



# Method Validation

Requirements of ISO/IEC 17025:2005 and Accreditation

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*Delivering  
Confidence*

# Overview

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- 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

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- **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

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

# Outputs of Validation

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- 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

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- 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](http://www.vam.org.uk)

# Method Validation Courses

- 3 day residential course run by LGC in conjunction with UKAS
- Refer to [www.ukas.com](http://www.ukas.com) or [www.lgc.co.uk](http://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

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## QUESTIONS