Technical Note – ISO 17025:2017

Decision Rule based on Simple Acceptance for Count Efficiency Testing

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When it comes to Particle Counter calibration many end users of particle counters are not aware of the calibration process a particle counter follows. The latest calibration standard for particle counter calibration is ISO 21501-4:2018, it is now the most common calibration standard followed in the Industry for airborne particle counters and it has been in use since 2007. There are at least 5 calibration tests that must be performed to verify the accuracy of a particle counter. The 5 tests are;

- Verification of size setting – particle sizes must be sized to within a ±10% tolerance of nominal size
- Counting Efficiency – 100% and 50% count efficiency with a ±10% and a ±20% tolerance respectively
- Flow rate – with a ±5% tolerance
- Size resolution – with a ≥ 15% tolerance
- False count – sample per m³ based on manufacturers specification

ISO 21501-4:2018 details the test and calibration procedures in section 7 of the document and it is up to the particle counter manufacturer to comply to each calibration test and provide test data and results on the calibration certificate. ISO 21501-4:2018 requires that the counting efficiency near the minimum detectable size be 50 ± 20%, and the larger particle size be 100 ± 10%. Counting Efficiency is tested to ensure that the particle counter is accurately counting the number of particles that pass through it compared to a reference particle counter.

The most challenging test of ISO 21501-4: 2018 is Counting Efficiency at the larger particle size. For instance the uncertainties in the reference particles and the reference equipment when combined could easily add up to a ±6-7% uncertainty in the calibration and if the as found counting efficiency is around 104-105% then applying a measurement uncertainty (MU ±6-7%) could actually push the test result outside the acceptable tolerance range ±10% for counting efficiency at 100%.

With Counting Efficiency testing at 100% and a tolerance of ±10% it is not difficult to see with a large MU in the calibration process that maintaining such a tight tolerance could become a bit of a challenge. Therefore a decision about the test results when the MU is applied must be made.

What is the "Decision Rule" all about? In a simple explanation the decision rule is about deciding whether a test result is within tolerance or not when the calculated measurement uncertainty (MU) is applied to that test result. The end user should also understand the risk of the test result and decide if that risk is acceptable to their process or not. In order to understand the Decision Rule we must look at some metrology graphically. Let us look at the Counting Efficiency testing as outlined in ISO 21501-4:2018 first.

Counting Efficiency is performed when the particle counter under test is compared against a higher sensitive reference particle counter where they both sample from the same reference particle aerosol. In ISO 21501-4: 2018 it is defined as "*The ratio of the number concentration measured by a light scattering airborne particle counter to that measured by a reference instrument for the same test aerosol*." Both particle counters are placed into a test setup so they can both measure from the same test aerosol. The test aerosol is one that has a close size to the minimum detectable particle size of the particle counter under test and another test aerosol that has a size 1.5 to 2 times larger than the minimum detectable particle size. Therefore two different aerosols are used separately with two different reference particle sizes for each test. The table below indicates the acceptable tolerances for both sizes and below is the test set-up as outlined in ISO 21501-4: 2018.

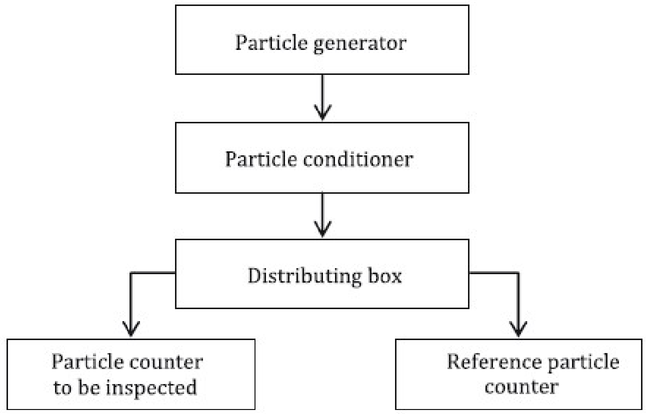

Fig 1.0 Example of Counting Efficiency Test System (ISO 21501-4:2018)

Counting Efficiency Size	Target Value	Tolerance
Counting Efficiency, η, at a size close to the minimum detectable particle size	50%	±20%
Counting Efficiency, η, at a size 1.5 to 2 times larger than the minimum detectable particle size	100%	±10%

The above criteria for Counting Efficiency details the requirements and the tolerances. 100% Counting Efficiency testing with a tolerance of ±10% considering the high MU probability of around 6-7% for larger particles and the test process you can see that a decision on the test result could be argued as being in tolerance or out of tolerance if the MU is applied. So how could this be the case and what is the associated risk? First of all let's understand the issue with a basic limits setup for the 100% ±10% Counting Efficiency test as seen below.

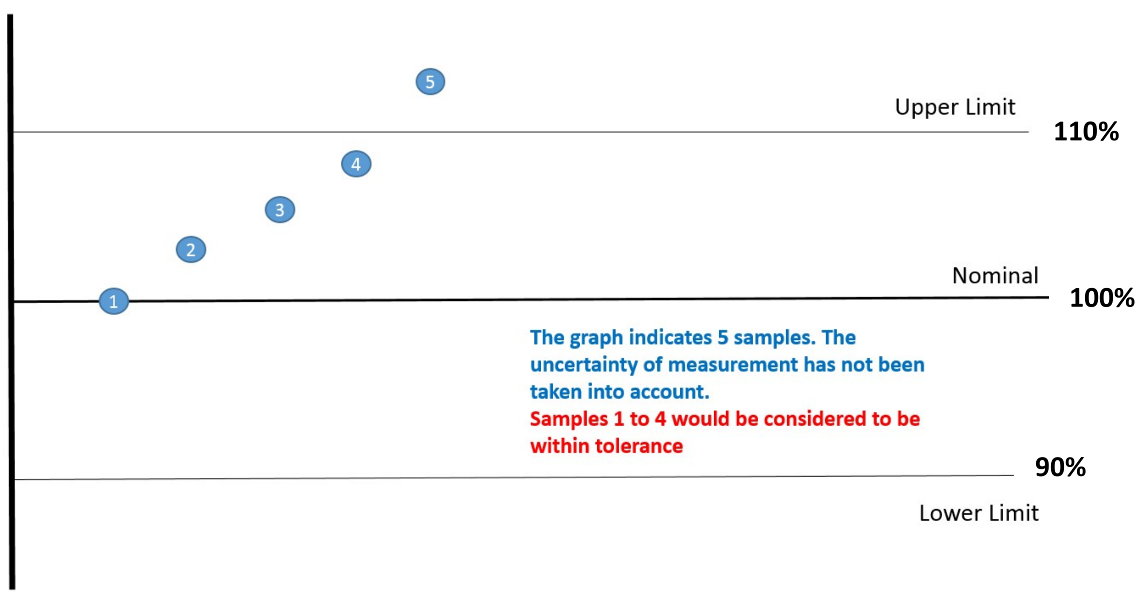

Fig 2.0 Set of samples with 4 samples within tolerance

In the case of figure 2.0 where the test sample does not have measurement uncertainty applied the first 4 samples could be considered to be within tolerance. With the MU applied in fig 3.0 then sample 4 could be questionable as the upper limit of the MU theoretically pushes the sample outside of tolerance if the upper MU limit is applied.

At the same time sample 4 could be considered within tolerance if the lower limit of MU is applied. In this case since the measurement result plus/minus the expanded uncertainty with a 95% coverage probability overlaps the limit, it is really not possible to state compliance or non-compliance. The measurement result and the expanded uncertainty with a 95% coverage probability could then be reported together with a statement indicating that neither compliance nor non-compliance was demonstrated.

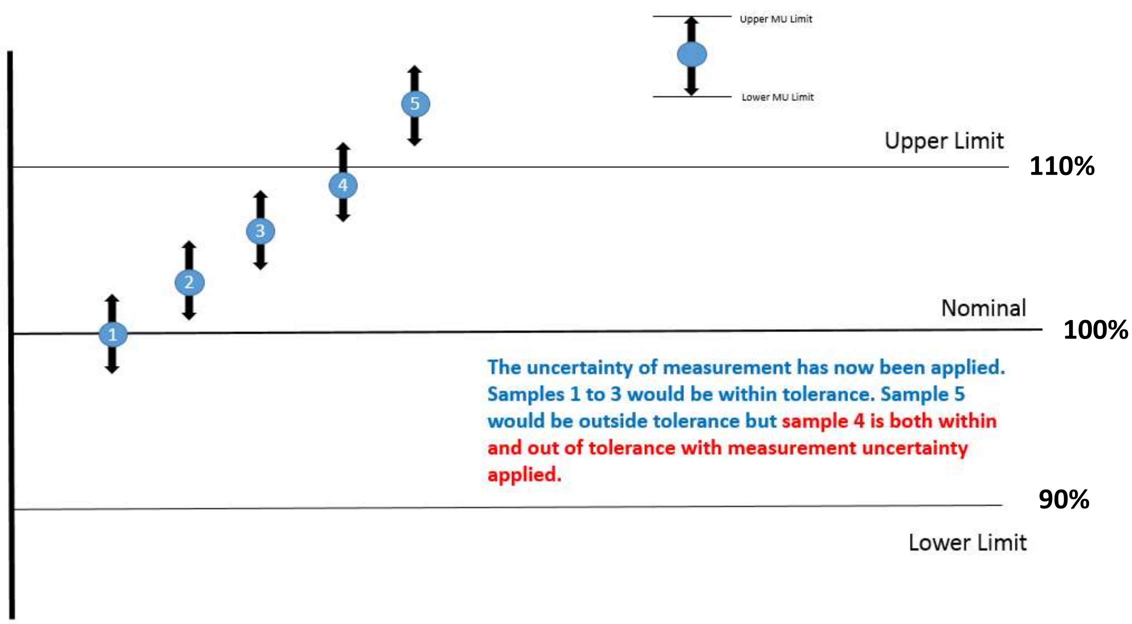

Fig 3.0 Set of samples with Measurement Uncertainty applied

Lighthouse approaches this issue by taking a Simple Acceptance approach on the decision and not applying the MU but reporting MU alongside the test results. Both Lighthouse and the Customer share the risk of the test result. The decision rule of simple acceptance allows the customer if they wish to apply the MU and decide if the test result is an acceptable risk to their process. Lighthouse will list uncertainties but not include them in the pass / fail decision as outlined in ISO 21501-4: 2018 below.

ISO 21501-4 states in Section E.4 Consideration of test uncertainties in the requirements for LSAPCs.

MPE values and test criteria in Clause 6 of this document are intended to be applied without taking the test uncertainty into account (see Table E.1). If taking an actual stated uncertainty from a test report/calibration certificate into account the MPE values and test criteria in Clause 6 may be modified accordingly

The standard instructs to apply the specs without uncertainty. It goes on to say if taking an actual stated uncertainty into account the end user can modify (expand) the spec accordingly. This is the basis for simple acceptance that Lighthouse will follow. Clause 6 includes:

Table E.1 — Test criteria without consideration to uncertainties

Name of quantity	Target value	Requirement	Relevant subclause
Size setting error, ε	0	0,10 ($\lvert \varepsilon \rvert \leq 0,10$)	6.1 7.1
Counting efficiency, η, at a size close to the minimum detectable particle size	0,50	0,20 ($0,30 \leq \eta \leq 0,70$)	6.2 7.2
Counting efficiency, η, at a size 1,5 to 2 times larger than the minimum detectable particle size	1,00	0,10 ($0,90 \leq \eta \leq 1,10$)	6.2 7.2
Size resolution, R	0	0,15 ($R \leq 0,15$)	6.3 7.3
False counts observed per m^3	As per manufacturer's specification	As per manufacturer's specification	6.4 7.4
Coincidence loss at the maximum particle number concentration, L	0	0,10 ($L \leq 0,10$)	6.5 7.5
Sampling flow rate error, ε_q	0	0,05 ($\lvert \varepsilon_q \rvert \leq 0,05$)	6.6 7.6
Sampling time error, ε_t	0	0,01 ($\lvert \varepsilon_t \rvert \leq 0,01$)	6.7 7.7
Response rate, R_r	0	0,005 ($R_r \leq 0,005$)	6.8 7.8

Fig 4.0 ISO 21501-4 Test Criteria and tolerance limits outlined

In the case of a higher counting efficiency the risk is considered low as there is a low overall impact of the result to the end user. If the particle counter was undercounting then the risk is high to the overall impact to the end user. With the decision rule applied both Lighthouse and the Customer assume this shared risk. However in the case of over counting and the test result over 110% with MU applied the impact is low and not as severe as the impact would be if the particle counter was observed to be undercounting with a test result below 90% when MU applied this undercounting could invalidate test results as not 100% of the test sample could be taken if the particle counter was found to be under counting. The impact of the particle counter counting too few particles is that the environment may have been dirtier than the instrument interpreted. With this knowledge regarding the risks the Customer can decide if the risk is acceptable or not. The Customer also has the ability based on the shared risked to increase the tolerance limits if desired.

References:

- ISO 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 21501-4: 2018 Light scattering airborne particle counter for clean spaces
- ILAC G-8:2009 Guidelines on the Reporting of Compliance with Specification
- JCGM 106:2012 Evaluation of Measurement Data – The role of measurement uncertainty in conformance assessment