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### **Purpose**

This procedure describes the actions required to approve deviations from all quality procedures.

# Scope

This procedure applies to all quality procedures within the Pitt County Sheriff's Office Forensic Services Unit.

#### **Definitions**

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

## **Procedure**

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

The analyst (chemist, technician, examiner) requesting the deviation (the initiator) shall complete Sections A through C of FORM# <u>4-1-5-F1</u>, <u>Deviation Request Form (DRF)</u>. 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.

The employee requesting the deviation shall submit the DRF to the Technical Leader or designee, 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 Quality Manager.

The Quality Manager or designee shall evaluate the proposed deviation with regard to good laboratory practice and potential impact on the Quality System. The Quality Manager or designee shall forward to the DRF to the Technical Leader who shall notify the employee of the authority to use the deviation.

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

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 Technical Leader and Quality Manager or designee and the technical procedure shall be revised.

For a DRF that is not case specific, the Quality Manager or designee shall place the DRF in front of the official copy of the procedure that is housed in DM Document Management. For a DRF that is case specific, the original DRF shall be maintained by the Quality Manager or designee and a copy of the DRF shall be placed in the case record.

When a DRF (not case specific) is approved for lab-wide and Section procedures, the Quality Manager shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet Log # <u>5-2-1-L1</u>, <u>Acknowledgement sheets</u> to indicate review of the document. The Acknowledgement Sheets shall be scanned and stored in DM Document Management.

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

### **Records**

Specific case-related Deviation Request Forms shall be documented in Master Case file. The Quality Manager or designee shall maintain a copy of each archived DRF.

REVISION HISTORY		
CURRENT VERSION	EFFECTIVE DATE	SUMMARY OF CHANGES
1	2016/07/01	Original version saved in DM
2	2018/04/01	Changed issue date to Effective Date, changed Rev# to Ver#, Changed Revision table to current format, Removed "Forensic Scientist" and added "designee and Quality Manager" to personnel authorized to approve deviation from test method or technical procedure.