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 Tech Talk articles are not peer-reviewed, but are selected for general interest and timeliness.

Beyond the ISO Cleanroom Standards—Comprehensive Guidance from IEST

By Roberta Burrows, Technical Advisor for ISO/TC 209 Secretariat, IEST and
Anne Marie Dixon-Heathman, US Head of Delegation to ISO/TC 209 and IEST Working Group Chair

Balancing the Needs of Global Uniformity and Specific Applications

Keywords
Cleanrooms, IEST, ISO, TC 209, 14644, 14698, Recommended Practices, RP, Standards

An example of IEST's nonprofit mission to aid industry and government in overcoming knowledge barriers can be seen in the inter-relationship of guidance documents developed by the IEST Contamination Control Division with standards developed by ISO Technical Committee 209 (ISO/TC 209) Cleanrooms and associated controlled environments. For IEST, the broad mission includes Recommended Practices (RP), Standards (STD), and Guides (G) that together embody the most complete range of contamination control resources currently available. For ISO/TC 209, the goal is a defined focus on a generic body of overarching international cleanroom standards under the ISO 14644 and ISO 14698 series. Together, the two sets of resources balance the need for a globally uniform set of requirements along with the demand for application-specific guidance.

IEST (in its earlier iteration as IES) has led the development of cleanroom guidance documents since the 1970s. In the 1980s, IES(T) was designated by the US General Services Administration as the Preparing Activity organization for US FED-STD-209, the recognized national classification guidance for cleanroom air cleanliness. By the 1990s, a growing global marketplace found itself grappling with a score of national cleanroom classification standards. Compounding the problem, a different numerical term was used to describe the air cleanliness level depending on country of operation. For example, a cleanroom currently designated as ISO Class 5 would have been known in 1990 as FED-STD-209E *M3.5/100* in the United States, *A+B* under the European cGMP, *4 000* in France, *3* in Germany, *E or F* in Great Britain, and *5* in Japan. This manufacturing and regulatory nightmare led IEST to petition for the creation of an ISO technical committee to establish international consensus, not only for air cleanliness classification but also for test methods, design criteria, and operational procedures. ISO/TC 209 was launched in 1992. IEST has continuously served as Secretariat to ISO/TC 209, Administrator to the US Technical Advisory Group, and has provided numerous experts and Convenors for ISO Working Groups.

As seen in the previous example of the myriad classification levels, ISO standards are developed specifically to ensure consistent international use that achieves global uniformity of products and practices. However, this obligation creates documents that are necessarily generic in approach. The ISO Standards contain the "what you shall achieve" but often rely on accredited standards developing organizations (SDOs) such as IEST to fill in the details regarding the who, what, why, where, when, and how—the foundational knowledge needed to successfully apply the Standards. Due to the strength of their content,

IEST Recommended Practices often serve as references within the ISO/TC 209 Standards. IEST Recommended Practices offer guidelines for methods, materials, and practices that can assist both the customer and supplier in improving processes and products.

In the ISO 14644 Standards, each document's proposed scope is analyzed to clearly identify the characteristics to be standardized. While both Standards and Recommended Practices provide specifications, an ISO Standard generally provides specifications recognized as needing uniform application as a *requirement*, while a Recommended Practice provides specifications recognized as *desirable and recommended*. IEST Recommended Practices can represent a leading-edge concept or a proven model or practice. Use of both the ISO Standards and IEST resources is voluntary, although they may be referenced in contracts between a customer and supplier, or incorporated into national or local regulations.

Table 1—ISO/TC 209 Standards and related IEST Documents.

Document Number	Title of Part	IEST Related Recommended Practices (RP), Standards (STD), Guides (G)
ISO 14644-1:2015 (Ed. 2)	Classification of air cleanliness by particle concentration	RP-CC 001, 002, 006, 007, 014, 019, 021, 034, 042; G-CC1003, G-CC1004
ISO 14644-2:2015 (Ed. 2)	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	RP-CC 005, 023, 046, 049
ISO 14644-3:2005	Test methods	RP-CC 001, 002, 006, 007, 013, 014, 019, 021, 034, 036
ISO 14644-4:2001	Design, construction, and start-up	RP-CC 001, 002, 006, 007, 008, 012, 013, 018, 022, 035, 044, 047, 049: RP-NANO 200, 205
ISO 14644-5:2004	Operations	RP-CC 003, 004, 005, 016, 018, 020, 022, 023, 026, 027, 044, 046, 048, 049
ISO 14644-7:2004	Separative devices (Clean air hoods, gloveboxes, isolators and mini-environments)	RP-CC 012
ISO 14644-8:2013 (Ed. 2)	Classification of air cleanliness by chemical concentration (ACC)	RP-CC 016, 031, 035, 042, 043
ISO 14644-9:2012	Classification of surface cleanliness by particle concentration	RP-CC 016, 031, 035, 042, 901, 902
ISO 14644-10:2013	Classification of surface cleanliness by chemical concentration	RP-CC 031, 035, 042, 901, 902
ISO/DIS 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	RP-NANO 200, 205
ISO 14644-13:2017	Cleaning of surfaces to achieve defined levels of cleanlinesss in terms of particle and chemical classifications	RP-CC 026, 901, 902
ISO 14644-14:2016	Assessment of suitability for use of equipment by airborne particle concentration	RP-CC 016, 026, 042, 044
ISO 14644-15:2017	Assessment of suitability for use of equipment and materials by airborne chemical concentration	RP-CC 016, 026, 042, 044, 901, 902
ISO/CD 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	RP-CC 012
ISO 14698-1:2003 ISO 14698-2:2003	Biocontamination control -- Part 1: General principles and methods Part 2: Evaluation and interpretation of biocontamination data	RP-CC 003, 004, 005, 018, 023, 026, 027, 048

DIS = Draft International Standard; CD = Committee Draft

Table 1 provides an update of a previous table in use by industry to select IEST resources that assist with the understanding or application of related ISO/TC 209 Standards. The table lists the current ISO/TC 209 Standard or draft standard and the IEST Recommended Practice(s) and other documents that provide additional detail, methods, or guidance.

Table 2 provides the complete titles of the IEST documents. The scopes for all ISO/TC 209 and IEST documents can be viewed on the IEST website www.iest.org within the IEST Bookstore.

Table 2—IEST Contamination Control Division Published Resources.

IEST Recommended Practices, Standards, Guides
IEST-RP-CC001: HEPA and ULPA Filters
IEST-RP-CC002: Unidirectional Flow Clean-Air Devices
IEST-RP-CC003: Garment System Considerations for Cleanrooms and Other Controlled Environments
IEST-RP-CC003 Supplement: Guide to Measuring Cleanroom Garments
IEST-RP-CC004: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC005: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC006: Testing Cleanrooms
IEST-RP-CC007: Testing ULPA Filters
IEST-RP-CC008: Gas-Phase Adsorber Cells
IEST-RP-CC012: Considerations in Cleanroom Design
IEST-RP-CC013: Calibration Procedures and Guidelines for Select Equipment used in Testing Cleanrooms and Other Controlled Environments
IEST-RP-CC014: Calibration and Characterization of Optical Airborne Particle Counters
IEST-RP-CC016: The Rate of Deposition of Nonvolatile Residue in Cleanrooms
IEST-RP-CC018: Cleanroom Housekeeping—Operating and Monitoring Procedures
IEST-RP-CC019: Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices
IEST-RP-CC020: Substrates and Forms for Documentation in Cleanrooms
IEST-RP-CC021: Testing HEPA and ULPA Filter Media
IEST-RP-CC022: Electrostatic Charge in Cleanrooms and Other Controlled Environments
IEST-RP-CC023: Microorganisms in Cleanrooms
IEST-RP-CC024: Measuring and Reporting Vibration in Microelectronics Facilities
IEST-RP-CC026: Cleanroom Operations
IEST-RP-CC027: Personnel in Cleanrooms
IEST-RP-CC028: Minienvironments
IEST-RP-CC031: Outgassing Performance Criteria for Cleanroom Materials

IEST-RP-CC032: Flexible Packaging Materials for Use in Cleanrooms and Other Controlled Environments
IEST-RP-CC034: HEPA and ULPA Filter Leak Tests
IEST-RP-CC036: Testing Fan Filter Units
IEST-RP-CC042: Sizing and Counting of Submicrometer Liquid-Borne Particles Using Optical Discrete-Particle Counters
IEST-RP-CC046: Controlled Environments (Aerospace, Non-cleanroom)
IEST-RP-CC044: Vacuum Cleaning Systems for Cleanrooms and Controlled Environments
IEST-RP-CC049: Controlled Environments for Regulated Industries
IEST-STD-CC1246: Product Cleanliness Levels – Applications, Requirements, and Determination
IEST-RP-NANO200: Planning of Nanoscale Science and Technology Facilities: Guidelines for Design, Construction, and Start-up
IEST-RP-NANO205: Nanotechnology Safety: Application of Prevention Through Design Principles to Nanotechnology Facilities
IEST-G-CC035: Design Considerations for Airborne Molecular Contamination Filtration Systems in Cleanrooms and Other Controlled Environments
IEST G-CC1001: Counting Airborne Particles for Classification and Monitoring of Cleanrooms and Clean Zones
IEST G-CC1002: Determination of the Concentration of Airborne Ultrafine Particles
IEST G-CC1003: Measurement of Airborne Macroparticles
IEST G-CC1004: Sequential-Sampling Plan for Use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones

An organization does not need to be engaged in using the ISO Standards to benefit from the guidance and support of the IEST Recommended Practices, Standards, and Guides. A review of the titles in Table 2 shows a wide range of guidance, with documents applicable to nearly any organization involved in cleanrooms and controlled environments.

To view further information regarding Recommended Practices, ISO/TC 209 Standards, and other technical documents for purchase from IEST, visit the IEST website and Bookstore. If you are interested in actively participating in the development of IEST Recommended Practices, we welcome you to observe a Working Group meeting during the IEST ESTECH Annual Technical Meeting held each spring or the IEST Fall Conference. Details on the upcoming meetings can be found on the IEST website.

Roberta Burrows is the Technical Advisor to IEST, the Secretariat to ISO/TC 209 on behalf of ANSI. She has served on the ISO/TC 209 Secretariat leadership team for twenty years.

Anne Marie Dixon-Heathman is the US Head of Delegation to ISO/TC 209, Convenor of ISO/TC 209 Working Group 10 Nanotechnologies, Chair of IEST Working Groups 18, 26, 49.

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.