

Test Method, Validation and Verification of Methods

APHL Quality Management System (QMS) Competency Guidelines

This course will help staff understand what is important when selecting a method and considerations for validating a method.

Objectives:

1. Participant will understand that only the most current, approved and appropriate method should be used.
2. Participant will comprehend the requirements for validating a non-standard or in-house method.

Methods should be appropriate and meet the needs of the customer

What is Validation? Confirming a method by examining through the use of objective evidence and particular requirements that it will fulfill its intended use.

For example: A method for determining a particular analyte or parameter will, indeed, be recovered and accurately measured throughout the preparation and determinative steps of the process.

New test methods description of procedures should include these items:

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- Identification, handling, transporting, storage, and preparation of items
- Checks to be made before work is started
- Checks that equipment is working properly, required calibration and adjustments are made prior to each use
- Method of recording observations and results
- Safety measures to be observed

Public health laboratory competency guidelines: General (GEN) domain

GEN 1.00 General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing (including technical, troubleshooting, mathematical and statistical skills). Documents actions and results using established paper or electronic systems



GEN 2.00 Reagent use and storage: adheres to policies and principles regarding the use and storage of laboratory reagents and supplies.

GEN 3.00 Equipment use: adheres to policies and principles regarding the use, maintenance, and calibration of laboratory equipment.

GEN 7.00 Regulatory compliance: complies with regulations and guidelines governing laboratory testing

Informatics (INF) domain

INF 7.00 Media, reagents, and controls: manages the manufacturing and inventory of media, reagents, and controls electronically.

Chemistry (CHM) domain

CHM 6.03 Method validation and performance verification:

Beginner: Participates in performance of method validation and performance verification

Competent: Compiles results of method validation and performance verification

Proficient: Evaluates method validation and performance verification results

Expert: Oversees the policies, processes, and procedures related to method validation and performance verification.

CHM 6.04 Development and validation of laboratory-developed tests (LDTs):

Beginner: Participates in the development of LDTs

Competent: Evaluates LDT validation data

Proficient: Creates processes and procedures for the development and validation of LDTs

Expert: Oversees the policies, processes, and procedures regarding the development and validation of LDTs

Quality Management System (QMS) domain

QMS 7.03 Method validation and performance verification processes

Beginner: Describes method validation and performance verification processes

Competent: Performs procedures for method validation and performance verification

Proficient: Develops method validation and performance verification processes and procedures

Expert: Oversees the policies, processes, and procedures for validation of new or modified tests or materials and for verification of existing tests or materials

Definitions

- **Accuracy**-(Method Bias) nearness to the true value; can be determined by one of the following techniques:
 - Use of certified reference materials;
 - Use of reference method of known uncertainty
 - Use of recovery from spiked samples



- Reference material, if available, should be carried through entire procedure with each batch of test samples. If fortified or spiked samples are used, the method of fortification should be described.
- **Bias**-systematic error manifested as a consistent unidirectional deviation from the true value
- **Calibration**-the comparison of two measurement devices or systems, one of known uncertainty (your standard) and one of unknown uncertainty (your test equipment)
- **Certified Reference Material (CRM)**-reference material that has documentation by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities
- **Laboratory developed methods**-methods that are developed using “in-house” procedures, or by changing an established reference procedure.
- **Reference method**-method that have been published or documented by an authorizing body
- **Validation**-the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled
- **Verification**-laboratory verifies by an established process that they are capable of using a validated method for its intended use

When Selecting a Method

It should be approved or published in

- International, regional or national standards
- Reputable technical organizations
- Relevant scientific journals
- Specified by manufacturer of equipment

Use the latest valid edition unless it is not appropriate or possible to do so

- Supplement with additional details when necessary to ensure consistent application
- The laboratory must confirm they can properly operate any standard method

Deviations shall occur only if the deviation has been

- Documented
- Technically justified
- Authorized and accepted by the customer

Appropriate for the test

Laboratory must confirm that it can properly operate the method before introducing the test. If the method changes, the confirmation must be repeated.