CRITICAL ANALYSIS
OF
CLEANROOM
AND
BIOLOGICAL SAFETY CABINETRY

CERTIFICATION & BALANCING REPORTS

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This book is dedicated to the memory of Winthrop Carter Brewer (1905-1975)

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Table of Contents

List of Tables

List of Figures

List of Equations

1. INTRODUCTION

In my first book I alluded to discrimination in a forensic statistical environment[1]. This exposition is what I had in mind. How does a client, lay person, auditor or quality assurance personnel evaluate the competency and fidelity of the certification company's deliverables? Certification reports include comprehensive cleanroom reports, biological safety cabinet, laminar (unidirectional) cabinets and other hepa filter systems. There are many perspectives involved in reviewing certification reports. Procedural standards, statements of compliance to prescribed industry and client standards, acceptance criteria, thoroughness, typographical accuracy and other considerations each provide potential for mistaken deliverables, either unintentional or otherwise. The certification report identifies the tests performed, the spatial and temporal frequency and density of sampling, the field-testing procedures followed by the certification technicians, the specific test acceptance criteria, the measured raw data and whether the test results satisfied the various acceptance criteria. Each and any of these levels have the potential to be misrepresented inside of the certification report.

Traditionally, due to the somewhat arcane nature of the discipline, the certification contractor's representations of required testing scope, industry practice and standards, acceptance criteria, procedural protocols, measured and reported data, and certification statements were entirely relied upon by client project managers. In the modern era, industry practice has been largely standardized and is available to any curios cleanroom practitioner.

This book is strictly concerned with the reported measured data. That is to say; is it believable? Were the measurements taken in a competent an honest fashion? Is it possible, by looking at and analyzing the data to determine that the reported data faithfully replicates the real time instrument readings? No, of course, that is not possible. However; is it possible by looking at and analyzing the data to determine that the data does not faithfully replicate the real time instrument readings? The answer is: yes, certainly, in many instances.

Unfortunately, the cleanroom testing industry has historically been beset with unscrupulous agencies and individuals[2] who are not ethically observant when conducting cleanroom and hepa filter testing. Some of these phenomena are owing to incompetence, knowingly or otherwise, and other situations result from blatant dishonesty. Psychologically, the certification agency or technician is *a priori* aware of the expected test value acceptance criteria, is almost never overseen in the field and feels comfortable in falsifying data to satisfy the various performance criteria. These personnel rely on the apotropaion that: "the numbers we reported represent a snapshot in

[1] Lemieux, Matthew C. Cleanroom Guidebook – Testing and Certification Chapter 6, page 40. www.suretechsys.com
[2] At least one certification agency has been issued an FDA 483 notification.

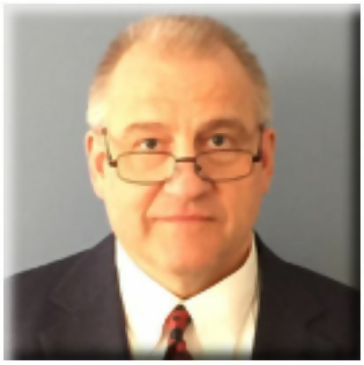
time", and "these were the values that existed at time of test." How can this data be disproven[3] after the fact since it is now a different time and "things have changed?"

What this book purports to demonstrate however; is that their complacency is misplaced. Rather than being a snapshot in time, collectively, their test reports reveal a time lapse photography, a cinematic production. One reported value found to be precisely at setpoint is possible, 10 successive precise setpoint values on the same test device is not possible.

Cleanroom certification has been eagerly undertaken for more than half a century. Many hundreds of millions of data points have been taken and reported. Statistical outliers are as obvious as if they had been reported in red ink. One just has to know how to look.

[3] To paraphrase a former American President: "It depends on what your definition of prove is."

ABOUT THE AUTHOR



Matthew Lemieux, SURETECH's founder,
has over 36 continuous years of field experience
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Mr. Lemieux has a B.S. in mechanical engineering from Northeastern University,
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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.