.1 Publications

The committee did not publish any deliverables this year.

### 5.2 Reviews

The committee did not review any national documents.

## 6 Work programme for 2025 onwards

In 2025, 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 and continue contributing to various international standard development projects.