



NSAI

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ANNUAL REPORT 2021

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

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1 Chairman's Statement

The pandemic continued to pose a challenge for experts that participate in NSAI/ETC/TC 10 as many work in frontline healthcare services. However, the committee continued to meet, provide some input on ballots and maintained participation in international meetings.

This year saw the mandate between the European Commission and CEN/CENELEC approved, listing the standards proposed for harmonization. This is important for all stakeholders in the medical device sector to demonstrate conformance with the Medical Device Regulation (EU) 2017/745.

New topics getting greater focus at the international level include Artificial Intelligence and medical device software and software systems. This is a welcome development as health services are moving more to digital and telemedicine applications.

Nationally some investigation work was carried out based on historical ETC publications for possible national work. However due to work constraints potential work has been deferred and may be revised at a later stage.

This year saw some changes for ETC/TC 10 with both a new Chair appointed and a new secretary. These new appointments will bring new talents and focus to the work of ETC/TC 10.

We look forward to another productive year in ETC/TC 10.

2 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 (CLC) documents. Many of the European standards developed by CLC/TC 62 are used to support the Medical Device Directive (MDD) and the new Medical Device Regulation (MDR).

The industry currently has 3 experts involved in international work.

A total of 24 active national members.

3 Scope of TC

NSAI/ETC/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 CLC/TC 62.

Wiring rules for medical applications also fall under the 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 & CLC/TC 64. European HD draft standards on Low-voltage electrical installations form inputs for national wiring rules. 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 national wiring rules were published in 2020 however work on the next revisions of

IEC 60364-7-710 continued along with the development of the next CENELEC HD version. Two national experts participated in this work attending IEC/TC 64/MT 40 and CLC/TC 64 WG 6. IEC 60364-7-710:2021 was published in May but the HD version is yet to be issued by CENELEC.

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
CLC/TC 64/WG6	Medical locations

4 Structure and Membership

There are 4 sub-committees 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 one active working group that focuses on contributions to international standards on electrical installations and advises on revisions to national wiring rules.

4.1 Members

This year saw some changes with the appointment of a new Chair. This is following a decision by the outgoing chair to step down after more than 10 years. NSAI and members of the committee are appreciative of the contribution and leadership of the outgoing chair. The appointment of a new Chair was approved by the committee and NSAI during 2021. There was also a change of secretary in 2021 as NSAI are providing further resources to the healthcare sector, in recognition of the importance of this sector nationally.

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

Organisation	Role
Naas General Hospital – HSE	2 expert members
Beaumont Hospital - HSE	2 Expert members
Tallaght Hospital - HSE	1 Expert member
IMSTA & Oxygen-Care	1 Expert member
Tullamore Hospital - HSE	1 Expert member
Crumlin Children’s Hospital	1 Expert member

National Maternity Hospital	1 Expert member
Independent Expert	2 Expert member
St. Luke's Hospital	1 Expert member
Letterkenny Hospital	1 Expert member
Cork University Hospital	1 Expert member
St. Vincents University Hospital	1 Expert member
HSE Estates	1 Expert member
O'Hara engineering	1 Expert member
HSE	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

One new member joined the committee in 2021.

5 Summary of 2021 Activities

5.1 National

Covid 19 Pandemic:

The pandemic, continued to impact standards work in 2021 with meetings held on-line. 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 did 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 2021.

5.1.1 Meetings

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

Meeting No.	Date	Minutes Reference ** optional**
1	24 th May	N1150
2	14 th Sept	N1159
Wiring SC	Number of meetings to finalise input on IEC FDIS CDV 60363-7-710 & equivalent CELENEC HD	See ETC/TC 10 Wiring SC documents

5.1.2 National Work

Some investigation was carried out among identified national stakeholders regarding use of a an historical ETC publications, ETC 218. The committee also reviewed the use of ETC 106. Both documents were reviewed with a view to a possible revision. In reviewing feedback from stakeholders and committee experts, a revision of these documents is not planned at this time. However this may be revisited as some time in the future.

The impact of new the newly published IEC 60364-7-710 and the expected CENELEC HD documents are also being reviewed by the committee to assess any impact on the national wiring rules – I.S. 10101. International/Regional

5.1.3 Meetings

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

Committee Name	Location	Date	No. of Attendees
IEC/TC 62 Plenary	Virtual	2021-04-23	1
IEC SC62A Plenary	Virtual	2021-04-15	1
IEC SC62B Plenary	Virtual	2021-04-20	1
IEC SC62C Plenary	Virtual	2021-04-13	1
IEC SC62D Plenary	Virtual	2021-04-19	1
CLC TC 62	Virtual	2021-05-27	2

5.1.4 International/Regional Work

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. There was one meeting of MT 40 with 3 national experts participating.

5.1.5 International/Regional Standards Reviewed

The work programme of both CLC/TC 62 and IEC/TC 62, SC 62A, 62B, 62C & 62D were monitored during 2021.

For CLC/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](#)

5.2 Regulatory Development/Update

Standards supporting the Medical Device Regulation (MDR) will be a key focus of the work programme for CLC/TC 62. The final approval of the European Commission mandate by CEN/CENELEC in May this year is a positive step however there are still issues with the HAS Consultant approval process in getting harmonised standards approved. Improvement of the process is ongoing between CEN/CENELEC, the Commission and the HAS consultants. The first implementing decision issued by the Commission in August lists the first harmonised standard for the MDR and IVDR and it is hoped further decisions adding to the list of standards will be issued in 2022. There was no change to deadline for standards revision for the MDR which is still May 27th 2024.

6 Irish Publications/Reviews

6.1 Publications

Currently there is no other national work under way.

7 Work programme for 2022 onwards

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.

8 Additional Information

None