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Purpose

To implement opportunities for needed improvement and prevent potential sources of nonconformance.

Scope / Field of Application

Any procedure or process relating to the Pitt County Forensic Services.

Definitions and Acronyms

Preventive Action – action taken to eliminate the causes of potential issue, defect, or other undesirable situation in order to prevent occurrence.

Preventive Action Request (PAR) – request to initiate preventive action.

Responsibilities

Originator - initiator of the preventive action or the supervisor of a work group.

Appointed Laboratory Personnel - those involved in preventing potential nonconformities or improving processes appointed by the Laboratory Director.

Materials (and Skills) Required

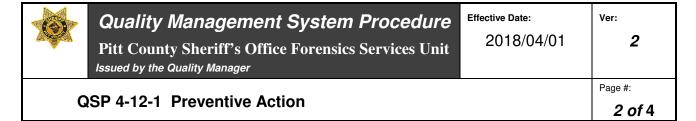
1. Quality tools such as Form# <u>4-12-1-F1</u>, *Preventive Action Requests* to identify the root cause of a potential issue.

Procedure

Preventive action plans are part of a proactive process for improvement of the quality system. A preventive action is undertaken to identify opportunities for improvement and to reduce the likelihood of a issue. Preventive action includes the use of audit results, quality records and complaints to detect, analyze, and eliminate potential causes of nonconformities.

The preventive action process consists of:

- ➤ Identifying and reviewing a potential issue.
- ➤ Determining the course of action to eliminate the issue from occurring.



- > Implementing the action.
- Ensuring the action is effective over time.

Identification of Conditions or Situations – If a condition exists that may be improved; the Laboratory employee identifying the issue shall notify his/her immediate supervisor. If a preventive action is identified through an internal audit or assessment, the Quality Manager or designee shall initiate the process.

Initiating a Preventive Action

When an opportunity for improvement is identified, the Originator shall complete Section I of the Preventive Action Request (PAR), then forward this to Quality Manager.

If the Quality Manager deems no preventive action is necessary, this shall be noted in Section II of the PAR.

If the Quality Manager/Technical Leader deems that preventive action is necessary, the Quality Manager shall assign the responsible person to develop the preventive action plan. This action plan shall be included in Section III and shall contain step(s) necessary to implement the preventive action.

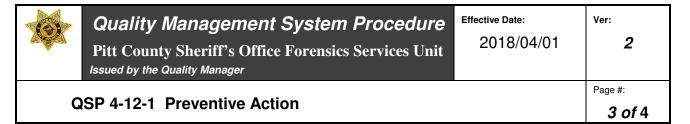
Sections III of the form shall be completed and forwarded to the Quality Manager/Technical Leader for review.

After discussion with the Quality Manager/Technical Leader, the Quality Manager/Technical Leader shall determine if the preventive action is acceptable. If approved, the Quality Manager/Technical Leader shall sign and date Section IV of the PAR. If not approved, the Quality Manager/Technical Leader shall explain in Section IV.

The person responsible for completing the preventive action shall notify the Quality Manager/Technical Leader upon completion. The notification shall include demonstrable proof that the action had the intended effect. This person shall sign and date section V and return to the Quality Manager/Technical Leader.

The Quality Manager shall verify the effectiveness of the preventive action. This verification may be accomplished through review of supporting documentation. Once effectiveness has been verified, the Quality Manager/Technical Leader shall sign and date in Section VI.

It shall be noted in Section VI that the plan has been effective and the Preventive Action is closed.



After the Preventive Action is closed, the action shall be incorporated into the appropriate document.

Records – The PAR and any supporting documentation shall be retained by the Quality Manager .

Documentation

Records are logged, identified and kept on file as laboratory improvements.

Reference Procedures

QSP 4-11-1 Corrective Action PAR form CAR/NCR/PAR Log

References

Quality Manual Section 4.12.

REVISION HISTORY		
CURRENT VERSION	EFFECTIVE DATE	SUMMARY OF CHANGES
1	2016/07/01	Original Version
2	2018/04/01	Cahnge revision history table, issue date to effective date, rev# to ver#