

# Update of ISO Technical Committee 209 Cleanrooms and Associated Controlled Environments

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## Keywords

ISO/TC 209, standards, cleanrooms

## Abstract

International Organization for Standardization (ISO) Technical Committee (TC) 209's first meeting was held in November 1993. The focus was on cleanrooms and controlled environments and the activities within cleanrooms. The TC has moved in recent years to generic operations documents such as a systematic approach for procuring disposables and particle deposition rate monitoring to improve the quality of products manufactured in a cleanroom. ISO stresses development of standards with requirements to support sustainability. A recently published standard on energy management in a cleanroom supports that need. ISO has a range of publication formats with different rigor in balloting to reduce document development being considered by the TC. ISO/TC 209 begins its third decade taking a more integrated approach to standardization with the goal of responding to the needs of industry.

## 1. Introduction

ISO Technical Committee (TC) 209 was organized in 1993 with American National Standards Institute ANSI (USA) holding the Secretariat. The administration of the Secretariat was delegated to the Institute of Environmental Sciences and Technology (IEST). The motivation for organizing the TC at that time was the need to simplify global cleanroom commerce due to the large number of national airborne particulate cleanliness classification standards with differing requirements. The TC focuses on cleanrooms and the activities within cleanrooms to improve quality of outcomes for research, development, manufacturing, and construction activities. There are 25 participating member organizations and 21 observer member organizations.<sup>[1]</sup> The decisions taken and some supporting information in the 2019 Plenary Meeting held in Chicago and the 2020 Web Based Plenary meeting held virtually are summarized in this report. The COVID-19 pandemic forced the holding of all meetings virtually instead of face-to-face starting in early 2020 through 2021. One of the goals in the last few years was to improve the TC's processes by forming a Strategic Study Group to evaluate various developmental approaches.

## 2. Work Program

The current work program of ISO/TC 209 is summarized in Table 1. There is a significant level of activity planned for the next several years.

**Table 1**—*Projects under ISO/TC 209 “Cleanrooms and associated controlled environments”*

| Document Number                      | Title of Part   | Date for next action | Action  |
|--------------------------------------|---|----------------------|---|
| ISO 14644-1:2015 (Ed. 2)             | Classification of air cleanliness by particle concentration   | 2025                 | Standard published  |
| ISO 14644-2:2015 (Ed. 2)             | Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration    | 2025                 | Standard published  |
| ISO 14644-3:2019 (Ed. 2)             | Test methods  | 2024                 | Standard published; Corrected version issued                  |
| ISO 14644-4:2001 (Ed. 1)             | Design, construction, and start-up  |                      | Revision in progress  |
| ISO 14644-5:2004 (Ed. 1)             | Operations  |                      | Revision started in 2021                                      |
| ISO 14644-7:2004 (Ed. 1)             | Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)                               |                      | Revision will start in 2022                                   |
| ISO 14644-8:2013 (Ed. 2)             | Classification of air cleanliness by chemical concentration (ACC)   |                      | Minor revision without altering technical content underway    |
| ISO 14644-9:2013 (Ed. 1)             | Classification of surface cleanliness by particle concentration   |                      | Minor revision without altering technical content underway    |
| ISO 14644-10:2013 (Ed. 1)            | Classification of surface cleanliness by chemical concentration   |                      | Minor revision without altering technical content underway    |
| ISO 14644-12:2018                    | Specifications for monitoring air cleanliness by nanoscale particle concentration                               | 2023                 | Standard published  |
| ISO 14644-13:2017 (Ed. 1)            | Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications | 2022                 | Standard published  |
| ISO 14644-14:2016 (Ed. 1)            | Assessment of suitability for use of equipment by airborne particle concentration                               | 2021                 | Standard published  |
| ISO 14644-15:2017 (Ed. 1)            | Assessment of suitability for use of equipment and materials by airborne chemical concentration                 | 2022                 | Standard published  |
| ISO 14644-16:2019                    | Energy efficiency in cleanrooms and separative devices  | 2024                 | Standard published  |
| ISO 14644-17: 2020                   | Particle deposition rate application  | 2025                 | Standard published  |
| ISO 14644-18                         | Assessment of suitability of consumables  |                      | Under development   |
| ISO 14698-1:2003 (Ed. 1)             | Biocontamination control -- Part 1: General principles and methods  |                      | Revision will start in 2021                                   |
| ISO 14698-2:2003 (Ed. 1)             | Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data                      |                      | Revision will start in 2021                                   |
| ISO 14698-2:2003/ Cor 1:2004 (Ed. 1) | Part 2 Technical Corrigendum 1  |                      | Will be withdrawn after new edition of ISO 14698 is published |

## 3. Projects Under Development

Working Group 4 (WG4) led by the Netherlands is revising ISO 14644-4:2001 (Ed. 1) *Design, construction, and start-up*. A goal of this working group is to finish the revised document in 2022.

The TC has moved to generic process documents. An example in an early stage of development is a systematic approach for procuring disposables in WG11 led by Germany (ISO 14644-18 *Assessment of*

*suitability of consumables*). The cleanroom industry is plagued by consumables with variable quality. Establishing minimum quality requirements would have benefits for both suppliers and buyers. The document under preparation identifies many of the existing protocols currently used, including IEST Recommended Practices for testing consumables.

During the virtual Plenary Meeting in October 2020, Standardization Administration of China (SAC) proposed a new project to establish a Technical Specification (TS) for facility requirements for isolation of patents to prevent disease transmission. The proposal from SAC for a Technical Specification on *General technical requirements of modular isolation units for emergency medical use* received the required number of willing participants and was accepted as a new work item by the TC. A new working group will be established to develop this TS, with Li Xianfeng nominated as the Convenor/Project Leader.

#### 4. Systematic Reviews

The ISO Directives Part 1 requires that published standards are systematically reviewed every five years to ensure that the material is up to date with respect to current technology and industrial practice. A ballot of the TC is conducted to review of the document: the choices are to confirm, revise, or withdrawal.<sup>[2]</sup>

**4.1** Revision of ISO 14644-5 *Operations* is starting in a newly reconstituted WG5 effort led by the United States. A review of intellectual property was conducted in the present document in conformance to copyright restrictions. The document will be updated emphasizing the value of the IEST recommended practices along with ISO 14644-18 *Assessment of suitability of consumables* when published.

**4.2** In the ISO 14677-7 *Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)* document systematic review discussion at the 2019 Plenary Meeting in Chicago, it was noted that the ballot results were evenly divided between confirming and revising the document. The standard was published in 2004. Some of the material is out of date or not used. At the time of publication, the term “Separative Device” was coined reflecting that the standard was generic and deliberately did not codify commercial equipment. A study of the role of ISO 14644-7 was led by the United States at the request of the TC.

The document was discussed again at the ISO/TC 209 virtual Plenary Meeting in October 2020. ISO/TC 198 Sterilization of health care products relies on ISO 14644-7 for engineering and design requirements in its recently revised standard ISO 13408-6:2021 *Aseptic processing of health care products—Part 6: Isolator systems*.<sup>[3]</sup> In discussions, it was clear that the path forward was to simply modernize the document and to remove unused material. The document has applications in controlled environments for example in machine shops. Also, the separative device term has gained wide use. This working group is scheduled to meet in 2022 to begin work on the revision.

**4.3** The effort of WG2 with the responsibility to revise ISO 14698 *Biocontamination control—Part 1: General principles and methods* and *Biocontamination control—Part 2. Evaluation and interpretation of biocontamination data* was dissolved in 2014 because the experts could not reach consensus with respect to some fundamental biocontamination concepts, and the convenor resigned. The existing standards of ISO 14698-1, -2:2003 were left in place ending the work of ISO/TC 209 on the biocontamination standardization until the next systematic review scheduled for 2019.

The Vienna Agreement<sup>[4]</sup> was established by the European Committee for Standardization (CEN, French: Comité Européen de Normalisation)<sup>[5]</sup> and ISO in 1990 and published in 1991 to reduce duplication, wasted effort, and confusion within the user community of standards undertaken by the two standards groups. The Vienna Agreement provides for either ISO or CEN to take the lead of a standards development project, the agreement to lead a joint project by one organization must be approved by the other organization. When one organization takes the lead under the Vienna Agreement, the other organization is allowed to ballot the documents and offer comments prior to publishing as their document. The standards developed by ISO/TC 209 are typically developed under the Vienna Agreement with ISO/TC 209 leading, where the CEN/TC 243 Cleanroom technology<sup>[6]</sup> will conduct a parallel working group, balloting, and publishing selected ISO standards. The ISO standards published by CEN have a EN ISO prefix.

CEN/TC 243 started a working group to write its own version of ISO 14698-1.-2 with the same title soon after the work was dissolved in ISO/TC 209. The standard was developed OUTSIDE of the Vienna Agreement as a CEN document although the text was based on work in ISO/TC 209 WG2. Central CEN assigned the different standard number of 17141 to make it clear the new document, although with the same title as the 14698 documents, contained different requirements than the published ISO 14698-1, -2:2003.<sup>[7]</sup> When EN 17141 was published in August of 2020, CEN withdrew EN ISO 14698-1, -2. However, ISO 14698-1, -2:2003 still remains in force. An additional source of confusion was that an annex on cleanroom garments in the ISO 14698-1, -2:2003 document was dropped in EN 17141:2020.

The solution taken in the ISO/TC 209 2020 virtual Plenary Meeting was to reopen WG2 Biocontamination to develop an ISO version with Ireland (NSAI) providing convenorship. EN 17141 will be used as the preliminary document. The new ISO 14698 document will replace ISO 14698-1-2:2003, and because the document will be developed under the Vienna Agreement, it will be issued as a future EN ISO 14698 document. At that time, the CEN 17141 document will be withdrawn by CEN. The goal of ISO/TC 209 is to reduce confusion and error in the user community by using an accepted and recognizable standard number (14698) and harmonize the documents used by both ISO and CEN to publish an improved, single standard.

**4.4** In a decision reached in the plenary meeting in 2015, it was decided that the term “classification” shall be reserved for numbering systems of airborne particle cleanliness. ISO 14644-8 contains a scheme expressing chemical airborne concentration ( $\text{g m}^{-3}$ ) in scientific notation using the exponents in whole numbers as a classification system. ISO 14644-9, -10 uses a similar concept for surface contamination for chemicals and particles.

The problem arose when the term “classification” was carelessly applied generically to cleanrooms by contracting or regulating entities by specifying only ISO 14644 and required class number without identifying the exact document. Therefore, it is not clear to the performer whether the specification applied to particles, chemicals, or surfaces. Due to the inadequacy of the specification, it would be possible to construct a “dirty cleanroom” and still meet the requirements of the agreement, although the expectation was construction of a cleanroom with particle control. This is an unintended consequence of the practice of developing a standards series with a common root number (14644) for the convenience of users. The usual practice is to first specify the class of the cleanroom using ISO 14644-1 and use that as the basis of design. Other attributes are specified as needed. This protocol was included in ISO 14644-1, -2 during the last systematic review and revision of those two documents in 2015. If for example, a user only wanted to control chemical contamination, the appropriate standard to specify would be ISO 14644-8:2013 *Classification of air cleanliness by chemical concentration (ACC)*.

This leaves the question of modification of ISO 14644-8, -9, -10, which all use “classification” in a nonairborne particulate context. In the Strategic Study Group, discussed in the next section, the solution suggested was to modify the terminology in the three documents to reduce the confusion with particulate air cleanliness classification. During the 2020 virtual Plenary Meeting, it was determined that a minor editorial revision without modification of technical content was required to just revise the terminology in the documents. Much of the revision had already been done in WG8 by a small number of members in the UK. The intent of the TC is to complete the minor editing of these documents and, after approval by the TC in a FDIS (Final Draft International Standard) ballot, reissue as new editions.

## 5. Strategic Study Group (SSG)

**5.1** A study group may be organized by a TC under the ISO Directives Part 1 to address topics that cannot be dealt with effectively in a yearly plenary meeting. The selection the leadership and members are up to the leadership of the TC and the duration may extend several years. However, when the work of the study group is finished, the group is disbanded, ISO Directives Part 1, Section 1.13 Groups having advisory functions within a committee.<sup>[2]</sup> Previously, ISO/TC 209 formed short term *ad hoc* groups to mainly explore the content of future standards. The objective of a strategic study group as chartered by ISO/TC 209 is to focus on a selected number of tasks to be addressed in a short time such as one or two years. The ISO/TC

209 Strategic Study Group (SSG) typically conducted virtual meetings monthly, members were selected for global balance, and the results reported at the annual plenary meeting. The ISO/TC 209 Chairman chaired the meetings. The SSG was organized in 2015, paused in 2018, reopened in 2019, and dissolved at the end of 2020. The incoming chair starting in 2021 will have an opportunity to develop their own programs.

Some topics undertaken by the ISO/TC 209 SSG were as follows:

- Revision of the Scope
- Revision of the Strategic Business Plan (twice)
- Addressing the classification issue
- Strategic planning and roadmaps
- Identification of ways to improve the standards development process
- Identification of best practices within ISO/TC 209

Because many of the results of the SSG discussion have been implemented and mentioned earlier, only a few of the topics will be discussed.

### **5.2 Revision of the scope**

An ISO/TC Scope provides the overall vision of the TC and defines the domain of work to prevent infringement by other organizations. A scope written at a high level without using specific examples of topics has the advantage of not restraining future topics for documents as technology changes. The same consideration is true if topics are excluded from scope.

The scope of ISO/TC 209 was revised in 2016 as follows and is on the website<sup>[1]</sup>:

*Standardization for cleanrooms and associated controlled environments for controlling cleanliness, as well as other attributes and characteristics, relating to facilities, sustainability, equipment, processes and operations.*

The revised scope, in addition to dealing with more than cleanrooms and associated controlled environments as an enclosure, has a more holistic approach. Inclusion of the terms sustainability and processes is intended to allow development of generic documents related to the activities in the cleanroom that are common for several related industries. Current societal concerns have elevated the priority of sustainability.

### **5.3 Strategic planning and roadmaps**

One of the tools in administrating a technical committee is to create a roadmap to determine potential direction. Roadmaps can take different forms depending on the work and the interests of the TC. A common Gantt Chart approach was developed using the standards listed in Table 1 with more detail in a calendar-based schedule, which allowed the group to review the existing schedule of projects and forecast planned development. Two additional approaches were developed: a mind map and a relationship chart. The mind map for ISO/TC 209 was developed by Berthold D  thorn, Head of Delegation for Germany, relating the logical progression of the standards and identified technical gaps. The relationship map was developed by David Ensor and is shown in Table 2.

**Table 2—A relationship chart**

| Cleanroom Life Cycle |                           |             |              |            |                     |                    |
|----------------------|---------------------------|-------------|--------------|------------|---------------------|--------------------|
|                      | Establish Control         |             |              |            | Demonstrate Control |                    |
| Scope Domains        | Requirements              | Design      | Construction | Start-up   | Operations          | Monitoring         |
| Equipment            | 1, 8, 9, 10               | 1, 8, 9, 10 |              | 1          | 1, 8, 9, 10         |                    |
| Facilities           | 3, 4, 7                   | 4, 7        | 4            | 3, 4       | 3, 7                | 7                  |
| Processes            | 13, 14, 15, 17            |             |              | 13, 14, 15 | 13, 14, 15          | 17                 |
| Operations           | 2, 5, 12, 18;<br>146981,2 |             |              | 5          | 2, 5, 18            | 2, 12;<br>146981,2 |
| Sustainability       | 16                        | 16          |              |            | 16                  | 16                 |

The idea was to plot, as an example, elements of the ISO/TC 209 Scope against the cleanroom life cycle. Comparison of the scope domains of key concept with the stages in a cleanroom life cycle intended to understand the landscape of the family of standards. The numbers refer to the sub-number of the 14644 series (refer to Table 1 for the title of the document). This material was presented at the 2018 ISCC conference in The Hague, Netherlands.<sup>[8]</sup> This allows identification of the related critical parts of the standards effort and needs of the users. The family of ISO/TC 209 standards were developed sequentially over a 30-year period and only now the similar parts of the documents are being identified. One efficiency might be to identify requirements of cleanroom and associated controlled environments which are common for all attributes of interest to develop documents with less duplication. Some common practices of achieving control and maintaining control for various attributes might considered in the future and could ensure the coherence of the documents.

#### 5.4 Revision of ISO/TC 209 Strategic Business Plan

A Strategic Business Plan (SBP) is required and revised every three years for every ISO/TC. The last revision was in 2018 and is available on the ISO website.<sup>[9]</sup> The SBP was revised again in 2020 and approved by the TC. The SBP for TC 209 has the following emphasis:

- Listing the industries using the ISO 14644 and ISO 14698 standards and identifying other industries that may need standardization with needs to improve cleanliness to improve product quality
- Naming the challenges to developing documents such as availability of experts and resources, and mitigations such as improving project management
- Operating principles such as holding a minimum of one plenary meeting annually, rotating face-to-face meetings globally and if practical hold virtual meetings to reduce travel burden on members

#### 5.5 Identification of ways to improve standards development process

**5.5.1** Standards are copyrighted. Simply copying text from other documents without appropriate permissions and attributions is against the law. It is assumed if an expert contributes material to the drafting of a document that copyright permissions have been obtained. The justification for this practice is a potential advantage of a user needing only to buy one encyclopedic document instead of many documents. There is not a cost advantage to users because ISO prices documents by the page count. In addition to legal consequences, the source standard may be modified without the knowledge of the using organization. Similarly, to transform a national or trade standard into an ISO standard has trademark implications.

**5.5.2** The ISO directives have flexibilities in the ISO process for consideration by ISO/TC 209 that may reduce effort in the document development effort. Normative references may be used as a requirement in

the text and there is no need to reproduce the content of the reference (10.2 Permitted referenced documents, Directives Part 2.).<sup>[10]</sup> The ISO Directives indicate that either an ISO or IEC document is preferred. However, if ISO or IEC documents are not available, documents published by other bodies may be listed as normative provided that:

1. The referenced document is recognized by the committee as having wide acceptance and authoritative status,
2. The committee has the agreement of the authors or publishers of the referenced document for its inclusion as a reference,
3. The authors or publishers have also agreed to inform the committee of their intention to revise the referenced and what points the revision will affect,
4. The document is available under commercial terms which are fair, reasonable, and nondiscriminatory.

The ISO policy supporting alternative normative references was published in Directives Part 1 2013 edition as normative Annex SN.<sup>[11]</sup> When the normative reference requirement was moved from Part 1 to Part 2, Annex SN was not moved to the new editions. The justification of the alternative references policy was to improve efficiency of document development by reducing time and effort to development by leveraging existing material in the market. The practice of transposing a non-ISO document into an ISO document solely for the purpose of a Normative reference is wasteful, creates redundant information, and may lead to copyright infringement issues.

**5.5.3** ISO Directives<sup>[2]</sup> have a range of publication formats with different rigor in balloting to reduce the developmental time (see Table 3). For example, technical reports can be issued initially providing background information on standards planned for development as part of a multistep effort to develop a new standard in an emerging field. A technical specification has the legal status of a normative document but is subject to approval only at the TC level. The technical specification offers a way to rapidly introduce standardization of a topic for industry to evaluate. Technical specifications are systematically reviewed every three years allowing rapid feedback from industry and other users. Depending on the acceptance by industry, the technical specification can be withdrawn, refined, or undergo the additional developmental and approval process and be issued as an international standard. This approach could be used to reduce the total working group time to develop a standard. ISO limits the time for a working group to debate and write a standard to three years. This limitation is intended to force a TC to produce a product in a reasonable and responsive time. Many organizations sponsoring experts have difficulty in making longer commitments because of the costs required for travel and release time.

**Table 3**—ISO document categories and their progression to a published document

| Document                                | Normative | Proposal                                 | Preparatory Working Draft                | Committee Committee Draft                | Enquiry Draft International Draft | Approval Final Draft International Draft                      | Life   |
|---|-----------|--|--|--|-----------------------------------|---|--|
| <b>International Standard</b>           | yes       | Acceptance requires 2/3 affirmative vote | Acceptance requires 2/3 affirmative vote | Acceptance requires 2/3 affirmative vote | Acceptance >2/3 <1/4 negative     | Acceptance requires 2/3 affirmative vote; correct errors only | Review every 5 years                         |
| <b>Technical Specification</b>          | yes       | Acceptance requires 2/3 affirmative vote | Acceptance requires 2/3 affirmative vote | Acceptance requires 2/3 affirmative vote |                                   |   | Review every 3 years                         |
| <b>Publicly Available Specification</b> | yes       | Acceptance requires 2/3 affirmative vote | Acceptance requires 2/3 affirmative vote | Acceptance requires a majority vote      |                                   |   | Review every 3 years; withdraw after 6 years |
| <b>Technical Report</b>                 | no        | Majority approval                        | Majority approval                        |  |                                   |   | Open   |

#### 5.5.4 Virtual or web-based meetings

One of the barriers of ISO participation has been the cost and time required for international travel. The use of web-based meetings has been a goal of the ISO/TC 209 Strategic Business Plan for several years. Until the COVID-19 pandemic, electronic meetings had only been implemented on a limited basis. Typically, a face-to-face meeting would be augmented with a conference call. ISO Central Secretariat has developed procedures for Web-based meetings for conferencing software, and a select group of TCs used them on a trial basis. It was found that a much different approach is needed for a web-based meeting than a face-to-face meeting. Global time zones are an inconvenience, some parts of the globe need to rise early, and others may need to work into the night. Web-based meetings should be limited to shorter sessions of two to four hours and require more detailed organization of the presentation material. However, the sessions may be convened over several weeks or on a frequent schedule because the members are not locked into a travel schedule. A shortcoming is lack of personal contact, somewhat offset by images of the participants, and the lack of face-to-face networking.

Since the onset of the pandemic in March 2020, ISO/TC 209 has conducted all its meetings for working groups and the TC Plenary Meeting virtually. The ISO/TC 209 normal two-day Plenary Meeting was instead conducted in 2020 in four three-hour sessions. The time was selected for an early start in North America and a late start in Asia and Australia.

**5.5.5** One ongoing problem with the development of ISO documents has been multiyear efforts often taken to complete the documents. Prolonged development times often result in increased burden on experts to engage in extended work schedules. There has been an effort in ISO to develop educational materials based on the Directives with explanation of the rules and implementation. There has been an initiative to promote the principles of program management within the committees.<sup>[12]</sup> In addition, the traditional Committee Secretary has been empowered to serve as a Committee Manager. The Committee Manager's role is to assist and mentor Convenors and project leaders as part of the initial proposal to develop a realistic schedule and identify critical milestones. The factor that is difficult to forecast is the time required to achieve consensus. ISO/TC 209 decided not to duplicate the ISO initiatives but to identify approaches that have been fruitful to improve the process.

**5.5.5.1** A high-quality standard is not necessarily long. One of the best practices is to keep the goals of the standard narrowly focused and strive for concise text. It is the responsibility of the TC to



develop documents planned to solve a need within the TC scope but have a narrow enough scope to allow completion in relatively short time. Ideally, the main body of the document (normative part) containing the requirements should be no more than 20 pages. If possible, other standards should be referenced rather than inclusion of duplicative text. Supporting material such as interlaboratory studies and other explanations should be in Annexes. It is not a good practice to put information that the working group cannot agree on in an Annex.

**5.5.5.2** The cycles of development of a document involves two-steps: 1) consensus within the working group during drafting a document suitable for ballot, and 2) ballots at various points in the process for approval by the members of the TC. The process of applying consensus is described in Section 2.5.6 in the Directories Part 1.<sup>[2]</sup> Ideally the goal to obtain consensus should be applied at all stages of document development. Of particular importance are the responsibilities of the leadership of the TC and members of the working group. Consensus in ISO is defined by:

*“Consensus: general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. NOTE: Consensus need not imply unanimity.”*

However, every situation in a working group is different with respect to the issues of ‘sustained opposition’ and ‘substantial issues’ and identifying people who are the ‘concerned interests.’ It requires judgement by the TC. For example, a ‘concerned interest’ could imply an expert with either a deep technical understanding or another with a significant economic stake in the outcome. (ISO documents are intended to facilitate global trade.) The consensus process is the heart of the document development process and if misapplied could cause extended development times or poor-quality documents. In particular, a document should be a compromise between competing ideas to avoid ‘sustained opposition.’ For that reason, improving the consensus process in the TC is a high priority.

#### **5.5.5.3 Drafting the document**

Every working group is different. The usual guidance is for the Convener or Project Leader to write the document fully engaging the experts. Clearly every expert needs to be given the opportunity to contribute and comment on the contributions of others. However, the new work item proposal is supported by an example of the content of the new document. The example may be an outline, an extended outline, a complete first draft, or an existing national standard. This material may be written by an individual or an entirely different standards group. The style of the leader is between dictatorial or laissez-faire. A convener or project leader needs to provide firm leadership, and the approach may be assigning tasks such as drafting and revising text and reviewing comments on an existing draft. The practice of opening a Preliminary Work Item prior to the more rigid standard development track leading to a published document allows development of a draft document for a three-year period. The draft document developed during the preliminary work can be used as an example in the proposal to start the standard development track.

## **6. Sustainability**

ISO now stresses development of standards with requirements to support sustainability supporting a United Nations initiative.<sup>[13]</sup> Cleanrooms and associated controlled environments are very resource-intensive facilities. The recently published standard on energy management in cleanrooms (ISO 14644–17) supports that need. The better management of the energy required by cleanrooms reduces broader energy requirements and operating costs. The direction of WG11 to develop guidance with respect procurement of consumables may also affect sustainability. There may be other opportunities in the future to address sustainability.

## 7. Summary

ISO/TC 209 begins its third decade taking a more integrated approach to standardization with the goal of responding to the needs of industry. An effort is being made by the TC to better understand the ISO tools available to do its work. There may be need to support an emerging number of industries requiring cleaner manufacturing control in areas that traditionally have not required cleanrooms and controlled environments in the past.

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## About ISO/TC 209

The use of cleanrooms and associated controlled environments is becoming more and more common and a key enabling technology for production. In response, ISO/TC 209 working groups (WGs) have contributed standards for design, testing, and use of cleanrooms and associated controlled environments to aid in the acceptance of this beneficial technology by different user groups and regions.

There are currently 25 participating member (P members) countries, which are eligible to nominate experts for WGs and vote on standards in development or systematic review. There are currently 21 countries (O members) that can observe the work of ISO/TC 209.

ISO/TC 209 standards are written generically in that they can be applied for testing and monitoring, or in a broader sense to control cleanliness in various industries such as

- automotive,
- aerospace,
- electronics,
- semiconductors,
- food,
- life sciences (e.g. pharmaceuticals, health care, hospitals),
- scientific research.

In addition, industry or national standards and guidelines are sometimes used to provide deviating or more specific requirements and aspects.

ISO/TC 209 has established formal liaisons with seven other ISO TCs and the International Confederation of Contamination Control Societies (ICCCS) to ensure transparency and consistency in its

standardization efforts. In 2017, ISO/TC 209 revised its business plan and scope to capture and address current and future standardization needs of consumers, regulators, and industry regarding cleanrooms. The revised scope reflects technical progress and the recognition that cleanroom technology has become more widely applied in various industries and the applications have become more diverse.

## About the Authors

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IEST is the leading global nonprofit contamination control society and Secretariat for ISO Technical Committee 209 (ISO/TC 209), the committee developing the ISO 14644 Standards. IEST has served as the Secretariat for ISO/TC 209 for more than 25 years with an established international leadership role based on more than 45 years of expertise in cleanrooms and controlled environments.

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<sup>1</sup> Mr. Gordon Ely is the ISO/TC 209 Chairman for the period of 2021 to 2026.