# ANNUAL REPORT 2022

**NSAI**

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

# Contents

# 1 Chairperson's Statement

We began 2022 with many similar challenges as the previous year with everyone facing challenges on time and availability. Therefore the decision to meet virtually has remained for TC 10. It was through determined and dedicated voluntary experts that we continued to manage to meet the schedule of TC 10.

We also succeeded in growing the membership of the committee and will seek to improve this further in 2023. As the work activities within CENELEC began to grow, so too did TC 10's workload for voting, commentary, and technical feedback.

Of particular note has been the recognition of the use of community prescribed patient medical devices and systems in use in acute clinical and medical environments.

This has been recognised with comprehensive guideline documentation 62A/1491/NP PNW TS 62A-1491 ED1: Health software and health IT systems safety, effectiveness and security - Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls.

This is a very welcome guidance document as the prevalence of community prescribed equipment being brought into the clinical environment is becoming increasingly common. The challenges of application software as a medical device for diagnostics, treatments and therapeutics continues to develop in digital health.

As a follow on from last investigation work was put on hold as we await further development on wiring rules in medical installations in other TC's, based on historical ETC publications for possible national work.

We hope that the dedicated respective subgroups will be able to progress matters in 2023 and that more good work in the area will continue.

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.

In 2023 IEC/TC 62 and three of its four subcommittees revised their committee titles and scopes to recognise the emergence of software as a medical device. The updated titles are listed below;

| Committee Name | Former Title | New Title |
|---|---|---|
| **IEC/TC 62** | Electrical Equipment in medical locations | Medical equipment, software, and systems |
| **IEC/SC 62A** | Common aspects of electrical equipment used in medical practice | Common aspects of medical equipment, software, and systems |
| **IEC/SC 62B** | Diagnostic imaging equipment | Medical imaging equipment, software, and systems |
| **IEC/SC 62D** | Electromedical equipment | Particular medical equipment, software, and systems |

# 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:

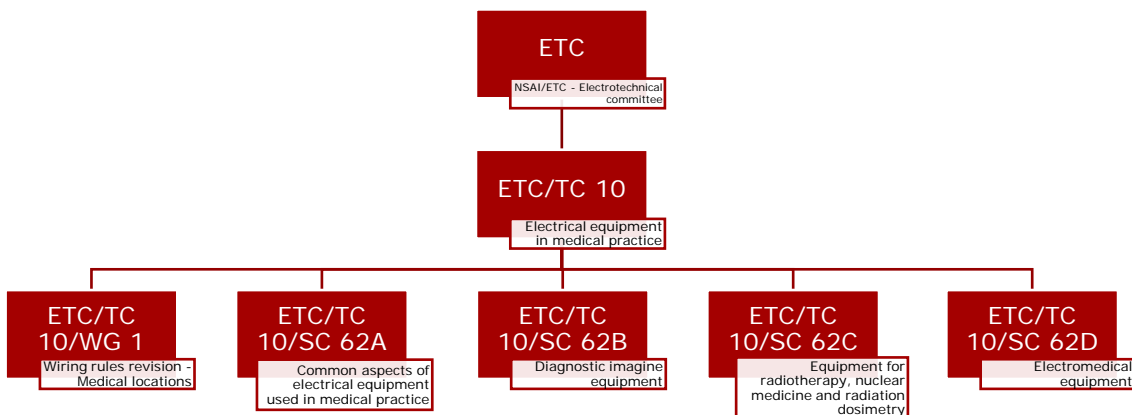| Committee Name | Committee Title | Membership |
|---|---|---|
| **IEC/TC 62** | Medical equipment, software, and systems | P-Member |
| **IEC/TC 62A** | Common aspects of medical equipment, software, and systems | P-Member |
| **IEC/TC 62B** | Medical imaging equipment, software, and systems | O-Member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

Additionally, the committee mirrors the following;

| Committee Name | Committee Title |
|---|---|
| **IEC/TC 64/MT40** | Electrical installations and protection against electric shock - Maintenance of IEC 60364-7-710 - Medical locations |
| **CLC/TC 64/WG6** | 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 active 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 2022:

| Organisation | Role |
|---|---|
| **Naas General Hospital – HSE** | 3 expert members |
| **Beaumont Hospital - HSE** | 2 Expert members |

| Tallaght Hospital - HSE | 1 Expert member |
|---|---|
| Oxygen-Care | 1 Expert member |
| Tullamore Hospital - HSE | 1 Expert member |
| Crumlin Children's Hospital | 1 Expert member |
| St James Hospital | 1 Expert member |
| National Maternity Hospital | 1 Expert member |
| Independent Expert | 3 Expert members |
| St. Luke's Hospital | 1 Expert member |
| Cork University Hospital | 1 Expert member |
| HSE Estates | 2 Expert members |
| O'Hara engineering | 1 Expert member |
| Bender | 1 Expert member |
| Mercury Engineering | 1 Expert member |
| NSAI Certification | 1 Expert member |
| Boston Scientific | 1 Expert member |
| Tyndall National Institute | 1 Expert member |
| NSAI | Committee secretary |

# 5  Summary of 2022 Activities

## 5.1 National
### 5.1.1 Meetings

Committee members participated in following national meetings;

| Meeting No. | Date | Minutes Reference |
|---|---|---|
| 1 | 11th January | N1166 |
| 2 | 6th September | N1174 |
| 3 | 29th November | N1178 |

### 5.1.2 National Work

NSAI/ETC/TC 10 had no national deliverables in 2022. 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 | 2022-05-24 | 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 2022 with a 100% overall voting record.

IEC/SC 62A: Ireland voted on all documents closed in 2022 with a 100% overall voting record.

IEC/SC 62D: Ireland voted on all documents closed in 2022 with a 100% overall voting record.

CLC/TC 62: Ireland voted on all documents closed in 2022 with a 100% overall voting record.

## 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 2022

## 5.3 Regulatory Development/Update

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 2022, 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 2022.

# 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 2023 onwards

In 2023, 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.