BUSINESS PLAN

CEN/TC 239

RESCUE SYSTEMS

EXECUTIVE SUMMARY

Business Environment

CEN/TC 239 is engaged in the standardization of ambulances as emergency medical vehicles and/or crafts and their associated accessories in the interests of providing safe and comfortable transport and pre-hospital treatment for patients.

The following European Council New Approach Directives are relevant to the work of CEN/TC 239:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

In close connection to the work of CEN/TC 239 are the following European Council Directive:

- Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles Directive
- Commission Delegated Regulation (EU) 2022/2236 of 20 June 2022 amending Annexes I, II, IV and V to Regulation (EU) 2018/858 of the European Parliament and of the Council as regards the technical requirements for vehicles produced in unlimited series, vehicles produced in small series, fully automated vehicles produced in small series and special purpose vehicles, and as regards software update
- Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC

Benefits

The standards developed by CEN/TC 239 support the uniform implementation of the requirements of the above-mentioned European Council Directives and Regulations.

The standards developed by CEN/TC 239 support the needs of industry but also of notified bodies, competent authorities, healthcare facilities, emergency medical services, emergency doctors and emergency medical personnel, patients and other users of emergency devices.

Priorities

CEN/TC 239 seeks to develop and maintain relevant up to date standards on emergency medical devices and associated accessories with the objective to provide safe and comfortable transport and pre-hospital treatment for patients.

1 BUSINESS ENVIRONMENT OF THE CEN/TC 239

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC 239, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Emergency medical services is organized emergency aid whose objective is to provide emergency patients with life-saving support and to facilitate their transportation − avoiding supplementary injury − in a safe and appropriate manner to a health facility/hospital. It is the aim to optimize prehospital care and facilitate transportation of patients including cross-border transfer and major disasters.

The standards of CEN/TC 239 are required by a large number of different parties. Interested parties in the standardization progress are manufacturers of medical devices and medical vehicles, emergency medical services, emergency doctors and emergency medical personnel, authorized bodies and their existing representative organizations.

Details about size of companies, customers, market share according to all countries are not available.

Organized emergency medical services are structured as follows:
− ground/surface emergency medical services;
− air emergency medical services;
− mountain emergency medical services;
− water emergency medical services.

The export and import of the products covered by the scope of CEN/TC 239 is not confined to the European market.

During the preparation and maintenance of standards on emergency medical devices and associated accessories, CEN/TC 239 considers the developments in emergency technologies but also in the design and construction of the medical devices that need to be processed. These developments include new processes, new equipment and techniques used for the monitoring of processes, new and very often sophisticated design of medical devices including the new materials used for their construction. These developments are a great challenge for CEN/TC 239 during the development of appropriate requirements and test methods for the equipment and also for its associated accessories.

Emergency medical devices and their associated accessories are used in different fields of applications. Standards of CEN/TC 239 have to address their specific needs and conditions. A number of the projects and standards of CEN/TC 239 are mandated under M/575 and are already (or will become in the near future) Harmonized European Standards. The relevant Regulation is (EU) 2017/745 on medical devices.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN /TC 239:

Political indicators:
International use requires standardized rules and guidelines for emergency medical services, particularly where different social priorities and cultures exist.

Social indicators:
An above-average social engagement is expected from emergency medical personnel and the emergency doctor. The selfless commitment of the personnel is a prerequisite for the success of the work to be carried out in emergency medical services.

Economical indicators:
Economic benefit shall arise through harmonization of the market in emergency medical services. Standardized medical devices can provide significant savings through economy of scale. Consequently standardization has a great influence on the production costs of the service. Therefore it is important to deliver emergency medical services in an effective way and to carry out quality assurance and management at each stage of the services operation.

Technical indicators:
Continuously rising technical requirements demand further harmonization regarding equipment, devices, quality assurance and materials. Interoperability and interface requirements for the continuity of patient care are necessary elements of the standards.

Legal indicators:
Standards on emergency medical services are necessary in order to support relevant EU Directives without duplicating the contents. The nature of emergency medical services can expose them to potential litigation if quality standards in services are not established and maintained.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 239

The standards developed by CEN/TC 239

- assist manufacturers of emergency medical devices and their associated accessories to demonstrate fulfilment of the applicable Essential Requirements of the Medical Device Directive and provide manufacturers, notified bodies, test houses with a clear route to CE marking;
- contribute to the elimination of trade barriers and favour the global market;
- support medium-sized enterprises;
- reduce costs by rationalisation of specifications for emergency medical devices and associated
- equipment particularly with regard to dimensions and performance, to allow interchangeability;
- ensure that equipment and accessories are supplied with the appropriate instructions and technical performance;
- provide agreed test methods;
- consider environmental aspects.

3 PARTICIPATION IN THE CEN/TC 239

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain

conditions. To participate in the activities of this CEN/TC 239, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC 239 AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC 239

The objectives of CEN/TC 239 are to develop and maintain up to date standards and in order:

- to achieve safe and effective transport, monitoring and treatment by standardizing medical vehicles and their medical devices;
- to develop standardized performance test procedures;
- to provide requirements on operator safety;
- to promote uniformity and clarity in understanding by adoption of standardized terminology.

4.2 Identified strategies to achieve the CEN/TC 239 s defined objectives.

Creating quality functional and testing requirements for emergency medical services. This ensures a safe application of emergency medical services for the variety of different uses. Emergency medical services require special knowledge and the development of useful standards by experts and within an own Technical Committee. For drafting standards, concepts of similar technologies are used for transparency, consistency and for synergy effects.

The work is carried out in working groups. If required, Joint Working Groups and ad hoc groups will be arranged at TC level and Working Group level respectively.

Liaisons have been established with other European and International Technical Committees in order to ensure coherency of standards work.

These other Technical Committees are:

- CEN/TC 192 “Fire and Rescue Service Equipment“
- CEN/TC 205 “Non-active medical devices“
- CEN/TC 215 “Respiratory and anaesthetic equipment“
- CEN/TC 251 “Health informatics“
- CEN/TC 259 “Medical alarms and signals“
- IEC/TC 62 “Electrical equipment in medical practice“
- ISO/TC 20 “Aircraft and space vehicles”
- ISO/TC 22 “Road vehicles“
- ISO/TC 215 “Health informatics”
- ISO/TC 121 “Anaesthetic and respiratory equipment“
- ISO/TC 173 “Assistive products“

4.3 Environmental aspects

Since the Technical Committee is focused on rescue service environmental aspects are of minor importance. Environmental aspects are being considered in e.g. the selection of test methods and alternative energies. In the case that environmental aspects become a matter, for example disposal of materials or toxic substances, they will be considered in the respective standards.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 239 WORK PROGRAMME

The availability of emergency medical services experts and financial support is limited. Drafting of standards on a continuous basis and in an appropriate time schedule is achieved only by sufficient participation of voluntary experts from TC member countries and sufficient government and industrial finance. Therefore, the voluntary power of the industry must be supported by means of mandates in order to achieve successful continuity of the standardization work.