1.0 Purpose

This procedure describes how control limits for quality control (QC) standards are calculated and used within the laboratory. The laboratory uses ± 3 standard deviations from the mean as control limits and when known standard results are outside of these limits the laboratory implements a correction or corrective action. The laboratory uses these limits to ensure correct method performance and to assess the measurement uncertainty (MU) associated with the quantitative analyses and measurements performed by the laboratory.
Control charts are constructed from the statistical determined control limits and used to identify trends in laboratory data. This procedure describes what the laboratory considers a trend and how the laboratory responds to trends identified.

2.0 Discussion

The laboratory uses control limits to ensure correct method performance and to assess the uncertainty of measurement associated with quantitative analyses performed by the laboratory. The laboratory investigates trends in QC data as they may indicate a change in method and/or instrument performance over time. As part of the laboratory's commitment to quality, trends that have the potential to adversely affect the quality of laboratory data, are investigated and resolved.

3.0 Definitions

3.1 Standard Deviation (sd): The root of the mean of the squares of the differences from the average

3.2 Control limit: ± 3 standard deviations from the mean of at least 15 analyses of a standard with a known value. Standards used by the laboratory for QC are NIST traceable.

3.3 Warning limits:± 2 standard deviations from the mean of at least 15 analyses of a standard with a known value. Standards used by the laboratory for QC are NIST traceable.

3.4 Control Chart: Graphic representation of data that identifies variations in a process over time.

4.0 Procedure

4.1 Control limits

4.1.1 The Quality Manager is responsible for calculation and updating control limits.

4.1.2 The minimum number of data points required for calculation of control limits is 15. If more data points exist they are used in the calculation up to a maximum of 50 points and if they are no more than one year old.

4.1.3 The standard deviation is calculated using the following formula:

$$S=\sqrt{\frac{\sum(X-M)^2}{n}}$$

where, S = sd X =analytical value M = mean n = number of data points

4.1.4 QC Limits are calculated as ± 3 standard deviations from the mean used in the above formula. Any QC sample recovery that does not meet these criteria is considered a failure that requires investigation. Firstly, the actions identified in the applicable technical procedure(s) are implemented. If the QC failure remains the laboratory's non-conforming work procedure is initiated, concluding with either correction of the problem or initiation of the corrective action process.

4.1.5 Control limits are recalculated on an annual basis unless otherwise indicated by QC recoveries.

4.1.6 The analytical processes used by the laboratory are stable and reproducible and over time the calculated sd may become so small as to be unusable. If this occurs the laboratory either:

- defaults to a sd of ± 0.003;
- recalculate the limits using the last 15 points only (if there were more included in the original calculation).

4.1.7 The Quality Manager provides the data and calculations to the Forensic Lab Manager for review. The Forensic Lab Manager signifies concurrence with the calculations by initialing the calculation sheets.

4.1.8 The Quality Manager posts the control limits electronically and informs laboratory personnel by email that updated limits have been posted.

4.1.9 Records of data, calculations and review are maintained.

4.2 Control Charts

4.2.1 Control charts are generated using recovery data from analysis of known, NIST traceable, standards. These standards are used as QC standards that are analyzed with unknown samples.

4.2.2 Data that are outside of control limits are included in the data set unless a cause for the failure is established.

4.2.3 The control charts include a center line (mean), warning limit line at ± 2 sd and control limits at ± 3 sd.

4.2.4 Control charts are updated by the analyst or designee as data points are obtained then reviewed on a quarterly basis by the Quality Manager.

4.2.5 The laboratory considers the following to constitute a trend:

- eight consecutive points either increasing or decreasing;
- eight consecutive points on the same side of the mean

4.2.6 When a trend is detected, the Quality Manager initiates the laboratory's control of nonconforming work process. The Quality Manager may designate laboratory personnel to investigate the possible cause(s) of trends observed. Correction may include recalculating control limits and re-graphing data as appropriate or discarding the current known standard.

4.2.7 A new trend chart is initiated after change of QC standards or major instrument changes.

4.2.8 An outlier is a data point that appears to be different to the general pattern of data. Causes of outlier points include a measurement that was read, recorded or transcribed incorrectly, a faulty instrument, or incorrect calculations. When needed, the laboratory uses the Dixon's Q Test for Outliers to exclude such data points. Refer to FAA SOP, TP101, Section 11.5.3, for procedure to determine an outlier.

5.0 Health and Safety

There are no specific health or safety requirements associated with this procedure.

6.0 Records Management

The Quality Manager is responsible to ensure the proper storage, backup and retention of all laboratory records in accordance with procedure QP101.13, Quality and Technical Records.

6.1 QC limit data and calculations.
6.2 Control limits, current and historical.
6.3 Control charts, current and historical.
6.4 Email communications.

7.0 References

7.1 WPCL Quality Document, QD001, section 2.9

8.0 Appendices

None

9.0 Revision Table

Revision #	Effective date	Revised by	Description of Revisions
Original Issue	10/01/2012	B. Pridgen	
#1	12/15/2014	B. Pridgen	4.2.4 Change responsibility of recording data points in electronic control charts to analyst
#2	04/09/2015	B. Pridgen	Change Lab Manager to Director

Authorization

This Standard Operating Procedure, Revision Issue #2, has been approved and authorized by:

Bethany P. Pridgen, MFS Forensic Lab Director	Date
Ralph M. Evangelous Chief of Police	Date