ISO 17025 Accreditation/Quality Management Systems Panel Discussion

AAFCO 2014 Annual Meeting

Laboratory Methods & Service Committee

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Association of American Feed Control Officials

Validation and Verification of Analytical Methods

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Relevant section of the standard

5.4 Method Validation

What is Validation?

Defined in ISO/IEC 17025:2005 Section 5.4.1

"The confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled."

IN ENGLISH PLEASE!

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- Defined performance characteristics
- Must compare to a reference method
- Statistical evaluation is performed to show equivalence to a reference method

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When is a Validation Required?

- New method is developed
- Modifications are made to an existing method/official method
- Extension of scope (i.e., additional matrices not evaluated, changes in the intended use)
- Significant changes in instrument parameters, reagents, time, temperature, etc.
- A change in technology/instrumentation

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What is Verification?

- Demonstration that a previously validated method can meet the analytical requirements (i.e., precision, accuracy, interferences, matrices, analyst) and suitability in YOUR lab
- Fit for use – an established method will meet customer or laboratory requirements for detection limits, sample types, etc.
- Validation has already been performed and the method is well established

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When is Verification Required

- Each analysis in your laboratory for which you did not validate
- Can you run a specific method in **your** lab with your equipment, your analysts, your reagents, etc.
- Can your lab meet the performance criteria of the method?
- Remember, if you change/alter/deviate from a validated method, you must **validate** that the change you made is equivalent in performance to the originally validated method!
- FDA Guidance on in-house verification of a validated method

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Performance Characteristic	Validation	Verification
Ruggedness (usually performed prior to beginning validation)	Yes	No
Selectivity	Yes	No unless matrices differ
Robustness/Matrix Effects/cross-sensitivity	Yes	No unless matrices differ
Limit of Detection (LOD)	Yes	Yes – can you meet listed
Limit of Quantitation (LOQ)	Yes	Yes – can you meet listed
Analytical Range	Yes	Yes – can you meet listed
Linearity	Yes	No
Accuracy (Using a CRM)	Yes	Yes
Precision	Yes	Yes
Repeatability	Yes	Yes - once
Reproducibility	Yes	Yes
Measurement Uncertainty	Yes	Yes/No

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Resources and Guidance

- **How to Meet ISO17025 Requirements for Method Verification, AOAC International**, *www.aoac.org/imis15.../alacc_guide_2008.pdf*
- ***Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories,*** *www.inab.ie/media/PS15.pdf*
- ***Guidelines for Validation and Verification of Quantitative and Qualitative Test Methods, National Association of Testing Authorities (NATA)*** *http://www.nata.com.au/nata/accreditation-publication/nata-accreditation-guidance-and-information/category/50-nata-tech-notes-info-papers*
- ***Harmonized Guidelines for Single-Laboratory Method Validation of Chemical Test Methods, IUPAC Technical Report*** *http://www.iupac.org/publications/pac/74/5/0835/*
- ***FERN-ADM.0008.00 FERN Validation Guidelines for FERN Chemical, Microbiological and Radiological Methods, Original, 06/22/10.***
- ***AOAC International Method Validation Programs Manual*** *http://www.aoac.org/iMIS15_Prod/AOAC/Publications/Guidelines/AOAC_Member/Pubs/Guides/Guidelines.aspx?hkey=965b2306-1083-404c-b41a-bf159216a610*

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