TECH TALK | IEST Secretariat Update

Tech Talk provides a medium for industry professionals to share ideas about trends, new methods, and cost-saving techniques. Tech Talk articles are not peer-reviewed but are selected for general interest and timeliness.

ISO/TC 209 Tackles Revisions of ISO 14644 Standards

By Roberta Burrows, Technical Advisor for ISO/TC 209 Secretariat, IEST; David Ensor, Chair, ISO/TC 209; Jennifer Sklena, Manager, Technical Programs for ISO/TC 209 Secretariat, IEST

New edition of cleanroom testing standard nears completion as three current standards begin revision

Keywords

ISO, TC 209, 14644, 14698, cleanroom, test methods, monitoring, surface cleanliness, particle concentration, chemical concentration

Overview

Three new cleanroom standards continue to progress through the ISO Technical Committee (TC) 209 work program of *Cleanrooms and associated controlled environments*, but the primary concentration of the global cleanroom experts in 2019 may be the reshaping of five current ISO 14644 standards. These and other outcomes were discussed by delegates from 20 nations during the 30th plenary meeting of ISO/TC 209 in the Hague, Netherlands in October 2018. As outlined in Table 1, ISO/TC 209 experts will be facing a varied and complex workload in the coming year.

Pending revisions of early ISO 14644 standards

High on the list of the committee's revision projects under the ISO 14644 umbrella is *ISO 14644-3:2005, Test methods*. The standard is critical in supplying test methods to support operations of cleanrooms and clean zones in meeting air cleanliness classifications, other cleanliness attributes, and related controlled conditions. The revised edition, due for FDIS vote in early 2019, includes significant revisions. The detailed supporting test method annex is being overhauled, particularly in simplifying the installed filter system leakage test sections.

Within ISO 14644-3, performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional airflow and those with non-unidirectional airflow, and in three possible occupancy states: as-built, at-rest and operational. The standard provides test methods, recommended apparatus, and procedures for determining performance parameters.

ISO 14644-4:2001, Design, construction and start-up is the oldest, unrevised standard in the ISO 14644 series. Working Group 4, which is drafting a new edition, plans to have a well-developed document for Committee Draft (CD) vote in early 2019.

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 (Ed. 2)	Test methods	6/8/2019 (IS)	FDIS
ISO 14644-4:2001 (Ed. 1)	Design, construction and start-up	-	Standard published; Ed. 2 in progress
ISO/AWI 14644-4 (Ed. 2)	Design, construction and start-up	-	CD
ISO 14644-5:2004	Operations	-	Standard published
ISO 14644-7:2004	Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	3/4/2019	Systematic Review
ISO 14644-8:2013 (Ed. 2)	Classification of air cleanliness by chemical concentration	-	Standard published
ISO/PWI 14644-8 (Ed. 3)	Classification of air cleanliness by chemical concentration	-	NWIP
ISO 14644-9:2012 (Ed. 1)	Classification of surface cleanliness by particle concentration	-	Standard published
ISO/PWI 14644-9 (Ed. 2)	Classification of surface cleanliness by particle concentration	-	NWIP
ISO 14644-10:2013 (Ed. 1)	Classification of surface cleanliness by chemical concentration	-	Standard published
ISO/PWI 14644-10 (Ed. 2)	Classification of surface cleanliness by particle concentration	-	NWIP
ISO 14644-12:2018	Specifications for monitoring air cleanliness by nanoscale particle concentration	-	Standard published
ISO 14644-13:2017	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	-	Standard published
ISO 14644-14:2016	Assessment of suitability for use of equipment by airborne particle concentration	-	Standard published
ISO 14644-15:2017	Assessment of suitability for use of equipment and materials by airborne chemical concentration	-	Standard published
ISO/DIS 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	12/9/2019 (IS)	FDIS
ISO/AWI 14644-17	Particle deposition rate application	-	CD
ISO/PWI 14644-18	Assessment of cleanliness suitability of consumables	-	NWIP
ISO 14698-1:2003	Biocontamination control -- Part 1: General principles and methods	10/15/2019	Systematic Review
ISO 14698-2:2003 and Cor 1:2004	Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data, and Technical Corrigendum 1	10/15/2019	Systematic Review

***Table 1**—Projects under the ISO/TC 209 title "Cleanrooms and associated controlled environments"*

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

Joint revision of three monitoring standards approved

Three intertwined monitoring standards will be jointly revised under the convenorship of the United Kingdom. The standards address control of other contaminants in addition to the controlled airborne particle environment. *ISO 14644-8: Classification of air cleanliness by chemical concentration (ACC)* 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. The standard designates the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic meter. *ISO 14644-9: Classification of surface cleanliness by particle concentration* and *ISO 14644-10: Classification of surface cleanliness by chemical concentration* follow a similar path, providing designations of surface cleanliness by chemical concentration and by particle concentration per unit area.

While the three standards include the term "classification" within their titles, the standards providing support for monitoring and do not classify cleanrooms in the same way as *ISO 14644-1: Classification of air cleanliness*. This difference in the specifications in the current documents may lead to confusion in applications. Part of the revision process to be undertaken by ISO/TC 209 will be the elimination of the term "classification" within the three monitoring standards and adoption of a different (yet to be decided) terminology, discussion examples include "characteristic," "level," or "attribute." To clarify yet another terminology issue, the term "cleanroom" will only be used when ISO 14644-1 is applied. When standards use other cleanliness attributes or characteristics, the term such as "controlled zone" will be used. The rationale for this change stems from the understanding that an important application of these standards will be cleanroom monitoring based on plans establishing critical control points, therefore a "controlled zone" provides a clearer designation.

In addition to the changes in terminology for the revisions, a new topic area will be under consideration for incorporation into the monitoring standards. During the plenary meeting, the South Korean delegation provided a presentation by Professor Sueng-Ki Chae from Sungkyunkwan University, Seoul, regarding continuous, on-line, ppt-level ACC monitoring in large-area cleanrooms. Inorganic airborne molecular contamination (AMC) monitoring and organic ACC monitoring has expanded in the semiconductor and display industry, but authoritative standard guidance has yet to be developed and could be included within the ISO/TC 209 program.

New standards on horizon

During 2019, work will continue on three new standards. ISO 14644-16, which is nearing completion, focuses on improving energy efficiency in cleanrooms and clean air devices. ISO 14644-17 will develop measurements and specifications regarding particle deposition rates, potentially including real-time instrumentation specifications. ISO 14644-18 will provide guidance on the assessment of the suitability of consumables in cleanrooms.

And the revision work continues…

In addition to ISO/TC 209's pressing workload of new projects and revisions, two standards face decisions in 2019 based on the mandatory ISO Systematic Reviews of published standards at five-year points in the standard's lifecycle. *ISO 14644-7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)* is currently out for Systematic Review with voting closing in March 2019. *ISO 14644-5: Operations* completed a Systematic Review earlier in 2018 reconfirming the standard, but sufficient votes were cast in favor of revision that ISO/TC 209 may

yet reopen the document. Further information is being gathered and will be presented to the TC during the next plenary meeting, hosted by IEST, in Chicago November 14-15, 2019.

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.