Policy Name: Quality Assurance/Quality Control Program		Policy #: TOX-P9
North Carolina Office of the Chief Medical Examiner Toxicology Laboratory	**Revision:**	**Revision Date/Initials:**
Approving Authority Name	**Approving Authority Signature**	**Approval Date**
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Purpose:

The goal of the NC-OCME Toxicology Laboratory QA/QC Program is to guarantee the generation of precise and accurate analytical data.

Policy:

Quality assurance involves the planned and systematic actions necessary to provide confidence in each analytical result. The QA/QC Program has two components: Quality Assurance (QA) - the system used to verify that the entire analytical process is operating within acceptable limits and Quality Control (QC) - the mechanisms established to measure non-conforming method performance.

The toxicology laboratory has a designated QA/QC Chemist position. This individual reports QA/QC issues directly to the Chief Toxicologist.

The quality assurance program includes but is not limited to quality control, equipment maintenance, staff training (TOX-P5), proficiency testing, analytical method validation, security (TOX-P3), safety (TOX-P10), and data review (TOX-P17). These objectives are documented in the NC-OCME Toxicology QA/QC Manual or addressed in a separate policy.

The NC-OCME Toxicology Laboratory Standard Operating Procedure (SOP) Manual contains the information required to perform assays or miscellaneous procedures which are necessary to complete testing and report results in compliance with the ABFT Accreditation program. All laboratory personnel must review the SOP as part of their new employee training and refer to it if any questions arise regarding the performance of a procedure. Changes to a procedure must be authorized by the Chief Toxicologist. When new procedures are initiated or old procedures replaced or modified, all copies must be signed and dated, and employees are notified through laboratory meetings and/or personal communication. Old procedures are archived indefinitely for future reference. In addition, all procedures will be reviewed on an annual basis.

Due to the unique nature of postmortem forensic work, it may be necessary on occasion to deviate from written procedures to accommodate an unusual sample type or condition, unusual analytes, etc. Such deviations are only possible upon approval of the Chief Toxicologist and must include a

Special Analysis Note to File (QA Manual) for the affected batch and/or the case in question as to the nature of the deviation and why it was needed and criteria used to assess the analysis.

The laboratory participates in a variety of proficiency testing programs including College of American Pathologists (CAP) and California Association of Toxicologists (CAT). A detailed list of programs, procedure for analysis and review of results (including protocols for unacceptable results) is outlined in the QA/QC manual. The Review of Proficiency Form should be filled out by the QA/QC Chemist and signed by the Chief Toxicologist after the result evaluations are received from each set of proficiency samples.

Procedures and/or Forms:

QA/QC Manual
Standard Operating Procedures (SOP) Manual
NC-OCME Training Manual
Review of Proficiency Form