Procedure for Authorizing Deviations

Version 3

Effective Date: 12/7/2012

- **1.0 Purpose** This procedure describes the actions required to approve deviations from technical procedures.
- **2.0 Scope** This procedure applies to all technical 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 signature/initials 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 Forensic Scientist Manager, who shall evaluate the appropriateness and impact of the deviation with the Technical Leader. If the merits outweigh any undesirable impacts, the Forensic Scientist Manager or Technical Leader shall signify approval by completing Section D, placing his/her signature and date upon the DRF, and forwarding the request to the Deputy Assistant Director/Quality Manager (QM).
 - **4.3.2** The Deputy Assistant Director/QM, or the Quality Control Officer (QCO) in his absence, shall evaluate the proposed deviation with regard to good laboratory practice and potential impact on the Quality System. The Deputy Assistant Director/QM or designee shall signify approval by signing and dating the DRF and returning it to the Forensic Scientist Manager. The Forensic Scientist Manager or Technical Leader shall notify the employee of the authority to use the deviation.
- **4.4** 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 Lab Director and the technical procedure shall be revised as provided in the Procedure for Writing Technical Procedures.
- **4.5** The Section Document Custodian shall place the DRF on the Section shared drive and shall notify Section employees of the deviation immediately via email transmittal.

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- **4.6** Once the DRF has expired, or the associated technical procedure has been updated, the DRF shall be archived by the Section Document Custodian.
- **5.0 Records** Specific case-related Deviation Request Forms shall be scanned into the Case Object Repository. Case related changes to a technical procedure shall be noted in the case analysis documentation. The Quality Control Manager shall maintain a copy of each completed DRF.
- **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." |
| 12/7/2012 | 3 | Added case related DRFs will be scanned into the Case Object Repository in 5.0. |
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