

Summary - Test Deviations during Validation

This guidance provides recommendations for investigation and reporting of test deviations during a validation exercise.

Deviations may be identified by the tester during execution of the protocol or by a reviewer.

Where a protocol error is identified, it is recommended that the deviation procedure makes a clear distinction between typographical and other minor errors where the intent of the protocol is still clear, and errors that require correction to allow the test to be executed. It is considered acceptable to hand-amend (per applicable site documentation practices) typographical and other minor errors that have no impact on the test method or acceptance criteria. Where correction is required to allow the test to be executed, including determining whether the test passes or fails, then a deviation should be raised.

Where the deviation and any corrective actions do not impact the intent of the original validation test, then testing should be allowed to proceed.

If corrective actions identified impact ongoing validation activities (including moving to the next phase of validation), validation testing should be stopped, the actions should be implemented and confirmed and the deviation should be closed before continuing testing. Where testing that has already been completed is impacted, consideration of the repetition of those tests should be included in the corrective actions.

An out-of-specification (OOS) result generated by the laboratory is a deviation and should be investigated according to applicable procedure and procedures for laboratory OOS results. Another common deviation is missing or lost data. The impact of the missing or lost data should be evaluated to determine the criticality of the unavailable information and its impact on providing evidence of validation or qualification of the system or process.

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