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ISO Technical Committee on Cleanrooms and Associated Controlled Environments Enters Third Decade with New Changes on Horizon

David S. Ensor, ISO Technical Committee 209 Chair

ISO Technical Committee (TC) 209: "Cleanrooms and associated controlled environments" produced many significant standards during its first 20 years of existence. Much remains to be accomplished, however, as the committee is on the verge of completing revisions to two major standards while it also embarks on creating vital new documents.

KEYWORDS
Air cleanliness, cleanrooms, contamination control, controlled environments, ISO 14644, ISO/TC 209, nanoscale, nanotechnology, particle concentration

Historically, US Federal Standard 209, developed by the Institute of Environmental Sciences and Technology (IEST) for the US Department of Defense, was the earliest cleanroom classification standard. However, a number of countries adopted versions that were slightly different, creating confusion in the global marketplace. The initial reason for forming ISO/TC 209 was to develop international consensus on a single standard for cleanroom classification. This was accomplished with the publication of ISO 14644-1 in 1999. Two decades later, ISO/TC 209 has published 12 standards and faces a hefty workload of both standards revision and development.

ISO/TC 209, administered by the IEST Secretariat, held its most recent plenary meeting in Reno, Nevada, in October 2013, with 15 member countries in attendance. The TC was organized in 1993 with the American National Standards Institute (ANSI) holding the chairmanship but delegating the responsibility to IEST. After a very successful 20 years, ISO/TC 209 is moving to include new topics such as nanotechnology and energy management. The ISO website (http://www.iso.org) has a description of ISO and the ISO/TC 209 technical program. In addition, the bibliography of this article lists the current standards that have been published and the dates of publication. The current active projects are summarized in Table 1 with comments on their status.

Revision of ISO 14644-1 and ISO 14644-2 is complete and expected to be ready for a second Draft International Standard (DIS) ballot shortly. The revision process has required a number of years to complete mainly because these standards are the keystone of the other ISO standards written by ISO/TC 209. They are the primary documents for classification of cleanrooms and associated controlled environments. A second DIS ballot is planned because the first ballot revealed a number of issues requiring additional work.

The discussion of the progress on the ISO 14644-1 and ISO 14644-2 documents leads to formulating a better understanding of how the ISO/TC 209 series of documents should be applied in practice. Of these documents, only ISO 14644-1 and ISO/DIS 14644-12 are intended for classification of a cleanroom.

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Other documents such as ISO 14644-9, -10, and -11 should be applied in cleanrooms that have first been classified by ISO 14644-1 for particulate levels. ISO 14644-9, -10, and -11 provide levels of cleanliness for other attributes. Although these attributes may be important in some applications, there is a concern that standards in the ISO/TC 209 library might be applied without first using ISO 14644-1, and this practice could lead to a "dirty cleanroom." To help differentiate between the classification of cleanrooms with application of ISO 14644-1 and classification using the other documents in the 14644 series, classification by application of 14644-1 will simply be: ISO Class *N*, where *N* is the number depicting the level of cleanliness classification by particle concentration. For example, application of ISO 14644-8 to determine the levels of chemicals allowed after the initial cleanroom classification for particles will include the following information: air cleanliness classification by chemicals (ACC) or ISO ACC *N'*. (Note: *N* and *N'* may have different values.)

ISO/DIS 14644-12 for nanoscale (100 nm and smaller) particles was approved in a DIS ballot and will be revised to answer the reviewers comments. In reality, the nanoparticle document may have its application as a monitoring document for facilities classified by ISO 14644-1. It is likely the revision may reflect that thinking.

Nanotechnology facilities have recently been designed and constructed using *ad hoc* standards for vibration. ISO/TC 209 has been considering the establishment of new vibration standards, which has led to some questions: Should the nanotechnology working group or the measurements standard (ISO 14644-3) take on this topic? Should the material be written as a stand-alone document or included as a section in an existing standard such as ISO 14644-4 on design, construction, and start-up? ISO/TC 209 decided to postpone any decision until the future of ISO 14644-4 is decided.

ISO 14644-4 passed the systematic review, but some ISO/TC 209 members believe the document should be modernized. A survey has been conducted, and a final decision on reopening the document will be made at the committee's plenary meeting in October.

Cleanrooms are energy-intensive facilities that require high recirculation rates of clean air to transport contamination from workspaces and close tolerances of temperature and relative humidity for many industries. BS 8568: "Cleanroom energy. Code of practice for improving energy efficiency in cleanrooms and clean air devices," was published in 2013 by the British Standards Institution (BSI). This document is a management standard conforming to ISO 50001 to guide designers and operators in developing programs to manage energy. China also has a national program on cleanroom-energy management at a technical level.

ISO/TC 209 resolved to encourage the United Kingdom and China to develop a new work-item proposal to describe the approach for development and the content of the standards. One idea is that the energy standards might be more effective in a stand-alone document because the principles can be applied to old facilities as well as in the design of new facilities. ISO 14644-4 is intended for new facilities. It is believed that development of cleanroom energy standards would have wide application. Since the 2013 fall meeting, this new work item proposal has been approved by the members, and the working group will be launched this coming fall.

ISO/TC 209 will maintain its current standards library while continuing to develop standards in emerging areas as needed by industry. The TC will meet again in Seoul, Republic of Korea on October 20-21, 2014 in conjunction with the International Symposium on Contamination Control organized by the International Confederation of Contamination Control Societies.

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Table 1. Summary of ISO initiatives.

WG	Covenership	Documents	Comment
1	United Kingdom	ISO/DIS 14644-1 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration ISO/DIS 14644-2 Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	Revision of the 1999 documents. The ultrafine (nano) particle material in the 1999 edition was moved to ISO/DIS 14644-12. The documents were subjected to a DIS ballot and many comments were received. The current documents will be balloted in a second DIS ballot, and the drafts are expected to be sent out for vote in 2014.
3	Japan	ISO/NP 14644-3 Cleanrooms and associated controlled environments—Part 3: Test methods	Revision of the 2005 document. The ultrafine (nano) particle material was moved to ISO/DIS 14644-12. It is anticipated that a DIS ballot will be conducted later in 2014.
10	United States	ISO/DIS 14644-12 Cleanrooms and associated controlled environments—Part 12: Classification of air cleanliness by nanoscale particle concentration	Currently comments are being resolved from the DIS ballot.
12	Switzerland	ISO/WD 14644-13 Cleanrooms and associated controlled environments—Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	New working group with focus to integrate surface cleaning requirements with the surface contamination standards.

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11	Germany	ISO/CD 14644-14 Cleanrooms and associated controlled environments—Part 14: Assessment of suitability for use of equipment by airborne particle concentration ISO/WD 14644-15 Cleanrooms and associated controlled environments—Part 15: Assessment of suitability for use of equipment and materials by airborne chemical and surface chemical concentration	New working group with a focus on quantification of emissions from equipment. It is planned to advance ISO/CD 14644-14 to a CD ballot in the next few months.
2	United Kingdom	ISO/CD 14698 Cleanrooms and associated controlled environments—Biocontamination control—Microbial cleanliness levels	The 2003 editions are being revised. A CD ballot was closed in May 2014. Comments received from voting are currently being reviewed.
13 (tenta-tive)	United Kingdom (Convenor and Project Leader along with China)	ISO/NP 19836 Cleanrooms and associated controlled environments: Cleanroom energy—Code of practice for improving energy efficiency in cleanrooms and clean air devices	Approved as a new work item. The Working Group will have its first meeting in October in Seoul, Republic of Korea.

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The Institute of Environmental Sciences and Technology (IEST), founded in 1953, is a multidisciplinary, international technical society whose members are internationally recognized for their contributions to the environmental sciences in the areas of contamination control in electronics manufacturing and pharmaceutical processes; design, test, and evaluation of commercial and military equipment; and product reliability issues associated with commercial and military systems. IEST is an ANSI-accredited standards-developing organization. For more information about the many benefits of IEST membership, visit www.iest.org.

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