



ISO 17025:2017 vs. ANSI Z540.3

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This white paper covers some Frequently Asked Questions we receive from customers about the differences between ISO-17025:2017 vs. ANSI Z540.3.

Q: What are the definitions of ISO-17025:2017 vs. ANSI Z540.3?

A: *ISO/IEC-17025:2017 (3rd Edition 2017-11) General Requirements for The Competence of Testing and Calibration Laboratories -- ANSI/NCSL Z540.3-2006 Requirements for the Calibration of Measuring Test Equipment.*

Q: What do ISO-17025:2017 and ANSI Z540.3 cover?

A: Both standards address how a Calibration or Testing Laboratory should operate.

Q: What is the difference between these two standards?

A: ISO/IEC-17025:2017 essentially covers all the requirements of ANSI/NCSL Z540.3 except for Z540.3 Section 5.3 (b): 5.3 b) "Where calibrations provide for verification that measurement quantities are within specified tolerances, the probability that incorrect acceptance decisions (false accept) will result from calibration tests shall not exceed 2% and shall be documented. Where it is not practicable to estimate this probability, the test uncertainty ratio shall be equal to or greater than 4:1. NOTE: Achieving these requirements may involve adjustment and management of calibration system parameters such as: measurement reliability, calibration intervals, measurement uncertainty, calibration tolerances, and/or guard bands."

This requires the laboratory to limit the Probability of False Acceptance (PFA) due to the laboratory's calibration process uncertainty to no more than 2%. Or put another way, the laboratory's reported value needs to have a 98% Probability of Compliance to the Specification (PCS). Simplified Definition: (PFA) The probability of making an acceptance decision when the Unit Under Test (UTT) is observed and reported to be in-tolerance but is out-of-tolerance.



Q: Why is Section 5.3(b) important?

A: No measurement is perfect, there is always some doubt (uncertainty) about every measurement: it is a gray area. This uncertainty is not a problem until you need to call a measurement In-tolerance/Out-of-Tolerance; Good/Bad; Pass/Fail. When the observed value lies close to the test limit, the laboratory's uncertainty may prevent a definitive answer. There are many ways to handle the calibration process uncertainty when making a statement of compliance. The industry standard practice is to use a Simple Acceptance / Simple Rejection Decision rule, this decision rule allows for a PFA up to 50%. It is important to communicate your desired decision rule to the calibration provider, and/or to know which decision rule the calibration provider will use as a default. Z540.3 Section 5.3(b) defines a maximum allowable PFA of 2% for any decision rule to mitigate the risk associated with the calibration process uncertainty.

Q: What can be done if a PFA is greater than 2%?

A: There are several ways to improve the PFA and mitigate risk as identified in Z540.3 Measurement Reliability:

1. The measurement reliability of both the M&TE being calibrated and those used as calibration standards affect the estimated PFA. If either or both are increased, the PFA would be expected to decrease. The increase in measurement reliability may be accomplished by shortening calibration intervals, using measurement control processes, etc.
2. Calibration intervals: Calibration intervals are established to achieve measurement reliability and/or uncertainty goals. Shortening an interval for a given set of M&TE, such as through raising the measurement reliability target, will result in a reduced PFA.
3. Measurement uncertainty: Calibration process uncertainty. If the calibration process uncertainty is reduced, the PFA is reduced. Reducing the calibration process uncertainty also increases the Test Uncertainty Ratio (TUR). The reduction of calibration process uncertainty may be accomplished by use of shortened calibration intervals, using measurement control processes, etc.
4. Calibration tolerances: If the test tolerances of the M&TE being calibrated are increased, both PFA and TUR are affected. An increase in the M&TE test tolerance would reduce PFA and increase TUR. This improvement may be at the expense of added controls and limiting the application of the M&TE.
5. Guard bands: If a guard band is applied to an M&TE test tolerance to create acceptance limits inside the tolerance, the PFA is reduced. This reduction can be at the expense of an increase in the number of measurement quantities rejected and additional costs for increases in adjustment and repair actions.



Q: What do calibration laboratories do to address this Z540.3 requirement?

A: Laboratories developed methods, policies and procedures to mitigate the calibration process uncertainty impact on the PFA for accredited calibration by:

1. Routinely monitoring the reliability of the laboratory standards and adjusting calibration intervals, implementing process control charts, using guard-banding techniques on our standards and striving to improve the calibration uncertainty available to our customers as part of our dedication to process improvement.
2. Selecting laboratory standards, methods and test points which prevent TURs <4:1 whenever practical, thus avoiding a < 2% PFA as per Z540.3 5.3(b) entirely.
3. Identifying all TUR < 4:1 and providing the Calibration Process Uncertainty. This information allows the customer to compute the actual PFA of the reported value if they so desire.
4. Developing custom datasheets using any specification or tolerance a client chooses to use. The use of custom tolerances can further mitigate or eliminate risks associated with TURs <4:1 or high PFAs.