

* Verification & validation of examination procedure requirement

→ Validation of examination procedure:-

- Validate examination procedure derived from following sources

1 - Non standard method

2 - Laboratory designed or developed method

3 - Validated methods used outside their intended scope

4 - Validated methods subsequently modified

→ Validation shall be ^{as} extensive as necessary to confirm through provision of objective evidence (in the form of performance characteristics), that the specific requirements for intended use of examination have been fulfilled.

→ Performance characteristics should include

↓
measurement trueness
measurement accuracy
measurement precision
[measurement repeatability]
[measurement intermediate precision]
measurement uncertainty,
Analytical sensitivity
Detection limit
quantitation limit
measuring interval
Diagnostic specificity
Diagnostic sensitivity

→ Document procedure used for validation & Record results obtained.

→ Staff with authority - review validation results & record the review

→ when changes are made to validated examination procedure, the influence of such changes shall be documented & when appropriate, a new validation shall be carried out.

→ Verification of examination procedure :-

- Validated examination procedures used without modification shall be subject to independent verification by laboratory before being introduced into routine use.
- The laboratory shall obtain information from manufacturer / method developer for confirming the performance characteristics of procedure.
- The independent verification by laboratory shall confirm, through obtaining objective evidence [in form of performance characteristics] that the performance claims for the examination procedure have been met.
- Document procedure used for verification & record the results obtained.
- Staff with appropriate authority shall review verification results & record the review.