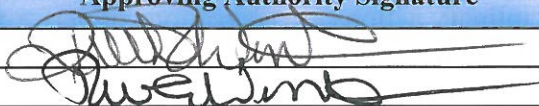


Policy Name:		Policy #:
Laboratory Documentation Policy		TOX-P11
North Carolina Office of the Chief Medical Examiner Toxicology Laboratory	Revision:	Revision Date/Initials:
Approving Authority Name	Approving Authority Signature	Approval Date
Ruth E. Winecker, Ph.D.		5/16/16 11/1/17

Purpose:

These guidelines are to be followed when events needing documentation occur. Events requiring documentation vary in severity from a Note to File, which is simply a record of an event, to a written warning, which is a punitive action for non-acceptable practices.

Policy:

In the instance that real life events vary from specified procedure or practice, generally due to modification in protocol or analyst/instrument error, a record must be made in the form of a **Note To File** to explain any non-normal paperwork resulting from minor non-standard procedural event (e.g. re-injections, dropped specimens, etc). The Note To File should include the load number, assay type, S & T number of affected samples, a brief description of the purpose, and, if applicable, a plan of action to prevent future occurrence of the event. The Note to File is an internal document that should be signed and dated by the analyst and a senior staff reviewer, and a copy should be placed in the folder of all affected samples or batch. Forms are available for Special Analysis and Standard Additions as a way to improve communication between senior staff and analytical staff when unusual circumstances requiring unique requests arise.

In the case of an incident resulting in a more serious error, such as a switched sample, or a preventable issue severe enough to justify such a document (per direction of the Chief Toxicologist), a **Discrepancy Report** is required. A Discrepancy Report should include the load number, assay type, S & T number of affected samples, a brief description of the problem, the consequence, the discovery and the resolution. This will serve as a plan of action to prevent future occurrence of the error. When a Discrepancy Report is generated, two copies will be made and placed in the Discrepancy Report binder located in the Chief Toxicologist's office and the employee's personnel file, respectively and the original will be placed in the affected case folder. The Discrepancy report is an internal document and can only be approved by the Chief Toxicologist.

Corrective action reports (CAR) are internal documents that are a part of the root cause analysis process for finding the true causes of events, identifying and implementing corrective actions, assessing the effectiveness of corrective actions and preventing the recurrence of the events. There are several types of Corrective Action Reports that can occur in the laboratory. CAR reports are to be utilized when processes deviate outside the normal expected course of business

consistently (e.g. batch failures, QA/QC problems), a critical mistake is identified (e.g. unacceptable grade on a proficiency specimen), or an incorrect result is reported on a Toxicology Report that has been certified. The generation of a CAR will be directed and approved by the Chief Toxicologist. A Reporting Error Logbook will be kept in the Chief Toxicologist's office that contains all the CARs in respect to Reporting Errors, while CARs in respect to QA/QC matters will be kept in the QA/QC office.

The DHHS Performance **Documented Counseling** is implemented at any time that an employee falls below the successful level of performance as outlined on the DHHS Work Performance Plan. This action is non-disciplinary and is used to help an employee get back on track to meet specific expectations.

The purpose of DHHS disciplinary actions are corrections of performance problems that employees may have and elimination of unacceptable employee conduct. The basis of the discipline would be for one of two bases: unsatisfactory job performance, including grossly inefficient job performance, or unacceptable personal conduct. An **Improvement Plan** which also serves as a first **Written Warning** is intended to bring about a permanent improvement in job performance. The Improvement plan will be given for a finite period of time and employee progress will be tracked by their supervisor. Should the required improvement later deteriorate, or other inadequacies occur, and there are one or more active warnings in the employee's personnel file, then further disciplinary action may be considered. Further details regarding DHHS policies and procedures for disciplinary actions can be found on their website.

Procedures and/or Forms:

Note To File template

Special Analysis Note-to-file template

Standard Addition Note-to-file template

Discrepancy template

Corrective Action Report (CAR) template

Improvement Plan: <http://www.ncdhhs.gov/humanresources/forms/employee/emp404f-improvement.doc>

Written Warning: http://info.dhhs.state.nc.us/olm/manuals/dhs/pol-50/man/pol2_er_disciplineact1.htm

DHHS Policy Manual: <http://www.ncdhhs.gov/humanresources/policies/>
