Equipment Calibration and Maintenance

1.0 Purpose - This procedure specifies the required elements for the use of general laboratory equipment.

2.0 Scope - This procedure applies to Toxicology in the Raleigh, Triad, and Western locations of the State Crime Laboratory.

3.0 Definitions

- Refer to Toxicology Definitions list.

4.0 Equipment, Materials and Reagents

4.1. Equipment

- Mechanical pipettes
- Class A Volumetric flasks
- pH Meter with Electrode - pH combination, double junction, Ag/AgCl reference and thermometer
- Top Loading Balance
- Analytical Balance
- Liquid Handling Systems (LHS)
- Toxicology refrigerators/freezers

4.2. Materials and Reagents

- Deionized water
- Beakers
- Reference standard weights
- Weighing vessels
- 10 % bleach solution

4.3 Commercial Reagents

- Buffer solutions, pH 4.00, pH 7.00, and pH 10.00, and other buffer solution strengths as needed.
- 4 M Potassium Chloride saturated solution

5.0 New Equipment

5.1. A new and unique resource shall be created in Forensic Advantage (FA) Resource Manager for each new piece of general laboratory equipment.

5.1.1 At a minimum it shall contain the date received, a unique identifier (Serial Number), manufacturer, a description, the date the verification was performed, and the results of the performance verification.

5.2. A Certificate of Calibration shall be added to FA prior to use for all the following:

- Pipettes
- Liquid Handling Systems
- Volumetric Flasks

5.3. Pipettes and Liquid Handling Systems

5.3.1 All pipettes and liquid handling systems shall have a performance check (refer to **8.0**) performed prior to use with casework.

5.4. Balances

5.4.1 New balances shall be installed and leveled according to manufacturer's specifications. A calibration shall be performed by an outside vendor prior to use.

5.5. Volumetric Flasks

5.5.1 New volumetric flasks used to make quantitative solutions will have their calibration checked prior to use.

5.5.1.1 Class A volumetric glassware must not exhibit a deviation from listed value greater than two percent.

5.5.1.2 The calibration check will be performed in duplicate, and the results documented as an action history in its respective FA resource.

5.5.1.3 Calibration Check Procedure

5.5.1.3.1 Use a calibrated balance capable of reading a +/- 2% deviation of the volumetric glassware being checked.

5.5.1.3.2 Tare the clean, dry glassware on the balance.

5.5.1.3.3 Remove the glassware and fill to the appropriate mark with ambient temperature deionized water.

5.5.1.3.4 Place on the balance and record the reading.

5.5.1.3.5 Calculate the percent deviation by the following equation:

% deviation = (100) (| (Weight of water in grams/Volume of glassware in milliliters) - 1.00|)

5.6. Refrigerators and Freezers

5.6.1 New refrigerators and freezers used for storing evidence, temperature-sensitive chemicals, or critical reagents shall have the temperature checked using a NIST traceable thermometer prior to use.

5.6.1.1 The acceptable temperature range of the refrigerators shall be 2 °C – 8 °C.

5.6.1.2 The freezers shall be at 0 °C or below.

5.6.1.3 Digital displays on fridges and remote temperature monitoring results shall be within +/- 2 °C of the traceable thermometer.

5.6.1.4 If necessary, automatic chart recorders shall be adjusted to visibly chart the temperature within +/- 2 °C of the traceable thermometer.

5.6.1.5 The temperature check results will be documented as an action history in the respective FA resource.

6.0 Maintenance

6.1. Prior to returning equipment to use, correct operation shall be demonstrated by a performance check or calibration.

6.2. Pipettes

6.2.1 Clean with deionized water or 10% bleach solution as needed.

6.3. Volumetric Flasks

6.3.1 Clean with the appropriate solvent.

6.3.2 Volumetric Flasks that are damaged or cannot be cleaned thoroughly must be discarded.

6.4. Liquid Handling Systems

6.4.1 The Blood Alcohol Key Operator or designee shall flush the tubing with a 10 % bleach solution, or equivalent, once every **two months** to remove protein build-up and prevent bacterial growth in the tubing.

6.4.2 Syringes shall be replaced **yearly**.

6.4.3 Tubing shall be replaced as needed.

6.4.4 Any maintenance shall be documented in the action history of the FA resource.

6.5. Balance

6.5.1 Maintain analytical balance level using the air bubble. If air bubble is not centered, use leveling feet to adjust.

6.5.2 Always place weighing sample in the middle of the weighing pan to prevent corner load errors.

6.5.3 Any maintenance shall be documented in the action history of the FA resource.

6.6. Refrigerators and Freezers

6.6.1 Any maintenance to the coolant systems must be performed by a qualified refrigeration specialist.

6.6.2 Any refrigerator or freezer found to be out of tolerance or having maintenance performed shall have its contents transferred to a comparable refrigerator/freezer.

6.6.3 Any maintenance shall be documented in the action history of the FA resource.

6.7. pH Meter

6.7.1 Fill the electrode with 4 M potassium chloride saturated solution as needed.

6.7.2 Replace the electrode as needed.

6.7.2.1 The electrode will be entered as a component of the pH Meter.

6.7.3 Any maintenance shall be documented in the action history of the FA resource.

7.0 Calibration

7.1. For all the following, calibrations shall be done on a yearly basis by an approved ISO accredited outside vendor. Certificates of Calibration shall be maintained in FA Resource Manager:

- Pipettes
- Liquid Handling Systems
- Balances

7.2. All external calibrations shall be documented in the action history of the FA resource.

7.3. Reference Standard Weights

7.3.1 Secondary Reference Standard Weights maintained by the Toxicology Section shall be checked annually against the Primary Reference Standard Weights maintained by the Drug Chemistry Section Balance Coordinator.

7.3.2 The Toxicology Balance coordinator will maintain the secondary weight sets. They are responsible for performing and documenting the annual check.

7.3.2.1 The annual check will be documented on the Toxicology Secondary Weight Check Form and stored in its FA resource.

7.3.2.2 The annual check will be documented as an action history in its respective FA resource.

7.3.3 A successful recheck will require that the weights recorded for the primary and secondary reference weights agree with their respective expected values within two times the readability of the balance.

7.3.3.1 If a weight fails to meet acceptance criteria after two attempts, the balance and the weight will be inspected and wiped down if needed.

7.3.3.2 If a subsequent weight check fails to meet acceptance criteria, the weight will be removed from service and the Toxicology Technical Leader will be notified to determine the appropriate next steps.

7.3.3.3 The weights must be checked on each type of balance (Top Loader and Analytical) in use in the Toxicology lab and must meet both sets of acceptance criteria.

7.4. pH Meters

7.4.1 pH meters shall have a calibration performed daily prior to use.

7.4.2 For each calibration, the slope, along with the buffers lot # and expiration dates will be stored as an action history in its respective FA resource.

7.4.3 The slope (electrode efficiency) must be greater than 95%. The calibration may be repeated if necessary to meet the requirement. Notify the pH meter coordinator or designee if a slope greater than 95% cannot be obtained.

7.4.4 The pH meter coordinator or designee shall evaluate the instrument and replace the electrode if necessary. If the problem cannot be corrected by replacing the electrode, service or replacement will be provided. The instrument shall be placed out of service until a slope greater than 95% is obtained.

8.0 Performance Checks

8.1. All performance checks shall be documented as an action history in the corresponding FA resource.

8.2. Mechanical Pipettes

8.2.1 The Pipette Coordinator or designee shall check the calibration every **two months** using a calibrated balance and deionized water.

8.2.1.1 Each check will be performed in duplicate.

8.2.1.2 The results shall be within 3% for volumes greater than 10 µL or 10% for volumes less than or equal to 10 µL of the expected value.

8.2.1.3 For a single volume mechanical pipette:

8.2.1.3.1 Dispense the volume of deionized water into the container and record the results.

8.2.1.4 For an adjustable mechanical pipette, the calibration check shall be performed at both the lowest and highest settings of the pipette:

8.2.1.4.1 Dispense the lowest volume of deionized water into the container and record the results. Repeat for the highest volume setting.

8.2.1.5 If the results are outside of the accepted range, clean the pipette and repeat the entire performance check. If the results are still outside of the accepted range, remove from service and notify the Toxicology Technical Leader

8.3. Liquid Handling Systems

8.3.1 The Pipette Coordinator or designee shall check the calibration every **two months** using a calibrated balance and deionized water.

8.3.1.1 Each check will be performed in duplicate.

8.3.1.2 The results shall be within 3% of the expected value.

8.3.1.3 Aspirate and dispense an air sample and the appropriate diluent volume into a container and weigh.

8.3.1.3.1 The result should be equivalent to the total volume dispensed. If the results are outside of 3%, remove from service and notify the Toxicology Technical Leader.

8.3.1.4 Aspirate the appropriate sample volume from the container and re-weigh the container.

8.3.1.5 Subtract **8.3.1.4** from **8.3.1.3**. Record the result of the subtraction. The result will be equivalent to the volume of sample removed in **8.3.1.4**. If the results are outside of 3%, remove from service and notify the Toxicology Technical Leader.

8.4. Balances

Prior to use, a QC check using two reference standard weights that bracket the weight of the items of interest shall be performed.

8.4.1.1 The results shall be within 3% for weights greater than 0.01 grams, and 10% for weights less than or equal to 0.01 grams of the expected value.

8.4.1.2 If acceptance criteria are not met, the balance shall be placed out of service until all necessary steps have been taken to bring the balance back into compliance and notify the Toxicology Technical Leader.

8.5. Refrigerators and Freezers

8.5.1 Each refrigerator and freezer shall have the temperature monitored. Temperature charts shall be maintained in the FA Resource Manager. All charts shall be labeled with the refrigerator serial number.

8.5.1.1 The acceptable temperature range of the refrigerators shall be 2 °C – 8 °C. The freezers shall be at 0 °C or below.

8.5.1.2 For refrigerators and freezers with automatic temperature charts, the charts shall be reviewed and changed weekly.

8.5.1.3 If the refrigerator or freezer storing evidence does not have automated temperature recording or monitoring, the temperature shall be recorded on the manual temperature chart each working day.

8.5.1.3.1 The Thermometer used for monitoring will be entered as a component of the respective FA resource.

8.5.1.4 If the refrigerator or freezer storing temperature-sensitive chemicals or critical reagents does not have automated temperature recording or monitoring, the manual temperature chart shall be initialed each working day.

8.5.1.5 A temperature monitoring system that records refrigerator/freezer temperatures at least daily, and alerts section management or designee to unacceptable temperature deviations may be used. The records shall be reviewed monthly and archived monthly into the FA resource.

8.5.2 The thermometers monitoring the daily temperature of the refrigerators and freezers shall be checked annually with a NIST traceable thermometer, as described for the new equipment performance check listed above. If a refrigerator or freezer is found to be out of compliance, the Toxicology Technical Leader shall be notified immediately.

8.5.3 If the temperature of a refrigerator or freezer is out of range, adjustments should be made and the temperature rechecked and readjusted until the reading is in range.

8.5.4 If the temperature remains outside the range stated above, the person who identified the problem is responsible for informing section management and the Technical Leader or designee. Section management is responsible for arranging any necessary repairs or replacements.

9.0 Calculations - N/A

10.0 Uncertainty of Measurement - N/A

11.0 Limitations - N/A

12.0 Safety

12.1. Use gloves when dealing with equipment which has been used with blood.

12.2. Assume that all body fluids contain bloodborne pathogens and handle accordingly.

12.3. If the examination involves a biohazard, wear proper personal protective equipment such as eye protection, lab coat, and/or gloves.

13.0 References - Operator Manuals for equipment used.

14.0 Records

- Temperature control record for Toxicology refrigerator/freezers
- Pipette certificates
- Secondary Weight Check Form

15.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
03/14/2025	5	Updated grammar and punctuation throughout. 5.5.12, 5.6.1.5 – Added requirement to document new equipment check as an action history in FA Resource. 6.2.1 – Inserted "or 10% bleach solution". 6.4.4, 6.7.3 – Added requirement to document maintenance as action history in FA Resource. 6.7.2, 6.7.2.1, 7.2, 7.4.2, 8.4.1.1, and 8.5.1.3.1 – New 7.3 – Restructured, added reference to secondary weight check form, added primary and secondary weight acceptance criteria, added action history requirement. 7.4.3 – replaced Tox TL with pH Meter Coordinator. 8.1 – inserted "as an action history". 8.2.1, 8.3.1, 8.4.1, and 14.0 – removed reference to respective performance check logs. 8.3.1 – Restructured, updated reference numbers in 8.3.1.5. 8.5.2 and 8.5.3 – restructured.