



# STRATEGIC BUSINESS PLAN

## ISO/TC 209

### EXECUTIVE SUMMARY

The following are examples, but not an exhaustive list, of industries requiring cleanrooms and controlled environments:

- aerospace
- assorted consumer products
- automotive
- biotechnology
- defense
- electronics
- food
- healthcare
- life sciences
- nanotechnology
- nuclear
- optics
- scientific research

Conservative estimates would place the overall size of each end-user market served by these industries for products produced in cleanrooms in the range of trillions of dollars (US\$) per year.

## **Benefits already realized and/or expected through the availability of the standards.**

The international nature of the cleanroom industry has increased the need for corresponding international standards for use in the global market. Since the organization of ISO/TC 209 in 1993, significant progress has been made in developing a family of standards to specify cleanrooms that has significantly reduced the duplication of national standards. Therefore, the development of international consensus standards for cleanrooms contributes to requirements reflecting the ever changing market. The support of regulatory bodies may be likely to increase even more in response to public concerns about methods of production of consumer products. Even in the United States where these standards will be voluntary, it is likely that the international standards will be recognized by governmental regulatory bodies such as the Food and Drug Administration.

## **Main objectives and priorities in the work of the committee**

The primary objectives and priorities in the work of ISO/TC 209 are to develop and keep up to date a family of generic international standards to address the needs specific to cleanrooms and associated controlled environments used to control contamination and environmental parameters that may affect the quality and performance of products, and services, found in the fields of applications. Associated controlled environments include separative devices, applying barrier technologies such as clean air hoods, glove boxes, isolators, biosafety cabinets, and minienvironments. The standardization work includes all aspects of the life cycle of a facility including design, construction, testing, and operations with respect to contamination control and control of the indoor environment. Emerging topics for cleanrooms include sustainability, nanotechnology, process suitability, energy reduction, robotics, AI applications to cleanrooms and controlled environments, cell therapy and advanced therapeutics, and clean controlled environments requiring containment.

## **1. INTRODUCTION**

### **1.1 *ISO technical committees and business planning***

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize various different standards projects, to identify the benefits expected

from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

## **1.2 *International standardization and the role of ISO***

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

## **2. BUSINESS ENVIRONMENT OF THE ISO/TC**

## **2.1 Description of the Business Environment**

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

Cleanrooms and associated controlled environments are high technological elements of various global industries requiring contamination control and environmental control within a facility. Associated controlled environments include separative devices such as clean air hoods, glove boxes, isolators, and minienvironments. Cleanrooms utilizing hardware and operational procedures protect the interior from external and internally-generated environmental contaminants. Sustainability considerations include the electrical energy required per the area footprint of the facility and consumable supplies. Substantial and ongoing user interest in cleanroom technology exists in the industries described in the Executive Summary.

Recent technological advances in genetics and genetically-engineered food products will lead to increased use of cleanrooms and associated controlled environments. In addition, increased public concern for hygiene and safety in food processing and consumer products and a growing market for pharmaceuticals, personalized medicines, and cell therapy products, will lead to a demand for more and better controls in the production environments.

The international nature of the cleanrooms industry is bringing about an increasing need for corresponding international standards for use in the global market. This need 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. Governmental agencies and other public regulatory organizations are demonstrating increasing support for the use of consensus standards as a means of regulation. Therefore, the development of international standards for contamination control in the cleanrooms industry will contribute to the establishment of control measures reflecting the market. The support of regulatory bodies may likely increase even more in response to public concerns about methods of food and pharmaceutical production. Even in the United States where these standards will be voluntary, it is likely that international standards will be recognized by governmental regulatory bodies such as the Food and Drug Administration.

Industries served by ISO/TC 209 demand that the documents are reflective of best practices, reliable, scientifically valid, up to date and relevant.

## **2.2 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 ISO/TC:

The affected industries employ millions of workers world-wide, with annual trade estimated in the trillions (US\$). The growing relaxation and elimination of international trade and technological barriers will cause the global market for these industries to continue to increase.

CEN Technical Committee 243 has already published the standards developed by the TC under the Vienna Agreement. Additionally, the CEN/TC 243 work programme is coordinated with the production of ISO/TC 209 standards.

Other national bodies represented as “P” members of the ISO/TC 209 have adopted the standards developed by the TC, as well.

### **3. BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC**

The documents produced by ISO/TC 209 mitigate much of the confusion caused by a multiplicity of national standards in the industries served by the TC. Additionally, by producing a “family of standards” related to cleanrooms and associated controlled environments, the TC will eliminate much of the duplicity of effort, time, and resources currently spent in producing and updating national standards.

The world-wide community of users of the standards will benefit by having the ISO standards available as generic requirements. National standards-writing bodies or their agents can then address the specific needs of the various industries in writing more specific guidelines for those industries.

## 4. REPRESENTATION AND PARTICIPATION IN THE ISO/TC

### 4.1 Membership

<https://www.iso.org/committee/54874.html?view=participation>

### 4.2 Analysis of the participation

The “P” members of the TC generally represent industrialized countries; however, developing countries join as “O” members as growing and evolving domestic industries require cleanrooms. “O” members may migrate to “P” members as industrial levels grow.

Because of the high technological focus of the cleanrooms industry, developing countries may find it difficult to actively participate in the TC activities due to a shortage of experts with background and experience in the cleanroom industry. Financial and human resources available to developing nations for participation may also be a factor.

Established “P” members may be challenged by retirement of industry leaders and ability to recruit the next generation of experts. Current issues have had a significant effect on ability to travel to TC meetings.

In order to encourage participation, ISO/TC 209 schedules its meetings back-to-back with other conferences in the contamination control industries. Also, working group meetings are often scheduled prior to the plenary in the same venue to facilitate communication, increase participation, and reduce travel expenses. Each participating nation is given a chance to host the meeting in its country or region. The TC also conducts as much business as possible via electronic communication. In particular, the use of web based conferencing is encouraged for working group meetings.

Liaison members of ISO/TC 209 are as follows: CEN/TC 243 Cleanroom technology; ISO/TC 24/SC4 Particle characterization including sieving; ISO/TC 34/SC9 Food products; ISO/TC 142 Cleaning equipment for air and other gases; ISO/TC 146 Air quality; ISO/TC 198 Sterilization of healthcare products; ISO/TC 210 Quality management and corresponding general aspects for medical devices; ISO/TC 229 Nanotechnologies; and ICCCS (International Confederation of Contamination Control Societies).

## 5. OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

### 5.1 *Defined objectives of the ISO/TC*

- a) Maintain a road map to identify standardization needs, reflecting industrial advancement and continuously improve development processes.
- b) Revisit the Scope of ISO/TC 209 by 2023, and update, if necessary.
- c) Continue with publishing introductory outreach information for the ISO/TC 209 family of standards.
- d) Include sustainability requirements in all new standards and revisions from 2021 onward.
- e) Investigate new areas and technologies requiring clean operations, as well as standardization of new techniques for cleanrooms and clean spaces.

### 5.2 *Identified strategies to achieve the ISO/TC's defined objectives*

- a) Continue running a group to advise the TC and maintain a roadmap to identify future standardization needs and projects within its remit.
- b) The ISO/TC and Working Groups preference is to conduct their business by electronic means including web based meetings and to minimize physical meetings whenever possible.
- c) The ISO/TC 209 plenary meeting is scheduled at least annually.
- d) Apply ISO custom of rotating face to face physical meetings for the plenary and working group meetings globally.

- e) Production of generic standards (including TS and TR) which may be employed across the whole range of industries and applications in which cleanrooms and controlled environments can be found.
  
- f) Outreach to countries with emerging industries requiring cleanrooms and associated controlled environments to stress the advantages of actively participating in ISO/TC 209 standardization work.
  
- g) Application of the Vienna Agreement, whereby duplication of effort between European standards-writing bodies such as CEN/TC 243 and ISO/TC 209 will be avoided.
  
- h) In common with the majority of standards, the use of English as the working language up to the point of issue of a draft for public inquiry.
  
- i) Continued liaison with appropriate other bodies.
  
- j) ISO TC 209 shall consider the use of Joint Working Groups with other TCs for specific topics. This will offer additional expertise and expand the worldwide use of specific documents.

## 6. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Possible risk factors to the completion of the standards or business community acceptance and use of the ISO/TC 209 standards are:

a) Shortage of resources. Historically, as a general rule, the importance of these standards to industry has ensured that sufficient resources are volunteered to perform the drafting work. Businesses will continue to be challenged with restrictions on travel. This can be mitigated by the use of virtual meetings.

b) Lack of technical expertise. This is mitigated by the division of the standards into separate parts. This diminishes the need for a participant to be an expert in all fields related to contamination control in cleanrooms and also promotes cross discipline discussion. Also, interaction with professional societies can increase the interest of experts in participation.

c) Delay in developing standards. The industry need for the standards is great, and all reasonable haste must be maintained while conforming to ISO Directives requirements for consensus so that high quality standards are available as soon as possible. Obtaining the translations required can delay the publication of documents. Concise, accurate, well-organized documents will be emphasized during development to reduce the effort and time required in publication.

d) Lack of standards development knowledge. The TC members are encouraged to train their experts, conveners, project leaders and members of their delegation with ISO or member body training programs on what is the most appropriate route to standardization (IS, TS or TR) and on continuously seeking consensus among experts. Adoption and training of the project management principles developed by ISO are a best practice to improve efficiency of document development.

## **7. STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC**

### **Information on ISO online**

The link below is to the TC's page on ISO's website:

***<https://www.iso.org/committee/54874.html>***

Click on the tabs and links on this page to find the following information:

- About (Secretariat, Secretary, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools
- Work programme (published standards and standards under development)

### **Reference information**

***Glossary of terms and abbreviations used in ISO/TC Business Plans***

***General information on the principles of ISO's technical work***