7.0 DOCUMENTATION

7.1 Reagents, Solvents, and Standards

7.1.1 Reagent and Solvents

7.1.1.1 Lot numbers for all chemicals used in analysis will be traceable to each case file. A logbook will be maintained to record the lot numbers and expiration dates of these chemicals. "Until consumed (u/c or uc)" will be used for any chemicals without a manufacturer-supplied expiration date.

7.1.1.2 All lab-prepared reagent containers will be labeled with the reagent name, expiration date, and the preparer's initials. Logbook entries for these reagents will list the names, lot numbers, and amounts of chemicals and solvents used to prepare the reagent, the preparer's initials, preparation date, and expiration date. Positive and negative control verifications will also be recorded on these log entries.

7.1.1.3 All reagents and solvents dispensed in the laboratory will be recorded in the appropriate log book. Any reagents or solvents stored in the analyst's workspace will be labeled with the reagent or solvent name, the date the container was filled, the preparation date or lot number, expiration date (if applicable), and the dispenser's initials.

7.1.2 Primary Reference Standards

7.1.2.1 Primary reference standard logs will list the standard's name, source, schedule (if applicable), weight, and usage information.

7.1.2.2 Any order of a Schedule I or II solid state primary standard must be accompanied by a completed DEA Form 222. A copy of this completed form must be kept for a period of no less than five years after the date of order. The DEA 222 forms are maintained by the TBI FCU.

7.1.3 Secondary Standards

Secondary standards will be documented in the same manner as primary standards. All secondary standards will be assigned a unique Sample Identification number in lieu of a lot number.

7.1.4 Working Standards

7.1.4.1 Lab-prepared working standards will be labeled at a minimum with the standard name, preparer's initials, and the expiration date. The working standard log sheet will also include this information, as well as the supplier information and lot numbers of the standard and solvent, the concentration, the preparer's initials, and the date it was prepared.

7.1.4.2 Commercially procured working standards are pre-labeled with the concentration, source, solvent, and lot number.

7.1.5 Certificates of analyses (if applicable), in-lab verification data, and procedural blanks for primary reference, secondary, and working standards will be maintained in the appropriate standard log.

7.2 Instrumentation

7.2.1 Maintenance Records and Operation Instructions

7.2.1.1 An instrument maintenance logbook will be maintained for each instrument. All maintenance that is conducted on the instrument and the accompanying verification data will be maintained in this logbook. These records will include the date, initials of the person conducting the maintenance, and the type of maintenance performed.

7.2.1.2 Operating instructions will be included in the Instrument Operation Manuals folder in Ensur. GC, GC-MS, LC-MS, and GC-IR methods are maintained in each instrument's logbook.

7.2.2 Instrument Data

7.2.2.1 Hard copies of generated spectra and chromatograms will remain with the case file in accordance with the TBI Quality Assurance Manual.

7.2.2.2 All GC, GC-MS, LC-MS, and GC-IR instrument data, blanks, washes, and sequence files are electronically stored on each instrument's computer hard drive and backed up to an external hard drive quarterly if possible. File overwriting is not permitted. Sequence files will be printed and available for review for instruments that do not have backup capabilities.

7.3 Casework

7.3.1 General Requirements

7.3.1.1 All pages of casework documentation must include the following: the laboratory case number, date, page number(s), and the analyst's handwritten initials or signature.

7.3.1.2 All final results will be clearly delineated in the case notes.

7.3.1.3 The subject/victim(s) name (if available) and agency case number **as written on the evidence** will be recorded in the case notes. This information will assist the technical reviewer that the case adheres to the guidelines set in 10.1.1.

7.3.1.4 The start/stop date(s) of analysis must be recorded at least once in the case notes.

The TBI FCU will define the start date of analysis as the date the examiner begins documenting the exhibits present in the evidence. The stop date of analysis will be defined as the date the analyst interprets the data obtained from his/her analysis and documents the results.

7.3.1.5 If all exhibits are completely analyzed on the same date, the start and stop date can be recorded as a single date.

7.3.1.6 The TBI FCU has several acceptable worksheets for casework documentation available in Ensur that will be used for casework testing and results. Additional notes may be taken for inventory of large or numerous submissions.

7.3.1.7 Computer-generated paperwork associated with instrumental analysis must be marked with the case number, exhibit number, instrument's laboratory ID, the date generated, and the analyst's handwritten initials or signature.

7.3.1.8 By initialing any and all generated data, the analyst acknowledges that they have reviewed all discernable peaks, spectra, and other results relating to the identification of legally significant substances (or lack thereof) in a tested exhibit.

7.3.1.9 Refer to Section 14.4 for weight documentation requirements.

7.3.2 Color tests

Color test results will be recorded in the case notes by describing the resulting color or the lack thereof. Other observations of physical changes may also be recorded.

7.3.3 Thin Layer Chromatography

Accurate notes regarding the type of TLC system used must be included in case notes. A photograph of the plate will be made and placed into the case file for both positive and negative results.

7.3.4 Pharmaceutical Identifiers

Printed copies of web references will be included in the case. Citations of published references will include the reference title, year published, and page number of the reference for case review. Refer to the Pharmaceutical Identifiers chapter for acceptable references.

7.3.5 GC-MS

Each chromatogram and spectrum will include documentation of the GC-MS method and solvent used. If the instrument conditions are routine to the laboratory, the method name is adequate as long as the method parameters are traceable to a logbook or other storage location.

7.3.6 GC-IR

Older versions of GC-IR Omnic software do not allow for methods to be created or stored. Therefore, each chromatogram collected will include the GC operating parameters used in analysis. Additionally, each spectrum generated will include the FTIR operating parameters that were used in analysis. The same criteria for GC-MS documentation will apply for newer instruments with method storage capabilities.

7.3.7 GC

Each chromatogram will include documentation of the GC method and solvent used. If the instrument conditions are routine to the laboratory, the method name is adequate as long as the method parameters are traceable to a logbook or other storage location. The analyst may either write the retention times obtained or "consistent with" the drug identified in their case notes.

7.3.8 FT-IR

Each spectrum will include operating parameters as well as the sample preparation or lack thereof.

7.3.9 UV-Vis

Each spectrum will list the solvent or reagent used in the analysis. The analyst may either write the wavelength of the peaks obtained or “consistent with” the drug identified in their case notes.

7.3.10 LC-MS

Each chromatogram and spectrum will include documentation of the LC-MS method and solvent used. If the instrument conditions are routine to the laboratory, the method name is adequate as long as the method parameters are traceable to a logbook or other storage location.

7.3.11 THC Quantitation

All instrumental documentation and procedural blank requirements apply to any THC quantitation. In addition to these requirements, lot numbers of standards and reagents, critical equipment identifications, and crucial weight measurements will be documented.

7.3.12 Background Spectra, Procedural and Non-Instrumental Blanks

The procedural blank and/or background spectra obtained immediately before each analyzed sample will be included in the case file for all instrumentation performed except for UV-shifting substances. Refer to 19.5 for shifting blank requirements. Instrument-specific procedural blank requirements can be found in each instrumentation chapter.

Non-instrumental blanks will be documented in the case file with a description of the blank results.

7.3.13 Data not used for final identification must be clearly identified in the case file.

7.4 Primary Reference Data Collections

Primary reference spectral data are maintained electronically within the TBI. These collections are also available in hard copy format and securely maintained in the TBI FCU.

Instrument comparison libraries are electronically stored on each instrument’s computer hard drive and backed up to an external hard drive quarterly if possible.

Note: All log sheets and worksheets are located in the Lab Documentation folder in Ensur.