3.0 ARTEL PCS 2™ Pipette Calibration System for POVA Intermediate Check

3.1 BACKGROUND

Colorimetry measures the intensity of a color and relates it to the concentration of the solution. The relationship between concentration and intensity is obtained through determining the degree of light absorbance by a solution at a particular wavelength. The fraction of the incident light that is absorbed by a solution depends on the thickness of the sample, the concentration of the absorbing compounds in the solution, and the chemical nature of the absorbing compound. This relationship is defined by the Beer-Lambert law:

$$A = \epsilon bc$$

A = Absorbance

b = Internal path length (cm) of solution vial

c = Concentration of sample solution

ϵ = Molar absorptivity of sample solution

The ARTEL PCS 2™ pipette calibration system is a colorimetric method for an intermediate check of pipette dispensing accuracy and precision. The system utilizes a photometer coupled with NIST-traceable reagents to measure liquid delivery. The system is set up so that as additional solution (V_{P1}) is added to pre-mixed volume of blank solution (V_B), the absorbance change is proportional to the volume delivered by the pipette. The volume of solution pipetted (V_{P1}) is calculated as follows:

$$V_{P1} = V_B \left[A_1 / \epsilon bc - A_1 \right]$$

The volume of repetitions (V_{P2}) is determined by the following relationship:

$$V_{P2} = V_B + V_{P1} \left[A_2 - A_1 / \epsilon bc - A_2 \right]$$

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3.2 SCOPE

The reliability of the volume delivered by piston or plunger operated volumetric apparatus is dependent upon verification of calibration. This method sets forth the requirements for both intermediate checks and calibration. The intermediate check is performed to maintain confidence in calibration. The ARTEL instrument utilizes a system which optimizes the application of the Beer-Lambert Law to provide a reliable, time efficient, pipette intermediate check that is traceable to NIST standards. When needed, an approved external service provider performs actual POVA calibration. This analytical method applies to the Dilutor/Pipetter

used to prepare samples for volatiles analysis. The term *calibration* used in the analytical method is used for consistency with ARTEL nomenclature. No actual calibration is being performed during this process.

3.3 EQUIPMENT, SUPPLIES AND REAGENTS

3.3.1 PCS 2™ Instrument
3.3.2 Printer
3.3.3 Printer Paper
3.3.4 ARTEL Instrument Calibration Kit
3.3.5 Appropriate ARTEL Reagent Kit
3.3.6 Semi-Automatic Dilutor/Pipetter equipped with sample and reagent syringes capable of dispensing 250µL and 2000µL, respectively.

3.4 INTERMEDIATE CHECK PROCEDURE

3.4.1 Refer to manufacturer's *Standard Operating Procedure for the PCS 2™ Pipette Calibration System and PCS 2™ Pipette Calibration System Procedure Guide.*

3.4.2 PCS 2™ Instrument Calibration Check

3.4.2.1 The calibration check of PCS 2™ instrument is valid for one-month providing the instrument stays in proper working order.

3.4.2.2 PCS 2™ calibration check printouts, and/or a copy thereof, are to be initialed and placed in PCS 2™ logbook. A copy is permissible due to the nature of the thermal paper printout.

3.4.2.3 The calibration kit lot number, imprecision and inaccuracy results of the instrument calibration check should be recorded on the PCS 2™ instrument calibration log sheet.

3.4.2.4 The results of the calibration check should be evaluated and a pass or fail indicated on the PCS 2™ instrument calibration log sheet.

3.4.3 PCS 2™ Intermediate Checks

3.4.3.1 **General**

3.4.3.1.1 Intermediate check of the calibration of the Dilutor/Pipetter is valid for four-months provided no maintenance was necessary during this period.

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3.4.3.1.2 An intermediate check must be performed after any significant Dilutor/Pipetter repair or maintenance.

3.4.3.1.3 A Dilutor/Pipetter not in-use need not be current for scheduled intermediate checks, however, an intermediate check must be performed prior to use.

3.4.3.1.4 PCS 2™ instrument printouts, or a copy thereof, are to be initialed and placed in PCS 2™ logbook. A copy is permissible due to the nature of the thermal paper printout.

3.4.3.1.5 A PCS 2™ intermediate check log sheet must be maintained for each Dilutor/Pipetter by serial number or other unique identifier.

3.4.3.1.6 The imprecision and inaccuracy results of the intermediate check must be recorded on the appropriate PCS 2™ calibration check log sheet.

3.4.3.2 **Intermediate Check**

3.4.3.2.1 Set 250µL *sample* syringe volume to 0. Prime 2500µL *Reagent* syringe. Prepare PCS 2™ instrument and collect a minimum of 10-data points.

3.4.3.2.2 Set *Reagent* syringe volume to 0. Prime 250µL *sample* syringe. Prepare PCS 2™ instrument and collect a minimum of 10-data points.

3.4.3.2.3 The results of the intermediate check should be evaluated as described in section 3.4.3.3 and a pass or fail indicated on the appropriate PCS 2™ calibration check log sheet.

3.4.3.3 **Acceptance Criteria**

3.4.3.3.1 Acceptance criteria are listed in the following table. The values are based upon Artel® recommendations. The limit values are based on two percent of full scale at all volume settings.[3.6.6]

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Imprecision (CV%)	*Inaccuracy*
1.0%	2.0%

3.4.3.3.2 The ARTEL tolerance limits should be compared to manufacturer specifications keeping in mind the controlled environment that the manufacturer specifications are generated under.

3.4.3.3.3 Note that the ARTEL values are maximum allowable values. When a history for an individual pipette or syringe is established, the tolerance limits should be fine-tuned and tightened accordingly. If the values obtained for a new dilutor dispenser are small, they should remain so. For instance if the initial imprecision value is 0.25%, obtaining a 1% imprecision value on the following intermediate check is a significant departure.

3.4.3.3.4 Refer to ARTEL® publication issue 5 (Updated 2003 Version) for additional information regarding tolerance setting.

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3.5 CALIBRATION CHECKS

3.5.1 All pipettes and syringes crucial for the quality of quantitative analysis will be calibrated when analytical method quality control values and an intermediate check indicate unacceptable performance.

3.5.2 The calibration will be outsourced to an approved vendor/service provider.

3.6 REFERENCES

3.6.1 Standard Operating Procedure for the PCS 2™ Pipette Calibration System, Artel® Document #310A2715A, April 1997,

3.6.2 PCS 2™ Pipette Calibration System Procedure Guide, Artel® Document # 15A2135, Version 5.1, 03-28-1997.

3.6.3 ASTM Method E 1154-89 (reapproved 2003), **Standard Specification for Piston or Plunger Operated Volumetric Apparatus.**

3.6.4 Segel, I.H., Spectrophotometry and Other Optical Methods. pp. 324-329. *In:* "Biochemical Calculations", Second ed., John Wiley & Sons, New York, 1976.

3.6.5 Kolthoff, I.M., Sandell, E.B., Meehan, E.J. and Bruckenstein, S., Absorption Spectrophotometry. pp. 967-970, *In:* "Quantitative Chemical Analysis", Fourth ed., Macmillan, New York, 1969.

3.6.6 Setting Tolerances for Pipettes in the Laboratory, Artel® Lab Report, Issue 5, Updated 2003.

3.6.7 Curtis, R.H., *Performance Verification of Manual Action Pipets: Part I,* Am. Clin. Lab. 12(7):8-9; 1994.

3.6.8 Curtis, R.H., *Performance Verification of Manual Action Pipets: Part II,* Am. Clin. Lab. 12(9):16-17; 1994.

3.6.9 Eppendorf Series 2000 Reference Fixed-Volume Pipettes Instruction Manual

3.6.10 Eppendorf Series 2000 Reference Adjustable-Volume Pipettes Instruction Manual

3.6.11 Eppendorf Repeater® Plus Pipette Instruction Manual

3.6.12 Eppendorf Repeater™ Pipette Instruction Manual

3.6.13 MLA Macro and Macro Selectable Pipette Operator's Manual

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Revision History

3.0 ARTEL PCS 2™ Pipette Calibration System for POVA Intermediate Check

Revision #	Issue Date	History
0	11-27-2001	Original Issue
1	02-02-2005	Quality requirements detailed and updated.
2	05-07-2007	Updated QA measures and reformatting.
3	06-29-2007	Added yearly outsourcing for calibration.
0	01-20-2011	Initial version as 3.0, split from toxicology discipline analytical methods. Formerly AM 5.1.1. Major changes: Outsourcing for Hamilton Microlab Autodilutor no longer required, initial pipette tolerance tightened.

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Gamette, Matthew

From: Johnston, Jeremy
Sent: Friday, August 19, 2011 1:04 PM
To: Gamette, Matthew
Subject: rescind

AM 2.0, 3.0, 5.0 and 9.0 are no longer in use or have been incorporated into other AM's and can be archived as no longer in use.

AM 2.0 has been incorporated into AM 1.0
AM 9.0 has been incorporate into AM 8.0
AM 5.0 is redundant to the requirements of Tox or Drug AM's and referenced as such.
AM 3.0 is redundant with Tox AM's

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