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**REVISION OF FED-STD-209D AND MIL-STD-1246B AND  
DEVELOPMENT OF IES CONTAMINATION CONTROL RECOMMENDED  
PRACTICES IN THE UNITED STATES OF AMERICA**

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Introduction

In the United States of America, numerous organizations are writing standards and recommended practices for contamination control and cleanroom applications. The American Society for Testing and Materials (ASTM), the Institute of Environmental Sciences (IES), and various U. S. Government agencies are among the organizations with a vested interest in publishing standards and recommended practices on these subjects. In the early years of contamination control and cleanroom technology, significant work was done in the U.S. on standards and recommended practices. Proprietary standards were established by companies and other documents were produced by Federal agencies and technical organizations. In 1982, the IES began to focus on recommended practices, and the U.S. General Services Administration (GSA) commissioned the IES to review and rewrite U.S. Federal Standard 209 (FED-STD-209). The ASTM continues to review and update their standards on cleanroom applications on a periodic basis. Now, in 1990, U.S. military organizations are beginning to review their cleanroom documents as well.

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This paper will discuss the preparation of IES Recommended Practices and Standards for contamination control and cleanroom applications. It will describe the current status of four IES Recommended Practices and two U.S. Government documents.

### Background

In 1982, the IES initiated a Standards and Practices program. The first meeting of Working Groups, held in Dallas, Texas, in December 1982, included discussions on FED-STD-209B, testing laminar flow clean air devices, testing garments, wipers, and gloves used in cleanrooms, testing cleanrooms, and testing HEPA filters, ULPA filters, and gas-phase adsorber cells. These Working Groups have nearly tripled in number between 1982 and 1990.

Along the way, some Working Groups experienced false starts, and others have outlived their need. The IES currently has thirteen documents published in either formal release or tentative status (Table 1) and is the technical society designated by the GSA to review FED-STD-209.

### IES Standards and Practices Program

The IES has designated twenty-eight Working Groups for producing Contamination Control Recommended Practices and Standards (Table 2). Of these, twelve groups are working on new Recommended Practices, five groups are updating the current published documents, eight groups are preparing to review their published documents, two groups are

writing standards for the U.S. Government, and one group, WG-017, Ultrapure Water, is still being formed.

New Working Groups are created as needs arise. Among the topics soon to be considered are: cleanroom chairs and tables, air showers, and surface cleanliness test methods.

Among active Working Groups, four are working in areas known to be of special interest. Their progress is summarized below.

WG-003

This group is updating IES-RP-CC-003-87-T, "Recommended Practice for Garments Required in Cleanrooms and Controlled Environmental Areas." This document establishes material recommendations, cleanliness categories, and procedures for testing and evaluating garments designed for use in cleanrooms. The committee reconvened in April 1990 to update the document, with over forty participants in attendance. The group recognized that some basic changes are required and has established an aggressive schedule to effect revisions to the document over the next year.

WG-006

This group is updating IES-RP-CC-006-84T, "Recommended Practice for Testing Cleanrooms." Of all the IES Recommended Practices, this is the most popular; therefore, there is keen interest in having this document republished.

Changes resulting from this group's work will include the following:

17

- Grouping tests according to the level of certification they support; e.g.,
  - Airborne particulate cleanliness
  - Air movement and particle migration
  - Subsidiary cleanroom characteristics
- Extensive revision of HEPA Filter Leak Testing section, including:
  - More complete background information on filter scan methods to overcome confusion on the applicability of photometer vs. particle counter scanning.
  - Inclusion of a procedure for determining a suitable scanning rate.
- Recommendations for diagnosing problem areas detected during air cleanliness testing per Federal Standard 209D.
- Deletion of the section on Air Supply Volume and Reserve Capacity Tests
- Revision of the Temperature and Humidity section to include:
  - Addition of a dew point test alternative to humidity testing;
  - Expansion of procedures and equipment to allow for a broader range of testing protocols to match specific user needs and test capabilities;
  - Addition of an appendix to provide guidance on statistical treatment of temperature and moisture test data.

The revised document is scheduled for publication in early 1991.

7

WG-014

This new group will be writing a Recommended Practice dealing with calibration of particle counters. At the first working meeting in April 1990, thirteen members were present, representing particle counter manufacturers, users, academe, and the U.S. National Institute of Standards and Technology. The group decided to produce a Recommended Practice for calibrating and characterizing optical aerosol particle counters only. Liquid particle counters and condensation nucleus counters will be left for a future document.

The Recommended Practice will include procedures for determining both sizing and counting accuracy. Counting efficiency will probably be the most significant contribution of this document. Although there are several standards that address sizing accuracy, there are no formal guidelines for determining the counting efficiency of an optical particle counter. The group will provide a detailed method for measuring the counting efficiency of an optical particle counter. The procedure may require test instruments not readily available to all users; however, it is likely that the working group will also include a procedure to estimate counting efficiency by comparing the particle counter to one with certified characteristics. Also included will be sections on verifying the sample flow rate and determining false count rates. These issues will be clearly defined as the document takes shape.

WG-023

This group is writing a Recommended Practice on biocontamination control practices. This topic generates much debate within the pharmaceutical industry and a Recommended Practice is desperately needed. This Recommended Practice is in draft form and will cover procedures for determining the bioburden of areas and surfaces. It will include sampling plans, sampling methods, airborne sampling devices, measurement under special climatic conditions, preparation and sterilizing of sampling devices, surface sampling methods and materials, disinfectants, their properties, and methods of application, and evaluation of decontamination agents. The document will also include definitions and statistical process control methods for determining sampling plans and evaluating data.

This group plans to complete its Recommended Practice on this complicated subject by the end of summer 1990 and publish the document in early 1991.

There are, of course, other exciting Recommended Practice projects currently underway within the IES Standards and Practices program; however, time and space prohibits going into them in detail.

United States Government Standards

FED-STD-209

Probably the most used (and misused) contamination control document throughout the world is FED-STD-209. Since the first issue in 1962, there have been four

revisions. This document is under the control of the United States General Services Administration (GSA). The GSA recognized the IES to be a leading technical society in the contamination control and cleanroom fields and authorized the IES to maintain a standing committee to offer proposals for revisions and change notices to FED-STD-209. The IES has formed Working Group 100 (WG-100) to this end. This group currently meets twice each year and is composed of twenty-one members and five technical advisors from a cross section of the contamination control and cleanroom fields.

Working Group 100 has met four times, starting in September 1988. During this period, the following topics have been discussed for possible inclusion in FED-STD-209E:

- The standard will use metric units as the primary definition of quantitative measure. English units will be used in parallel.
- An extension of cleanliness levels below Class 1 is being discussed. To verify such "ultrafine" designations, a condensation nucleus counter with a cutoff at 0.02 micrometer is being considered.
- Discussions have taken place on expanding the scope of FED-STD-209. However, since it is a government document, constraints limit the breadth of the areas that can be encompassed by the document. Therefore, the scope will remain essentially unchanged. It is recognized by the group that additional documents need to be developed to cover other areas of concern that have been considered.
- The section on monitoring is being restructured to allow and encourage users to monitor, without restricting the methods for doing so.

- The revision may include counting methods and equipment other than those currently specified; i.e., optical particle counters for measurement of particles larger than 0.1 micrometer and membrane filtration with microscope observation for particles larger than 5 micrometers. These could include aerodynamic particle sizers and condensation nucleus counters. Any methods added will be addressed by revising Appendix A and Appendix B.
- The group will determine whether all particle sizes listed for a class must meet their concentration limits even if the specified particle size meets its limit.
- The revision will require that particle concentrations be reported as particles per unit volume of air, regardless of sample size. However, the overall sample size must be reported for the sample. The standard will still allow different sample volumes at different locations.
- The revision will address particle sampling system requirements so that gravitational and turbulent depositions for large particles and diffusion for small particles are minimized. This will be accomplished by requiring that sample acquisition and transport systems be based on good sampling practices for inlet probe efficiency, minimal transport losses, and adequate sample quantity.
- Although FED-STD-209D provides for multiple clean zones within a cleanroom at different cleanliness classification levels, the revision will attempt to expound on this fact. In both aerospace and pharmaceutical applications this then permits more economical facilities based on program needs.
- The group has discussed the possibility of some form of sequential sampling for areas that have ten or more locations to be sampled. No conclusions have been finalized at this time.



- The group is reviewing the need for the Upper Confidence Limit (UCL) for ten or more sample locations. If it is decided that the UCL is not needed in such cases, the only criterion would be that each sample location average must be below the Class Limit.
- The definitions section will be scrutinized to either add to or better define terms such as clean zone, cleanroom, confidence interval, entrance plane, isoaxial, mean, monitoring, and verification.
- The group is struggling with the complex specification for horizontal unidirectional clean zones, i.e., how many sample locations and at what heights samples should be taken.
- Because some subjects cannot be adequately addressed within the 209 document but nevertheless need to be published, WG-100 is initiating a number of monographs that will be referenced in the document. These monographs will define good procedures in certain areas that are presently understood by only a few experts.

Working Group 100 has sent GSA a correction to FED-STD-209D that will shortly be published as a Change Notice to the document. Federal Standard 209E will cover air cleanliness over a wide range, from Class 100,000 to below the current Class 1. The group intends to write a document that will not be immediately obsolete. Both the future needs of industry and the rapid advance of technology will make this a difficult task.

#### MIL-STD-1246

The Army Missile Command of the U.S. Army has commissioned the IES to revise MIL-STD-1246B, "Product Cleanliness Levels and Contamination Control Program." The Army Missile Command has jurisdiction over this Military Standard.

MIL-STD-1246 "provides a basis and a uniform method for specifying product cleanliness and contamination control program requirements." Originally produced in 1962, MIL-STD-1246 has been revised twice, most recently in 1987. Over the years, product cleanliness requirements have become much more stringent and detection instrumentation has improved. Another revision is needed to incorporate recent developments for compatibility with current user requirements. Because the document pertains to product cleanliness, both in and on product, the significance of this standard is quite evident.

The IES has formed Working Group 1246 (WG-1246), which has six task groups charged with the detailed study of the following discrete aspects: air, gases, liquids, surfaces, contamination control plan, and appendixes. The two areas of greatest emphasis are the surface cleanliness and the contamination control plan. The Working Group had its first meeting in April 1990.

#### Conclusion

In conclusion, there is much going on within the IES relating to standards and recommended practices. Other organizations such as the ASTM and the U.S. Government are also reviewing and revising their standards. Recently, the IES published a *Handbook of Recommended Practices*, which includes all of the IES contamination control documents, as well as FED-STD-209D and MIL-STD-1246B. These documents are living documents and therefore need to be periodically reviewed. To this end, the IES Contamination Control Division currently has twenty-eight standing working groups dedicated to furnishing up-to-date and accurate documents which provide technical knowledge and establish test methods for those who require information on contamination control and cleanroom applications.

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**MIL-STD 1246B, Product Cleanliness Levels and Contamination Control Program,**

U.S. Army Missile Command, Redstone Arsenal, Alabama, 4 September 1987.

Leiberman, Alvin, "U.S. Federal Standard 209D, Modification Plans 1989/1990,"

Proceedings of the Scottish Society Contamination Control and Cleanrooms Conference, 18 April 1990, p.50-57.

TABLE 1

## IES Contamination Control Recommended Practices\*

<u>IES Sequence No.</u>	<u>Recommended Practice Title (Subject)</u>
IES-RP-CC-001-86	HEPA Filters
IES-RP-CC-002-86	Laminar Flow Clean Air Devices
IES-RP-CC-003-87-T	Garments Required in Cleanrooms and Controlled Environmental Areas
IES-RP-CC-004-87-T	Wipers Used in Cleanrooms and Controlled Environments
IES-RP-CC-005-87-T	Cleanroom Gloves and Finger Cots
IES-RP-CC-006-84-T	Testing Cleanrooms
IES-RP-CC-008-84	Gas-Phase Adsorber Cells
IES-CC-009-84*	Compendium of Standards, Practices, Methods, Relating to Contamination Control
IES-CC-011-85-T*	A Glossary of Terms, Definitions and Similar Related Documents to Contamination Control
IES-RP-CC-013-86-T	Equipment Calibration or Validation Procedures
IES-RP-CC-015-87-T	Cleanroom Production and Support Equipment
IES-RP-CC-018-89-T	Cleanroom Housekeeping-Operating and Monitoring Procedures
IES-RP-CC-020-88-T	Substrates and Forms for Documentation in Cleanrooms

\*Although not strictly Recommended Practices, IES-CC-009-84 and IES-CC-011-85-T were developed through the auspices of the IES Standards and Practices Committee as useful complements to the Practices.

TABLE 2

## IES Working Groups Related to Contamination Control

<u>Working Group No.</u>	<u>Subject Matter of Working Group</u>
WG-001	HEPA Filters
WG-002	Laminar Flow Clean Air Devices
WG-003	Garments Required in Cleanrooms and Controlled Environment Areas
WG-004	Wipers Used in Cleanrooms and Controlled Environments
WG-005	Cleanroom Gloves and Finger Cots
WG-006	Testing and Certification of Cleanrooms
WG-007	Testing ULPA Filters
WG-008	Gas-Phase Adsorber Cells
WG-009	Compendium of Standards, Practices, Methods and Similar Documents Related to Contamination Control
WG-010	Committee for the Revision of Federal Standard 209B
WG-011	Glossary of Terms and Definitions Related to Contamination Control
WG-012	Considerations for the Design of Cleanrooms
WG-013	Procedures for the Calibration or Validation of Equipment
WG-014	Particle Counter Calibration Methods
WG-015	Installation of Cleanroom Production Equipment
WG-016	Deposition of Nonvolatile Residue in Cleanrooms
WG-017	Ultrapure Water: Contamination Analysis and Control
WG-018	Cleanroom Housekeeping - Operating and Monitoring Procedures
WG-019	Qualification for Agencies and Personnel Engaged in the Testing and Certification of Cleanrooms and Clean Air Devices
WG-020	Substrates and Forms for Documentation in Cleanrooms
WG-021	Testing HEPA and ULPA Filtration Media
WG-022	Electrostatic Charge in Cleanrooms and Other Controlled Environments
WG-023	Biocontamination Control Practices
WG-024	Measuring and Reporting Vibration in Semiconductor Facilities
WG-025	Evaluation of Swabs Used in Cleanrooms
WG-026	Ancillary Operations in Cleanrooms
WG-027	Personnel in Cleanrooms
WG-050	Federal Standard 209C Writing Committee
WG-100	Federal Standard 209D Revision Working Group
WG-1246	Product Cleanliness Levels and Contamination Control Program MIL-STD-1246B Revision Working Group

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