Title: TX 5: Case Documentation and Review

1.0 PURPOSE:

The purpose of this procedure is to establish the processes for preparation, review, storage, and retention of case documents within the Toxicology Unit. This procedure applies to all personnel involved in the daily practices of the Toxicology Unit.

2.0 DEFINITION:

2.1 Analyst (FSE or Chemist): one who is assigned to the unit and usually has the designation of Forensic Science Examiner (FSE). Other designations of analysts may include Chemist or Principal Chemist in their titles. Analysts are authorized to perform tests within the unit and analyze evidence. Various analysts have degrees of responsibility in the preparation of case documentation and participation in review processes.

2.2 Batch Reviewer (aka: Batch Technical Reviewer): one who has the knowledge, skills, and authorization to adequately review sequences and resulting data from batches of samples that were collected during an analytical experiment. While complete knowledge of the area being reviewed is required, it is recommended that batch reviewers be competent in the operation of the technique that is being reviewed. Batch reviewers are authorized based on thorough evaluation of their knowledge, skills, and abilities within each area that they are allowed to review. Authorized analysts who produce data and who have been deemed competent in the practical operation of instrumentation through casework are deemed authorized to perform batch/technical reviews. The batch reviewer cannot be the analyst/author of the batch.

2.3 Technical Reviewer: one who has the technical knowledge, skills, and authorization to adequately review the science within the data of case files.

2.3.1 Final Technical Reviewer:
Ensures the technical accuracy for the totality of the case that is under review. The technical reviewer can, but is not required to, review data that has been previously batch reviewed (e.g., blanks, controls, calibrators, and related samples). Aside from previously-reviewed batch data, the remaining analytical data must be technically reviewed to ensure that the reported findings are supported and valid. Technical reviewers cannot review their own data. It is permissible to have multiple technical reviewers on a case (e.g., when the main technical reviewer isn't authorized to review all of the analytical procedures within a case and another reviewer is needed to perform a technical review on specific aspects of the case file). Persons performing technical reviews will determine whether the appropriate examinations have been performed, that the

conclusions were consistent with the documented data and that they were within the limitations of the discipline, and that there was sufficient supporting documentation for the conclusion(s) of the report. As verifier, the technical reviewer will independently confirm reported conclusions by reviewing or examining relevant information including, but not limited to, data, notes, and charts.

2.3.2 Batch Technical Reviewer
Batch reviewers are analysts who have the knowledge and authorization to evaluate the technical accuracy of batches/sequences as a whole for specific types of analyses.

2.4 Administrative Reviewer: one who has the knowledge, skills and authorization to adequately review case files for conformance to administrative quality. In general administrative reviews can be performed by laboratory support personnel or by anyone assigned by the Unit Lead to complete the task. Administrative reviewers need not be analysts or a qualified examiners/scientists. An administrative reviewer will ensure that reports are clear, concise, accurate, complete (with respect to the requests that were submitted), in compliance with DSS general laboratory (GL) procedures, and verify that a technical review has been performed. Additional duties of an administrative reviewer may include, but not be limited to, obtaining handwritten signatures from analysts (when needed), physical sending of copies of report, and filing.

3.0 PROCEDURE

3.1 Preparation of case jacket:
When evidence is transferred to the Toxicology Unit it should be transferred with the related case paperwork. Case jackets (various colored file folders) are used to hold paperwork for each case submission. Multiple case folders should be used for different submissions of the same case (same laboratory numbers can have multiple case file folders).

3.1.1 A self-adhesive milestone label on the front of the file folder and a case summary sheet TX-5.3 allows for information to be readily seen for each case file. Use of the milestone labels are for reference only and are not considered administrative documents. The TX-5.3 case summary sheet, when used, will be considered an examination document.

3.1.2 Barcode labels for each item submitted within a case should be placed on file folders. These labels list the number of submissions (items) that are related to that case jacket.

3.1.3 Colors of the case jackets:
Red file folders are used for fatality-type [antemortem] cases
Yellow folders are used for drug-facilitated sexual assault-type cases (DFSA)
Green folders are used for proficiency test cases
Blue folders are used for postmortem-type cases
Manila-colored folder are used for driving under the influence-type (DUI) [antemortem] and other cases

3.1.4 Administrative paperwork can either be placed within the case file folder or can be found within the JusticeTrax laboratory information management system (LIMS).

3.2 Case jackets containing paperwork for all active cases (i.e., those where reports have yet to be released) should be stored within the laboratory space. When cases have been completed (i.e., all reports have been released), case file folders and the folders are placed within locked filing cabinets. As space availability dictates, the completed case file folders may be archived and moved to another secure storage location. Electronic reports need not be printed and kept within case file folders as they are stored on the LIMS.

3.3 Batches: Analyses in the Toxicology Unit are often performed as part of a batch (or sequence). Batches usually include multiple case samples, calibrators, and control solutions. Batches are used for efficiency purposes wherein multiple items of evidence are analyzed within one sequence. Either copies of relevant batch data sheets and batch summary information are to be filed within each applicable case file folder or within LIMS. The completed batch/sequence paperwork will include at minimum (if applicable): calibrators, controls, blanks, instrumental parameter/sequence printouts, and proof of successful batch technical review. Batch paperwork will be filed in a secure location (e.g. Toxicology Unit laboratory space) and will be trackable (i.e., a list, file, or other type of system exists wherein cases/lab numbers are associated/linked to batches).

3.4 Reviews

3.4.1 Technical Reviews

3.4.1.1 Batch Technical Reviews: Instead of conducting separate technical reviews on each case, each batch of data can be 'Batch Reviewed' by a Batch [Technical] Reviewer. Batch reviews are performed after the analyst who set up the batch/sequence has evaluated their data. All batch reviews of data need to be clearly identified on the batch/sequence paperwork. After batch technical reviews are complete, each case must contain a cross-reference to each batch/sequence.

If there are problems with batches/sequences and a batch review fails (i.e., the batch doesn't meet acceptance criteria), the failure must be easily identifiable within the batch paperwork and reasons for the failure (e.g., annotated on the batch coversheet) must be present. As with all batch paperwork, cases must be cross-referenced to all batches, either within case file folders or within LIMS.

3.4.1.2 Technical Review (Final): Final reviews of cases are performed by authorized analysts, Unit Leads, or other designees (e.g., Director, Deputy Director) after all analytical work has been completed and "Draft Reports" have been done. A technical review checklist (form TX 5.1, 'Technical and Administrative Review Checklist' or TX 5.2 'Technical and Administrative Review OCME Case Specific') is used as a guide. The information on the milestone stickers on the case file folder jackets are used for convenience but are not considered administrative notes. Technical reviews are done to ensure the technical accuracy of the data within each case file folder. Documentation that batch reviews have been done must be found within case file folders or within LIMS. The data/information within batches are not required to be technically reviewed during the final technical review because such reviews have already occurred. Final technical reviews must ensure that any batches within case file folders have been reviewed and were acceptable relevant to the cases in question. Any data/information not already technically reviewed will be assessed during a final technical review.

Final Technical Reviews will ensure:

- Evaluation of case documentation for consistency and accuracy among analytical batch data, other analytical data, and all reported findings.
- Manual calculations will be reviewed and documentation of such reviews (e.g., initials of reviewer) should be evident.
- All uncertainty statements are correct.
- Appropriate testing has been performed and relevant questions have been answered.
- Problems or limitations in casework are clearly explained in case files (e.g., case notes) and, when applicable, within reports.
- Appropriate checklists are used during technical reviews (e.g., TX-5.1, TX-5.2)
- Ensure that reviewers of batches have documented their reviews (e.g., initialing the coverpage of the batch).

- All notes/comments from technical reviewers will occur on the appropriate checklists. Technical reviewers should not add any information to casefile paperwork (administrative or examination documents). Corrective (or other) comments should be limited to only being placed directly on Draft Report pages and/or on review checklists.
- Submit case back to appropriate analyst(s) for any corrections/additions that are needed.
- Submit case files for Administrative Reviews upon acceptance of technical reviews
- Appropriate milestones within LIMS will be updated.

3.4.2 Administrative Review: Administrative reviews are performed after completion of final technical reviews and before reports are released. Administrative reviewers are individuals who will ensure that administrative information is accurate, free from clerical errors, and abide by certain quality assurance/quality control guidelines. Administrative reviewers should use the appropriate checklist portion of form TX 5.1 (Toxicology Technical and Administrative Review Checklist) or TX 5.2 (Technical and Administrative Review Checklist- OCME Specific) when conducting reviews.

Administrative Reviews will ensure accuracy regarding:

- Information within reports corresponds to what was requested within Request For Analysis (RFA) forms.
- Name of Submitting Agency (Name of medical examiner for OCME cases)
- Subject's Name (if applicable)
- Subject's initials for sexual assault cases
- No subject name on OCME cases
- Subject's address (DUI cases only)
- Case number correct
- Agency case number correct
- Other demographics (as appropriate to the case)
- Grammatical and/or clerical aspects of the case (any minor errors may be changed by Unit Lead or equivalent)
- DSS case number (Lab #) is correct on all Administrative and Examination Documents (this can be added by the Administrative Reviewer, if needed)
- Appropriate analyst initials are on all Examination Documents
- Final technical reviewers must have initialed, at a minimum, appropriate technical and administrative review worksheets (TX-5.1 or TX-5.2)

- Any administrative errors or changes shall be documented in either case file folders or within LIMS. If handwritten, all additions or changes will be initialed by the person making said additions/changes.
- All notes/comments from administrative reviewers will occur on the appropriate checklists. Reviewers should not add any information to case file paperwork (administrative or examination documents). Corrective (or other) comments should be limited to only being placed directly on Draft Report pages and/or on review checklists.
- Appropriate milestones should be completed on case file folders, but these are for convenience and are not considered administrative documents.
- Appropriate milestones within LIMS will be updated.
- If required for distribution, the Administrative Reviewer will print the final report
- Distribution of reports may be performed by the Administrative Reviewers or their designee.

3.5 Ethanol Conversion Reports.
Ethanol conversion cases are maintained electronically in JusticeTrax (JT). Technical and Administrative reviews will be documented in JT under milestones. No casefiles or case file folders will be maintained within the Toxicology Unit for these types of requests. These reports do not fall under guidelines of 3.1 (above). Conversion reports will contain technical and administrative reviews just like other casework. When finalized, conversion reports will be faxed, mailed, or sent out electronically.

3.6 Final Reports

3.6.1 If reports contain handwritten signatures of analysts, the original report will be kept with case file folders and will be securely stored (e.g., in Toxicology Unit cabinets).

3.6.2 If reports are generated with electronic signatures, original reports are stored in JusticeTrax and copies may be included within case file folders.

3.7 Issuance of Reports

3.7.1 DUI Cases

3.7.1.1 A copy of the report is sent (e.g., U.S. Postal Service) to the subject/source.

3.7.1.2 Additional copies of reports are sent (e.g., fax, electronic, mail) to the submitting agency and others, as appropriate (e.g., State's Attorney, DMV).

3.7.1.3 If reports need to be corrected, any new report will be clearly marked as being revised along with an explanation as to why revisions were necessary. Both the incorrect and the corrected information will be listed so customers are fully aware of changes within reports.

3.7.1.4 If additional information needs to be added to reports, any new reports will be clearly marked as being supplemental and description(s) as to what the addition(s) were will be included in all supplemental reports.

3.7.1.5 Documentation that reports have been sent will be either included in case file folders or within LIMS.

3.7.2 Postmortem Cases for the Office of the Chief Medical Examiner (OCME)

3.7.2.1 Reports will be sent electronically, but other means may be necessary.

3.7.2.2 Documentation that reports have been sent will be either included in case file folders or within LIMS.

3.7.2.3 Filenames for electronic copies of reports should contain the initials of the medical examiner associated with the case (e.g., DSS-16-00123 JG for Dr. James Gill)

3.7.3 Sexual Assault Cases (or other cases)

3.7.3.1 Two copies of the report are made.

3.7.3.2 The report is itemized in LIMS following the guidance of GL-11 'Records Control' and is transferred to the Evidence Receiving Unit for distribution to the customer.

3.7.3.3 A copy of the report can be either stored in the case file folder or in LIMS.

3.8 Documents generally found in the case jacket (or may be found electronically in LIMS)

- Copy of reports (Draft Report, Released Report)
- Administrative Documents
  - Review sheets (Technical and Administrative)
  - Request for Analysis (RFA) form
  - Medical reports
- Examination Documents
  - Case Summary Sheet
  - Analytical Data – including Batch information (e.g., Batch Summary Sheets)

3.9 Record Retention – refer to GL-11 (Records Control)

Rev. #	History
6	Added verbiage and updated formatting within the entire document. Added to definitions section and clarified roles of reviewers. Simplified color definitions and added OCME type of case. Made milestone labels not required, but useful. Storage of case documents can either occur in file folders and/or in JusticeTrax (JT). Clarified information regarding batches (e.g., batch review process, retrieval of batch information, linking batch information to case information). Clarified definitions of 'reviews' within document. Simplified Ethanol Conversion Report section. Added ability to document sending out of reports to be electronic within JT. Removed unnecessary verbiage throughout document. Added OCME reporting information. Added History section.
7	3.1.2 changed items to submissions 3.2 removed the need to print the final report and place in case file 3.4.2 updated to allow for reports not to be printed, maintained electronically and allowing for person other than the Administrative Reviewer to distribute case reports.