BUSINESS PLAN

CENELEC/TC or SC	Secretariat	Date
62	United Kingdom	2018-11

Please ensure this form is annexed to the TC Report to the CENELEC Technical Board if it has been prepared during a meeting, or sent to CCMC promptly after its contents have been agreed by the Committee by correspondence.

TC or SC title: Electrical equipment in medical practice

A Background

CLC/TC 62 mirrors the work of IEC/TC 62 and its sub-committees. It works closely with IEC/TC 62 and publishes their standards without technical changes as European Norms, i.e., EN IEC standards. It is the policy of CLC/TC 62 only in exceptional cases to draft "Common Modifications" or to develop unique European standards. Delegates and experts in CLC/TC 62 are also active in IEC/TC 62.

IEC/TC 62 prepares international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

The EN IEC 60601 family is, with its collateral and particular standards, the foundation for safety of medical electrical equipment and systems in the European single market. Within the EN IEC 60601/80601[1] series, the particular standards address specific issues related to categories of medical devices in detail. Next to standards in the IEC 60601 family, IEC/TC 62 develops other standards and related publications, increasingly in collaboration with other Technical Committees in IEC and ISO.

In recent years, IEC/TC 62 has increasingly worked in the field of software, IT and networks and has developed new International Standards and other publications in that area.

Standards published by IEC/TC 62 and its subcommittees cover safety and performance for specific products, such as diagnostic imaging, radiotherapy, nuclear medicine, radiation dosimetry, electro-medicine, anesthesia, critical care, surgery, artificial respiration and pediatrics.

Where appropriate and if related to safety and performance, other aspects such as data security, integrity and privacy and radiation protection of patients, operators and environment are covered.

Where elements of "ambient assisted living" relate to equipment for healthcare, these are within the scope of TC 62. Ambient assisted living addresses items and features supporting persons with reduced ability in their daily life.

The world's leading experts are working within IEC/TC 62. Hardware and software engineers, physicists and physicians, and test engineers come from industry, hospitals, test houses, consulting firms, academia and governmental bodies. They have the specialized knowledge needed to understand how these products should be designed, produced, operated and maintained. Regulators from Europe, North America and Asia participate in this work.

As mentioned before, where appropriate, IEC/TC 62 and its Subcommittees cooperate with other Committees of IEC, ISO, or other organizations, based on the expertise each organization embodies. To ensure that International Standards in the healthcare sector fit together seamlessly, joint projects and standards combine expertise from other organizations.

[1] 80601 is the designation for particular standards ("parts 2") in the 60601 family that result from close collaboration of IEC and ISO. These standards may even have been developed under ISO-lead.

The ISO 14971 and the IEC/EN 60601 series enable medical electrical equipment manufacturers to produce safe and effective products, including complex systems and assemblies.

B Business Environment

B.1 General

External environment:

Healthcare services and the application of medical electrical equipment, healthcare software and IT networks are growing rapidly driven by the facts that

- the life-expectancy of the population is increasing,
- the population is significantly growing,
- there is an increasing impact of information technology,
- new technologies such as bioengineering are contributing,
- cost saving goals are gaining importance in medical practice and
- developing countries are generating new equipment markets.

Internal environment:

Regulation affecting medical devices is increasing with a growing emphasis on quality systems and standards. Within the European Union, compliance with standards plays a key role in demonstrating conformity with the Medical Devices Directive (MDD) 93/42/EC, Active Implantable Medical Devices (AIMD) 90/395/EC and In Vitro Diagnostic medical devices (IVD) 98/79/EC Directives. In 2017, two regulations were published for the sector of medical devices: 745/2017 for non-IVD medical devices, and 746/2017 for IVD medical devices. Regulation 745/2017 replaces both the MDD and the AIMD.

B.2 Market demand

Customers of standards:

Safety standards for healthcare equipment should meet the demands of users and manufacturers, legislative organizations and confirmatory and regulatory bodies. Solutions for diagnosis and treatment that are scientifically and ethically sound as well as cost effective are kept in focus.

IEC/TC 62 has achieved a considerable active representation of its standards users. However, further participation from the regulator's side as well as the medical and academic community is desirable. On this part, much is expected from the intended liaison between IEC/TC 62 and IMDRF; see below. The high rate of innovations in healthcare sets the pace for the development and maintenance of standards.

Medical electrical equipment within the scope of TC 62 is often complex, and affordable development costs along with the expected high performance to the benefit of the patient can be achieved on global markets only. For that reason, there is an increasing need for global harmonization of legislation and regulation and as a consequence for international rather than for local standards. This is why CLC/TC 62 in principle only adopts ENs that are identical to IEC/TC 62 standards. Where a standardization request cannot be fulfilled by a suitable IEC/TC 62 subcommittee, CLC/TC 62 installs a working group to carry out the drafting work and the final standard is published as EN 5xxxx.

The business environment of TC 62 requires a broad approach for product risk management. EN ISO 14971 and EN IEC 60601 Ed 3 cover the healthcare needs on safety and essential performance. The Committee has provided adequate risk management for compliance with legal and regulatory requirements specific in the healthcare area.

B.3 Trends in technology

Software and the integration of medical electrical equipment and systems with IT-networks will be an integral element affecting almost all aspects of the work of IEC/TC 62. This is one area where the changing technology is creating a demand for standards and other documents that is outstripping the ability of the traditional project model to deliver the needed documents in a timely manner. The TC will adapt its traditional ways of working to meet the demands both for international standards and for other document types (e.g. technical reports, technical specifications, publicly available specifications and industry technical agreements) that address the needs of a rapidly changing technological landscape. However, the full consensus process will continue to be applied for standards written to support regulation. This is repeated in the parallel CLC/TC 62 voting procedure.

Medical electrical equipment is of increasing importance in areas that were traditionally covered by non-electrical medical equipment. Also in order to keep track of the innovations in the healthcare field there will be an increasing need for cooperation with other organisations.

Highest reliability and cost effectiveness are essential.

Emerging new technologies such as “Artificial Intelligence”, “Augmented Reality”, and “Virtual reality”, have entered the domain of Electrical Equipment in Medical Practice and will become a significant feature for future equipment. Therefore, IEC/TC 62 will actively monitor these developments and collaborate with other Committees in ISO and IEC, such as SC 42 of ISO/IEC JTC 1, to determine when (AI)-specific guidelines or standards will need to be established.”

B.4 Market trends

The trade for medical electrical equipment is global whereas the regulatory environment is local to each specific jurisdiction. This lends emphasis and importance to an international approach to standardization and would call for wider regulatory adoption of the knowledge encompassed in these international standards.

The Global Harmonization Task Force (GHTF), with the aim of international convergence of regulations has been an important liaison with CLC/TC 62 until its disbandment end of 2012. The successor organization, the International Medical Device Regulator’s Forum (IMDRF) is the custodian of the GHTF legacy and has projects in place to support and enhance the wider adoption of international standards. Such projects include MDSAP, Essential Principles, and Improvement of Standards for Regulatory Purposes. It is expected that in 2018 IMDRF will become a category A liaison to IEC/TC 62. Through this connection, CLC/TC 62 effectively would liaise with IMDRF too.

Some countries tend to regulate the safety aspects of healthcare software the same way as of medical equipment. Healthcare Software and IT networks are increasingly subject to governmental regulation and often are classified as medical devices. Within the European Community, there is no fully coherent approach and that situation is expected to improve with appropriate standards. In European Countries requirements from machinery equipment have been introduced into the medical device regulations; however there are indications that the current revision of these regulations may undo such inclusion.

B.5 Ecological environment

Compatibility of the equipment to natural environment is of growing significance to users and manufacturers. Environmental protection is increasingly addressed in the standards. It is noted that, following the publication of IEC/PAS 63077, on refurbishment of medical imaging equipment, this document is now under development to become an International Standard. Also IEC 63120, another initiative in a similar context, is under development. Under safety related aspects the standardization on human interfaces in medical electrical equipment will be enforced.

B.6 Involvement of societal stakeholders

TC 62 participation is largely from manufacturers, test houses and certification bodies, understandable from the mirror function of TC 62. At the level of IEC/TC 62, however, this situation is different as, also through the system of national members, societal stakeholders have access to and participate in the actual work of drafting IEC standards that, normally, are adopted as ENs without modification of the normative parts. TC 62 officers from time to time contribute to the development of FAQs on standards aspects that help users of standards.

B.7 Involvement of SMEs

Representatives of NORMAPME have attended TC 62 meetings representing SMEs. They were made aware that CLC/TC 62 standards are drafted in IEC/TC 62 and comments need to be made on draft standards through the IEC route to be able to be taken into account. This is the only way to influence the development of standards adopted by TC 62. CENELEC Guide 17 “Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs” is known to TC 62.

C System approach aspects

System Committees (TC 62 as a supplier)

Medical electrical equipment and software are part of the hospital and homecare environment. Furthermore the standards of TC 62 are used to demonstrate compliance to the regulations in the Member Countries. TC 62 therefore encourages the participation of clinicians, health academics and medical device regulators.

Furthermore TC 62 maintains liaisons to stakeholder organizations representing its customers:

- ABHS (Advisory Board for Healthcare Standards)
- COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)

Within CENELEC, the following Committees refer to and use the standards of TC 62:

- SR 29: Electroacoustics
- TC 64: Electrical installations and protection against electric shock
- TC 76: Optical radiation safety and laser equipment
- SR 87: Ultrasonics

Component committees (TC 62 as a customer)

The standards of CLC/TC 62 reference the standards of the following Committees of CLC:

TC 8 Systems aspects for electrical energy supply

TC 16: Basic and safety principles for man-machine interface, marking and identification
TC 20: Electric cables
SC 23B: Plugs, socket-outlets and switches
SC 23G: Appliance couplers
TC 29: Electroacoustics
TC 31: Equipment for explosive atmospheres
SC 32C: Miniature fuses
TC 33: Power capacitors
TC 35: Primary cells and batteries
TC 39: Electronic tubes
TC 40: Capacitors and resistors for electronic equipment
TC 55: Winding wires
TC 61: Capacitors and resistors for electronic equipment
TC 64: Electrical installations and protection against electric shock
TC 70: Degrees of protection provided by enclosures
TC 72: Automatic controls for household use
TC 76: Optical radiation safety and laser equipment
TC 87: Ultrasonics
TC 89: Fire hazard testing
TC 96: Transformers, reactors, power supply units and similar products for low voltage up to 1100 V
TC 104: Environmental conditions, classification and methods of test
TC 108X: Safety of electronic equipment within the field of audio/video, information technology and communication technology
TC 109: Insulation co-ordination for low-voltage equipment
TC 111X: Environment
TC 112: Evaluation and qualification of electrical insulating materials and systems

D Objectives and strategies (3 to 5 years)

- Timely EN adoptions of IEC/TC 62 publications
- Feedback of European requirements to IEC/TC 62 particularly any negative assessments by the HAS consultant for the relevant EU legislation
- Encouraging active participation of CLC members at both CLC and IEC level
- Occasionally contribute to FAQs on CLC/TC 62 standards

E Action plan

All in D are on-going.

F Useful links to CENELEC web site

https://www.cenelec.eu/dyn/www/f?p=104:7:550000297343501::::FSP_ORG_ID,FSP_LANG_ID:1257161,25

TC home page giving access to Membership, TC/SC Officers, Scope, Publications, Work programme [password-protected area].