



Method Validation

Requirements of ISO/IEC 17025:2005 and Accreditation

Jeff Ruddle: NSUF 22nd May 2007

*Delivering
Confidence*

Overview

- What is Method Validation?
- Accreditation Requirements
- Standard Vs In-House Methods
- Output of Validation Exercises

What is Method Validation?

ISO/IEC 17025:2005 5.4.5

“Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.”

Method is **Fit for Purpose**

Fitness for Purpose

- **Intended use of analytical data**
 - Precision, Bias & Uncertainty
 - Range
 - Limit of Detection
 - Matrices of Interest

Accreditation Requirements

ISO/IEC 17025 5.4.5.2

“The laboratory shall validate non-standard methods, laboratory designed/developed methods, standard methods outside their intended scope, and amplifications and modifications of standard methods to **confirm that the methods are fit for their intended use**. The validation shall be as **extensive as is necessary to meet the needs of the given application or field of application**. The laboratory shall record the results obtained, the procedure used for validation, and a statement as to whether the method is fit for the intended use.”

Accreditation Requirements

ISO/IEC 17025 5.4.5.3

“The range and accuracy of the values obtainable from validated methods (e.g the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross – sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers’ needs.”

Accreditation Requirements

- Robustness
- Reproducibility
- Traceability
- Linearity
- Matrix Effects
- Extraction Efficiency

Outputs of Validation

- Validation Plan
- Records of Validation Studies
 - Data
 - Decisions and Conclusions
- Use of Reference Materials – TPS 57
- Participation in Proficiency Testing – TPS 47

Standard Vs In-House Methods

- Methods published by a competent body
 - ISO, CEN, BS, etc....
- Validity already demonstrated
- Performance parameters published
- Demonstration of Effective Implementation

Validation Publications

- Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and related topics – Eurochem Guide.
- In-house method validation: A guide for chemical laboratories (LGC)
- Both are available from the www.vam.org.uk

Method Validation Courses

- 3 day residential course run by LGC in conjunction with UKAS
- Refer to www.ukas.com or www.lgc.co.uk
- This course will help delegates understand method validation and its requirements; select and apply the statistics required during method validation; select and use the appropriate types of method validation studies and appreciate and understand the links with measurement uncertainty.



Thank You

QUESTIONS