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Title: Assigning Ruggedness Factors as Fixed or Random Consistent with Goal of a Procedure Performance Qualification (Validation)

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In accordance with the lifecycle approach for analytical procedures, demonstration that a procedure is fit for intended use requires a statistical test to prove that the standard uncertainty of the analytical procedure is less than the total measurement uncertainty (TMU). The selected experimental design should be chosen consistent with this objective. Ruggedness design factors such as analyst, day, or equipment must be properly classified as either fixed or random in order to achieve the experimental goal. This presentation will consider the case where analyst is an impactful ruggedness factor and demonstrate how designation as either fixed or random will impact the practicality of the experimental conclusions.