

March 8, 2024

ISO/IEC 17025 Compliance and Decision Rule Acknowledgment for Eppendorf Pipette Calibration Services

Dear customers,

Eppendorf is committed to providing high-quality calibration services that comply with the highest international standards. As part of our continuous improvement and adherence to ISO/IEC 17025 requirements, we are implementing essential changes to our calibration processes that will directly impact how we report conformity to specifications for our calibration services. This document outlines the necessary information about the decision rule requirement under ISO/IEC 17025 and its implications for our customers.

Understanding the Decision Rule Requirement

The ISO/IEC 17025 standard mandates a clear definition and agreement on the decision rule used when stating conformity with a specified requirement during calibration. A decision rule is critical for interpreting measurement uncertainty and its impact on the pass/fail status of the unit under test (UUT). Our new approach aligns with ISO/IEC Guide 98-4 principles, ensuring transparency and reliability in our calibration certifications.

Key Definitions

- **Decision Rule (ISO/IEC 17025):** Describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
- **Decision Rule (ISO/IEC Guide 98-4):** A documented rule that details the consideration of measurement uncertainty in accepting or rejecting an item based on a specified requirement and measurement result.
- **Measurement Result (ISO/IEC Guide 98-4):** A set of quantity values attributed to a measurand, accompanied by any relevant information.

What's Changing

- **Implementation of Decision Rule:** We will adopt a decision rule as per ILAC – G8/4.2.2, updating our calibration software to include binary statements with guard banding.
- **Updated Calibration Certificate:** The certificate will now include a decision rule statement specifying that:
 - Where statements of conformity are made in this report, the following decision rules are applied: Pass - Results +/- expanded uncertainty is within limits/specifications. Fail - Results +/- expanded uncertainty exceeds limits/specifications.

Why This Change is Necessary

This update ensures our continued compliance with the ISO/IEC 17025 standard, particularly section 7.1.3, and addresses the guidance provided in ISO/IEC Guide 98-4 regarding the risks of incorrect decisions when measurement values are close to tolerance limits. Implementing a decision rule mitigates the risk of accepting non-conforming items or rejecting conforming ones by introducing guard banding.

Your Acknowledgment Required

To proceed with the purchase of any ISO 17025 Accredited Calibration service, customers must agree to the changes outlined in this document. This agreement ensures that we maintain transparency and align expectations regarding the calibration process and outcomes.

Next Steps

Please review this information carefully. Your continued partnership and compliance with these changes are crucial for ensuring the highest standards of calibration service. Should you have any questions or need further clarification, do not hesitate to contact us.

Thank you for your attention to this important update and for your continued trust in Eppendorf for your calibration needs.

Questions?

Please direct any questions or inquiries you might have to 800-645-3050.

Regards,

Eppendorf Customer Care Team

custserv@eppendorf.com