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 PROCEDURE

2.1 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).

2.1.1 A self-adhesive milestone label on the front of the file folder 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.

2.1.2 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.

2.1.3 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

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

2.2 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 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.

2.3 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).

2.4 Reviews

2.4.1 Technical Reviews

2.4.1.1 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. 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.

2.4.1.2 Technical Review (Final): Final reviews of cases are performed by authorized reviewers 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') 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. The data/information within batche files are not required to be technically reviewed during the final technical review as such reviews has already occurred.

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, if applicable.
- 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)
- 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.

2.4.2 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) 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
- Subject's Name (if applicable)
- Subject's initials for sexual assault 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)
- 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.

2.5 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). When finalized, conversion reports will be sent out electronically.

2.6 Final Reports

2.6.1 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).

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

2.7 Issuance of Reports

2.7.1 DUI Cases, DFC and other types of cases

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

2.7.1.2 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).

2.7.1.3 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.

2.7.1.4 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.

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

2.8 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, if used
  - Analytical Data – including Batch information (e.g., Batch Summary Sheets)

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