

# CLEANROOM GUIDEBOOK

## Testing & Certification

document



Matthew Lemieux

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## **CLEANROOM TESTING GUIDEBOOK**

Matthew C. Lemieux

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*To Trung Thanh Dao, Amy Joan Lemieux-Mita & Dr. Einat Grunfeld  
without whom none of this would be possible.*

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# 1. INTRODUCTION

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*The White Rabbit put on his spectacles. 'Where shall I begin, please your Majesty?' he asked. 'Begin at the beginning,' the King said gravely, 'and go on till you come to the end: then stop.'*

Lewis Carrol - Alice's Adventures in Wonderland.

## 1.1. PURPOSE

This CLEANROOM TESTING GUIDEBOOK is intended as a multipurpose publication for a diverse audience. For cleanroom testing and certification professionals, the guidebook provides an authoritative reference manual for performing, conducting, presenting and interpreting cleanroom testing results. For cleanroom owners, this guidebook is a single source industry reference; facilitating interpretation of delivered cleanroom testing reports. For facilities managers, the guidebook provides a demystified explanation of cleanroom testing and a benchmark document for evaluating third-party certification contracts and deliverables. For quality assurance professionals, this guidebook condenses the most pertinent industry standards into one, comprehensive reference manual. For cleanroom design engineers, the guidebook represents the stakeholder interests of cleanroom certification professionals in intelligent and informed cleanroom design. Compounding pharmacy professionals can find clear, colloquial explanations of esoteric HVAC engineering concepts and the broader cleanroom industry. Certification agency owners will find this book indispensable for formal technician training of new and experienced technicians owing to the copious worked out examples provided herein.

Cleanroom stakeholders may include process engineers, facilities personnel, manufacturing supervisors, and managers, manufacturing shop forepersons, responsible engineers, contamination control engineers, subject matter experts, laboratory research personnel, environmental health and safety professionals, hospital personnel, pharmacists and any other interested parties. The guidebook endeavors to faithfully represent any and all pertinent industry standards where they are deemed accurate and correct and to make necessary improvements and clarifications thereon.

Cleanroom testing technicians and professionals will also value this guidebook as an indispensable manual to assist in career advancement and facilitate professional certification and accreditation.

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end of preview

## ABOUT THE AUTHOR

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Matthew Lemieux, SURETECH's founder, has over 36 continuous years of field experience as a biological safety cabinet certifier, air and water balancer & cleanroom certifier.

Mr. Lemieux has a B.S. in mechanical engineering from Northeastern University, a Massachusetts E.I.T. registration, an associate's degree in electronics engineering from ITT Technical Institute, a former Massachusetts HVAC license, Eagleson Institute honor member recognition and has been an ANSI/NSF-49 accredited biological safety cabinet certifier since 1997. He is a NEBB CPT-CP certified professional as well as a CETA accredited RCCP-SCF for sterile compounding facilities.

Mr. Lemieux's broad expertise involves ANSI/NSF-49, N.E.B.B., I.E.S.T., ISO 14644, USP, ASHRAE and many other industry standards and documentation. He was a co-founder of Omni Testing, LLC, (1984) Certco, INC. (1989), Airgo Instruments, INC. (2000) and research and development engineer of SBB Testing, LLC. (2006). He presently serves as vice president of quality and training at AIR SYSTEMS TECHNOLOGIES of Avon, MA (2016), the region's premier provider of quality certification and contracting services. Mr. Lemieux is the most sought-after controlled environment instructor in the United States and Asia. His proprietary and unique instructional approaches, methods and material nearly always guarantee both written and practical accreditation exam success with only the minimum requisite field experience mandated by the accrediting bodies.

The CLEANROOM GUIDEBOOK, TESTING & CERTIFICATION, is an indispensable reference for any and all cleanroom stakeholders.

Rather than being a mile wide and an inch deep, this book leaves no depths unplumbed. It covers all the relevant topics involved in cleanroom technology from the standpoint of testing and certification, where the rubber meets the road. No other book explores in detail the relevant performance tests and certification parameters. Written by a hand-on certification engineer with 37 years' experience, this is a cleanroom owner's and practitioner's book alike. Lavishly illustrated, with many previously unpublished formulas and relationships concerning cleanroom design, performance, & maintenance, the CLEANROOM GUIDEBOOK, TESTING & CERTIFICATION is unique. Some of the invaluable topics include:

- Cleanroom classification under any and all classification standards
- Aerosol photometers and discrete particle counters in HEPA integrity testing
- Locating missing volumetric airflow (CFM)
- Room pressurization explained
- Room recovery times and ISO class
- Hepa filter replacement algorithms
- Air exchange rates and room recovery
- Air exchanges and ISO classes
- Origins of common industry conventions
- Statistical uncertainty and confidence in measurement
- Critiques of present industry standards
- Identifying contractor types and how to recognize them
- Unspoken industry secrets revealed
- Air exchange, room pressure, and room recovery empirical formulas
- Comprehensive illustrated cleanroom design types
- Hundreds of worked out example calculations

With over 200 tables, figures, illustrations and formulas, the CLEANROOM GUIDEBOOK, TESTING & CERTIFICATION is mandatory for Facilities Managers, Engineers, HVAC Maintenance Personnel, Environmental Monitoring Technicians, Professional Certifiers, Compounding Pharmacists, Manufacturing Supervisors, Validation Engineers, Quality Engineers, Building Commissioners, Air Balancers, and anyone else impacted by cleanroom technology.