FORENSIC TOXICOLOGY LABORATORY
OFFICE OF CHIEF MEDICAL EXAMINER
CITY OF NEW YORK

QUALITY ASSURANCE AND QUALITY CONTROL

PRINCIPLE

Quality assurance (QA) encompasses all aspects of the analytical process from specimen receiving through analysis, data review and reporting of results. A quality assurance program should obviously include a quality control (QC) program which is used to evaluate whether the analysis is operating within the defined tolerance limits. An effective program should detect both random and systematic errors in a timely manner and allow the laboratory to take corrective action.

Quality assurance assumes a unique role in the forensic science disciplines because results are subject to challenge in the "adversarial" justice system.

The components of a QA/QC program include proper quality control specimens, the use of validated testing procedures, timely evaluation of QC specimen results and implementation and documentation of corrective action.

DEFINITIONS

Reference material is a material or substance with one or more properties sufficiently established to be used for calibration of an apparatus, assessing a measurement or assigning values to material.

Certified reference material is a reference material possessing one or more properties certified by a valid procedure or accompanied by a certificate or other documentation issued by a certifying body.

Standards are reference materials possessing one or more properties that are sufficiently well established for use in the preparation of calibrators.

Calibrators are prepared either from the reference material or purchased and are used to calibrate the assay. Calibrators should be prepared in a matrix similar to that of the specimen, whenever possible.

Controls are prepared either from the reference material (separately from the calibrators, i.e., weighed or measured separately), purchased, or obtained from a pool of previously analyzed specimens. Controls from any of these three sources are used to determine the validity of the calibration, i.e., the stability of a quantitative determination over time. Controls should be prepared in a matrix similar to that of the specimen, whenever possible.

Ideally, a control is a test specimen identical to the unknown, but containing the analyte at a known

concentration. Controls should be carried through the procedure with the unknowns with each analytical run, whether a single specimen or a batch and whether the test is qualitative or quantitative. Each batch of specimens should include at a minimum one negative and one positive control. Although there is no need to monitor the concentration of a positive control in a qualitative assay, the target concentration of the control must challenge the assay. Concentration of the analyte(s) in the control must be validated prior to use.

Providing a true control for some forensic toxicology procedures is no more difficult than for any other test. Fortifying drug free matrices such as blood, urine or tissue homogenate is acceptable. For other procedures, the matrix may be unique (e.g., decomposed tissue, maggots, bone) and providing a true control is very difficult. In such cases the most appropriate available matrix should be selected to prepare the control.

PREPARATION OF INTERNAL CALIBRATORS AND CONTROLS

Primary standards used for the preparation of internal controls and primary standards used for the preparation of calibrators should be obtained from two different sources whenever possible. In cases where only one source of the primary standard is available, separate stock solutions must be prepared for calibrators and controls. Such stock solutions must be prepared by two different analysts or, if they are prepared by the same analyst, they must be prepared on different dates.

Internal calibrator (C) and control (Q) solution labels need to contain the following information:

Analyte(s)
Solution concentration
Lot number (date prepared followed by C for calibrator or Q for control)
Preparation date
Expiration date (1yr from preparation date unless stated otherwise)
Preparer's initials
Quantity prepared

Example: Cocaine, 1000mg/L, Lot#030513C, Prep. Date 03/05/13, Exp. Date 03/05/14, RF,1 of 5

QA/QC IMPLEMENTATION

Implementation of the QA/QC program, review and any necessary corrective action must be documented and this documentation retained for the same time period as the case records.

The day to day responsibility for QA/QC for each section is assigned to the supervisor of the respective section. Section supervisors report to the laboratory QA/QC Supervisor regarding all QA/QC related issues.

QA/QC data are reviewed weekly by the QA/QC Supervisor and monthly by the Laboratory Director, Assistant Director for Administrative Support or Assistant Director for Technical Support.

The QA/QC program, as a whole, will be reviewed annually by the QA/QC Supervisor, respective section supervisors, the Assistant Director for Administrative Support, the Assistant Director for

Technical Support and the Laboratory Director to ensure that it is up to date and effective.