

BUSINESS PLAN

CEN/TC 204

STERILIZATION OF MEDICAL DEVICES

EXECUTIVE SUMMARY

Business Environment

The following New Approach EC Directives are relevant to the work:

- Medical devices [93/42/EEC of 14 June 1993];
- Active implantable medical devices [90/385/EEC of 20 June 1990];
- *In-vitro* diagnostic medical devices [98/79/EC of 27 Oct 1998].

These Directives are currently under revision.

TC 204 works in close collaboration with ISO/TC 198 under the Vienna agreement, with either ISO or CEN lead, thus ensuring common requirements within and outside Europe.

Parties involved:

- Medical devices manufacturers, large and small (including in vitro diagnostic medical devices);
- Medical devices users/professional societies;
- Providers of healthcare (public and private);
- Regulatory bodies;
- European Commission

Benefits

- to assure appropriate sterilization of medical devices and thereby reduce the risk of infection;
- to assist manufacturers to demonstrate fulfilment of essential requirements of the Medical Device Directives;
- to provide presumption of conformity with these essential requirements;
- to support and promote uniform implementation of the requirements of these Directives and a common understanding of the technical requirements.

Priorities

To develop standards for:

- designation of medical devices as sterile
- sterilization of medical devices by common sterilization methods, i.e. ethylene oxide, radiation and moist heat;
- supporting activities such as bioburden determinations and on information to be provided for re-processing of re-sterilizable medical devices;
- other possible sterilization methods and aseptic processing.

1 BUSINESS ENVIRONMENT OF THE CEN/TC 204

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:

Legal factors

The following European Council Directives are relevant to the work of CEN/TC 204: Medical devices [93/42/EEC of 14 June 1993], Active implantable medical devices [90/385/EEC of 20 June 1990] and the *In-vitro* diagnostic medical devices [98/79/EC of 27 Oct 1998]. All are new approach Directives. Work is advanced in the European Council and European Parliament to revise the *In-vitro* diagnostic medical devices Directive, and revise and combine the medical devices and active implantable medical devices Directives, with the revised legislation to be published as Regulations.

International trade

The TC works in close collaboration with ISO/TC 198, Sterilization of health care products, with a number of common standards developed under the Vienna agreement, with either an ISO or a CEN lead, thus ensuring common requirements internationally, both within and outside Europe.

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:

Interested parties

- Medical devices industry (including *in vitro* diagnostic medical devices)
- Medical devices users/professional societies
- Providers of healthcare (public and private)
- Regulatory bodies
- European Commission

Structure of market

- Mix of large, multinational companies, medium-sized companies to very small manufacturers;
- Customers range from large healthcare institutions and public or private purchasing organizations to the general public.

General

The Standards developed by CEN/TC 204 are intended to be used by manufacturers of medical devices to be placed onto the European market that are provided in a sterile state or provided non-sterile with the intention of being sterilized by the user prior to use. Interested parties are:

- manufacturers of such medical devices;
- regulatory and conformity assessment bodies;
- healthcare organizations and institutions as users of sterile medical devices;
- professional users of medical devices; and
- patients on whom these medical devices will be used, and as appropriate their care givers, and who seek assurance that the medical devices will present no undue health hazards.

An increased focus on quality management systems to assure product safety and performance in healthcare and on patient safety from the general public, as well as from media and from politicians, highlights the importance of the standards developed by CEN/TC 204.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The standards developed by CEN/TC 204 are intended to assist manufacturers of sterile medical devices, and manufacturers of medical devices supplied non-sterile but intended to be sterilized prior to use, to demonstrate fulfilment of essential requirements for safety and performance of the Medical Devices legislation. Therefore, they are essential components of the quality assurance programme for manufacturers of such medical devices.

As harmonized European standards providing a presumption of conformity with the Medical Devices legislation, the standards developed by CEN/TC 204 support the uniform implementation of the requirements of this legislation and a common understanding of the technical requirements between Competent Authorities, Notified Bodies, manufacturers, purchasers and users.

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.

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

4.1 Defined objectives of the CEN/TC

Elaboration of standards on processes for the sterilization of medical devices, mainly the development, validation and routine control of such processes.

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

The two strategies employed by TC 204 to achieve its objectives have been:

- i) strict prioritization of its work; and,
- ii) effective co-operation with ISO TC 198 to maximize the use of available resources, including expertise.

Prioritization

Priority 1

The first priority of the TC has been to develop standards specifying requirements for medical devices to be designated sterile. This has been achieved. The requirements for designating a terminally sterilized device as sterile have been published and subsequently revised in two parts (one dealing with terminally-sterilized medical devices and the other with aseptically-produced medical devices). The part dealing with terminally-sterilized medical devices has been confirmed at review and the part dealing with aseptically-processed medical devices has been revised and is circulating for CEN enquiry.

Priority 2

The second priority has been to develop standards for the validation and routine control of the three most common sterilization methods; ethylene oxide, radiation and moist heat. This too was fulfilled. The standards have been published and revisions, prepared under the Vienna Agreement with ISO lead, have either been published.

Priority 3

A third priority has been to develop standards that support the effective implementation of consistent processes for validation and routine control of sterilization, or the implementation of sterilization processes for medical devices supplied non-sterile and requiring sterilization prior to use, namely:

- i) microbiological methods for performance of bioburden determinations and performance of tests of sterility in developing and validating sterilization processes, and
- ii) information to be provided by manufacturers for re-processing of re-sterilizable medical devices

Priority 4

A fourth priority has been to develop standards for sterilization processes that are applied less commonly for medical devices, namely:

- i) standards for aseptic processing of medical devices,
- ii) a general standard covering other potential sterilization methods, which has also been used as a template for a common structure for standards on validation and routine control of sterilization processes,
- iii) a standard for development, validation and routine control of sterilization of medical devices incorporating components of animal origin by liquid sterilants,
- iv) a standard for validation and routine control of sterilization of low temperature steam and formaldehyde, and
- v) a standard for development, validation and routine control of sterilization by dry heat.

Collaboration

As mentioned above, the TC works in close collaboration with ISO/TC 198 to develop common European and international standards. Much of the work has been completed and the attention of the committee is focused on maintaining the portfolio of standards that it has developed. The continued technical suitability of these standards is kept under review and revisions or

amendments are prepared and approved as appropriate. Members are actively involved in the revision or amendment process and the TC monitors the activity to ensure that the resulting standards meet the needs of the European Medical Devices legislation.

It has been an obvious principle for the TC to work through a number of WGs, each working on one standard or a group of related standards.

A number of other Technical Committees work on subjects related to those of TC 204. It has been natural to create liaisons with them (e.g. CEN/TC 102, CEN/TC 205 and CENELEC/TC 62).

4.3 Environmental aspects

The standards prepared by TC 204 are process standards and neither product standards nor service standards. The potential environmental effects of sterilization processes will vary by process and would arise from the potential for accidental or deliberate release of substances that might have a negative environmental impact. The format for standards on development, validation and routine control has a section entitled 'Safety and the environment'. This section requires assessment of any the environmental impact from the sterilization process together with the identification and recording of any necessary control measures.

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

Few constraints on the completion of the TC's work programme are foreseen. However, the involvement of experts from regulatory authorities has been declining over time and it has been difficult to obtain the involvement of experts from conformity assessment bodies, making it necessary to pay close attention to the balance of participation on Working Groups and the inclusion of appropriate requirements in the resulting standards that address the regulatory expectations.