12. Toxicology

A. Reagents, Chemicals and Critical Standards

1. The operational guidelines set forth in Section 4.B. of the Drug Chemistry Section Quality Assurance Manual will be followed to ensure that all reagents and chemicals are properly prepared, stored, and disposed.

2. Critical standards used to prepare calibration and verification standards will be obtained from companies that provide certificates of analysis. The Coordinator for Toxicology will maintain a file of the certificate of analysis for all critical standards.

3. Extraction blanks of the internal standards must not show any unacceptable impurities (e.g. identifiable concentration of the undeuterated species).

B. Instrument Certification, Calibration, and Verification.

1. Operation of Scientific Instruments

Operators of instruments will be knowledgeable in their use. Operator training will occur during the training program and will cover the manufacturer's instructions, theory of application, procedures to be used, and any calibration or verification requirements. Operator training will also include in-house training and, when possible, specialized training schools and seminars. All members of the Toxicology Unit are considered primary operators of the shared instruments and equipment, and each member is responsible for proper maintenance.

2. Equipment Maintenance Forms

Whenever an instrument or other equipment in the Toxicology Unit requires service or maintenance outside routine maintenance, a record of the service or maintenance will be kept.

3. Pipette Verification/Certification

Pipettes used in methods that involve quantitative measurements must be

certified or verified. Glass pipettes used for quantitative measurements in the Toxicology Unit must be class A. Glass class A pipettes that are damaged or cannot be cleaned thoroughly must be discarded. Glass class A pipettes do not need to be verified or certified annually. Mechanical pipettes used in the Toxicology Unit will have the calibration verified or certified at least once a year.

4. Blood Alcohol Gas Chromatographs

Calibration and verification data generated for each master file shall be maintained as an administrative document that shall be placed in a gray folder and kept with the folder for the laboratory case file designated as the master file.

5. Enzyme Multiplied Immunoassay Technique

The EMIT maintenance log book will be filled out at the completion of any set of EMIT runs. Any other maintenance or service performed on this instrument will be documented in the log book.

The raw data transcribed to an EMIT worksheet will be reviewed by another chemist. The chemist who reviews the transcription shall sign and date that the transcription was reviewed. The original EMIT data print out will be maintained in a case file folder as part of that case. All cases referencing EMIT data from that run will list the case number that contains the original EMIT print out.

6. Gas and Liquid Chromatographs / Mass Spectrometers

These instruments will be calibrated on an appropriate schedule using the appropriate standards. Instrument calibration will be documented and these calibration records will be maintained. The instrument calibration requirements are contained in the Drug Chemistry Section Technical Procedures Manual.

The electronic raw data files generated for case samples will be maintained on electronic media for a period of at least 60 days after the report has been issued.

D. Criteria for Identifying and Reporting Alcohol and Drugs.

1. Alcohol and Other Volatiles

To be identified, a component must show resolution on two columns with different elution orders and retention times.

2. Enzyme Multiplied Immunoassay Technique

Assays for each class of drugs must test at or above 14 units below the calibrator value for the appropriate class of drugs for that test to be considered positive.

Samples that test positive for one or more classes of drug must have the drugs confirmed by other tests to be reported as an identification. Samples that test positive for one or more classes of drugs and do not have the drugs confirmed may be reported as preliminary screening tests indicated the presence of that class of drugs.

3. Gas or Liquid Chromatography / Mass Spectrometry

Drugs that test positive by EMIT, or are not tested by EMIT, but are identified in the full scan mass spectrometric mode may be reported. The criteria for full scan mass spectrometric identification are as follows:
a. Proper gas or liquid chromatographic retention time or relative retention time +/- 5% of the target.
b. Characteristic mass spectrum.
c. The extraction batch negative does not contain the drug being identified, but does contain the appropriate internal standard.

A table of critical values will be kept with the mass spectrometer log books. This table will include the LRI (Lowest Reportable Identification value) and Cal. Limit (the highest calibrator). The LRI is the lowest concentration which is deemed positive and may be reported as a positive identification. Measured values below this value are not reportable.

Drugs that test positive by EMIT that are identified in the selected ion monitoring mode may be reported. The criteria for selected ion monitoring mass spectrometric identification are as follows:
a. Proper gas or liquid chromatographic retention time or relative

retention time +/- 5% of the target.
b. At least one quantifier and two qualifier ions must be selected for each drug that is identified, and these quantifier and qualifier ions must be present in the sample being examined. Internal standards require only one qualifier for identification.
c. The sample qualifier ions must be within +/- 20% of the qualifier ions in the verifier that was run in the same batch as the sample being examined.
d. A verifier for that drug, which is extracted in the same batch as the sample, must quantitate within the ranges specified in the Drug Chemistry Section Technical Procedures Manual.
e. The measured sample concentration must be above the LRI, or, if more than one measured sample concentration is obtained then the average sample concentration must be above the LRI.
f. The extraction batch negative does not contain the drug being identified, but does contain the appropriate internal standard.

E. Drug Quantitations by Mass Spectrometry

For quantitative values to be reported for a drug, the following criteria must be met:
a. The criteria for identification must be met.
b. A verifier for that drug which is extracted in the same batch as the sample must quantitate within the ranges specified in the Drug Chemistry Section Technical Procedures Manual.
c. The measured quantitative value for the drug must be above the LRI and below the Cal. Limit for that specific drug. If more than one measured sample concentration is obtained then the average sample concentration must be above the LRI and below the Cal. Limit.
Note that drugs with measured quantitative values that exceed the Cal. Limit may be identified and reported as quantitating greater than the Cal. Limit. If the sample is appropriately diluted to where the measured quantitative value is between the LRI and the Cal. Limit then the calculated quantitative value may be reported.

F. Criteria for Reporting The Absence of Drugs

To report that no controlled substances were identified at least one of the following criteria must be satisfied:
a. Two negative EMIT screens or,

b. One negative EMIT screen and negative confirmative results from one or more appropriate extractions (acid, base, cannabinoids, or GHB) that does have the appropriate internal standard identified or,
c. A positive EMIT screen and negative confirmative results from one or more appropriate extractions (acid, base, cannabinoids, or GHB) that does have the appropriate internal standard identified.