

 <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#: 19-002

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 5.4.1.2 requires an evaluation of data from unknowns that will be compared to knowns (GCMS and IR) to be evaluated prior to comparison. Currently there are no instructions in the GCMS or FTIR technical procedures to describe how to identify spectra of sufficient quality prior to searching the unknown against a library of standards.

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: TL Nancy Gregory

Response required by: 4-27-19 [1 week from date of issue if easily corrected]
[1 month from date of issue if more involved]

Quality Manager: Wallace Moore

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 Procedures for Gas Chromatograph Mass Spectrometry and the Technical Procedure for Infrared Spectroscopy, it was determined that these procedures were written under ISO 17025:2005 2011 Supplemental requirements. ANAB Standard AR 3028 5.4.1.2 requires a procedure for the evaluation of the unknown item to identify characteristics suitable for comparison.

Plan of Action:

All casework was suspended on 3-27-19. The technical procedures for GCMS and FTIR were revised (effective 4-2-19)

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to include procedures for the evaluation of unknown data to identify characteristics suitable for comparison prior to comparison with known standards or published reference spectra. Casework was resumed on 4-2-19.

On 4-13-19 we were informed by the Lead Assessor through the Quality Manager that the technical procedure changes that were made for GCMS and IR needed more clarification. The casework performed from 4-2-19 to 4-13-19 was reviewed and still met the new requirements. For this reason, the quality of casework was not affected and no further action is required following the new revisions to the technical procedures as outlined below.

The Drug Chemistry Technical Procedure for Gas Chromatograph/Mass Spectrometry (GC-MS) will be re-revised to include the following statements:

5.5.5 Criteria for Initial Evaluation

5.5.5.1 The data generated from an unknown substance shall be evaluated to ensure that it is suitable prior to comparison to known reference standards or published spectral data.

5.5.5.1.1 Initial evaluation shall include the assessment of peaks in the total ion chromatogram (TIC), mass fragmentation patterns/ion distributions, retention times and relative abundance of greater than 10,000 counts.

The Drug Chemistry Technical Procedure for Infrared Spectroscopy will be revised to include the following statements:

5.4.3 Criteria for Initial Evaluation

5.4.3.1 The spectral peaks obtained from an unknown shall be evaluated prior to comparison to ensure they are of sufficient intensity to make an accurate comparison to known reference standards or published spectral data.

5.4.3.1.1 Any peaks generated that are below 100% transmission (for FTIR) and /or 100% reflectance (for ATR) will be considered of sufficient intensity and will be valid for further comparison.

Sign-off: TL Nancy Gregory

Date: 4-2-16-19

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 and Forensic Chemist Chuck McClelland will assist TL Nancy Gregory in the revision of the Drug Chemistry Technical Procedures for GCMS and IR.

Person responsible for action: TL Nancy Gregory

Target completion date: 4-27-19 [1 week from section III date if easily corrected]
[1 month from section III date if more involved]

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Technical Leader / Quality Manager: TL Mamey Gray

Date: 4-16-19

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. These cases were analyzed and reported in accordance with ISO 17025:2005 and the Pitt County Sheriff's Office Drug Chemistry Section Technical Procedures for GCMS and IR. There were no written requirements for evaluation of data prior to comparison to known standards or published reference spectra. However, the technical review of both forensic chemists' casework revealed that the data used for comparison meets the criteria in the revised procedure noted above in Section III, and therefore the quality of casework was not affected.

The Technical Procedures for GCMS and IR have been re-revised.

Sign-off: TL Mamey Gray

Date: 4-16-19

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. yes
5. Was effectiveness verified? yes
6. Date effectiveness verified. 4-16-19

Comments/Suggestions:

QM/TL: TL Mamey Gray
Walter J. Moore

Date: 4-16-19
4-16-19