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ISO/TC 209 Launches New Cleanroom Standards and Outreach Projects

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US-led Outreach Task Team to foster promotion and education of the expanding body of ISO/TC 209 Standards

Keywords

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Overview

The October 2017 ISO Technical Committee (TC) 209 meeting held in Sydney Australia centered on creating a coordinated approach for the standards within the committee's work program of *Cleanrooms and associated controlled environments*. The approach is well needed as ISO/TC 209 introduces two projects—a New Work Item Proposal (NWIP) ISO 14644-17 on particle deposition rates and a Preliminary Work Item (PWI) on the assessment of the suitability of consumables in cleanrooms.

Adding to the intensity of ISO/TC 209's workload are not only new projects, but mandatory ISO Systematic Reviews of published standards at five-year points in the standard's lifecycle. When the hallmark cleanroom standard *ISO 14644-1: Classification of air cleanliness* was proposed in 1993, ISO/TC 209 leadership estimated the work would only encompass ten standards. In 2018, the Secretariat anticipates having 20 documents within the ISO work program, with more than half in development or review. The current work program for ISO/TC 209 is shown in Table 1.

As often happens after standards are used in the field, interpretations develop that require subsequent clarification. To that end, the committee is laying groundwork to clarify important terminology used within the ISO 14644 standard series. Through outreach to user communities and harmonization of all projects within the work program, ISO/TC 209 moves proactively to fulfill the ISO mission "…to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity."

Table 1. Projects under the ISO/TC 209 title *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	-	Standard published
ISO 14644-2:2015 (Ed. 2)	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	-	Standard published
ISO 14644-3:2005 (Ed. 1)	Test methods	-	Standard published; Ed. 2 in progress
ISO/DIS 14644-3	Test methods	6/8/2019 (IS)	Second DIS
ISO 14644-4:2001 (Ed. 1)	Design, construction, and start-up	-	Standard published; Ed. 2 in progress
ISO/PWI 14644-4	Design, construction, and start-up	-	NWIP
ISO 14644-5:2004 (Ed. 1)	Operations	1/15/2018	Systematic Review
ISO 14644-7:2004 (Ed. 1)	Separative devices (Clean air hoods, gloveboxes, isolators and mini-environments)	10/15/2018	Systematic Review
ISO 14644-8:2013 (Ed. 2)	Classification of air cleanliness by chemical concentration (ACC)	1/15/2018	Systematic Review
ISO 14644-9:2012 (Ed. 1)	Classification of surface cleanliness by particle concentration	1/15/2018	Systematic Review
ISO 14644-10:2013 (Ed. 1)	Classification of surface cleanliness by chemical concentration	1/15/2018	Systematic Review
ISO/DIS 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	12/15/2019 (IS)	FDIS
ISO 14644-13:2017 (Ed. 1)	Cleaning of surfaces to achieve defined levels of cleanlinesss in terms of particle and chemical classifications	-	Standard published
ISO 14644-14:2016 (Ed. 1)	Assessment of suitability for use of equipment by airborne particle concentration	-	Standard published
ISO 14644-15:2017 (Ed. 1)	Assessment of suitability for use of equipment and materials by airborne chemical concentration	-	Standard published
ISO/CD 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	12/9/2017	DIS
ISO/PWI 14644-17	Specification of requirements for particle deposition monitoring	-	NWIP
ISO 14698-1:2003 (Ed. 1)	Biocontamination control -- Part 1: General principles and methods	10/15/2019	Systematic Review
ISO 14698-2:2003 (Ed. 1)	Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data	10/15/2019	Systematic Review
ISO 14698-2:2003/ Cor 1:2004 (Ed. 1)	Part 2 Technical Corrigendum 1	-	

IS = International Standard; FDIS = Final Draft International Standard; DIS = Draft International Standard; NWIP = New Work Item Proposal.

Delegates to the 29th meeting of ISO Technical Committee 209, hosted in October 2017 by Standards Australia in Sydney.

Outreach Task Team

To foster a coordinated approach for the promotion and education of the 14644 and 14698 series standards, a new Outreach Task Team will be launched under the leadership of US Head of Delegation Anne Marie Dixon-Heathman. IEST, the ISO/TC 209 Secretariat and US TAG Administrator, will lend support to the team, which is anticipated to comprise a global cross-section of ISO/TC 209's 21 voting member nations. The details of the scope and membership of the Outreach Task Team will be developed in the coming year. With the publication of each new ISO/TC 209 Standard, the Outreach Task Team will release complementary information to help advance understanding and usage. The information will be made available to ISO/TC 209 member nations for distribution and potential translation for their user communities. The core of the initial outreach will likely be a whitepaper from the Convenor of the ISO/TC 209 Working Group responsible for the development of each newly published standard. In the US, information will be distributed through IEST as the US member on behalf of ANSI.

Clarification of "class" and "cleanroom" concepts within 14644 Standards

With advancing technology demanding new requirements, ISO/TC 209 expanded its scope during the past decade to encompass not only the classification and control of air cleanliness, but the control of other attributes and characteristics. The newest remit of ISO/TC 209 takes on "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."

Historically, dating back to Federal Standard 209 standards, the focus was on airborne particle cleanliness. A "cleanroom" referred to a room developed primarily to provide a controlled airborne particle environment with known contamination concentrations. Approximately 15 years ago, many cleanroom users began requiring the control of other contaminants in addition to a controlled airborne particle environment.

Chemical contaminants were first elaborated in *ISO 14644-8: Classification of air cleanliness by chemical concentration (ACC)*, which focuses on air cleanliness in terms of airborne concentrations of specific chemical substances where the product or process is deemed to be at risk from air chemical contamination. ISO 14644-1 had provided the globally recognized ISO Class numbers 1-9, which represent a designation of the maximum allowable concentration of particles in a unit volume of air. ISO 14644-1 specifically stated in its scope that it could not be used to characterize the chemical, physical,

radiological, viable or other nature of airborne particles. During development of ISO 14644-8, the experts adopted the use of a "class" designation indicating the level of air cleanliness by chemical concentration expressed in terms of an ISO-ACC Class *N*. The designation represented the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic meter. Subsequently, *ISO 14644-9: Classification of surface cleanliness by particle concentration* and *ISO 14644-10: Classification of surface cleanliness by chemical concentration* followed a similar path, providing designations of ISO-SCC (surface cleanliness by chemical concentration) and ISO-SPC (surface cleanliness by particle concentration).

However, through feedback from member nations, ISO/TC 209 leadership soon noted the process of "classification" as used in the 14644-8, -9, and -10 standards could be misinterpreted and used independently of the benchmark for cleanroom classification in ISO 14644-1 and result in construction of a "dirty cleanroom," if applied incorrectly. A Strategic Study Group created from ISO/TC 209 experts reviewed the issue and called for the terminology to be aligned.

In Sydney, ISO/TC 209 agreed that ISO 14644-8, -9 and -10 should be revised to remove the term "classification" and "class" from the text of the standards. The only "ISO Class" reference would be based on the criteria for class designation as spelled out in ISO 14644-1. A suitable replacement term for "class" will be decided in 2018. All three standards will be facing Systematic Review in the first quarter of 2018.

In an effort to clarify another terminology issue, the term "cleanroom" will only be used when ISO 14644-1 is applied, building upon historical precedent. When standards use other cleanliness attributes or characteristics (such as those listed in ISO 14644-8, -9, and -10 for airborne chemicals and chemicals and particles on surfaces), the term "controlled zone" will be used. The rationale for this change is that an important application of these standards will be cleanroom monitoring based on plans establishing critical control points, hence a "controlled zone."

Renewed focus on harmonization with new projects

Due to the expanding number of standards, ISO/TC 209 is stepping up efforts to harmonize all standards within the series to avoid conflicts as new projects are undertaken. To that end, ISO/TC 209 resolved that the new work project on particle deposition rates must align with the work already undertaken in *ISO/DIS 14644-3: Test methods,* as well as ISO 14644-9 as it moves through the Systematic Review process. The preliminary work project on consumables will also require harmonization with *ISO 14644-5: Cleanrooms and associated controlled environments—Operations*, which will also be under Systematic Review and potential revision beginning in 2018.

The year ahead

As outlined in Table 1, ISO/TC 209 leadership anticipates a high level of activity during 2018 by volunteers and by the Secretariat. It is expected that two standards will be published, a new standards project will be undertaken, and a number of Systematic Reviews may lead to new efforts that revise current standards. The 2018 ISO/TC 209 meeting is planned for the Netherlands, held in conjunction with the ICCCS Symposium, and is anticipated to be just as productive as the 2017 Sydney meeting.

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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.