BUSINESS PLAN

CEN/TC 243
Cleanroom technology

EXECUTIVE SUMMARY

Technical Committee CEN/TC 243 is engaged in standardization and classification of cleanrooms and other such controlled environments and in the fixing of criteria for controlling contamination in such spaces. This includes the consideration of: guidance on the design, construction and operation of such environments, taking into account sources of contamination, including air, liquids, materials, equipment and personnel as well as the interactions between these; provisions for airborne contamination control (particulate, chemical and biological); provisions for surface contamination control (particulate and chemical); assessment of equipment suitability for use in cleanrooms; good practice for achieving energy efficiency. Methods of aseptic processing are excluded, as are methods of cleaning and disinfection except with particular reference to inert surfaces in cleanrooms.

CEN/TC 243 works closely with international committee ISO/TC 209, under the terms of the Vienna Agreement. The standards thus developed are generic in nature, being applicable in industries as diverse as the aerospace, automotive, defence, food, electronics, healthcare, nuclear, pharmaceutical and semiconductor industries.

CEN/TC 243 seeks to develop and maintain relevant and up to date standards, which will support the needs of industry and back up relevant legislation. The areas of national and international activity where such standards may be used are potentially very great, since they include all the industries listed above.

CEN/TC 243 liaises with other European and international bodies to ensure its standards take due account of related work being undertaken elsewhere. In particular, it liaises with the European Medicines Agency concerning its development of European GMP Guidelines.

1 BUSINESS ENVIRONMENT OF CEN/TC 243

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.

There are numerous major industries with a substantial user interest in cleanroom technology for the purposes of ensuring safety and process control. They include the aerospace, automotive, defence, food, electronics, healthcare, nuclear, pharmaceutical and semiconductor industries. In addition, hospitals and the scientific research community employ cleanroom technology widely. The growth of industries relying on nanotechnology will also entail a significant increase in the use of cleanroom technology.

Governments, public authorities and regulatory bodies have a significant interest in cleanroom technology for the purpose of regulation, primarily in the areas of healthcare and pharmaceuticals.

The increasingly international nature of the cleanrooms industry has given rise to a corresponding need for international standards to satisfy the convergence of requirements in the global market. This is noticeable both at the level of commercial cooperation across borders and at the level of regulatory enforcement, where at present there is a diversity of requirements from one country to another. Governments and public authorities with regulatory duties are showing increasing support for the use of standards as a means of regulation and the development of European and international standards for the cleanrooms industry will contribute to the establishment of controls reflecting the market. The support of the regulatory bodies is likely to grow even more with the desire for increased controls in response to public concern about methods of food production.

Although the preparation of European/international standards for cleanroom technology is not under mandate from the European Commission in support of a European Directive, they are likely to be of importance as a means of regulation in Europe. For example, the European legislative framework for the production of pharmaceutical products is one in which cleanroom technology standards play a major role. Likewise they have been endorsed for use elsewhere, for example by the Food and Drugs Administration in the United States.

In many instances, the use of cleanrooms standards can be expected to be applied in conjunction with standards for management systems, such as the EN ISO 9000 and EN ISO 14000 series.

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 CEN /TC 243.

The business environment and the corresponding market structure is one in which companies of all sizes are concerned, with market shares being divided primarily between the United States, Europe and the Pacific rim. A majority of the trade is international. The cleanrooms industry is high technology and requires considerable investment, which in Europe can involve a degree of grant support, e.g. in the form of E. U. regional funding via national agencies. Turnover is high and increasing as the hygiene and, especially, the food industry controls its production environments to a greater degree. Present studies of food production, e.g. in connection with the use of genetically modified organisms, will lead to increased use of controlled environments.

2 BENEFITS EXPECTED FROM THE WORK OF CEN/TC 243

The business environment described in 1 above has benefited and continues to benefit from progress in the work of CEN/TC 243 and its ISO counterpart, ISO/TC 209. This activity has the potential to contribute greatly to the harmonization of national and regional standards for cleanroom technology. In particular, the requirement for CEN members to adopt European Standards as their national standards plays a particular part in aligning requirements across Europe. Noting in particular that these standards, in their ISO form, now receive wide acceptance in the United States and elsewhere, e.g. in place of Federal Standard 209E-1992 (withdrawn in favour of ISO 14644-1:1999), the benefits of their development are clearly very considerable.

3 PARTICIPATION IN CEN/TC 243

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 by 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 CEN/TC 243 AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of CEN/TC 243

CEN/TC 243 has undertaken to develop standards addressing the following aspects of cleanroom technology:

a) Cleanrooms and associated controlled environments

- classification of air cleanliness
- testing and monitoring to ensure continued cleanliness
- test methods for evaluating cleanroom performance
- design and construction of cleanrooms
- operation of cleanroom facilities
- terms and definitions used in cleanroom technology
- separative enclosures (e.g. clean air hoods, gloveboxes, isolators and minienvironments)
- monitoring of airborne chemical contamination
- monitoring and measurmement of surface particulate and chemical contamination

b) Biocontamination control in cleanrooms

- general principles and methods
- evaluation and interpretation of biocontamination data
- provisions for airborne biocontamination control

c) Assessment of equipment suitability for use in cleanrooms

d) Good practice for achieving energy efficiency in cleanroom operation

N.B. The above list does not reflect exactly the titles of the work items of CEN/TC 243. For these, reference should be made to both those CEN/TC 243 standards already published and to the current CEN/TC 243 work programme, as can be found on the CEN website.

Of the above, the document giving the classification of air cleanliness may be considered the primary document, on which the others will depend.

4.2 Identified strategies to achieve CEN/TC 243's defined objectives.

CEN/TC 243 will pursue the following strategies to achieve its objectives:-

(i) production of generic standards, which can be employed across the full range of industries in which cleanrooms are found;

(ii) use of the Vienna Agreement as far as possible, whereby duplication of effort between CEN/TC 243 and ISO/TC 209 will be avoided;

(iii) in common with the majority of international standards work, the use of English as the working language up to the time of issue of a draft for public enquiry;

(iv) liaison with appropriate other bodies, at present including:

- ISO/TC 209 'Cleanrooms and associated controlled environments'

- CEN/TC 195 'Air filters for general air cleaning'
- CEN/TC 204 'Sterilization of medical devices'

- European Confederation of Medical Devices Associations
- European Medicines Agency (informal liaison)

To further the liaison between CEN/TC 243 and ISO/TC 209, European meetings will normally be held 'back to back'. It may be noted that the European members of ISO/TC 209 have a major influence on the direction of that committee, by virtue of their numbers, and that CEN/TC 243 is potentially a forum for rationalizing/streamlining the European participation in the international committee.

4.3 Environmental aspects

While environmental considerations will not impinge directly on all work items of CEN/TC 243 (e.g. work items relating to the classification of cleanrooms and related spaces will not require energy and material consumption to be addressed), other work items of the committee may be considered very relevant in an environmental context, e.g. the new work to address energy efficiency in a cleanroom setting.
Attention is drawn to the expectation of CEN that environmental considerations will be taken into account in all CEN new work item proposals.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 243 WORK PROGRAMME

Shortage of resource

As a general rule, the importance of these standards to industry ensures that sufficient resources are volunteered to carry out the drafting work and other tasks, without a shortage being perceived. There have been isolated instances in the work so far, where absences have reduced the effectiveness of debate, but overall this is not considered a serious problem, especially in

consideration of the fraction of the world cleanrooms market for which Europe is responsible (estimated at 30-35 %, including European facilities owned by non-European companies.

Lack of expertise

Likewise, the necessary expertise is anticipated (and has been found thus far) to be available for all the technical areas covered. This is due in part to the cohesion of the series of standards as a whole, which allows for a high degree of cross-fertilization in the drafting of the separate documents.