PRO: Validation of New Procedures

Introduction

5.4.2

Accurate analyses depend upon the selection and proper use of suitable procedures that have been proven to be reliable by an objective evaluation process.

5.4.2.1
5.4.4

Before the laboratory adopts a new procedure, it must be evaluated to determine that it works as expected. The extent to which a procedure needs to be evaluated varies greatly depending upon the nature of the test. The individual validation process will be determined by the appropriate peer group, working with management, or by established industry standards.

Definition

5.4.5.1

Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled.

General validation issues

Validation of new procedures will be assigned to qualified personnel and, depending upon the nature of the procedure, may address the following issues:

5.4.3

- understanding the theoretical basis of the procedure, including a review of the appropriate technical literature
- characterizing reagents used in the test including such factors as

5.4.5.3

  – specificity
  – sensitivity
  – stability
- determining accuracy and precision at relative concentrations which are representative of casework samples
- testing the procedure using known samples to simulate case samples including such factors as
  – matrix
  – sample age
  – degradation
  – sample heterogeneity

5.4.2

- testing the procedure with an appropriate set of samples with target values unknown to the analyst

Continued on next page

PRO: Validation of New Procedures, Continued

Discipline-specific validation requirements

Discipline-specific validation requirements are addressed in the quality assurance chapters of the individual procedures manuals.

Method verification
5.4.5.4

Prior to applying a new technical procedure to the examination of evidence, the reliability of the procedure shall be demonstrated against any documented performance characteristics. Records of this performance verification shall be maintained according to the Procedure for Validation of Technical Procedures.

New instrument validation

A new instrument installed in the laboratory for the purpose of replacing an older version of the same instrument should be subjected to the following testing:

- performance testing to ensure adherence to the specifications stated in the purchase contract
- testing to define
  - specificity
  - sensitivity
  - reproducibility
  - repeatability

An instrument installed for the purpose of implementing new methodology must be tested as described above. In addition, validation addressing the appropriate general and discipline-specific validation issues must be conducted using the instrument.

NOTE: In this situation, a competency test will be performed by all personnel that are not involved in the method development.

Calibration and maintenance procedures for new instruments will also be developed to ensure monitoring of performance.

Continued on next page

PRO: Validation of New Procedures, Continued

General validation process

This table gives the general process for conducting a validation study for a new procedure or instrument.

Stage	Description
1	The peer group determines the appropriate validation issues to be addressed based upon the type of procedure or instrument to be validated. NOTE: The validation plan should be reviewed and updated, if needed, as the process proceeds.
2	The supervisor selects a validation study leader who is responsible for monitoring the progress of the study and for collecting the validation records.
3	The validation study is performed and supporting data is collected and recorded.
4	The peer group evaluates the validation data and determines if the new procedure or instrument is acceptable for use in casework.
5	A written recommendation for acceptance, with a summary or outline of the validation issues addressed, should be included with the study records and signed for the group by the validation study leader.
6	The peer group presents the validation data, the written procedure used, and a written recommendation for acceptance to the unit supervisor for review and approval. If approved, the supervisor must sign and date the recommendation or validation records.
7	The validation records are reviewed by the Quality Manager and/or Laboratory Director.
8	The validated procedure or instrumental method is written into the manual format and then is submitted to the Quality Manager and Laboratory Director for approval. Once approved, the procedure is incorporated into the authorized version of the appropriate procedures manual (see *MGS: Document Control, Document changes*) and is then available for casework. Prior to casework, if a new type of instrument is utilized for the validated procedure, a competency test will be assigned to all personnel who did not participate in the validation.

5.4.3
5.4.5.2
5.4.5.3

Continued on next page

PRO: Validation of New Procedures, Continued

Procedural freedom

The need for procedural freedom can be addressed by leaving sufficient room in written procedures for the expected variations.

The use of "shall", "must", and "will" in written procedures is used only where necessary to protect the scientific acceptability of a procedure and the safety of analysts and co-workers.

When appropriate, an analyst may use their professional judgment on a choice of procedural variation. The appropriateness of the analyst's choice will be evaluated by the supervisor prior to a final report.

Validation records

5.4.2.1

Clearly marked binders or files containing completed validation study records will be kept in the appropriate laboratory area. The validation study may be placed in laboratory long-term storage after at least one accreditation cycle (5-years).