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1.0 **PURPOSE**:

The purpose of this procedure is to establish the processes for preparation, storage and retention of case documents in the Toxicology Unit.

2.0 **DEFINITION:**

- 2.1 Analyst (FSE or Chemist): the FSE or Chemist assigned to perform a specific test with in the unit. The analyst is responsible to properly prepare case documentation.
- 2.2 Batch Reviewer or Batch Technical Reviewer: any Chemist or FSE that performs the task of reviewing analytical batches. The batch reviewer must be competent/authorized to perform the analysis being reviewed. The batch reviewer cannot be the analyst/author of the batch.
- 2.3 Technical Reviewer: any unit analyst, Unit Lead or the Deputy Director that performs the review of the case in totality. The Technical reviewer need not review the portions of batches that are previously batch reviewed (such as blanks, controls and calibrators). The Technical reviewer must review the analytical data, for the substances being reported, to assure the data supports the reported findings. The technical reviewer cannot be an analyst of the case.
- 2.4 Administrative Reviewer: in general administrative reviews can be performed by laboratory support personnel or by anyone assigned by the Unit Lead to complete the task. The administrative reviewer need not be a competent analyst.

3.0 PROCEDURE

- 3.1 Preparation of case jacket: When evidence is transferred to the Toxicology Unit, it is transferred with the related case paperwork. For each case a case jacket is prepared using a manila or colored file folder.
 - 3.1.1 A self-adhesive label with the checklist for Toxicology cases will placed on the front of the file folder or a case summary sheet TX-5.2 will be placed in the case file.
 - 3.1.2 A bar code label for each specimen submitted is placed on the file folder.
 - 3.1.3 A red file folder is used if the "Request for Examination of Physical Evidence" form indicates that the evidence is related to a fatality.

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A yellow folder is used for DFSA.

A green folder is used for Proficiency Tests

A blue folder is used for poisonings

A manila folder is used for DUI and other cases

- 3.1.4 The "Request for Examination of Specimens for Alcohol/Drugs" form(s), Evidence Receipt and any related administrative paperwork is placed in the case jacket.
- 3.2 Case jackets for all active Toxicology cases are stored within the unit. When the case is completed (all analysis alcohol and drug report are issued) the reports are placed in file and the file is placed in the file cabinets in the Toxicology unit. These may be archived as needed for space to other storage locations within the DSS facility.
- 3.3 Analytical Batch Review: Each analysis in the Toxicology Unit is performed as part of a unique batch, including calibrators and controls as specified in individual SOP's. Each analytical batch is subjected to both analyst review, and a "Batch Technical Review". Batch reviews are performed by an analyst competent to evaluate the forensic validity of the batch as a whole, and the individual case results. All batch review processes are clearly annotated on the batch paperwork, and individual case data sheets. After the Batch Technical review is complete and is found to be satisfactory, the data sheets are filed in the specific case files. The complete batch paperwork (calibrators, controls, blanks and instrument sequence) is filed within the Toxicology laboratory.

If a batch "fails" (i.e. does not meet the criteria of acceptance) the batch paperwork will be annotated as failed and as to why it failed on the batch coversheet. Each related case will either have a note added that the batch was performed but failed (the batch id must be included) or a copy of the coversheet of the batch will be placed in each case file as annotation of this work.

- Case Final Review (Technical Review): A "final review" of the case is performed by a competent analyst, a Unit Lead or Deputy Director (or designee) upon completion of analytical work, and preparation of the "Draft" report. In other Toxicology SOPs there is a reference to "Directors Review" this is a case technical review. This review is documented on form TX 5.1, 'Technical and Administrative Review Checklist', on the case jacket milestones label, and in LIMS and consists of:
 - A. An evaluation of the case documentation to ensure consistency between the analytical batch data, screen information and reported

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findings. This includes a check of any calculations made. For cases where a quantitative result is reported a review of the uncertainty statement is also performed.

B. An evaluation of case findings, vis-à-vis case information and screen results, to ensure that all appropriate testing has been performed.

C. When conclusions cannot be made or analysis cannot be performed the technical reviewer will assure that the report clearly states the reason.

The case final reviewer (technical reviewer) will document those items checked or evaluated by use of form TX-5.1. Any notes added during the review will be initialed by the individual adding the information. Following the final review (technical review), the case will be submitted for Administrative Review.

- 3.5 Administrative Review: An administrative review is performed upon completion of the Final/technical review. The administrative reviewer competed the administrative review portion of form TX 5.1 'Technical and Administrative Review Checklist'.
 - 3.5.1 The information from the Draft Report is compared with the information provided on the "Request for Examination of Specimens for Alcohol/Drugs".
 - 3.5.2 The following items are reviewed for accuracy on the Draft Report (If the analyst or technical reviewer has checked the items, the reviewer does not need to recheck the information).
 - a. Name of Submitting Agency
 - b. Subject's Name (subject's initials for Sexual Assault cases)
 - c. Subject's Address (for DUI cases)
 - d. DSS Case Number
 - e. Agency Case Number
 - f. Other demographics as appropriate to the case
 - 3.5.2.1 If typographical or other non-trivial errors are discovered in the case demographic information during the Administrative Review process, the case jacket is given to the Unit Lead.

Depending on the nature of the error the Unit Lead may instruct the administrative reviewer to correct the issue or the Unit Lead may contact the appropriate ECO to have corrections made.

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- The DSS case number and the analyst's initials.

- The analyst that generated the result must have initialed each page of the batch.

The administrative reviewer examines each page of the case file for:

- The batch technical reviewer has documented review of the batch technical review (generally by initialing the cover page of the batch).
- The final technical reviewer must have initialed at minimum the Toxicology Technical and Administrative review worksheet (TX-5.1).

If the case number is missing the Administrative Reviewer can add it as needed. If the analyst's initials are missing, or a non-trivial error is noted, the case jacket will be given to the Unit Lead or the analyst for correction. Any errors or changes shall be maintained in the case file along with any communication relating to the analysis of the evidence. All such communications are initialed by the person adding them to the case.

- 3.5.3 When the Administrative Review is completed the reviewer completes the Administrative Review section of the checklist label on the front of the file folder, and completes this section of form TX-5.1. The administrative reviewer also updates the milestone in JusticeTrax and prints the final report to be signed.
- 3.5.4 The case file is returned for signature by the analyst(s) and Technical Reviewer. The administrative reviewer verifies that the report was signed, and the title of the analysts are present prior to preparing the report for distribution. The report is issued as listed below.

As electronic signatures are phased into use, the administrative reviewer will print the final report and prepare the report for distribution.

- 3.6 Ethanol Conversion Reports. Ethanol conversions cases are maintained electronically in Justice Trax. Technical and Administrative review will be documented in JT in the milestones, there will be no case file maintained within the Toxicology unit. These reports do not fall under guidelines of 3.1 to 3.5 above.
 - 3.6.1 The Technical reviewer will verify the value and check the calculation.
 - 3.6.2 The Administrative reviewer will check the demographic information. Note the Technical and Administrative reviewer may be the same person.
 - 3.6.3 Documentation of both the Technical and Administrative review will be through

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updating the milestone in JT.

3.6.4 The conversion report will be faxed, emailed or mailed to the submitting agency.

3.7 Issuance of the Final Report

3.7.1 The final report is kept in the case jacket and the photocopies of the final report are placed in envelopes.

3.7.2 DUI Cases

- 3.7.2.1 A copy of the report is mailed to the Subject.
- 3.7.2.2 Case report(s) are faxed to the submitting agency and others as appropriate.
- 3.7.2.3 Copies of the report are mailed to the submitting agency and the appropriate State's Attorney's Office.
- 3.7.2.4 If a report is released with an error, a clearly marked REVISED REPORT will be prepared, the submitting agency will be advised of the need for a revised report and the revised report will be released. The case will be clearly annotated to document why the revision was required, should also be added to the synopsis tab in JusticeTrax.
- 3.7.2.5 If additional testing is requested after a final report is sent, a clearly marked Supplemental Report is produced and noted in the case file.
- 3.7.3 Other Case Types (sexual assaults, poisonings):
- 3.7.3.1 Two copies of the report are made. The report is itemized in LIMS following the guidance of GL-11 'Records Control'. This is transferred to Evidence Receiving for distribution to the customer.
- 3.8 Completed case files are filed in file cabinets within the unit. In cases where more work is required the case file is returned to the laboratory area.
- 3.9 General order of documents in the case jacket

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- 3.9.1 Final Report(s)
- 3.9.2 Request for Examination of Specimens for Alcohol/Drugs
- 3.9.3 The Technical and Administrative Review Checklist.
- 3.9.4 Analytical data (including appropriate batch coversheets).
- 3.9.5 Photographs (if appropriate)
- 3.9.6 Other Administrative Documents

3.10 Record Retention

3.10.1 Refer to GL-11 Records Control



Documents outside of Qualtrax are considered uncontrolled.