Hach Whitepaper

Airborne Particle Monitoring: Impact of ISO 21501-4 Calibration

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Abstract

Dependable, consistent and repeatable results in monitoring airborne particles in cleanrooms and clean zones depend both on the sampling technique of the analyst and on the performance of the particle counting instrument. The control of the sampling technique often is the subject of a unique SOP (Standard Operating Procedure) while the performance of the instrument is typically reviewed and verified through an annual or semi-annual calibration process

The calibration process itself has been subject to a greater degree of variability in actual practice and throughout the lengthy life of the instrument than would be desired, due to different calibration techniques magnified by infrequent maintenance and calibration. This variability can be minimized by the implementation of the ISO 21501-4 calibration standard. Although there will be additional time and cost in the calibration process, the end result will be a noteworthy improvement in repeatability over the lifetime of the instrument and also improvement in reproducibility between instruments.

Introduction

International standards for the monitoring of airborne particles are used by all industries that employ cleanrooms or clean zones. Some form of airborne sampling for particles is needed for these controlled environments in order to ensure the quality of the product being manufactured or the success of the process that is being conducted in this controlled or critical environment. Many variables will affect the success of the operations in these areas; the particulate levels in the air are often a significant element in the control of the risk of failure (or, inversely, the likelihood of success!) for the controlled operation.

"The purpose of this part of ISO 21501 is to provide a calibration procedure and verification method for particle counters, so as to minimize the inaccuracy in the measurement result by a counter, as well as the differences in the results measured by different instruments."

TRANSLATION:

What you'll get if you use ISO 21501-4 methods:
1. Better repeatability over the lifetime of the instrument
2. Better agreement between different instruments

And it will probably cost more because:
1. more tests = more technician time
2. extra tests = extra test equipment

The initial standard for classification of clean rooms and clean zones from the United States, known as "Federal Standard 209E", had a global impact for many years but was officially replaced in 1999 by a new global standard, ISO 14644-1.

Revision of ISO 14644-1 and -2 (TC209 Working Group 1)

For the past several years, an international committee known as TC209 Working Group 1 (WG1) has been examining potential revisions to the first two sections of the ISO 14644 document. The initial general vote on the proposed revisions by the larger body of nations closes 02 May 2011; there is the potential that the effective date of the revisions could be placed six months thereafter, or as early as November 2011.

Proposed wording of Section 2 of 2011 revision of ISO 14644-1

2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this part of ISO 14644. Subsequent amendments to or revisions of this publication do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative document indicated below.

ISO 21501-4:2007, *Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces*

One key change in the proposed revision of ISO 14644-1 is the normative reference to a calibration standard for the instrument to be used for cleanroom classification. Previously, no mention of a calibration method had been made in ISO 14644-1.

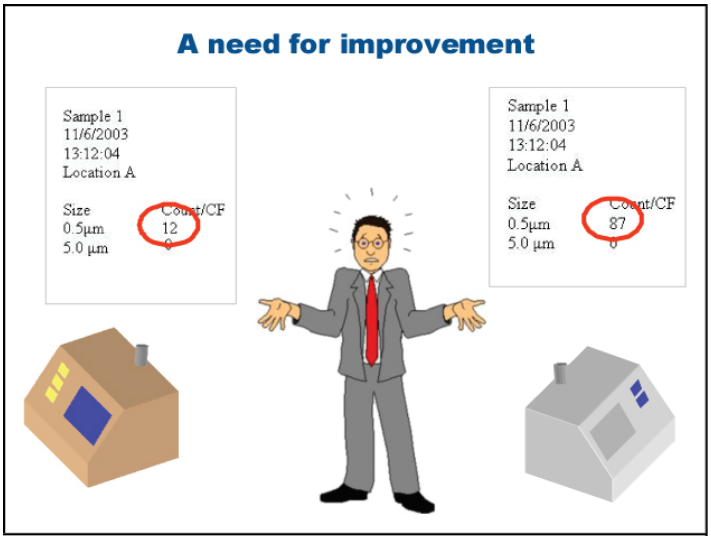
But it is well-known that the variability of the calibration techniques or methods can have a significant effect on the performance of a particle counting instrument and on the reproducibility between instruments.

The Ultimate Quest

A common expectation for customers having multiple particle counting instruments is that each instrument would give the same result as any other when sampling in the same physical space. This is an unrealistic hope, due to the reality that the same aerosol cannot be simultaneously or even sequentially sampled by a pair of instruments. The particle levels in a room or zone can change significantly over time, depending on activity, number of personnel, speed of activity (even walking), temperature gradients, and changes in air flow rates - to name just a few of the variables. Airborne particle counts in an active area could be compared to counting cars on a road or freeway: each sample might be quite valid for the time it was taken but the numbers one might obtain during the middle of the night could be markedly different than those obtained at the peak of the commute hours! Add into this any concern with the reliability of the instrument being used, and the effort to define the airborne particle levels becomes even more challenging!!!

Controlling variability between instruments through ISO 21501-4

The variability of the concentration of airborne particles is a matter of cleanroom design coupled with the control of the process and activities with the clean zone whereas the variability of the measuring instrument is one of calibration, proper use and maintenance. ISO 21501-4 provides a thorough platform to gain control of the potential variability of the instruments. In many cases, calibrations of an instrument done in the years following its initial manufacture could take many forms. Stories abound of 1-point “calibrations” performed by independent or unqualified contractors with little or no traceability to national standards organizations such as NIST, DANAK, BSI, DIN, JIS, etc. Methods also



Variability in readings of airborne particles in cleanrooms can be due to the contributions of a) constantly changing particulate levels, b) sampling technique and c) instrument calibration and maintenance

varied between different instrument manufacturers. Most calibrations done by qualified technicians in the field can often consist of only 3 or 4 tests. When a calibration is performed following ISO 21501-4, typically at least 8 different tests are executed. These tests require both additional time and additional equipment. Although calibration according to ISO 21501-4 will likely create some additional cost in comparison to what is currently performed, there will be noteworthy benefits in both the repeatability and the reproducibility of measurements obtained.

Repeatability refers to the stability of the values obtained by a given instrument when taking multiple measurements of the same environment with a consistent particulate level. Reproducibility refers to the ability of two or more instruments to obtain the same results when measuring the same environment with a consistent particulate level.

As noted previously, it is almost impossible to have a consistent level of airborne particulates in an environment in the real world so the variation of readings from one instrument taking consecutive readings, or between two instruments taking parallel readings, will always exist.

What ISO 21501-4 provides is verification that under controlled circumstances and in testing a controlled and consistent aerosol, the instrument can provide predictable and consistent readings. This process thus creates the basis for confidence that the readings obtained "in the real world" — with its inherent variability — will be a true reflection of the contamination level at a given moment.

ISO 21501-4 Parameters	Target Limit
Size Calibration	± 5%
Counting Efficiency at First Channel	50% ± 20%
Counting Efficiency at particle Size 1.5 to 2 times First Channel	100% ± 10%
Instrument Resolution (at the size specified by manufacturer)	≤ 15%
Zero Count test	≤ 1 count in 5 mins
Maximum particle number concentration (specified by manufacturer)	≤ 10%
Sampling Flow Rate (volumetric)	± 5%
Sampling Time	± 1%
Calibration Interval	≤ 1 year

Resources

Direct assistance: contact ISO 21501 support at ISO21501@hach.com

For assistance in auditing your particle counter fleet:

1. Request a more detailed review of ISO 21501-4:
   • Whitepaper: ISO 21501-4: Calibration of Air Particle Counters from a Metrology Perspective (Latimer and Ping)

2. Request an ISO 21501 Source Book/Whitepaper:
   • ISO 21501: A Standard Methodology to Optical Particle Counter Calibration and What it Means to Cleanroom Owners.
   • Whitepaper: Optical Particle Counters and Counting Efficiency

Published articles

Gecsey, J. Airborne Particle Monitoring: Satisfying the Changing Demands in Regulations and Methods, Cleanrooms Magazine, September 2009, pages 14-18.

Harrison, T., ISO 21501 - A Standard Methodology to Optical Particle Counter Calibration and What it Means to Cleanroom Owners, The Cleanroom Monitor, August 2009, Issue 61, The Scottish Society for Contamination Control.

About the Author

Joe Gecsey is the Life Sciences Application Manager at HACH in Grants Pass, Oregon, USA. He is responsible for tracking regulatory changes regarding particulate counting in the Life Science industry and is one of two US representatives on the TC 209 Working Group (WG1) tasked with finalizing the revisions to ISO 14644-1 and 14644-2. He has conducted seminars throughout the world on particle counter design and applications. He received a Bachelor of Science degree in Electronic Engineering from the University of California in 1974 and has been employed as an engineer and technical advisor by Hach Company (previously MET ONE) since 1984.

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