Procedure for Authorizing Deviations

1.0 Purpose - This procedure describes the actions required to approve deviations from quality system procedures.

2.0 Scope - This procedure applies to all quality system procedures within the State Crime Laboratory (Laboratory).

3.0 Definitions

- **Deviation** – A departure from the standard method or technical procedure generally used in the analysis of evidence.

4.0 Procedure

4.1 Any deviations from technical procedures shall be discussed first with the Section Technical Leader and/or Forensic Scientist Manager who shall consider the appropriateness, benefits, and risks of the deviation before approving the proposed deviation.

4.2 The Forensic Scientist requesting the deviation (the initiator) shall complete Sections A through C of the Deviation Request Form (DRF). Additional continuation pages may be included. Sections A through C shall include:

- Name of the policy or procedure from which deviation is sought.
- Statement regarding the facts behind and the necessity for the deviation.
- Requested duration of the specified deviation.
- Date and name of the employee.

4.3 Two authorizations shall be required for a deviation.

4.3.1 The employee requesting the deviation shall submit the DRF to the Technical Leader, who shall evaluate the appropriateness and impact of the deviation. If the merits outweigh any undesirable impacts, the Technical Leader shall signify approval by completing Section D, placing his/her signature and date upon the DRF, and forwarding the request to the Forensic Scientist Manager. In the absence of the Technical Leader, the Quality Manager (QM) may complete Section D approval.

4.3.2 The Forensic Scientist Manager (FSM) or his/her designee shall evaluate the proposed deviation with regard to good laboratory practice and potential impact on the Quality System. The Forensic Scientist Manager or his/her designee shall signify authorization by signing and dating the DRF. The Forensic Scientist Manager or Technical Leader shall notify the employee of the authority to use the deviation. In the absence of the FSM, the QM may complete the authorization.

4.4 Deviations for Laboratory-wide procedures shall be approved using a DRF. The QM or designee shall evaluate the proposed deviation and shall signify approval by signing and dating the DRF.

4.5 Authorized deviations shall be valid for a specified period of time (or circumstance) not to exceed one year. An authorized deviation does not eliminate the requirement for validating modifications to technical procedures. If the deviation is used for a period of one year, the deviation shall be reviewed by

the QM and the technical procedure shall be revised as provided in the Procedure for Writing Technical Procedures.

4.6 For a DRF that is not case specific, the QM or designee shall place the DRF in front of the official copy of the procedure that is housed on the Laboratory shared drive. For a DRF that is case specific, the original DRF shall be placed in the case record. A record of all case specific DRF's shall be maintained by the Section Document Custodian.

4.7 When a DRF (not case specific) is approved for lab-wide and Section procedures, the QM and/or FSM shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet to indicate review of the document. The Acknowledgement Sheets shall be scanned and stored on the internal network file server.

4.8 Once the DRF has expired, or the associated technical procedure has been updated, the DRF shall be archived.

5.0 Records - Specific case-related Deviation Request Forms shall be scanned into the Case Record Object Repository. Case related changes to a technical procedure shall be noted in the case analysis documentation. The QM shall maintain with the associated procedure a copy of each archived DRF that is not case specific.

6.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
10/17/2012	2	Added 4.6 for archiving DRF forms and modified 5.0 to remove "on the laboratory shared drive."
12/07/2012	3	Added case related DRFs will be scanned into the Case Object Repository in 5.0.
02/15/2013	4	4.5 - Added statement on notification of DRF
03/08/2013	5	5.0 - Changed Quality Manager to Quality Officer
10/31/2013	6	Added issuing authority to header
08/29/2014	7	4.3.1, 4.3.2 - authorized approval of deviation to include Technical Leader and Forensic Scientist Manager; added new 4.4 – subsequent re-numbering; 4.5 - authorized 1 year review to be done by Deputy Assistant Director/QM; 4.6 - added case specific DRF to case record; added 4.7 - signing of acknowledgement sheet for DRF
12/19/2014	8	Removed Deputy Assistant Director throughout document; 4.6 - updated to reflect the placement of the DRF in front of the procedure; 5.0 - updated to reflect archival of DRF with the associated technical procedure and to match 4.6 for storage of DRF for case specific DRF
04/28/2017	9	4.2 – replaced signature/initials with name 4.3.1, 4.3.2 – added QM to the list of approvers/authorizers 4.3.2 – removed the requirement to send a copy of DRF to QM.
01/18/2019	10	4.6 – edited how DRF records are maintained, original in case record, copy maintained by section document custodian.