K9 Measurement Uncertainty (MU): A Novel Quality Assurance Use in Forensic Toxicology for Internal Proficiency Testing

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Learning Overview: The goal of this presentation is to show the process of using MU to determine acceptability of test performance by using illustrative examples based upon true proficiency test samples and root cause analysis outcomes to demonstrate the utility of this approach.

Impact on the Forensic Science Community: This presentation will impact the forensic science community by showing that MU established for an analytical method can be utilized for grading proficiency results.

Background/Introduction: Every measurement made has inherent uncertainty associated with it. MU allows an analytical result to be presented along with an associated interval that incorporates all identified error sources in the measurement process. The provided interval is the result of the accumulation of these errors and expansion of the final uncertainty to a predefined level of probability that the true value lies within this interval. In forensic toxicology, MU is most important for those cases where legal consequences are determined based upon *per se* laws and the reported analytical measurements. The utility of MU, however, is not limited to this purpose. Proficiency Testing (PT) is an essential component to any laboratory's Quality Assurance program, and objective measures of performance are needed. Ongoing PT provides assurance that reported data are accurate and that any issues are identified and appropriately addressed. While most PT programs grade the results, there may be instances where the program requires the laboratory to determine their own grading criteria for self-assessment purposes. While one common way to accomplish this task is to determine if the reported concentration (e.g., 180ng/mL) is within a certain percentage (e.g., +/- 20%) of the target concentration (e.g., 200ng/mL), this study, when faced with this circumstance, opted to use the MU established for the analytical method to grade the tested proficiency samples. This approach is applicable as it not only allows for assessment of the reported result, but also considers the applied MU range.

Methods: This approach was accomplished by taking the Grand Mean provided by the PT program for each positive sample and determining if this value was encompassed by the reported concentration and its associated MU interval for each internal result. Proficiency results were graded and, when applicable, Root Cause Analysis performed. Measures to address any quality performance issues were then implemented based upon the totality of the investigation.

Results: Results from one PT with use of this grading approach are shown in the following table:

Sample No.	Grand Mean (g/100mL)	Result Range (Reported Result + MU) (g/100mL)	Acceptable Result Range (g/100mL)	Proficiency Outcome
1	0.0543	0.048 ± 0.002	0.046 – 0.050	Investigate
2	0.3117	0.304 ± 0.009	0.295 – 0.313	Pass

In this instance, for Sample 1, the percent difference between the reported concentration (0.048g/100 mL) and the Grand Mean (0.0543g/100 mL) is -12%, which may be marked as Passing. Using the Acceptable Result Range, however, a low bias is noted and Sample 1 is marked as Investigate and an appropriate Root Cause Analysis can be initiated.

Conclusion/Discussion: Verification of result accuracy and the applied MU range should be used, where appropriate, to evaluated PT results. Furthermore, it is best practice due to *per se* laws that the utility of the MU be checked on a routine basis with PT being an evidenced-based way to do so. This approach provides a routine mechanism for staff to understand the value and limitations of MU as well as the associated explanation of its use.

Uncertainty, Proficiency, Quality