

**VALIDATION  
TRACEABILITY  
MEASUREMENT UNCERTAINTY  
CHALLENGES FOR THE 21<sup>ST</sup> CENTURY'S ANALYSTS**

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Workshop group 1.2:  
**Specifying performance criteria**


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## WG 1.2 questions

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- a. One of the descriptions of the concept of Method Validation found in the Fitness for Purpose guide reads "...confirming that the method under consideration has performance capabilities consistent with what the application requires" Is it always clear to the laboratory "...what the application requires"?
- b. Can these requirements always be transferred into specifications for the "traditional" performance characteristics for a method...  
( selectivity/specificity, limit of detection/quantification; measurement range; calibration function (linearity?); sensitivity; trueness; precision (repeatability/reproducibility); robustness) ???
- c. Do you as laboratory evaluate the relevance and importance of the various performance criteria?
- d. Are the specific performance criteria, you use as basis for planning a method validation study, based on communication (and discussion) with the actual clients(s) for the routine use of the method?
- e. Do you also specify performance criteria for the practical handling of the method in your own laboratory?
- f. Do you study any other specific "performance characteristics" in connection with a Method Validation Study than the "traditional" ones mentioned above?
- g. How do you relate Measurement Uncertainty to the performance criteria for a method?
- h. Which specific topics could be relevant to include in a revised Eurachem Guide on Method validation?

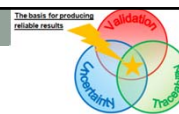


**a) One of the descriptions of the concept of Method Validation found in the Fitness for Purpose guide reads "...confirming that the method under consideration has performance capabilities consistent with what the application requires" Is it always clear to the laboratory "...what the application requires"?**

- Available in some fields;
- Criteria for assessing performance in PT can be used for defining the target MU (consensual standard deviation should not be used).

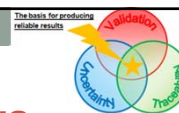
**b) Can these requirements always be transferred into specifications for the “traditional” performance characteristics for a method...?**

- Whenever requirements are available specific performance parameters are specified;
- Trueness, precision, measurement range and measurement uncertainty are the most relevant characteristics;




**c) Do you as laboratory evaluate the relevance and importance of the various performance criteria?**

- Most labs check performance in PT;
- Most labs study precision as relative standard deviation but no target values are used (exception: FDA -  $CV \leq 15\%$ ).



**d) Are the specific performance criteria, you use as basis for planning a method validation study, based on communication (and discussion) with the actual clients(s) for the routine use of the method?**

- No examples!




**e) Do you also specify performance criteria for the practical handling of the method in your own laboratory?**

- Tests quality control:
  - statistical control parameters for slope, intercept, CRM analysis result (control charts, statistical limits,...);
  - in some cases, measurement uncertainty of CRM value is not considered (negligible);
  - data from validation is used.

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CRM producers: are not using target values for the MU.



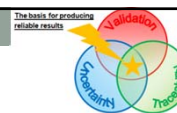
**f) Do you study any other specific “performance characteristics” in connection with a Method Validation Study than the “traditional” ones mentioned above?**

- Revalidate if major changes are performed.



**g) How do you relate Measurement Uncertainty to the performance criteria for a method?**

- Measurement uncertainty evaluation is part of measurement procedure validation.





**h) Which specific topics could be relevant to include in a revised Eurachem Guide on Method validation?**

- The link between measurement procedure validation and test quality control;