BUSINESS PLAN

CEN/TC 215
RESPIRATORY AND ANAESTHETIC EQUIPMENT

EXECUTIVE SUMMARY

Business environment

The following European Council New Approach directive and regulation are relevant to the work of CEN/TC 215:

- Medical devices directive [93/42/EEC of 14 June 1993] up to 25 May 2020;
- Medical device regulation [2017/745/UE of 5 April 2017] from 26 May 2020.

The TC works in close collaboration with ISO/TC 121, with a number of common standards developed under the Vienna agreement, with either an ISO or a CEN lead, thus seeking to ensure common requirements internationally, both within and outside Europe.

Benefits

As harmonized European standards, providing a presumption of conformity with the Medical Devices Directive, the standards developed by CEN/TC 215 support the uniform implementation of the requirements of this Directive and a common understanding of the technical requirements between Competent Authorities, Notified Bodies, manufacturers and users.

Priorities

Some anaesthetic and respiratory care equipment is considered as life-critical, and consequently many CEN/TC 215 work items are mandated. Priority is given to life-critical equipment.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

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, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

The rapid development of electronic and computer technologies and their application to medical devices means that a growing proportion of the work programme is related to increasingly sophisticated devices. Compatibility with computerized systems for data transmission, patient record keeping and device intra-operability is becoming increasingly important. This trend will continue, but so will the existence of a market, especially in less developed countries, for simple, mainly mechanical or electromechanical devices. In all areas of the world, healthcare budgets are under pressure, and it is important that device costs are not unnecessarily increased by over-specification.

There is also changing emphasis in the care of patients that has led to a greater number receiving treatment in the home. CEN/TC 215, through its close collaboration with ISO/TC 121, has and is continuing to develop several standards specifically for use in this homecare environment.

Innovation, particularly fresh design and marketing approaches, is a feature of the medical device industry, and CEN/TC 215 Standards are framed in such a way that such development is not stifled or excluded.

Assessment and monitoring of patient parameters and device performance, coupled with the provision of relevant alarm and protection systems will continue to expand.

Litigation following patient injury is rapidly increasing in some parts of the world, and the adequacy or otherwise of ‘standardized’ devices is being used increasingly by prosecutors and defendants to support their arguments in courts of law.

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:

The prime objective of CEN/TC 215 is to ensure as far as possible the safety of the patient undergoing anaesthesia and/or respiratory therapy care. Other major safety-related aims are to safeguard the operator of the equipment, to ensure connectability and compatibility between devices and to ensure devices are supplied with proper labelling, appropriate instructions for use and technical performance data. In view of these aims, factors such as the structure, size and value of the market, percentage of gross domestic product and other financial parameters are of relatively low importance to the raison d’être of CEN/TC 215 and are consequently not detailed here.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

CEN/TC 215 was formed to prepare European standards for respiratory and anaesthetic equipment. Inhalation anaesthetic equipment is used to convey the correct anaesthetic agents and

medical gases to the patient at controlled flows and pressures and to conduct excess and expired gases safely away from the patient and operating room staff, whilst monitoring both the patient undergoing treatment and the equipment. Respiratory therapy equipment is used to provide oxygen or drug therapy to the patient both in the hospital and increasingly in the homecare environment.

Anaesthesia is 'the reversible elimination of all sensation' whereas analgesia is 'the reversible elimination of the sensation of pain' and one or the other is employed in almost all surgical procedures. Analgesia is used extensively in dentistry, which is covered in CEN/TC 55 but is also used in obstetrics and trauma care to relive pain. Anaesthesia is thus an everyday occurrence in even the smallest surgical facility but yet is a procedure which, if not practised and managed correctly, can be extremely hazardous. Some anaesthetic and respiratory care equipment is considered as life-critical, and consequently many CEN/TC 215 work items are mandated.

Respiratory care equipment comprises a broad range of devices, some e.g. lung ventilators, intended to initiate or maintain the breathing of patients who cannot breathe spontaneously or to assist those who can do so only with difficulty, others intended to supply therapeutic gases and medication via inhalation. Ventilators are therefore considered life-support devices.

Monitors are intended to measure/indicate critical machine parameters and physiological functions in patients undergoing anaesthesia and respiratory care to guide, inform and warn the clinician about the condition of the patient or the performance of the device.

3 PARTICIPATION IN THE CEN/TC

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, please contact the national standards organization in your country.

Active participants in CEN/TC 215 include clinicians, manufacturers, test house and certification body staff and government health ministry staff

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

4.1 Defined objectives of the CEN/TC

To prepare and maintain standards and other CEN deliverables concerning anaesthetic and respiratory equipment for which a need has been demonstrated. The standards and deliverables have one or more of the following functions:

- to ensure as far as possible the safety of the patient and the user;
- to ensure as far as possible appropriate and adequate device performance and function;
- to reduce unnecessary variation and to foster interconnectability and compatibility of devices;
- to provide a basis for testing, certification and regulation of devices;
- to provide a basis for comparison and assessment of devices to assist clinicians and purchasers in the selection and purchase of devices;
- to minimize obstacles to international trade.

The work is managed through the Technical Committee itself plus its four Working Groups:

- WG 1 Anaesthetic machines, medical breathing systems and anaesthetic gas scavenging systems
- WG 2 Lung ventilators
- WG 3 Medical gas supply systems
- WG 4 Tracheal tubes and other equipment

During the last years CEN/TC 215 became more and more a "mirror" committee to ISO/TC 121, i.e. its working groups are not active and do not meet (see e. g. items 4.1, last paragraph, and also 4.2.

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

To develop CEN standards and deliverables ab initio or by adopting (modified or unchanged) specifications etc. prepared by other organizations, particularly by close co-operation with the corresponding International Standards Committee ISO/TC 121.

With some exceptions (e.g. vocabulary), three types of standards are prepared:

- those specifying performance requirements;
- those specifying performance parameters to be disclosed by the manufacturers, together with appropriate test methods by which the disclosed parameters are to be measured;
- more rarely, dimensional and design specifications.

Other types of deliverable (e.g. Technical Reports) are, or will be, prepared as appropriate. Standards for electromedical equipment are normally prepared in the form of ‘Particular Standards’ (also known as Parts 2) of EN 60601-1 ‘Medical electrical equipment – Part 1: General requirements for basic safety and essential performance’ in which only the minimum number of additions to, deletions from, or changes to EN 60601-1 are made. Consideration is being given to closer working with electrotechnical committees, both internationally and within Europe.

Most of the work programme is divided between the various Working Groups with projects of interest to more than one Working Group being handled by CEN/TC 215 itself, by joint meetings of the relevant Working Groups or by ad hoc meetings of appropriate experts. Each Working Group sets its own priorities and targets within principles set by CEN/TC 215, noting that most of the projects of CEN/TC 215 are mandated and priority is given to such projects.

All or nearly all the types of device addressed by CEN/TC 215 publications are expected to remain in clinical service and therefore, unless the principles on which standards are maintained are changed radically, a significant part of CEN/TC 215 future work will be concerned with the periodic review and updating of an increasing portfolio of publications.

4.3 Identified strategies to achieve the CEN/TC's defined objectives

CEN/TC 215 takes into account potential environmental issues associated with respiratory and anaesthetic equipment. The committee has agreed to consider effects on the environment during the preparation and revision of new work items taking account of the information and environmental check list given in CEN Guide 4 "Guide for addressing environmental issues in product standards"

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

Despite intravenous anaesthesia having been around for 30+ years there is still a need for inhalational anaesthesia equipment which will need updating as electronic technology continues to develop. The increasing change to homecare treatment of patients has led to the need for respiratory therapy equipment to be made safe in the hands of non-medically trained persons such as the patients themselves their carers and relatives.

CEN/TC 215 has consciously decided to relinquish all its work items to ISO/TC 121 and will in future through its close liaison and involvement adopt ISO/TC 121 standards through either the Vienna Agreement route or adoption of the published ISO standard as an EN ISO without modification.