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Practical Application of ISO Cleanroom Standards

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The original work of ISO Technical Committee (TC) 209 Cleanrooms and associated controlled environments is nearly complete. When the TC sat down in 1993 to begin developing a set of international standards, members could not have predicted all of the benefits these standards provide.

Keywords
ISO, ISO TC 209, 14644, 14698, cleanroom, standard, biocontamination

ISO Technical Committee 209 represents more than 1000 professionals and 40 countries in the development of the *Cleanrooms and associated controlled environments* International Standards. This 13-year cooperative effort has produced a collection of Standards (see table at end of article) now referenced by companies and regulatory agencies worldwide. All of the published Standards to date in the 14644 series have been accepted by the American National Standards Institute (ANSI) as nationally adopted International Standards.

The scope of the TC is the standardization of equipment, facilities, and operational methods; this includes procedural limits, operational limits, and testing procedures to achieve desired attributes to minimize contamination in cleanrooms and associated controlled environments.

In addition to meeting this scope and objective, these ISO Standards offer many benefits to users. For example:

- The information contained in the Standards can provide the basis for protocols and standard operating procedures.
- Some of the documents provide useful checklists to assist with implementation.
- The Standards can be applied to produce user specifications and validation documents.
- The two Standard documents in the ISO 14698 biocontamination control series serve as a tutorial covering all aspects of biocontamination.
- *ISO 14644-6 Cleanrooms and associated controlled environments—Part 6: Vocabulary* harmonizes the terms and definitions used in the ISO 14644 and ISO 14698 series and is an essential resource for every contamination control reference library. This document is pending final publication.
- Each document includes a Bibliography of resources for additional information on a related topic. Together, the 10 Standards provide an extensive collective reference of contamination control documents.

Let us look further at some of these benefits.

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Protocols and Procedures

ISO 14644-1 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness, which establishes airborne particulate cleanliness classes for cleanrooms and clean zones, has been adopted on a global scale. This document can serve as the basis for certification (qualification) testing of cleanrooms. The annexes present practical information to help the user to become proficient in this Standard. For example, a large ISO Class 4 cleanroom in the semiconductor industry faced with increasingly stringent specifications could dramatically reduce its sample volumes and sampling times by using sequential sampling as described in Annex F.

ISO 14644-2 Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 sets out the minimum requirements for testing and monitoring clean facilities. The document lists testing schedules and methods for particle count, air volume/velocity, and air pressure difference tests. In addition to specifying requirements by ISO classification, the document provides guidelines to help users develop a written plan for airborne-particle monitoring.

A cleanroom can use the information in *ISO 14644-3 Cleanrooms and associated controlled environments—Part 3: Test methods* to develop standard operating procedures (SOPs) that are tailored to a facility's needs. The document details the principle and purpose of each test, specific testing procedures, required apparatus, and reporting methods for 13 required and optional tests:

- Airborne particle count for classification and test measurement of cleanrooms and clean air devices
- Airborne particle count for ultrafine particles
- Airborne particle count for macroparticles
- Airflow test
- Air pressure difference test
- Installed filter system leakage test
- Airflow direction test and visualization
- Temperature test
- Humidity test
- Electrostatic and ion generator test
- Recovery test
- Containment leak test

In the area of Operations, requirements outlined in *ISO 14644-5 Cleanrooms and associated controlled environments—Part 5: Operations* can be incorporated into protocols, documents, and training programs, as described in the annexes. For example:

- In Annex A, Section A.2.2-2.6, users can find a list of risk factors for five critical elements of cleanroom operations: personnel, clothing, stationary equipment, mobile equipment, and cleaning.
- Annex A.4 discusses how to implement education and training and includes a course content list managers can use as the basis for developing a training curriculum.
- Annex B presents pertinent information on cleanroom garments, including design, assembly, and testing of fabrics.

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- To help users manage the primary source of contamination, personnel, Annex C covers personnel rules, regulations, and disciplines for operations, and includes a gowning procedure. This gowning procedure will assist in the development of internal procedures by offering assistance in the proper sequence of gowning.
- Annexes D and E address the second major source of contamination: admittance and installation or movement of mobile and stationary equipment. These annexes can be used as installation guides and training materials. Specifications are included for unpacking and transport to the cleanroom location of use.
- Annex E.5 also provides essential details on cleaning equipment and materials to assist users in purchasing and specifying these items.
- Annex F addresses the implementation of a cleaning program and covers surface classifications, cleaning practices, scheduling, and monitoring cleaning effectiveness. A schedule for cleaning during construction operations is included.

Convenient checklists

ISO 14644-3 Annex A presents a working checklist covering tests to be performed for the certification and qualification of a cleanroom. Test planners can use this checklist to assign the testing sequence, select the equipment to be used, and record comments.

ISO 14644-4 Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up reviews the specifics for the design, construction, and start-up of a facility. Annex H provides 12 pages of checklists to help ensure no portion of the facility design is overlooked in the planning stage. Users can fill in specified values and achieved performance for items in the following categories: process requirements, process contaminants, process equipment specifications, external factors, environmental requirements, safety requirements, standby/backup requirements, operations and maintenance factors, personnel factors affecting people and productivity, future developments, cost requirements, and schedule.

Generating documents

Several of the ISO Standards can form the basis for user specifications and validation documents. An example is *ISO 14644-7 Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*. Although this Standard does not address the operation within a separative device, it provides guidelines for the design and testing specific to the function of the device. Section 4 lists requirements for customers and suppliers to define, agree upon, and document. Two annexes present leak-testing methods and procedures. Companies have based their User Requirement Specifications (URS) and Factory Acceptance Tests (FAT) on this ISO Standard. In addition, the Standard can be incorporated into validation documents for operational qualifications.

Information in *ISO 14644-8 Cleanrooms and associated controlled environments—Part 8: Classification of airborne molecular contamination* can be incorporated into design and qualification documents. The document defines classifications for airborne molecular contamination (AMC) levels and covers test procedures to demonstrate compliance with those classifications. Section 5 outlines requirements for the test report, and Annex A explains how to establish design parameters. This document is pending final publication.

Biocontamination control resource

The two biocontamination Standards, *ISO 14698-1 Cleanrooms and associated controlled environments—Biocontamination control—Part 1: General principles and methods* and *14698-2 Cleanrooms and associated controlled environments—Biocontamination control—Part 2:*

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Evaluation and interpretation of biocontamination data, address the principles and basic methodology behind a formal biocontamination control system. These two documents serve as a tutorial covering various areas of biocontamination, including information on the following:

- Air sampling—selecting and validating samplers, designing a sampling plan, processing and culturing samples, evaluating data
- Determining biocontamination of surfaces, textiles, and liquids
- Validating laundering processes
- Training personnel

In addition, a step-by-step process is given for estimating and evaluating data from initial and routine microbiological monitoring phases.

ISO/TC 209 has achieved its mission to create a common denominator for international cleanroom standards. A solid foundation is in place for the ongoing work of maintaining the 14644 and 14698 Standard series. Those of us who have been involved during the past 13 years are pleased with the success of this committee and the commitment of all of the Working Groups to present the basic normative requirements as well as this informative library of contamination control.

Anne Marie Dixon chairs the US Technical Advisory Group to ISO TC 209 and represents ANSI as head of the US delegation to ISO Technical Committee 209, Cleanroom and Associated Controlled Environments. Dixon is managing partner of Cleanroom Management Associates, Inc., Carson City, Nevada, which specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management. She holds a BS in finance from the University of Illinois, a BS in engineering from the University of Nevada, and an MBA from the University of Chicago. Dixon is an IEST Fellow and Past President.

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ISO Document	Related IEST Documents
ISO 14644-1 Classification of air cleanliness	RP-CC001 HEPA and ULPA Filters RP-CC006 Testing Cleanrooms G-CC1001 Counting Airborne Particles for Classification and Monitoring of Cleanroom and Clean Zones G-CC1002 Determination of the Concentration of Airborne Ultrafine Particles G-CC1003 Measurement of Airborne Particles G-CC1004 Sequential-Sampling Plan for use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones
ISO 14644-2 Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	RP-CC001 HEPA and ULPA Filters RP-CC006 Testing Cleanrooms RP-CC007 Testing ULPA Filters RP-CC034 HEPA and ULPA Filter Leak Tests G-CC1001 Counting Airborne Particles for Classification and Monitoring of Cleanroom and Clean Zones G-CC1002 Determination of the Concentration of Airborne Ultrafine Particles G-CC1003 Measurement of Airborne Particles G-CC1004 Sequential-Sampling Plan for use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones
ISO 14644-3 Test methods	RP-CC001 HEPA and ULPA Filters RP-CC007 Testing ULPA Filters RP-CC013 Equipment Calibration or Validation Procedures RP-CC021 Testing HEPA and ULPA Filter Media RP-CC034 HEPA and ULPA Filter Leak Tests
ISO 14644-4 Design, construction and start-up	RP-CC001 HEPA and ULPA Filters RP-CC007 Testing ULPA Filters RP-CC021 Testing HEPA and ULPA Filter Media RP-CC022 Electrostatic Charge in Cleanrooms and Other Controlled Environments RP-CC024 Measuring and Reporting Vibration in Microelectronics Facilities
ISO 14644-5 Operations	RP-CC003 Garment System Considerations RP-CC004 Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments RP-CC005 Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments RP-CC018 Cleanroom Housekeeping: Operating and Monitoring Procedures RP-CC020 Substrates and Forms for Documentation in Cleanrooms RP-CC022 Electrostatic Charge in Cleanrooms and Other Controlled Environments RP-CC026 Cleanroom Operations RP-CC027 Personnel Practices and Procedures in Cleanrooms and Controlled Environments
ISO 14644-6 Vocabulary	RP-CC002 Unidirectional Flow Clean-Air Devices RP-CC011 A Glossary of Terms and Definitions Relating to Contamination Control RP-CC012 Considerations in Cleanroom Design RP-CC022 Electrostatic Charge in Cleanrooms and Other Controlled Environments RP-CC026 Cleanroom Operations RP-CC028 Minienvironments RP-CC034 HEPA and ULPA Filter Leak Tests
ISO 14644-7 Separative devices	RP-CC028 Minienvironments
ISO 14644-8 Classification of airborne molecular contamination	RP-CC016 The Rate of Deposition of Nonvolatile Residue in Cleanrooms RP-CC031 Method of Characterizing Outgassed Organic Compounds from Cleanroom Materials and Components
ISO 14698-1 Biocontamination control: General principles and methods	RP-CC013 Equipment Calibration or Validation Procedures RP-CC023 Microorganisms in Cleanrooms
ISO 14698-2 Biocontamination control: Evaluation and interpretation of biocontamination data	RP-CC013 Equipment Calibration or Validation Procedures RP-CC023 Microorganisms in Cleanrooms

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