

ISO 21501:

IS YOUR PARTICLE COUNTER VERIFIED FOR SIZE RESOLUTION and ACCURACY ?

The International Organization for Standardization (ISO) has created a technical committee ISO/TC 24 (Particle characterization including sieving) with the scope that covers standardization pertaining to equipment and methods used in size classification of particulate material in solid or liquid state. Within this scope, Subcommittee 4 “Sizing by methods other than sieving” exists several working groups. Of these working groups WG 9 “Single particle light interaction methods” has created a series of standards related to particle sizing. The convener of this process was the Japanese Industrial Standards Committee (JISC).

This standard ISO 21501 consists of the following parts, under the general title Determination of particle size distribution — Single particle light interaction methods:

- Part 1: Light scattering aerosol spectrometer (under preparation)
- Part 2: Light scattering liquid-borne particle counter
- Part 3: Light extinction liquid-borne particle counter
- Part 4: Light scattering airborne particle counter for clean spaces

Particle size analysis and characterization are intensely used in almost all industrial processes and productions. Of particular importance is the use of particle counters within the Life Science industries. With the regulatory requirements (US and EU GMP) for using particle counters in a “real-time” manner to monitor aseptic and critical processes, the importance of accurate and reliable instruments designed to perform to an international standard is critical.

For cleanroom operations, the ISO 14644-1 standard for cleanroom classification was published in 1999, however there was no international standard for particle counter performance or calibration.

ISO 14644-1 states: “A discrete particle counting light scattering instrument is used to determine the concentration of airborne particles, equal to or larger than the specified sizes, at designated sampling locations.” The new update to ISO 14644-1 references ISO 21501 for particle counter calibration.

On the design of the particle counter: “Discrete-particle counter (DPC), a light scattering device having a means of displaying or recording the count and size of discrete particles in air with a size discrimination capability to detect the total particle concentration in the appropriate particle size ranges for the class under consideration, and a suitable sampling system.”

Regarding calibration of the instrument: “The instrument shall have a valid calibration certificate, the frequency and method of calibration should be based upon current accepted practice.”

The amount of variance in design and calibration practices has been significant, particularly with 3rd party calibration being offered by untrained or unqualified companies. The result is significant variance in the collected particle count data. For cleanroom users having a specific and regulated particle count limit (as in pharmaceutical manufacturing), this variance in particle counter performance is unacceptable. Companies not conforming to ISO 21501 are not required to verify size resolution or count accuracy so there is no way of verifying the count efficiency (The overall accuracy of the particle counter). Some companies are only verifying size and assuming the accuracy is fine without actually testing or verifying it.

We believe this is an unaccepted practice for particle counter users. Remember the instrument is a particle counter (counts particles) not just a particle sizer.

For cleanroom users an international standard such as ISO 21501-4 for clean spaces (cleanrooms and controlled environments), consistency in particle counter performance is extremely important. This standard provides a calibration procedure as well as a verification method that helps eliminate inconsistency in particle counter performance. This helps minimize the inaccuracy in the measurement results by particle counters and reduces the differences in the results from the various manufacturers' instruments.

Kenelec Scientific offer ISO 21501 compliant particle counter calibrations in our NATA accredited facility. Our facility has been audited by NATA and our accreditation encompasses not only ISO 17025 (the main standard used by testing and calibration laboratories) but also ISO 21501 in our scope of accreditation.

Particle counter owners and users with specific questions or concerns regarding ISO 21501 are invited to email jason@kenelec.com.au



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