

ISO / IEC 17025 Calibration Explained

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What is ISO/IEC 17025?

ISO/IEC 17025 is a quality standard, similar to ISO 9001 Quality Management Systems, developed by the International Organization for Standardization (ISO) that defines requirements for laboratories to ensure quality, reliability and repeatability of performed tests or calibrations. Accreditation to the standard is used around the globe as an indicator of laboratories proven to deliver reliable results.

The standard provides guidance on the following areas;

- technical competence of laboratory employees,
- measurement traceability to international standards (e.g. NIST),
- the testing and maintenance of laboratory equipment to ensure reliable results,
- the evaluation and reporting of uncertainty of measurement
- and much more.

Why is ISO/IEC 17025 accreditation so important?

Laboratory accreditation to the ISO/IEC 17025 standard allows customers to ensure those laboratories adhere to a clearly defined standard for quality and management controls. These laboratories are evaluated and reevaluated routinely by an external certification body, such as A2LA, to ensure continued compliance to the standard.

The laboratory will be evaluated internally through our internal audit program and externally through annual certification body audits. This independent review of Lighthouse Worldwide Solutions' laboratory management system provides a necessary level of impartiality and objectivity to sustain and improve its functions and services provided.

Lighthouse Worldwide Solutions' ISO/IEC 17025 accreditation means that our laboratory calibrations and management systems meet or exceed the requirements of the standard, through independent external evaluation. Lighthouses more than two decades of industry experience, along with this accreditation, prove our dedication and ability to meet even the most thorough industry standards.

What is the benefit to you as the customer?

An ISO/IEC 17025 calibration is the highest level of calibration available for Lighthouse particle monitoring instruments. This level of calibration provides customers a certificate with increased data, including; “as received” and “as left” readings, as well as calculated uncertainty of measurement for all reference equipment used. All ISO/IEC 17025 calibrations are traceable to NIST and ISO standards, providing an unbroken chain of calibrations to reinforce confidence in the results. Our accreditation allows you to easily choose a calibration laboratory that is technically competent, validates all methods and employs a sound quality system, effectively minimizing your risk. For these reasons and regular third-party independent evaluation of Lighthouse’s laboratory management system, allows you to place your confidence in our testing and calibration services.

What to expect from your ISO/IEC 17025 Calibration?

ISO/IEC 17025 is a quality standard developed by the International Organization for Standardization (ISO) that defines requirements for laboratories to ensure quality, reliability, and repeatability of performed tests or calibrations. With regards to particle counting, this holds manufacturers to maintain the standard set forth by ISO 21501-4.

Calibration certificates issued by ISO/IEC 17025 accredited laboratories will cover the following parameters:

- **Size Setting Error**- The size setting error is the deviation from the particle counters programmed sizes. The pass/ fail criteria as per ISO 21501-4:2018 is $\pm 10\%$ of the particle size. The Uncertainty of each particle size is stated in μm .
- **Counting Efficiency**- The counting efficiency is determined by comparing a unit to a NIST (National Institute of Standards and Technology) traceable unit with a higher sensitivity. The ISO 21501-4 standard dictates a tolerance of 50% ($\pm 20\%$) of the minimum detectable size, and 100% ($\pm 10\%$) of a size 1.5 – 2 times larger than the minimum. The uncertainty is stated in percent counting efficiency.
- **Sampling Flow Rate Error**- The sampling flow rate tolerance is $\pm 5\%$ of the stated rate for the unit. The flow value uncertainty is stated in LPM.
- **Size Resolution**- The size resolution will be stated with the particle size used in μm and the criteria of less than 15% as stated per ISO 21501-4. The uncertainty will be stated in percent size resolution.
- **False Count**- The false count (also known as a zero-count test) is the number of particles detected on the minimum detectable channel in a certain volume of air stated at a 95% upper confidence level. We also state the false count rate in accordance with JIS B 9921, which gives a limit of one count per five minutes. Both values are stated as observed counts per five minutes.

What is uncertainty regarding ISO 21501-4?

Uncertainty of measurement is the doubt that exists about the results of any measurement. It is important to remember that with any device that yields a measurement there always will be some measurement of doubt. The uncertainties stated on our calibration certificates are all traceable. The uncertainties stated rely on the accuracy and specifications of our test equipment and reference particles. The formulas for calculating the uncertainty for the five parameters can be found in 21501-4:2018 Annex A:E.

Why is an ISO/IEC 17025 Calibration important?

ISO 21501-4 is the standard that has been used by most particle counter manufacturers to develop and produce their instruments. By being accredited ISO/IEC 17025, we have demonstrated to an accrediting body of auditors that we do more than just claim ISO 21501-4 compliance – we prove our technical competence and document it. The audit process evaluated our calibration and intermediate testing of reference equipment, calibration of customer equipment, proficiency testing between laboratories, and a wide range of other technical applications outlined in the ISO 21501-4 standard. With an ISO/IEC 17025 accredited calibration, you are guaranteed a fully documented chain of ISO-compliant calibration data tracing back to appropriate-stated references.

ISO 21501-4 Summary Overview

ISO 21501-4 provides a calibration procedure and verification method for airborne particle counters.

There are TEN particle counter test and calibration parameters that are required under ISO 21501-4: 2018;

- **Size Setting Error**
 - Target Limit: $\pm 5\%$
- **Counting Efficiency**
 - First Channel: $50\% \pm 20\%$
 - Particle Sizes 1.5 to 2 times
 - Second Channel: $100\% \pm 10\%$
- **Size Resolution**
 - $\leq 15\%$
- **False Count Rate**
- **Maximum Particle Number Concentration**

- Specified by Manufacturer
- **Sampling Flow Rate Error**
 - $\pm 5\%$
- **Sampling Time Error**
 - $\pm 1\%$
- **Response Rate**
 - $\pm 0.5\%$
- **Calibration Interval**
 - ≤ 1 year
- **Reporting Results from Test and Calibration**
 - Date of Calibration
 - Calibration Particle Sizes
 - Flow Rate
 - Size Resolution
 - Counting Efficiency (50% & 100%)
 - False Count Rate
 - Voltage Limit or Channel of Internal Pulse Height Analyzer (PHA)

Should you calibrate your particle counters to ISO 21501-4 from an accredited ISO 17025 calibration service facility?

Absolutely you should aim for the most current standard which offers the most accurate and best traceable calibration around. ISO 14644-1:2015 requires particle counter calibrations to follow the ISO 21501-4 calibration standard. So if you are certifying a cleanroom you will need to comply to meet ISO 14644-1:2015 fully. Remember the data from your particle counter is used to make major decisions in relation to how your cleanroom performance is determined and how sterile you're manufacturing process is in reality. Data integrity is paramount and the data your particle counter provides should be data that you as a decision maker are confident about. Always send your particle counter out for calibrations to a service provider who has traceability and is endorsed by the particle counter manufacturer as an authorized service center. Never use service providers who cannot offer such traceability and transparency. Vendor audits can help assist in making the right informed choice in selection of a particle counter supplier and service provider.