

For Comparative Testing, results generated by the Receiving Laboratory may be compared with historical data, or to data that have been generated in parallel by the Transferring Laboratory.

Validation of methods does not require any additional transfer documentation.

**4. The Transfer Plan Document(s) should detail the following:**

- The test(s) to be transferred,
- The modes of transfer,
- The justification for the modes of transfer selected, and
- Pre-determined acceptance criteria.

Both quantitative and qualitative methods should be assessed to determine if transfer of the methods is required. The complexity of the method should also be considered.

5. The Need for a Transfer Plan Amendment may arise during execution of the Transfer Plan. The amendment should provide a description and rationale for each change and should be approved by qualified personnel at the participating laboratories prior to implementation.
6. If Acceptance Criteria are Not Met, qualified personnel at the participating laboratories should conduct an investigation to identify the potential cause(s) of the failure.

If the root cause for the failure is attributed to the testing laboratories or the transfer strategy, additional testing may be necessary and documented in a Contingency Testing Plan.

If the cause for the failure is attributed to the capabilities of the method, Subject Matter Expert(s) (SME) should be identified and assigned to provide timely evaluation and resolution. Transfer work should be suspended until any necessary changes are made.

If the cause for failure cannot be attributed, a review and an assessment of the results should be made using the data generated during the transfer, the corresponding investigation, and any other information pertaining to the history and performance of the method. This evaluation is used to determine if additional testing is required or, under certain limited circumstances, to reassess the original acceptance criteria.

A justification for the acceptance of data that do not meet the acceptance criteria should be documented in the Laboratory Qualification Memo and a description of the investigation should be included.

If the qualified personnel at the participating laboratories determine that the transfer effort is to be discontinued, the reason for this determination should be documented and approved by the qualified personnel at the Transferring and Receiving Laboratories.