SMB/7261/SBP

STRATEGIC BUSINESS PLAN (SBP)

IEC/TC OR SC:	SECRETARIAT:	DATE:
TC 62	**Germany**	**Feb 03, 2021**

Please ensure this form is annexed to the Report to the Standardization Management Board if it has been prepared during a meeting or sent to the Central Office promptly after its contents have been agreed by the committee.

A. STATE TITLE AND SCOPE OF TC

Are there any new or emerging trends in technology that will impact the scope and work activities of the TC? Please describe briefly.

Do you need to update your scope to reflect new and emerging technologies? If yes, will these changes impact another TC's scope or work activities?

If yes, describe how these will impact another TC(s) and list the TC(s) it would impact

Title:

TC 62: Electrical equipment in medical practice

Scope:

To prepare 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.

NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy, artificial intelligence, robotics and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).

B. MANAGEMENT STRUCTURE OF THE TC

Describe the management structure of the TC (use of an organizational chart is acceptable) (should be integrated by CO automatically) and, if relevant (for example an unusual structure is used), provide the rationale as to why this structure is used.

Note: Check if the information on the IEC website is complete.

When was the last time the TC reviewed its management structure? Describe any changes made. When does the TC intend to review its current management structure? In the future, will the TC change the current structure, for example due to new and emerging technologies, product withdrawal, change in regulations etc. Please describe.

Make sure the overview includes:

- any joint working groups with other committees,
- any special groups like advisory groups, editing groups, etc.

Sub Committees:

SC 62A	Common aspects of electrical equipment used in medical practice
SC 62B	Diagnostic imaging equipment

SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry

SC 62D Electromedical equipment

Advisory and Working Groups:

AG 1 CAG Chairman Advisory Group

AG 2 IEC 60601 series architecture development

AG SNAIG Software, Networks and Artificial Intelligence Group

WG 4 Terminology

JAG 5 Life Cycle Aspects for Medical Devices

Note: Aside of these working groups at the TC62 level several JWG exist at the SC level. Information about these groups can be found via the dashboard of TC62

Liaisons:

Liaisons to IEC Committees

TC 29 Electroacoustics

TC 101 Electrostatics

TC 111 Environmental standardization for electrical and electronic products and systems

TC 124 Wearable electronic devices and technologies

SyC AAL Active Assisted Living

SyC LVDC Low Voltage Direct Current and Low Voltage Direct Current for Electricity Access

ISO / IEC JTC 1 / SC42 Artificial Intelligence

Liaisons to ISO:

ISO/TC 210 Quality management and corresponding general aspects for medical devices

ISO/TC 215 Health informatics

External Liaisons:

Category A

COCIR The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

EFOMP European Federation of Organisations for Medical Physics

IMDRF International Medical Device Regulators Forum

C. BUSINESS ENVIRONMENT

Provide the rationale for the market relevance of the future standards being produced in the TC.

If readily available, provide an indication of global or regional sales of products or services related to the TC/SC work and state the source of the data.

Specify if standards will be significantly effective for assessing regulatory compliance.

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

- the life-expectancy of the population is increasing,
- the world population continues to grow, particularly the percentage of elder persons,
- the per capita demand for healthcare is increasing,
- the impact of information technology is increasing,
- new technologies such as bioengineering are contributing,
- cost saving goals are gaining importance in medical practice and
- developing countries are generating new equipment markets.

The markets for medical devices and related services are global. The number of regional regulations affecting medical devices is increasing. More and more regulations refer to standards. The application of standards of IEC TC 62 and its SCs significantly eases the access to the markets of the European Union, USA, Japan and Australia. Countries like China, and nowadays India as well, require or are about to require the application of standards based on documents of IEC TC 62 and its SCs as technical market access requirements. New activities on global harmonization of regulations for medical devices resulted in several guidance documents of the international medical device regulators forum (IMDRF) which correlate with many standardization activities of IEC TC62.

As consequence, manufacturers, service providers and testing labs use international standards to develop and test products and services.

D. MARKET DEMAND

Provide a list of likely customers of the standards (suppliers, specifiers, testing bodies, regulators, installers, other TC/SC's etc.). Do not specify company names, only categories of customers.

The standards for healthcare equipment are used by manufacturers, legislative bodies, healthcare providers, test houses, notified bodies and regulatory bodies.

The standards and documents for healthcare in the scope of IEC TC62 support the United Nations Sustainable Development Goals (SDGs), especially SDG goal 3 'Safe medical devices'. TC62 also supports SDG goals 9, 10, 11, 12, 13 and 15 ('Industry, Innovation & Infrastructure', 'Equal access to global expertise', 'Sustainable urbanization', 'Responsible consumption & production', 'Climate action,' and 'Life on land.') in those parts correlated to medical practice

National Medical Device regulations are continuously updated. An example is the recently introduced Medical Device Regulation (MDR) in the European Union, which is causing a significant task to manufacturers world-wide and to notified bodies. The TC 62 standards are in constant evolution due to emerging technologies.

E. SUSTAINABILITY DEVELOPMENT GOALS

INDICATE THE SUSTAINABLE DEVELOPMENT GOALS (SDGS) THAT ARE ADDRESSED BY WORK WITHIN THE TC/SC. INDICATE EACH SDG INDICATOR AFFECTED (REFERENCE SPREADSHEET AVAILABLE AT https://www.iec.ch/SDG/, AND PROVIDE SPECIFIC INFORMATION ABOUT HOW THE TC/SC IS ADDRESSING THE SDG. CONSIDER BOTH DIRECT AND INDIRECT IMPACTS OF THE WORK OF THE TC/SC.

- ☐ **GOAL 1:** No Poverty
- ☐ **GOAL 2:** Zero Hunger
- ☒ **GOAL 3:** Good Health and Well-being
- ☐ **GOAL 4:** Quality Education
- ☐ **GOAL 5:** Gender Equality
- ☐ **GOAL 6:** Clean Water and Sanitation
- ☐ **GOAL 7:** Affordable and Clean Energy
- ☐ **GOAL 8:** Decent Work & Economic Growth
- ☒ **GOAL 9:** Industry, Innovation & Infrastructure
- ☒ **GOAL 10:** Reduced Inequality
- ☒ **GOAL 11:** Sustainable Cities and Communities
- ☒ **GOAL 12:** Responsible Consumption & Production
- ☒ **GOAL 13:** Climate Action
- ☐ **GOAL 14:** Life Below Water
- ☒ **GOAL 15:** Life on Land
- ☐ **GOAL 16:** Peace, Justice Strong Institutions
- ☐ **GOAL 17:** Partnerships to achieve the Goals

F. TRENDS IN TECHNOLOGY AND IN THE MARKET

If any, indicate the current or expected trends in the technology or in the market covered by the products of your TC/SC.

Electrically powered applications used in healthcare include a still growing number of hardware, software and data based technological solutions for diagnostic, therapeutic and health monitoring purposes. The following non-exclusive list gives some of the most important examples for that trends:

- robotic services in healthcare,
- wearable and smart devices,
- artificial intelligence in healthcare applications,
- 'big data' based diagnostics and therapy decisions,
- interoperable applications like in the concept of 'silent ICUs',
- connected medical devices in IT-networks,
- secure applications in healthcare networks,
- tele-medical applications,
- use of internet of things (IoT) capabilities in healthcare.

G. SYSTEMS APPROACH ASPECTS (SEE DIRECTIVES PART 1 ANNEX SP)

Does your TC/SC have a need for a systems approach?

If so:

- Will the Systems work be in a single TC or in multiple TCs?
- Will a Standardization Evaluation Group (SEG), Systems Committee (SyC), or Systems Resource Group be required?
- Is your TC/SC work of relevance to ISO?
- Is or are there fora or consortia working in parallel to IEC? Is there a chance to integrate this work in your TC/SC?

This should not only be restricted to the customer/supplier relationships with other TC/SCs indicating types of co-operation (e.g. liaisons, joint working groups) but be of a more generic nature.

Presently, there is no need for a systems approach as outlined in AC/33/2013. TC 62 operates using a systems approach in its activities, both internal and external. The TC regularly works collaboratively with other committees in IEC, ISO, and other organisations.
Note: The use of the term “system“ in this context should not be confused with the use of the term “medical electrical system”

IEC TC 62 collaborates with the following committees and organizations:

- IMDRF International Medical Device Regulators Forum (formerly GHTF Global Harmonization Task Force),
- COCIR, the European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries
- EFOMP European Federation of Organizations for Medical Physics, the umbrella organization for more than 9000 medical physicists and clinical engineers working in the field of medical physics,
- Technical Committees of regional standardization organizations,
- CENELEC TC 62

Various ISO Technical Committees including, but not limited to,

- ISO/TC 121 Anaesthetic and respiratory equipment
- ISO/TC 150 Implants for surgery
- ISO TC 210 Quality management and corresponding general aspects for medical devices
- ISO TC 215 Health informatics

Within the IEC the following Technical Committees refer to and use the standards of TC 62:

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

This list may not be complete.

The standards of IEC TC 62 and its Subcommittees reference the standards of the following Technical Committees of IEC:

- 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 65: Industrial-process measurement, control and automation
- 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 108: 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 112: Evaluation and qualification of electrical insulating materials and systems

H. CONFORMITY ASSESSMENT

With reference to Clause 33 of Part 2 of the ISO/IEC directives, are all you publications in line with the requirements related to conformity assessment aspects?

Will the TC/SC publications be used for IEC Conformity Assessment Systems (IECEE, IECEx, IECQ, IECRE)?

Will any of your standards include test specifications, reproducible test requirements, and test methods?

Are there likely to be special conformity assessment requirements generated by any standards projects? If yes, list which projects.

The publications of TC 62 are in line with clause 33 of Part 2 of the ISO/IEC directives. Most of the standards of TC 62 include test specifications, reproducible test requirements, and test methods.

I. 3-5 YEAR PROJECTED STRATEGIC OBJECTIVES, ACTIONS, TARGET DATES

STRATEGIC OBJECTIVES 3-5 YEARS	ACTIONS TO SUPPORT THE STRATEGIC OBJECTIVES	TARGET DATE(S) TO COMPLETE THE ACTIONS
Establishing a circular economy aspects plan for medical devices for the 'Green' circular economy including recycling, refurbishment and remanufacturing. The scope of the work should address basic safety and essential performance in a lifecycle perspective addressing the development, manufacture, use and decommissioning of these medical devices.	IEC TC 62 requests ISO TC 210 to establish a joint exploratory group	2018 done
	IEC TC 62 and ISO TC 210 agree on terms of the joint exploratory group	2020
	Publications	2024
4th edition of IEC 60601 series	Establish the architecture specification	2020 done
	Establish the design specification in SC 62A	2021
	Publication	Not before 2025
The importance of software and data supported applications in healthcare, like AI and "big data" supported applications, interoperable applications, secure applications, requires own activities and close cooperation with other committees and organisations in the software and IT network sector such as IEC/ISO JTC1 SC42, ISO TC 215, or DICOM.	The SNAIG starts its work to provide advice regarding these important topics.	2020
	The SNAIG includes at least 2 experts which are also part of other groups working on these	2020

	topics (e.g. ISO TC 215/AHG2 or ISO/IEC JTC1 SC42)	
	A flexible structure in TC62 is set up that allows to handle software and related topics (see E/technology) according to their importance in the market	2023
Note: The progress on the actions should be reported in the RSMB.		

Sustainable development goals.

TC 62 AND THE SUSTAINABLE DEVELOPMENT GOALS OF THE UNITED NATIONS
The United Nations has established their 2030 Agenda for Sustainable Development comprising 17 Strategic Development Goals (SDGs) covering such global challenges as the eradication of poverty and hunger, climate change, health, education, and economic growth for action by all countries. It is recognized that international bodies such as the IEC also have a key role. Consequently, IEC has published its own response to the UN initiative indicating synergies between the SDGs and IEC work programs. TC 62 contributes to several of the SDGs directly and indirectly, but to SDG3 our contribution is the strongest.

SDG 3 – Good health and wellbeing
Medical electrical equipment, electrical systems and software are important in the medical practice. They support the diagnose, the treatment and help restore or maintain good health and wellbeing. TC62 provides the standards to support medical service providers like physicians and nurses, enables patients a healthier life, but also supports the wellbeing as part of national health programs.

The possible effects of medical electrical equipment are predominantly beneficial, but only when adequate controls are in place. TC62 writes standards, who help especially but not solely the manufacturers to ensure safety and medical effectivity by technical means.

These standards are written considering that a good part of the electrical equipment in healthcare are regulated devices and that their usefulness for regulators is a factor in their potential to be beneficial for the patients and the societies.

SDG 9 – Industry, Innovation & Infrastructure,
SDG 10 - Reduced Inequality,
SDG 11 - Sustainable Cities and Communities,
SDG 12 - Responsible Consumption & Production,
SDG 13 - Climate Action and
SDG 15 - Life on Land

To avoid harm in the sense of injury or damage to the health of people, or damage to property or the environment (ISO/IEC guide 63:2019, 3.1) is one focus of the TC62's work. It supports therefore the safety of people, the security of the infrastructure as well as protects the environment in all aspects, which are related to the scope of TC62 irrespective of any financial or economic aspects.
The impact is often indirect and not immediately visible, but TC62 is aware of the impact regulated and non-regulated devices can have for these goals.