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**New Challenges in Contamination Control:
The Leadership Role of IEST in Shaping Future Research and Practices**

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A leading industrial standards writing organization since 1953, IEST has established seven tracks of Recommended Practices (RP) in the Standards and Practices (S&P) portion of the Contamination Control (CC) program, including the most recent program in Nanoscience and Nanotechnology. In addition, there are other parallel activities in IEST’s Design, Test, and Evaluation and Product Reliability division. Within each of these programs, scientists, engineers, and contamination control professionals from all over the world interact closely in working group meetings, seminars, and tutorials. Together they have developed, published, and disseminated technical information and industrial standards, including RPs, Reference Documents (RDs), and ISO Standards to address ever evolving challenges in contamination control and sustainable development of the industries served by IEST.

The series of Standards, RPs, and RDs are developed through years of discussion, deliberation and review thus providing peer-reviewed best practices, standardized procedures and test methods to furnish guidance and address problems in contamination control. In general, IEST’s procedures for the development of Standards, RPs, or RDs are in accordance with its status as an ANSI-accredited Standards Developer Organization (SDO). Specifically, RPs and RDs are formulated by IEST Working Groups (WGs) through a cooperative exchange of knowledge, experience and ideas that culminate in useful and timely information invaluable to all that avail themselves of this knowledge. These documents are reviewed every three years so that new knowledge, information, and methods may be integrated into them in a timely manner.

All WG member contributions are provided by professionals on a volunteer basis. There are increasing challenges associated with keeping up with new knowledge requirements. However, IEST has successfully relied on ever-evolving leadership and concerted efforts by numerous volunteers to develop, revise, and publish new documents at a faster pace than had been seen in recent decades. For example, eight updated revisions of existing or brand new RPs have been published since 2005 (marked as yellow), and approximately seven more RPs and RDs are well positioned in the pipeline for official publication by early 2007 (marked as green).

Due to their quality and timeliness, many IEST RPs are primary references and sources of information for compliance with the ISO 14644 series of International Standards developed by ISO Technical Committee (ISO/TC) 209, Cleanrooms and associated controlled environments. Additionally, IEST conducts technical seminars, workshops, and tutorials at its annual technical meeting (ESTECH), its Fall Conference, and online to assist related industries to better understand the “state-of-the art” philosophies and effectively utilize IEST Recommended Practices and ISO Standards.

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Being the leading organization and a voting member of the ANSI-accredited US Technical Advisory Group (TAG) to ISO/TC 229, Nanotechnologies, IEST is in a unique position to contribute its expertise in developing international standards for controlled environments to anticipate the unique needs of the emerging nanoscience/nanotechnology industry. For example, the IEST has formulated a new program to address the complex issues relevant to all industries working in this area and includes nanoparticles, other relevant contamination control issues, and building facilities to conduct research and produce products related to nanotechnology. Leading industry experts in this area have been gathering at IEST conferences since the Fall Conference in 2005 and are working diligently on a first-ever industry road map and subsequent RPs the IEST Recommended Practices NANO200 series. The first document titled “Planning, Design, Construction & Operations Considerations for Facilities Engaged in Research or Production at the Nanometer Scale” is, as mentioned earlier, the “road map document” for all industries building facilities to perform research and manufacturing at nanoscale levels. The document is scheduled for publication latter part of 2007.

IEST leaders are continually embracing new challenges and taking advantage of new opportunities to lead the way in the development of ground-breaking documents. We invite you to join in and participate in the relevant WGs, whether you are from the industrial sector or from academia. To increase your knowledge of the constantly evolving issues of the contamination control industry, you will want to purchase all of the recent versions of these documents and become an active part of the organization. For further information, please visit www.iest.org.

WG-CC001: HEPA and ULPA Filters

This Recommended Practice (RP) covers basic provisions for HEPA (high efficiency particulate air) and ULPA (ultra-low penetration air) filter units as a basis for agreement between buyers and sellers. Filters that meet the requirements of this Recommended Practice (RP) are suitable for use in clean air devices and cleanrooms that come within the scope of ISO 14644 -1 & 2 (formerly Federal Standard 209) and for use in supply air and contaminated exhaust systems for which extremely high filter efficiency (99.97% or higher) for sub-micrometer particles is required. Six levels of performance and six grades of construction are included in this discussion. *IEST-RP-CC001.4 was published in November 2005 and is due for review November 2008.*

WG-CC002: Unidirectional Flow Clean-Air Devices

This RP covers definitions, procedures for evaluating performance, and major requirements of unidirectional flow clean-air devices. It may be used to define a basis of agreement between customer and supplier in the specification, procurement, and certification testing of unidirectional flow clean-air devices with self-contained motor-blowers and nonpowered terminal units with replaceable filter. It also presents recommendations for recertification under direction of the customer on devices owned by the customer.

IEST-RP-CC002.2 was reviewed and validated in June 2004 and is due for review June 2007.

WG-CC003: Garment System Considerations for Cleanrooms and Other Controlled Environments

This RP addresses the gowning of personnel as an important aspect of cleanroom contamination control. It provides nonmandatory guidance for the selection, specification, maintenance, and

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testing of apparel and accessories appropriate for use in nonaseptic and aseptic cleanrooms and other controlled environments.

IEST-RP-CC003.3 was published in August 2003 and the Working Group is planning version 3.4.

WG-CC004: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments

This RP describes methods for evaluating, selecting and testing wipers used in cleanrooms and other controlled environments for characteristics related to both cleanliness and function based on intended usage.

IEST-RP-CC004.3 was published in August 2004 and is due for review August 2007.

WG-CC005: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments

This RP describes procedures for testing, selecting and evaluating gloves and finger cots used in cleanrooms and other controlled environments. Tests are provided for determining cleanliness, physical and chemical integrity, and other relevant properties. Guidelines are also provided to assist users in the proper selection of gloves or finger cots.

IEST-RP-CC005.3 was reviewed and validated in September 2006 and is due for review September 2009.

WG-CC006: Testing Cleanrooms

This RP covers testing methods for characterizing the performance of cleanrooms. It is intended to assist planners, designers, manufacturers, and buyers in preparing detailed specifications for cleanroom procurement and for assuring cleanroom operational compliance. Performance tests are recommended for three types of cleanrooms at three operational phases. Where the test method is affected by the type of cleanroom, alternative procedures are defined. For some of the tests, several different methods and instruments are allowed, so that different end-use considerations can be accommodated. The test methods also may be used or adapted for periodic monitoring of cleanroom or clean zone performance capability.

IEST-RP-CC006.3 was published in August 2004 and is due for review August 2007.

WG-CC007: Testing ULPA Filters

This RP covers production testing of filters for particle penetration and pressure drop of ultra low penetration air filters (ULPA). The penetration range of the procedure is 0.001% to 0.0001%, using particle counters. This procedure describes the equipment, aerosol properties, processes, and calculations for determining the efficiency of ultra low penetration air filters, using particle counters. The procedure may be applied to production applications. Guidelines are provided for constructing a suitable test duct and sampling system. Also provided are test criteria for quantifying penetration in the range of 0.001% to 0.0001%, using test aerosol particles in the size range of 0.1 µm to 0.2.

IEST-RP-CC007.1 was published in January 1992. IEST-RP-CC007.2 is now ready for WG ballot.

WG-CC008: Gas-Phase Adsorber Cells

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This Recommended Practice covers the design and testing of a modular gas-phase adsorber cell for use in once-through or re-circulating air cleaning systems where high efficiency removal of gaseous contaminants is a requirement. This practice covers two types of modular cells: Type I Pleated-bed cell, and Type II Flat-bed or tray type cell.

IEST-RP-CC008-84 was published in January 1984. IEST-RP-CC008.2 should be published in January 2007.

WG-CC009: Compendium of Standards, Practices, Methods, and Similar Documents Relating to Contamination Control

The references in this compendium relate to the field of contamination control. This compendium lists standards, practices, recommendations, and similar documents developed by government agencies, industry, technical societies and other standard development groups. Handbooks, monographs, technical papers, bibliographies and the like are not included. The documents reported were developed both in the United States and in other countries and are current as of July, 1999. There are a total of 400 listings viz., 209 from United States sources and 191 from non-United States sources.

The WG is in the process of developing and updating the information and welcomes your participation.

WG-CC011: Glossary of Terms and Definitions Relating to Contamination Control

The terms and definitions included in this document generally have distinctive meanings within the context of contamination control. Terms having a more generic nature are not included in this document; the definitions as found in the American Heritage Dictionary are considered acceptable.

IEST-RD-CC011.2 was published in January 1995. The WG is now in the process of updating the information contained in this document.

WG-CC012: Considerations in Cleanroom Design; Subgroup 1: Cleanroom Design Considerations; Subgroup 2: Installation of Cleanroom Production Equipment

The updated RP makes recommendations regarding factors to consider in the design of cleanroom facilities. This discussion is limited to those environmental conditions that typically confront cleanroom designers and users. This document is intended to provide users with a means to establish performance criteria for cleanrooms. The factors that it takes into consideration are those that are commonly encountered in cleanrooms, but discussion of these factors is not intended to be all-inclusive. The specified ranges and recommended criteria are intended only to stimulate discussion by providing a framework. Specific process or other needs may dictate requirements beyond the scope of this document. This document is not intended to supersede specific requirements established by a recognized national or international regulating body, such as the FDA.

IEST-RP-CC012.1 was published in March 1998. IEST-RP-CC012.2 is in editing.

WG-CC013: Calibration Procedures and Guidelines for Selecting Equipment Used in Testing Cleanrooms and Other Controlled Environments

This RP covers procedures for calibrating and verifying equipment used in characterizing cleanrooms and for determining intervals of calibration. The RP includes general procedures for

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calibrating photometers, aerosol generators, and anemometers. Where available, references for calibrating other instruments are provided.

IEST-RP-CC013.2 was published in October 2006.

WG-CC014.1: Calibration and Characterization of Optical Airborne Particle Counters

This RP covers procedures for calibrating and characterizing the performance of optical particle counters (OPC's) that detect and measure the size of single particles in air and other gases. These procedures are intended for use by OPC manufacturers, specialized test houses, and OPC users who maintain calibration and testing facilities to determine the sizing and counting accuracy of these instruments.

IEST-RP-CC014.1 was published in October 2006.

WG-CC016: The Rate of Deposition of Nonvolatile Residue in Cleanrooms

This RP provides a uniform method of testing and basis for defining the rates of deposition of nonvolatile residue (NVR) and other forms of molecular contamination on surfaces in cleanrooms. It is under active revision and will be published as CC016.3.

IEST-RP-CC016.2 was published in November 2002 and validated in April 2006 for another three years. The committee is considering whether the RP should be expanded or a new RP be established to include inorganic compounds (referred to as “. . . deposition of AMC . . .” instead of NVR).

WG-CC018: Cleanroom Housekeeping-Operating and Monitoring Procedures

This RP provides guidance for maintaining a cleanroom at the level for which it was designed. This document is intended to be used as a guide for establishing appropriate housekeeping procedures. In addition, test procedures are provided for use in establishing the frequency and monitoring the effectiveness of the housekeeping. The test methods also are designed to help determine appropriate levels of surface cleanliness for specific cleanrooms.

IEST-RP-CC018.3 was published in December 2002. The document is currently under active revision and the WG is planning publication of IEST-RP-CC018.4 in early 2008.

WG-CC019: Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices

This RP defines recommended qualifications for organizations engaged in the testing and certification of cleanrooms, clean-air devices, HEPA- and ULPA-filtered systems, and associated components. The document presents criteria to be used in qualifying personnel of certification agencies. It establishes professional categories of personnel who do testing and consists of recommended minimal requirements for education, training, and experience.

IEST-RP-CC019.1 was published in January 2006.

WG-CC020: Substrates and Forms for Documentation in Cleanrooms

This RP applies to substrates and forms used in cleanrooms for the purpose of documentation. Specifically included are: copy paper, writing paper, labels, tags, self-adhesive notes, perforated and punched forms, envelopes, bound materials, and all printed versions thereof. This RP provides appropriate methods for assessing the cleanliness of these items insofar as their suitability for use in cleanrooms is concerned.

IEST-RP-CC020.2 was published in January 1996.

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WG-CC021: Testing HEPA and ULPA Filter Media

This RP discusses test methods for physical and filtration properties of high efficiency particulate air (HEPA) and ultra low penetration air (ULPA) filtration media. Use of this RP should be applied to, but not be limited to, acceptance criteria for test methods; test aerosol and particle size; test face velocity.

IEST-RP-CC021.2 was published in September 2005.

WG-CC022: Electrostatic Charge in Cleanrooms and Other Controlled Environments

This RP discusses methods for specifying and evaluating the effectiveness of techniques for controlling electrostatic charge. Controlling electrostatic charge reduces surface contamination and electrostatic discharge. This document describes methods of testing, provides guidelines for verifying charge neutralization and resistivity of surfaces and materials, and describes typical control systems and their applications.

IEST-RP-CC022.2 was published in January 2004. The WG plans to convene at ESTECH 2007 for revision.

WG-CC023: Microorganisms in Cleanrooms

This RP provides guidelines for the control and quantitative measurement of viable contamination in the air and on surfaces in environments that require control of such contamination. This includes areas designated as aseptic and those considered nonsterile. The procedures and techniques employed to achieve the desired level of microbial control are dependent on the level of bioburden that can be tolerated. This RP presents an introduction to the currently accepted methods for bioburden control and environmental monitoring as well as the devices available for the quantification of airborne and surface viable contamination. The document also describes some of the disinfectants currently available, their lethality spectrum, and techniques for their application.

IEST-RP-CC023.2 was published in January 2006.

WG-CC024: Measuring and Reporting Vibration in Microelectronics Facilities

Equipment used in the manufacture, measurement, and inspection of integrated circuits is sensitive to vibration and sound. It is therefore necessary to establish levels of vibration sensitivity for them and to ensure that vibrations occurring in the facility or at the site at which they are located are below those levels. This RP is intended to provide guidance for use in the microelectronics industry. However, it may also be applicable in pharmaceutical and biological research, metrology laboratories, and other contexts in which vibration control is important.

IEST-RP-CC024.1 was published in January 1994. The WG has started to revise the RP and welcomes your participation.

WG-CC025: Evaluation of Swabs Used in Cleanrooms

This RP describes methods for testing swabs used in cleanrooms and other controlled environments for characteristics related to both cleanliness and function.

The WG is developing IEST-RP-CC025.1.

WG-CC026: Cleanroom Operations

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This RP provides guidance for maintaining the integrity of the cleanroom during ancillary operations. Ancillary operations include preparation of supplies and materials; modification of the facility; and installation and repair of equipment. Procedures are presented for verifying cleanliness of equipment, workstations, and the area after these ancillary operations are completed.

IEST-RP-CC026.2 was published in July 2004. The WG has started revision of the document in 2006.

WG-CC027: Personnel Practices and Procedures in Cleanrooms and Controlled Environments

This RP provides a basis for establishing personnel procedures and the development of training programs for cleanrooms and other contamination controlled environments.

IEST-RP-CC027.2 was published in March 2006.

WG-CC028: Minienvironments

This RP is intended to stimulate discussion of specifications and configurations for a specified application between the supplier and customer. The purpose of this document is to provide a framework for describing minienvironments for microelectronics and similar applications. Applications, planning, design, and evaluation are discussed in detail. This Recommended Practice does not address microbiological issues or applications.

IEST-RP-CC028.1 was published in September 2002. The WG has started to revise the document (expected to lead to IEST-RP-CC028.2) at IEST's 2006 Fall Conference.

WG-CC029: Contamination Control Considerations for Paint-Spray Applications

This RP provides guidelines and recommended procedures for controlling dirt contamination (particles, fibrous material, etc.) in controlled environments used for paint spraying.

IEST-RP-CC029.1 was published in June 1999 and validated in June 2004.

WG-CC031: Method for Characterizing Outgassed Organic Compounds from Cleanroom Materials and Components

This RP published in April 2003 describes a test method appropriate for semi qualitative characterization of organic compounds outgassed from materials or components exposed to air in cleanrooms or other controlled environments. The RP specifies four outgassing temperatures viz., 50 °C (122 °F), 75 °C (167 °F), 100 °C (212 °F), and 150 °C (302 °F) to baseline cleanroom materials and components. The RP may become the basis of an agreement between customer and supplier in the specification, procurement, and certification of materials.

IEST-RP-CC031.1 was published in April 2003. The WG has reconvened at IEST's 2006 Fall Conference to work on the next generation of the document viz., IEST-RP-CC031.2.

WG-CC032: Packaging Materials for Cleanrooms

This RP is intended to define required characteristics and test methods for evaluating flexible packaging for cleanroom products and supplies destined for use in controlled environments. Methods include, but not limited to cleanliness level, mechanical and chemical characteristics. In addition, this RP provides information related to the properties performance characteristics and usage issues for flexible packaging materials in order to prevent contamination of product/device due to molecular contamination as a result of leachables, extractables, and NVR's or other

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diffusion processes. These Guidelines may be used to establish agreement between supplier and the customer for specification procurement, and certification testing of clean flexible packaging material. This RP includes particle cleanliness level and material properties as they pertain to outgassing and endurance of flexible packaging material.

This document is in the final stages of preparation by the WG and will be published for the first time as IEST-RP-CC032.1 by late 2007 or early 2008.

WG-CC034: HEPA and ULPA Filter Leak Tests

This RP covers definitions, equipment, and procedures for leak testing HEPA and ULPA filters in the factory as they are produced, at the job site before they are installed, and after they are installed in cleanrooms and unidirectional-flow, clean-air devices. When used in conjunction with other RPs, *IEST-RP-CC001*, *IEST-RP-CC002*, *IEST-RP-CC006*, *IEST-RP-CC007*, or *IEST-RPCC021*, it may be used to define the basis of an agreement between customer and supplier in the specification and procurement of HEPA and ULPA filters, and in the certification testing of unidirectional flow, clean-air devices and cleanrooms. This RP also includes procedures for measuring the uniformity of the aerosol challenge approaching the filter under test.

IEST-RP-CC034.2 was published in June 2005.

WG-CC035: Design Considerations for Airborne Molecular Contamination Filtration Systems in Cleanrooms

The WG is planning a guide to AMC which describes important areas of concern when considering AMC filtration systems. It discusses various applications, potential points of use, filtration methods, materials of construction, performance comparison and follow-up assessment, secondary impacts of the filters on the rest of the HVAC system, and exterior impacts on the filtration system (including environmental conditions, upsets, spills, etc.). It establishes the types of information required to design and implement an effective AMC filtration system. While this document is targeted at cleanroom facilities, it could also form a framework for other applications as well.

The Working Group is developing either IEST-RP-CC035.1 or a Guide – To be determined..

WG-CC036: Testing Fan Filter Units

The RP is in the process of development and describes methods and definitions for testing the performance of fan filter units. Its purpose is to provide customers and suppliers of fan filter units the necessary test protocols for measuring performance in such a manner as to allow direct comparison of units provided by different manufacturers of varying designs and operating features. The test methods identify test equipment and testing procedures necessary to measure volumetric airflow rate, electric power parameters (watts, amps, voltage, and power factor), available external static pressure, sound pressure levels, sound power levels, filter air velocity uniformity, and housing vibration. These procedures are applicable for units with AC motors, with DC brushless motors, without airflow control, or with airflow control. These procedures are applicable to fan filter units with filter equal to or less than 4 feet in any direction.

The RP is expected to be published sometime in 2007.

WG-CC040: Cleaning of Equipment Surfaces in the Cleanroom and Controlled Environments

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This WG is developing an RP based on industry best practices of cleaning surfaces in cleanrooms and other controlled environments.

The RP is expected to be published sometime in 2008.

WG-CC041: Recovery from Disruption to Cleanrooms and Other Controlled Environments

This WG will develop a new RP to guide users in recovering controlled environments in the event of planned and unplanned disruptions. This RP will provide a framework for restoring controlled environments to their normal operating condition following interruption. This framework includes preparation prior to and actions following the disruption. Disruptions may be caused by various events, such as one or more of the following . . . utility or equipment failure, fire, natural disaster, planned shutdown, hazardous material, medical emergency, human error, cross-contamination.

The RP is expected to be published sometime in 2008.

WG-CC042: Liquid Particle Counters

This RP will cover procedures for calibrating and characterizing the performance of liquid particle counters (LPC's) that detect and measure the size of single particles in liquids.

The RP is expected to be published sometime in 2008.

WG-CC901: Product Cleanliness Levels and Contamination Control Program

This standard provides a basis and a uniform method for specifying product cleanliness levels and contamination control program requirements. The emphasis is on contaminants that can impact product performance.

IEST-STD-CC1246D was published in January 2002 and is in the process of being updated..

WG-CC902: MIL-HDBK-406: Contamination Control Technology: Cleaning Materials for Precision Pre-Cleaning and Use in Cleanrooms and Clean Work Stations; MIL-HDBK-407: Contamination Control Technology: Precision Cleaning Methods and Procedures

Specifies the cleaning procedures to achieve the product cleanliness levels specified in IEST-STD-CC1246D.

The military handbooks are ready for final editing by the military.

ABOUT THE AUTHORS



Dr. Tengfang (Tim) Xu, PE is a program manager with Lawrence Berkeley National Laboratory, managing and performing R&D projects to quantify energy efficiency and improve performance of commercial, residential, and industrial buildings, including cleanrooms, data centers, and healthcare buildings.

Dr. Xu is the Contamination Control Technical Vice President of IEST. He is a recipient of numerous national awards for scientific papers, publications, and professional services. At Berkeley Lab, he is involved in the development of innovative methods and protocols that are instrumental in formulating standards to characterize fan filter units. In addition, he manages and performs evaluations of energy, airflow and filtration requirements for cleanrooms and minienvironments. Xu's interests and accomplishments include the production and dissemination of new knowledge and techniques to improve environmental

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and energy performance of mission-critical buildings which include cleanrooms and minienvironments. Dr. Xu is a Technical Editor for the *Journal of the IEST*, and serves on the editorial board of *Building and Environment*, Elsevier Scientific. Email: TTXU@LBL.Gov; <http://eetd.lbl.gov/Staff/XuTT/>.



Jan Eudy is the Corporate Quality Assurance Manager for Cintas Corporation. At Cintas, Jan oversees research and development, directs the quality system and ISO registration at all cleanroom locations and supports validation and sterile services. She established and implemented the HACCP program at Cintas. She is the Past President of IEST. She is an active member of other professional organizations including the American Society of Clinical Pathologists, the National Registry of Microbiology, the American Society for Microbiology, the American Society for Quality, the International Society for Pharmaceutical Engineers and the Parenteral Drug Association. Jan represents Cintas on the FPA Advisory subcommittee to the FDA for the revision of the Food Processing cGMP's. Jan graduated with a degree in Medical Technology from the University of Wisconsin with graduate studies in Medical Microbiology at Creighton University. Jan's additional qualifications include Registered Medical Technologist and Specialist in Microbiology with ASCP, Registered Microbiologist with NRM in Consumer Product Testing and Quality Assurance, ISO 9000 Lead Assessor and Certified Quality Auditor with ASQ.



Charles W. Berndt is the principal in C. W. Berndt Associates, Highland Park, Illinois, which provides advisory services associated with human-sourced contamination control. He spent eight years as group manager of the Araclean Division of ARA/Aratex Services (now known as ARAMARK Cleanroom Services). He serves on the Editorial Advisory Board of *CleanRooms* magazine, chairs the Editorial Board of the peer-reviewed *Journal of the IEST*, is Communications Vice President of IEST, and serves on IEST's Executive Board. He chaired Working Group CC003 during the development of IEST-RP-003.3.

He currently chairs IEST Working Group CC029, Contamination Control Considerations for Paint Spray Applications. Berndt is the recipient of the 2001 Willis J. Whitfield Award presented "for substantial contributions to the field of contamination control through published papers, studies and reports," the 2004 Monroe Seligman Award "for his diligence and perseverance in carrying out the mission of the *Journal of the IEST*," and was named a Fellow of IEST in 2006 "for his unique technical knowledge, professional skills, and distinct contributions to advancing the environmental sciences through publications, innovation, and untiring service to IEST."

ABOUT IEST

IEST is an international technical society of engineers, scientists, and educators that serves its members and the industries they represent (simulating, testing, controlling, and teaching the environments of earth and space) through education and the development of recommended practices and standards. IEST is the Secretariat for ISO Technical Committee 209, Cleanrooms and associated controlled environments, charged with writing a family of international cleanroom standards. IEST is also an ANSI-accredited standards-development organization. For more information, contact IEST at iest@iest.org or visit the IEST website at www.iest.org.