

 <p align="center">Corrective Action Request Pitt County Sheriff's Office Forensics Services Unit <i>Issued by the Quality Manager</i></p>	Effective Date: 2018/04/01	Ver: 3
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Corrective Action Request

CAR#: 19-003

To initiate a CAR, complete section I and return to the Quality Manager.

Section I.

Originator: QM Wallace Moore

Date: 3-27-2019

State the nature of problem (or nonconformity or potential problem)

The ANAB Accreditation Requirement 5.7.1.1 subclause: c requires a minimum confidence level of 95.45% for hypergeometric sampling. The current calculations are based on 95%.

Section II.

The Quality Manager will assign a unique CAR# (upper right of this form) and record it in the CAR/NCR log. The Quality Manager will designate a person responsible to investigate the root cause of the problem and identify an appropriate response date. The Quality Manager will sign and date this section.

Person responsible for investigating problem: Drug Chemistry TL Nancy Gregory

Response required by: TL Nancy Gregory [1 week from date of issue if easily corrected]
[1 month from date of issue if more involved]

Quality Manager: 

Date: 3-27-19

Section III.

The person responsible for investigating the problem will complete section III. This will (1) identify what caused the problem, and (2) detail a plan of action. This person will then sign-off, date, and re-submit this form to the Quality Manager.

Root cause?

After review of Pitt County Sheriff's Office Drug Chemistry Technical Procedure for Sampling, it was determined that this procedure was written under ISO 17025:2005 2011 Supplemental requirements. A minimum confidence level of 95% was used for calculations and reporting. ANAB Standard 5.7.1.1 subclause: c requires a minimum of 95.45% for calculations and reporting.

Plan of Action:

All casework involving hypergeometric sampling shall be suspended until corrective action is complete.

The definition of Hypergeometric Sampling Plan will be revised to state "at least 95.45% (often referred to as "approximately 95%")" in the description of the confidence level.

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The chart in the Drug Chemistry Technical Procedure for Sampling used to determine the number of units analyzed for hypergeometric sampling will be revised (using the ENFSI-DWG Calculator for Qualitative Sampling of Seized Drugs - Version July 2017) to utilize calculations based on 95.45%.

Results wording will reflect "approximately" 95%. The ENFSI-DWG Calculator for Qualitative Sampling of Seized Drugs (Version July 2017) will be used to calculate measurement assurance values for extrapolated weights, and these values will be reported.

Sign-off: TL Nancy Gregory

Date: 4-2-19

Section IV.

If Plan of Action pertains to the Quality System, the Quality Manager will approve the plan and take action. If Plan of Action pertains to operations, the plan is forwarded to the Technical Leader for approval. The Technical Leader will approve the plan or decide on an alternative arrangement. If necessary, the Technical Leader will identify a person to take action on the above plan.

Comments/Suggestions:

This plan is approved for action. Forensic Chemist Frank Shaw will assist TL Nancy Gregory in hypergeometric chart value recalculations utilizing the ENFSI Excel spreadsheet.

Person responsible for action: TL Nancy Gregory

Target completion date: 4-2-2019 [1 week from section III date if easily corrected]
[1 month from section III date if more involved]

Technical Leader / Quality Manager: TL Nancy Gregory

Date: 4-2-19

Section V.

The person responsible for action will complete section V. This person will then sign-off, date, and re-submit this form to the Quality Manager.

Action Taken:

Casework from October 22, 2018 to present was reviewed to find cases involving hypergeometric sampling. These cases were analyzed and reported in accordance with ISO 17025:2005 2011 Supplemental and the Pitt County Sheriff's Office Drug Chemistry Section Technical Procedure for Sampling. Therefore the quality of these cases was not affected.

The hypergeometric sampling chart has been recalculated to 95.45% in accordance with ISO 17025:2005 and AR 3028, and new corresponding results statements have been implemented.

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Sign-off: TL Nancy Gregory

Date: 4-2-19

Section VI.

This section is completed by the Quality Manager/Technical Leader.

Final Resolution

1. Did action correct the problem? yes
2. Was action taken a temporary or permanent action? permanent
3. Was corrective action closed? yes
4. Date corrective action closed. 4-2-2019
5. Was effectiveness verified? yes
6. Date effectiveness verified. 4-2-2019

Comments/Suggestions:

Prior to implementation of Version 5 of the Drug Chemistry Technical Procedure for Sampling, Forensic Chemist Frank Shaw recalculated the hypergeometric sampling chart and it was verified by TL Nancy Gregory.

QM/TL: TL Nancy Gregory
Walter J. Shaw

Date: 4-2-19
4-2-19