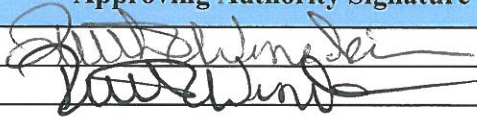
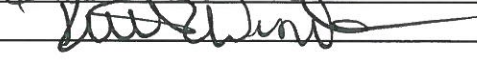


<b>Policy Name:</b>		<b>Policy #:</b>
<b>Data Review and Retention</b>		<b>TOX-P17</b>
North Carolina Office of the Chief Medical Examiner Toxicology Laboratory	<b>Revision:</b>	<b>Revision Date/Initials:</b>
<b>Approving Authority Name</b>	<b>Approving Authority Signature</b>	<b>Approval Date</b>
Ruth E. Winecker, Ph.D.		3/22/16
		1/11/17

**Purpose:**

This policy describes the data reviewing process in the laboratory as well as rules for the retention of both electronic data and paper data.

**Policy:**

The intent and goal of this laboratory staff is to provide reliable and accurate forensic toxicology reports with an average turn-around-time of 4-6 weeks for full drug testing. The completion of a given case in a reasonable amount of time is important to the facilitation of the legal and financial affairs of the family of the decedent. However, extenuating factors such as emerging substances requiring method validation and budget constraints may delay the certification of results on a case-by-case basis. The staff handles CO analysis and review in an expedient manner, typically on weekly basis, if resources permit. All case turn-around times are reviewed by the Laboratory Supervisor and Chief Toxicologist and the information is disseminated to all laboratory employees at the monthly laboratory meeting.

There is a multi-tiered data review process that is described in detail in the Batch Review and Case Review Section of the QA/QC Manual. The first stage of review is a self-review by the laboratory Chemist or Chemistry Technician who performed the batch analysis. The second stage of review is performed by a qualified Chemist or Toxicologist who has been trained on the review process for the particular assay. The first and second stage of review involves initialing the load checklist, thus certifying the results from that batch. After batch review, the load goes through an administrative process in which individual results are distributed to the case folders. The third and final stage of review is performed by a senior scientist or toxicologist who takes the opportunity to study the entire case folder prior to certifying the toxicology report. Only authorized personnel can certify toxicology reports.

Data is generated on paper and electronically. The policy for the maintenance and retention of data is as follows (See Disposal of Archived Records SOP-008 for details):

- Toxicology folders are filed in sequential order.
- Batch raw data packets are filed by type of analysis and in chronological order by date.
- Electronic Data is filed by instrument type, instrument number and batch number.
- **Electronic data, case files and batch raw data packs are retained for five years.**
- Validation data is retained for 10 years.

**Procedures and/or Forms:**

SOP-008 Disposal of Archived Records

QA/QC Manual