1.0 Principle;
Samples received for analysis by the Toxicology section are maintained as case evidence by the laboratory with complete documentation of Chain of Custody (COC) in the Laboratory LIMS system; utilizing unique alpha-numeric identifications. Cases are placed in storage upon initial receipt in a secure evidence handling area; toxicology samples are stored in a secured refrigerator until pick-up by a member of the Toxicology section. The first chemist accessing a sample verifies that the seal is in place and labels the inner containers, with the unique laboratory case number. If the sample suitability is in question for analysis, sample description does not correctly reflect the evidence, or more detail as to the type of analysis needed by the submitting agency is needed, the laboratory shall consult the submitting agency and keep a record in the case file. Following completion of the analytical process, the evidence is sealed and is stored in a locked refrigerator, the analyst prepares a report, and the case receives a technical review by the section supervisor or designee. The final report in the case is signed by the analyst and reviewer, the case folder is then given to the receiving department.

2.0 Safety Precautions: Cases in the Toxicology section will generally be biological fluids (urine or blood), with occasional poisoning cases which can take most any form. Universal precautions must be taken in this section when handling case materials. Other hazards in this section are chemicals used with the specific methods; see the individual SOPs for this safety information.

3.0 General Toxicology Procedures

3.1 Case Receipt; any analyst in the Toxicology section may access the storage refrigerator in the Evidence control section to pick-up case materials. The analyst takes physical custody of the evidence and the case folder. The analyst immediately goes into Justice Trax and updates the chain of custody to show that the evidence went from the storage location to the analyst and back to a new storage location. Each time a case is accessed by an analyst it must be tracked in Justice Trax.

3.2 Discrepancies; if a chemist notes a discrepancy in a case number, source name or other information this should be documented in the case file and brought to the attention of the Evidence Control section supervisor to be remedied.

3.3 Case Labels; the Evidence Control section generates case labels for each case; when the first analyst accesses the case they label the items contained in the evidence bag.

All case aliquots or extractions of case materials are properly identified by marking the test tube or specific container with the case number and the specific item number designation. EMIT tubes under analysis do not require this marking.

3.4 The Laboratory shall have appropriate facilities to safely and securely store evidence and protect it from loss or damage during analysis. These facilities (ie. refrigerators and lockups) shall be monitored for proper function to protect the condition of the evidence. See SOP tox 14 2.8.

4.0 Case Analysis; the types of analysis in the Toxicology section are Alcohol and Dug analysis~~.~~, EMIT ~~Drug screening~~, GC, ~~and~~ GC/MS or LCMS techniques may be used for screeining or Confirmatory analysis. Any sample going through the section may have all types of testing or just specific testing depending on the nature of the case and why it was sent to our laboratory.

Throughout the process of samples being accessed the chain of custody will be maintained in Justice Trax. Analysts will use their secure PIN to move cases from storage sites into their custody and back again. Since the majority of cases in the Toxicology section are not assigned to a single chemist it is not anticipated that a chemist will have a sample in their custody overnight.

Case types in the Toxicology section are in general Driving Under Influence (DUI), Department of Corrections (DOC), Drug Facilitated Sexual Assault, Fatal motor vehicle accidents, consumer protection cases and Poisonings. Each case type flows through the section in its own specific manner based on the needs of the sample.

4.1.1 **DUI** cases are first analyzed for alcohol ~~and volatiles~~ content then a general drug screen is performed by EMIT (the order of this is interchangeable the EMIT or Alcohol analysis can be first). DUI samples then have drug confirmation tests based on the EMIT and Alcohol results. A sample with an alcohol level of 0.1ug/dL or greater with a negative drug screen will be reported as negative for drugs while one with an alcohol level of less then 0.1ug/dL and a negative EMIT screen will have further work performed on it.

4.1.2 **DOC** cases are sent to the laboratory having been screened by the submitting agency. Therefore when the case is received by Toxicology they know they are looking for a specific drug (or several specific drugs). These cases have turn around requirements of five working days.

4.1.3 **Drug Facilitated Sexual Assaults** in general these cases will initially be analyzed for Alcohol and volatiles content, and drugs. ~~then by EMIT for a general drug screen~~. These cases

will additionally be screened for GHB and or sedative hypnotics like benzodiazepines or zolpidem depending upon case history and time of assault and specimen collection. ~~GBL~~. All DFSA samples have a general unknown drug screen analysis ~~GC/MS confirmation~~ performed regardless of alcohol and/or EMIT results.

4.1.4 **Fatal Motor Vehicle Accidents:** In general, these cases involve a fatal or potentially fatal accident. Our laboratory receives specimens from the driver(s) involved, but not killed. These samples are analyzed for alcohol and volatiles and drugs screened by EMIT. Regardless of these results a general unknown drug screen analysis ~~GC/MS confirmation~~ will be performed.

4.1.4 **Consumer protection** cases are those brought in which the question being answered is not does the sample contain a drug but does it contain the right drug and at the right concentration. These samples are unlikely to be screened by EMIT; but will be directly run to confirm the presence of the suspected substance.

4.1.5 **Poisoning** cases will be assessed by the Laboratory Director with the section supervisor and/or the chemists involved. Case history, nature of the submitted evidence, specific request form submitting agency will be used to quide the analyses. There is no general case flow for these samples since they could range from suspected drug poisoning to heavy metals or any other variety of possible poisoning methods.

4.4.6 **Proficeincy Testing** cases will be analyzed similar to actual cases in order to check the Laboratory system.

4.2 **Alcohol Analysis and Volatile Analysis**; in general and for the majority of cases alcohol and volatile analysis will be performed first, these are performed in batches of cases. Analysts retrieve samples from their storage location, track this in Justice Trax and perform the analysis per the specific SOP. After completing a batch the chemist gives the batch to the Section Supervisor or their designee for a technical review. Once a batch is reviewed and accepted the results are entered into Justice Trax and a report is generated. Alcohol reports are generated separately from drug reports, so it is common for any given case to have two final reports associated with it; one for the alcohol results and one for the drug results.

4.3 **EMIT**; this is a general drug screen performed on all DUI samples and on some other sample types, such as sexual assaults and fatals. When the EMIT chemist completes their findings, they give the batch to the section supervisor or their designee for a technical review when the results are reviewed and accepted the results are made available for further tesing if needed. Tests are scheduled in LIMS so that a worklists can be created.~~to the confirmatory chemists and are added to a series of clip boards which act as work lists for the confirmatory methods. The clip boards are labeled as "THC Case List", "WAN/BDS Case List",~~

~~"Cocaine/BE Case List", "Opiates Case List", "GHB Case List", "Special Benzo Case List" and "SMA's Case List".~~

4.4 **GC/MS or LC/MS confirmatory analysis**; confirmatory analysis are performed in batches following the SOP for the specific analysis needed for the specific case. The analyst determines the needed tests based on the EMIT results or the specific case type and information. When a batch is completed the chemist gives it to the section supervisor or their designee for a technical review. When the technical review is complete and the work accepted the analyst then enters the findings into Justice Trax; this is done until all needed work is completed for the case. The last analyst entering in a result on a case will draft complete the case and give it to the section supervisor or their designee for the Final Technical Review. Analysts performing confirmatory tests need to review individual cases for completeness to know at what point no further work is required and the report can be generated.

> Note: Case jackets in this section will have initials from multiple chemists; each batch will have the original chemist's initials and the technical reviewer's initials on each page. It is not expected that one chemist take ownership of a case and re-review each batch that has made up the case. The final reviewer will initial the pages they reviewed in the case to base their judgment of the cases acceptability.

5.0 Reagent Validation;

5.1 When a new lot of a solvent or reagent is needed, the new solution will be used to extract case materials as stated in the Sop of the specific procedure. A blank and any controls, if applicable, will also be run. The chemist will verify that the solution worked for the stated method and that there were no interfering or unexpected agents found. (Note that some solvents contain trace levels of substances such as formaldehyde in methanol which is inherent to the product; if these do not affect the test they are acceptable). Documentation for the acceptability will live with the batch and be noted on the batch work sheet.

A solution is considered validated and acceptable for use when;

5.2.1 The solution is shown to have worked in the procedure

5.2.2 The solution blank is shown not to contain contaminants that will interfere with the procedure.

5.2.3 Documentation is complete, including

5.2.3.1 Annotating the validation of the reagent on the batch run sheet and having the batch technically reviewed.

5.2.3.2 Complete the 'Reagent Log' book, this states the name of the reagent/solution, the date made by who and date validated.

5.2.4 The solution is marked with a green sticker, with method the solution is validated for, the date validated (the batch date) and the analyst's initials.

Solvents and some other substances are purchased in multi-bottle lots; once one bottle from the lot is found to be acceptable for a procedure then all the bottles in the lot can be marked as validated.
Bottles with working solutions will be labeled with

Solution name
Lot number (which is likely to be the date made)
Date filled (if only a transfer from a purchased solution or a larger batch of a made reagent)
Expiration date (if different then the standard one year for date of validation)
Analyst initials
Green label (with the validation information).
Required safety information

6.0 Case Reporting;

6.1 Case reports are generated through the LIMS (Justice Trax) program.
Once a report is generated and reviewed by a chemist; an administrative review and a Technical review is performed prior to the signed case report being released.

6.1.1 Administrative review; this consists of a 2nd person reviewing the case folder to determine that all pages are initialed by the analyst and that the case number is on all pages. The report is reviewed to check that the inputted clerical data is correct including the agency name, source name, agency case number, time and date of receipt and the receiving agent.

6.1.2 Technical review; this is performed by either the section supervisor or their designee. The technical reviewer is responsible to review the case to determine if the conclusions made by the chemist(s) are supported by the analytical data in the case file. They are required to make sure that all data entered on the report is appropriate and that no findings are left out. They are not required to re-review batches of work; they may if they feel it is needed to understand the final report.

The Case report (signed in ink) with completed case files is given to the receiving department for report distribution and storage. Each report is additionally dated.

6.2 Uncertainty:

Procedural Uncertainty is reported with all quantitative results, and is calculated and tabulated annually for each analytical method. The overall uncertainty for the procedure ("expanded uncertainty") is calculated based on an evaluation of control performance (variance) and bias, documentation of uncertainty in materials used to prepare standards used in calibration, and the uncertainty introduced in the process of standard preparation. Uncertainty associated with the performance of the procedure, and the preparation of controls is captured in the process of evaluation of the control variance.

Documentation of the calculation of uncertainty for each procedure is maintained in the "Procedural Uncertainty" Notebook, maintained in the laboratory. Included in this notebook is documentation (or appropriate references) of reference materials and equipment utilized in the procedure that could affect the quantitative accuracy of the method.

Notes:

1. Uncertainty is reported in the same units as the analyte concentration (e.g. ug/g, g/dL), as the analyte value, +/- the expanded uncertainty for the procedure, using a coverage factor (k) = 2 (corresponding to a 2SD range, and 95% confidence interval) .
(Note: Per State Statute (CT 14-227a) Ethyl Alcohol is reportable as a "weight percent", (grams/100 mL). Uncertainty for this procedure will be expressed in the same units reported, grams ethanol/100 mL blood, expressed as a percent.

2. Equipment:

A. Equipment Potentially Impacting Procedural Uncertainty
   1. Analytical Balance (Volatiles, GHB)
   2. Automatic Pipettor/Dilutor (Volatiles, GHB)
   3. Automatic Pipettes (Toxicology Procedures)
   4. Mass Spectrometers (Toxicology Procedures)

B. Calibration of the Headspace-GC is not a factor in quantitative performance.

C. Calibration of Mass-Spectrometer instrumentation (GC- or HPLC-) can be a factor in quantitative performance. Instrumental mass-axis calibration is

adjusted as necessary during tuning procedures performed on each day of use. Mass-axis calibration is essential for normal batch processing (mass-axis calibration error would result in calibrator, and/or internal standard spectral match failure, leading to batch rejection and identification of problem.) Tuning documentation is maintained in an instrument-specific notebook.

D. Pipettes are evaluated on an annual basis, by an ISO-certified (17025) vendor. Documentation of Pipette performance is maintained for each individual pipette in the "Validation of Miscellaneous Equipment" notebook, in the Toxicology Laboratory as per SOP TX-14; "Maintenance of General Equipment."

E. Balance calibration is performed annually and documented in the balance logbook, kept by the balance in the Toxicology Laboratory. Balance calibration must be performed by an ISO-accredited (17025) facility.

F. Reference masses are evaluated annually by an ISO-certified (17025) vendor. Documentation of mass evaluation is maintained by the Quality Section.

3. Reference Materials: Reference materials must be CRM provided by an ISO accredited vendor. Materials unavailable from ISO accredited providers must be evaluated and validated for use by the laboratory as per SOP TX-11; "Standard Validation". Documentation of standard materials, including (as applicable) validation information is maintained in the "Standard Validation Notebook" kept in the Toxicology Laboratory.

4. ISO accredited vendors used for calibration services will be assessed to assure that the service required is covered under the vendors scope of accreditation.

5. Providers of CRMs or Reference materials will be assesed to assure that they are a NMI or reference material producer that is ISO34:2009 accredited through ILAC – with appropriate scope of accreditation.

6.3 Toxicology abbreviations and symbols.

DUI	Driving under the influence
DOC	Department of corrections
DOC	Department of corrections
DFSA	Drug facilitated sexual assault
EtOH	Ethanol
MeOH	Methanol
IPA	Isopropanol
RT	Retention time
EMIT	Enzyme Multiplied Immunoassay Technique
GC MS	Gas Chromatography Mass Spectroscopy
IR	Infrared
UV	Ultravisible
LC MS	Liquid Chromatography Mass Spectroscopy
TX	Toxicology
CS	Controlled Substances
WAN	Weak Acid Neutral
BDS	Basic Drug Screen
BL	Blood
UR	Urine
CHEP	Cyproheptadine
DI H2O	De ionized Water
Neg	Negative
NDD	No Drugs Detected
SA	Sexual Assault
Coc	Cocaine
BE	Benzoylecgonine
Op	Opioids
THC	Delta-9-Tetrahydrocannabinol
Benzo	Benzodiazepine
SMA	Sympathomimetic Amines
GHB	Gamma Hydroxybutyrate