Deviation from Documented Procedures Form

Date of Deviation: March 16, 2022

Type of Deviation: GC/MS Method Documentation

Describe the Deviation: In the process of creating a new method through the modification of the current method on Seized Drugs GC/MS instrument 6890/5973 (Instrument #1), it was discovered that there is no proper documentation regarding the efficacy of the original method. The original method was developed in 1997. It was eventually modified for each instrument, GC/MS 7890B/5977A (Instrument #3) and GC/MS 7890B/5977B (Instrument #4) in 2013 and 2019, respectively. The method appears to have been grandfathered in as it was developed prior to the Laboratory adhering to ISO/IEC 17025 and the requirements of accreditation. The continued maintenance and verification of the instrument, along with an ongoing validation of a newly developed method, ensure that Instrument #1 is working properly and the current method is sound.

ISO/IEC 17025:2017
"7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).
7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary."

CS-19-05 GC/MS Drug Identification
"9.3.1 Method parameters shall be printed and maintained in the instrument binder or in a retrievable form.
9.3.2 Archived method parameters shall be maintained in electronic form on each instrument's external hard drive."

Reason for Deviation: Records of the validation of Seized Drugs GC/MS instrument 6890/5973 (Instrument #1) and the current method used could not be found.

Laboratory Number(s) (if applicable):

Applicable Analyst _____ Date 04/11/22

Applicable Analyst _____ Date 04/14/22

Quality Assurance Manager _____ Date 14 April 2022

Laboratory Director _____ Date 14 April 2022