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 Tech Talk articles are not peer reviewed but are selected for general interest and timeliness.

The Next Chapter in the History of International Cleanroom Standards

Editor's Note: This Tech Talk serves as a continuation of the article, "Progression of Cleanroom Standards Development, 1959-1970s," authored by Clifford "Bud" Frith of Frith and Associates and published in Volume 66, No. 1. In this installment, two additional distinguished, long-time members and past presidents of IEST provide their insights into the historical development of cleanroom standards.

By Richard A. Matthews, Filtration Technology, Inc., and Anne Marie Dixon-Heathman, Cleanroom Management Associates, Inc.

The development of cleanroom standards began in the United States Air Force and has grown into a global industry with the founding of ISO Technical Committee 209, Cleanrooms and associated controlled environments. The Institute of Environmental Sciences and Technology has played a vital role from the beginning.

Keywords
Cleanrooms, FED-STD-209, IES, IEST, ISO 14644, ISO/TC 209

Introduction

In the 1960s and 1970s, three parallel paths were developing in the area of contamination control. The United States (US) government was interested in turning AF Technical Order 00-25-203 into a broader document that could be used by other US government agencies interested in contamination control.

At the same time, the HEPA filter manufacturers were looking for standardization in the classification of their products. These manufacturers, their vendors, and their customers formed the American Association for Contamination Control (A2C2) as a forum for common ground.

In Europe, a group of contamination control professionals put together an informal group called the International Committee of Contamination Control Societies (ICCCS). It was during an ICCCS meeting in London in 1991 that the idea of a single contamination control standard was discussed. The idea was to somehow overcome the plethora, numbering in the hundreds, of various national standards currently covering cleanrooms.

The initial result of these paths was as follows:

- AF Technical Order 00-25-203 became Federal Standard 209 (FED-STD-209) in December 1963;
- A2C2 received support from PennWell Publishing Co. by creating an industry magazine and later industry trade shows; and
- ICCCS formalized itself in 1972.

This parallel activity resulted in A2C2 joining the Institute of Environmental Sciences (IES) in 1973, and IES becoming a member of ICCCS in 1974. In 1997, the IES board formally renamed the organization the Institute of Environmental Sciences and Technology (IEST) to fully reflect its growing scope.

The Cleanroom Industry in the United States

A2C2 was an informal group of like-minded people within an all-volunteer organization dedicated to cleanrooms. It needed a formal structure and a home with a professional staff to oversee its activities. IES was deemed the best fit because of its related activities and client base.

IES already had an established program for creating recommended practices for its members. It was an ideal setup for the A2C2 team, who needed to provide a common ground for sellers and buyers of contamination control products.

As a result of the merger of these two organizations, the development of a whole series of Contamination Control Recommended Practices (CC RPs)—starting with HEPA filters and eventually encompassing all manner of contamination control concerns and products—began in 1976.

In the meantime, changes were being made to FED-STD-209, *Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones,* by US government personnel. This resulted in FED-STD-209A being issued in 1966, followed by FED-STD-209B in 1973.

With the formal activity of IES instituting CC RPs, the US government was encouraged to turn over to IES the responsibility for keeping FED-STD-209 current, which it subsequently did while following the Reagan administration Paperwork Reduction Act of 1980. This change in responsibility resulted in FED-STD-209C being issued in 1987 and FED-STD-209D in 1988. The final issuance was FED-STD-209E in 1992.

Global Contamination Control Standards

In the 1980s, various countries were either writing their own national standards for contamination control or using FED-STD-209. However, in Europe, as countries were organizing to create a unified European market, the European Committee for Standardization (CEN) began work on its own series of contamination control standards. This work by CEN committees was being done in parallel with what IES was doing for FED-STD-209 and its own series of IES CC RPs.

The CEN group was aggressive in establishing European standards. The US cleanroom community was concerned that the EU standards would be forced upon US entities without any US input. Countries in the Pacific Rim were also writing standards that would be applicable to US companies building on their soil. In the US, IES was concerned about losing contamination control standards influence to Europe via their CEN standards.

A decision was made to leapfrog the EU by going directly to the International Standards Organization (ISO) and requesting that the responsibility for cleanroom standards be assigned to the US via the American National Standards Institute (ANSI). Because IES had already approached ANSI with a request to assume the responsibility for cleanrooms due to its earlier FED-STD-209 responsibility from the US government, it was a logical fit for IES to draft the proposal.

The contamination control members of IES asked the executive board to petition ANSI to assign the responsibility for US contamination control standards to IES. By doing so, IES could then ask ANSI to petition ISO to assign the international responsibility for contamination control to the US. This would allow the US to maintain its influence over contamination control standards on a global scale.

The Beginning of ISO/TC 209

In 1993, ANSI was given the international responsibility by ISO for writing the international cleanroom standards. ANSI promptly appointed IES as the Secretariat for ISO Technical Committee 209 (ISO/TC 209), Cleanrooms and associated controlled environments. It was a pure coincidence that the next number in the ISO Technical Committee sequential numbering system turned out to be 209. It could easily have been 208 or 210. Some European and Asian bodies felt the US had exerted special influence on ISO to have 209 assigned to the technical committee. This was definitely not the case.

The first meeting of ISO/TC 209 was hosted by IES in Chicago on November 7–8, 1993. Eight participating voting countries sent delegates to this first TC 209 meeting. The goal of ISO/TC 209 was the "standardization of equipment, facilities, and operational methods for cleanrooms and associated controlled environments."

At that meeting, five working groups were established with specific countries responsible for working group activities:

- WG 1 Airborne Particulate Cleanliness Classes (United Kingdom),
- WG 2 Biocontamination (France),
- WG 3 Metrology and Test Methods (Japan),
- WG 4 Design and Construction (Germany), and
- WG 5 In-Service Operations (United States).

Consideration for including "Terms and Definitions" (Switzerland) and "Clean Air Devices" (United States) was added to the assigned workloads.

Since much of the intercountry coordination had already been established via European CEN activities, CEN agreed to incorporate that work into the writing of the new ISO cleanroom standards. This initial group of ISO/TC 209 personnel were enthusiastic about what lay ahead. Members of the group were told by ISO that it took an average of 10 years to create and publish an ISO Standard. TC 209 personnel agreed they could do better than that. In fact, ISO/TC 209 created and published 10 international cleanroom standards in its first 12 years, thereby establishing a solid, stable base for the growth of the global cleanroom industry.

The work of ISO/TC 209 was deemed to be generic only (i.e., nonindustry specific). Personnel were instructed to only classify particles by size and quantity and not to be concerned by whether these particles were alive, dead, or radioactive and "glowing in the dark."

The First International Cleanroom Standards

The first ISO cleanroom standard developed and published was *ISO 14644 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness.* This document was

published in May 1999. In November 2001, the US government formally rescinded FED-STD-209E and referenced ISO Standard 14644-1 as its replacement.

Additional ISO 14644 cleanroom standards followed:

- *ISO 14644 Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1* (in 2000)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 4: Design, construction, and start-up* (in 2001)
- *ISO 14698 Cleanrooms and associated controlled environments—Biocontamination control—Part 1: General principles and methods* (in 2003)
- *ISO 14698 Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data* (in 2003)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 5: Operations* (in 2004)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)* (in 2004)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 3: Test methods* (in 2005)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 8: Classification of airborne molecular contamination* (in 2006)
- *ISO 14644 Cleanrooms and associated controlled environments—Part 6: Vocabulary* (in 2007; withdrawn in 2014)

Formation of the US Technical Advisory Group to ISO/TC 209

In April 1993, a committee was established: the IES ISO Secretariat TRAC (i.e., the Task Related Advisory Committee). IES had a dual responsibility as both the US TAG (i.e., Technical Advisory Group) Administrator for ISO/TC 209 and as the Secretariat of ISO/TC 209. Each US TAG (there are now many accredited US TAGs, each responsible for other technical committees) is made up of organizations interested in having a voice on the US delegation to the ISO TC. The task of the US TAG is to ensure the US position is well represented to the ISO TC. We identified the key elements for the global standard in priority order and determined how these activities would meet the objectives and deadlines as directed by ISO.

On June 2, 1993, invitations were sent to 28 organizations (professional societies and trade associations covering broad cleanroom interests) asking these groups to join the US TAG for ISO/TC 209. The US TAG is the official representative to ISO/TC 209. With the establishment of the US TAG, IES petitioned ANSI to become the TAG Administrator. The initial meeting was held in August 1993 in Chicago. The results of that meeting placed the No. 1 priority on air cleanliness classes.

Throughout the years, the US TAG membership has added private industry to the professional societies and trade associations that formulated its original members. However, private industry does not hold the majority voting membership. The TAG formally meets in person or virtually at least annually and will meet to discuss any major voting documents requiring discussion or explanations.

The US TAG approves the working group delegates for those working groups in which the US wants to participate. The delegates have always been industry professionals in their field representing both industrial (microelectronics, aerospace, consumer products, and so forth) and healthcare (pharma, biotech, medical device) cleanrooms. Throughout the years these delegates have traveled at their own expense and offered hundreds of hours of their time on committee work for the benefit of our contamination control sciences. We owe every one of these delegates and members of the US TAG our thanks for their efforts.

Summary

With the swiftly changing technology in the cleanroom and contamination control field, it was imperative that ISO/TC 209 write a current standard on classification quickly. By doing this all industries involved in international trade would have the benefit of a single, comprehensive global standard that should provide lower-cost trade access for all, which in turn would mean lower production costs for worldwide consumers—and that is what was achieved through the extraordinary efforts of many individuals and organizations.

Through the years, ISO/TC 209 has reaffirmed or updated the original standards and added many new standards. The following table is a list of the current standards.

Document	Abbreviated title	Status	Description
ISO 14644-1	Classification of air cleanliness by particle concentration	2015	Covers the classification of air cleanliness in cleanrooms and associated controlled environments.
ISO 14644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015	Specifies requirements for monitoring and periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1.
ISO 14644-3	Test methods	2019	Specifies test methods for designated classification of airborne particulate cleanliness for characterizing the performance of cleanrooms and clean zones.
ISO 14644-4	Design, construction and start-up	2022	Specifies requirements for the design and construction of cleanroom installations.
ISO 14644-5	Operations	2004 (in revision)	Specifies basic requirements for cleanroom operations.
ISO 14644-7	Separative devices (clean air hoods, gloveboxes, isolators, and mini-environments)	2004 (in revision)	Specifies the minimum requirements for the design, construction, installation, testing, and approval of separative devices.
ISO 14644-8	Assessment of air cleanliness by chemical concentration (ACC)	2022	Establishes assessment processes to determine grading levels of air chemical cleanliness (that is, ACC).
ISO 14644-9	Assessment of surface cleanliness for particle concentration	2022	Establishes a procedure for the assessment of particle cleanliness levels on solid surfaces.
ISO 14644-10	Assessment of surface cleanliness for chemical contamination	2022	Establishes appropriate testing processes to determine the cleanliness of surfaces with regard to the presence of chemical compounds or elements.
ISO 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	2018	Covers the monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles.
ISO 14644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	2017	Addresses the cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom, and surfaces of materials in a cleanroom.

Document	Abbreviated title	Status	Description
ISO 14644-14	Assessment of suitability for use of equipment by airborne particle concentration	2016	Specifies a methodology to assess the suitability of equipment for use in cleanrooms and associated controlled environments.
ISO 14644-15	Assessment of suitability for use of equipment and materials by airborne chemical concentration	2017	Provides requirements and guidance for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments.
ISO 14644-16	Energy efficiency in cleanrooms and separative devices	2019	Provides guidance and recommendations for optimizing energy usage and maintaining energy efficiency in new and existing cleanrooms, clean zones, and separative devices.
ISO 14644-17	Particle deposition rate applications	2021	Provides guidance on the interpretation and application of the results of the measurement of particle deposition rate on one or more vulnerable surfaces in a cleanroom as part of a contamination control program.
ISO 14644-18	Assessment of suitability of consumables	2023	Provides guidance for assessing personal and nonpersonal consumables for their appropriate use in cleanrooms, clean zones, or controlled zones based on product and process requirements, cleanliness attributes, and functional performance properties.
ISO/TR 14644-21	Airborne particle sampling techniques	2023	Provides clarification on the application of sound airborne particle sampling techniques in support of ISO 14644-1:2015 for classification of cleanrooms and clean zones, and ISO 14644-2:2015 for airborne particle monitoring, to provide evidence of cleanroom performance related to air cleanliness by particle concentration.
ISO 14698-1	Biocontamination control—Part 1: General principles and methods	2003	Describes the principles and basic methodology for a formal system to assess and control biocontamination in cleanrooms.
ISO 14698-2	Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data	2003	Gives guidance on basic principles and methodological requirements for all microbiological data evaluation, and the estimation of biocontamination data obtained from sampling for viable particles.

ISO/TC 209 continues its work by meeting either virtually or in person every year. As of 2024, the technical committee has 26 participating (voting) members and an additional 20 observer (nonvoting) members who provide additional input.

As we look to the future of standards, it is important to note that the IEST Recommended Practice Program has supported the information that is included in many of these published ISO standards and will continue to support the standards of the future.

About the Authors

Richard A. Matthews is the founder and chairman of Filtration Technology, Inc. located in Greensboro, North Carolina. Since 1971, Filtration Technology, Inc. has been meeting the specific and high demands of air filtration and contamination control requirements for critical environments and is committed to creating clear answers for industrial filtration and contamination control needs. Mr. Matthews began selling clean-air products in 1957 and worked with manufacturers of filtration products used in hospitals and other sterile environments. He is a former IEST president and the first chairman of ISO/TC 209.

Anne Marie Dixon-Heathman is the owner and president of Cleanroom Management Associates, Inc., a consulting firm based in The Villages, Florida, specializing in competitive benchmarking, training, and auditing of clean and aseptic operations and management. She has

been actively engaged in the field of contamination control for more than 40 years with extensive experience in the areas of cleanroom operations, training, technical writing, strategic consulting, facility startup, construction protocols, and process optimization. Ms. Dixon-Heathman has trained more than one million cleanroom technicians and managers and has authored numerous books and publications on all aspects of cleanrooms throughout her career. She is a past president of IEST and serves as the Head of Delegation for the US to ISO/TC 209, Cleanrooms and associated controlled environments.

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 30 years with an established international leadership role based on more than 50 years of expertise in cleanrooms and controlled environments.