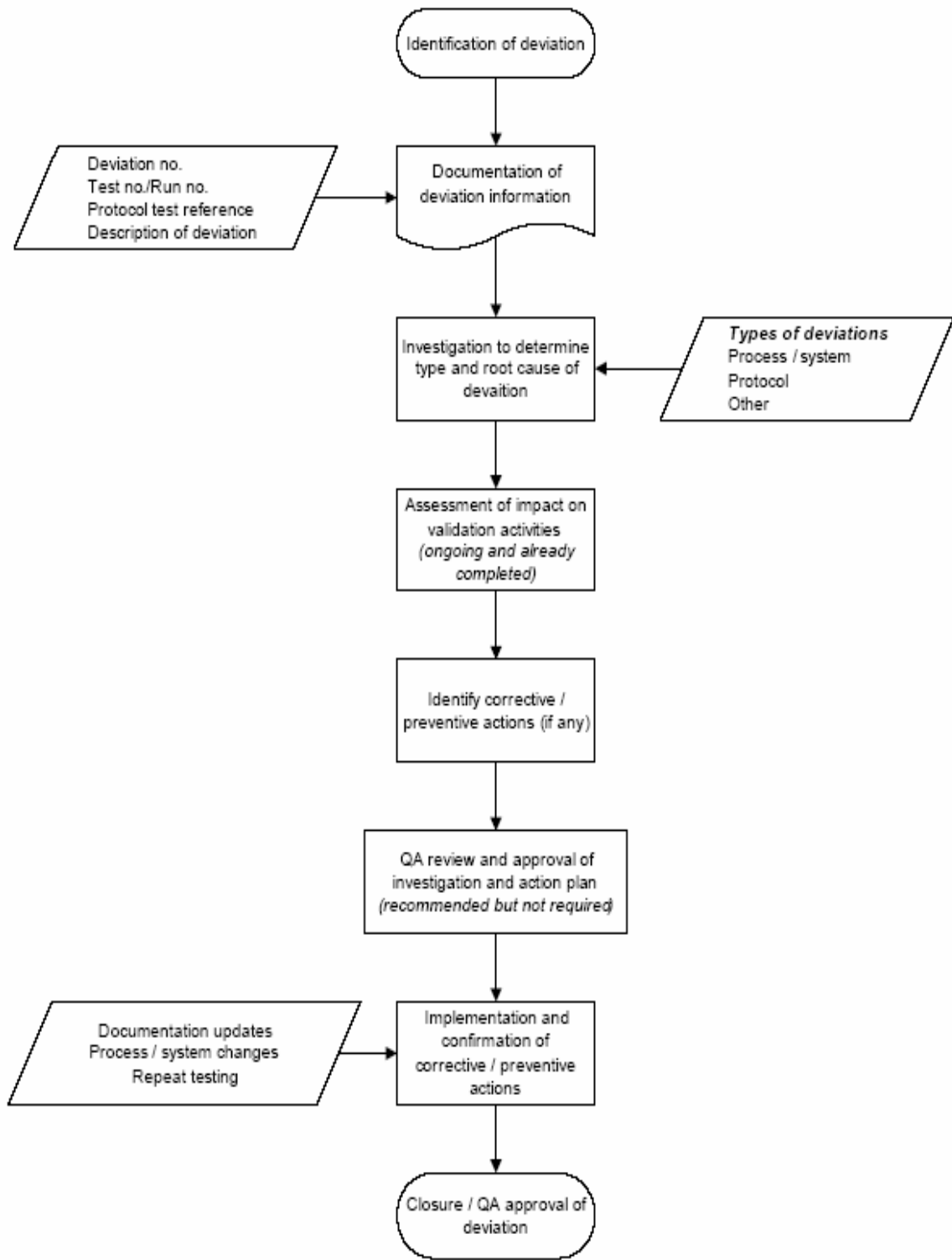


Guidance Number: 046

Documenting a Validation Deviation



Appendix I: Example Deviation Form

Appendix 1

| | | | | |
|---|--|----------------------|---------------------------------|----------------|
| Dev No. | | Protocol no. | | Page of |
| Test Ref. / Run No. | | Test Step No. | | |
| Description of Deviation: | | | | |
| Name: | | Signature: | | Date: |
| Investigation and Proposed Corrective Actions | | | | |
| Description: | | | | |
| System/Process Deviation <input type="checkbox"/> Protocol Deviation <input type="checkbox"/> Other <input type="checkbox"/> | | | | |
| Technical Rep Name: | | Signature: | | Date: |
| QA Name: | | Signature: | | Date: |
| Corrective Actions Completed, Closure of Deviation | | | | |
| Corrective actions were successfully implemented, tested satisfactorily where applicable and the results comply with the requirements. Yes <input type="checkbox"/> No <input type="checkbox"/> . | | | | |
| If No, comment below | | | | |
| Test Evidence provided? Yes <input type="checkbox"/> No <input type="checkbox"/> | | | Attachment Ref. : | |
| Are there any further actions to be performed under Change Control? Yes <input type="checkbox"/> No <input type="checkbox"/> | | | Change Control Ref. No.: | |
| Deviation closed out by: | | | | |
| Name: | | Signature: | | Date: |
| QA Approval of Deviation Closure: | | | | |
| Name: | | Signature: | | Date: |