

The Role of Measurement Uncertainty when Performing Conformity Assessments

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Abstract - Measurement uncertainty is vital to reliable conformity assessments, ensuring valid decisions about a device under test (DUT). This white paper explores the role of measurement uncertainty, emphasizing the Test Uncertainty Ratio (TUR) and its importance for minimizing risks. A TUR of at least 4:1 is identified as best practice, providing high confidence, while values below 3:1 are discouraged for critical applications. Adhering to standards such as ISO/IEC 17025, GUM, EA-4/02, and ILAC P14 ensures rigorous uncertainty evaluation and meaningful conformity decisions. Accurate assessment depends on keeping measurement uncertainty significantly smaller than the DUT's accuracy, safeguarding reliable compliance evaluations.

I. INTRODUCTION

Measurement uncertainty plays a critical role in ensuring the validity of conformity assessments. When determining whether a device under test (DUT) meets its specified requirements, it is essential to evaluate and manage measurement uncertainty. This white paper outlines the key principles, relevant standards, and recommended practices for managing measurement uncertainty, with a focus on ensuring reliable conformity assessments.

II. MEASUREMENT UNCERTAINTY IN CONFORMITY ASSESSMENTS

The relationship between measurement uncertainty and the accuracy of the DUT is critical in ensuring reliable conformity assessments.

III. TEST UNCERTAINTY RATIO (TUR)

The Test Uncertainty Ratio (TUR) is the ratio between the specification limits of the DUT and the measurement uncertainty of the assessment process (measurement uncertainty during calibration). It ensures that the uncertainty is small enough to make confident statements about the DUT's conformity. The concept of TUR is described in EA-4/02 and ILAC P14. While EA-4/02 explicitly recommends a minimum TUR of 1:3 and a preferred TUR of 1:4, ILAC P14 does not prescribe a specific ratio but emphasizes that measurement uncertainty must be small enough to ensure reliable conformity assessments. Laboratories are expected to apply TUR values that are appropriate to the criticality of the application and the client's needs:

- Minimum recommended TUR: $\geq 1:3$ (the specification limit is at least three times larger than the measurement uncertainty).
- Optimal TUR: $\geq 1:4$ (the specification limit is at least four times larger than the measurement uncertainty).

IV. IMPLICATIONS OF TUR

- TUR $\geq 4:1$: Provides high confidence in conformity assessment. The measurement uncertainty has minimal impact on the decision-making process, reducing the risk of false acceptance or rejection.
- TUR $\geq 3:1$: Acceptable in some cases, particularly when stringent TURs are not feasible. However, the margin of confidence

is reduced, necessitating careful reporting.

- TUR $< 3:1$: Not recommended for critical applications, as the overlap between uncertainty and specification limits increases the risk of erroneous decisions.
- TUR $< 1:1$: If the calibration uncertainty is equal or greater than the accuracy of the DUT, it becomes meaningless to assess conformity to specifications. In such cases, the measurement results cannot provide reliable information about whether the DUT meets its specified requirements, making the assessment invalid.

V. CONCLUSION

The relationship between measurement uncertainty and the accuracy of the DUT is foundational to reliable conformity assessments. Assessing conformity is only meaningful when the measurement uncertainty is significantly smaller than the DUT's accuracy. If the calibration uncertainty exceeds the accuracy of the DUT, the assessment becomes invalid, as it cannot reliably determine whether the DUT meets its specifications.

By adhering to international standards such as ISO/IEC 17025, GUM, EA-4/02, and ILAC P14, laboratories can ensure meaningful conformity decisions. Targeting a TUR of at least 4:1 represents best practice, offering confidence in conformity assessments and

VI. NORMATIVE REFERENCES

Several international standards provide guidelines on the evaluation and management of measurement uncertainty and conformity assessment:

1. ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories)

Specifies requirements for the competence of testing and calibration laboratories. Article 7.6 mandates that laboratories must evaluate measurement uncertainty and report it in test or calibration results. Additionally, article 7.8.6 requires the application of decision rules when assessing conformity with specifications, explicitly considering measurement uncertainty.

- GUM (Guide to the Expression of Uncertainty in Measurement):

This guide provides a universally accepted framework for calculating and expressing measurement uncertainty. It emphasizes statistical and mathematical rigor in evaluating uncertainty components.

- EA-4/02 (Evaluation of the Uncertainty of Measurement in Calibration):

The European Accreditation's EA-4/02 guideline offers additional insights into uncertainty evaluation for conformity assessments and emphasizes practical implementation aligned with ISO/IEC 17025.

- ILAC P14 (Policy for Uncertainty in Calibration)

This policy outlines the treatment of uncertainty in conformity assessments, particularly in relation to reporting. It mandates that laboratories consider