A. **PURPOSE:**

Several types of general or routine laboratory equipment are integral parts of the testing process. These items include, but are not limited to, analytical balances and automatic pipettes. Because such equipment can be used for quantitative analyses, systematic monitoring is necessary in order to ensure accuracy and consistency within procedures. Other equipment (e.g., refrigerator/freezer temperatures) may only require generalized monitoring. Proper function of equipment and instrumentation is essential to ensure that good laboratory practices are being performed. The functionality of equipment can be demonstrated through proper monitoring and through the use of appropriate blanks and control materials. Some equipment can be maintained by external vendors who perform calibration checks and provide dated certificates. The maintenance of analytical equipment which provide information pertaining to the identification of materials is not included in this procedure.

B. **DEFINITIONS:**

1. Accuracy: the degree of agreement between a measured (or calculated quantity) and the actual (true) value.
2. Precision: The degree of agreement among a series of individual measurements, values, or results.
3. Standard Deviation: A measure used to quantify the amount of dispersion (or variation) of a set of data values (or variable). The square root of the variance of a normally distributed variable.
4. Percent Recovery: a measure of the percent difference between an empirical value and its corresponding theoretical value.
5. Coefficient of Variation (CV) (aka: Relative Standard Deviation (RSD)): is a standardized measure of dispersion of a probability distribution or a frequency distribution. It is often expressed as a percentage and is defined as the ratio of the standard deviation (σ) to the mean (μ). The CV or RSD is widely used to express the precision and repeatability of a set of numbers.

C. **RESPONSIBILITY:**

All analysts (however titled) must ensure that they are using appropriate equipment, that the equipment has been validated and is in service, and that documentation is current.

D. **PROCEDURE:**

1. All mechanical pipettes should be marked with a unique identifier (e.g., TX-1, TX-2, TX-3)
2. Class A Volumetric Pipettes need not be checked for accuracy. However, such pipettes shall be discarded if the tips are cracked, chipped, or have indications which question accuracy measurement.

3. Mechanical pipettes will have been calibrated by an appropriate vendor according to General Laboratory (GL) policy. The Quality Section will facilitate this process. Certificates of calibration will be maintained within the Quality section and copies may be maintained within the Unit.
    i. Pipettes that have been calibrated may be verified in-house prior to use within casework.
        (a) The vendor's certificate can be reviewed to determine:
            (i) The "as found" condition: was it acceptable or out of range.
            (ii) The "as left" condition: was it acceptable or did it fail.
        (b) If the "as found" condition was acceptable and the as left condition was acceptable, a sticker will be on the pipette indicating that it can be used for casework.
        (c) If the "as found" condition was unacceptable, but the pipette was able to be remediated, a sticker will be on the pipette indicating that it can be used for casework.
        (d) If the "as left" condition is unacceptable, the pipette will be taken out of service and any pipette documentation paperwork will need to be updated.
4. Pipette check: An in-house check may be performed in order to verify the calibration, but it is not required.
    i. Using an appropriate balance pipette and accurately weigh 10 portions of room temperature water using a specific volume. Record the weights.
    ii. Complete the appropriate 'Pipette Calibration' form(s). When possible, weights should be recorded to the thousandths place (i.e., 3 decimal points).
    iii. If performance of the pipette is unacceptable, a lead scientist, supervisor (or designee), or the Quality section should be consulted. The pipette may need to be taken out of service or flagged for re-calibration. The pipette will not be used for casework until its performance is deemed acceptable.

B. Masses/Weights:

All masses/weights will have been calibrated by an appropriate vendor according to General Laboratory (GL) policy. The Quality Section will facilitate this process. Certificates of calibration will be maintained within the Quality section and copies may be maintained within the Unit. If new masses have been purchased, the calibration documentation provided with the masses can be used to determine the working ranges for the masses. Acceptability of the masses/weights will be described within General Laboratory (GL) policy.

All masses/weights shall be performance checked annually according to the General Laboratory (GL) policy and performance-check data sheets shall be maintained in the Unit.

C. Thermometers:

1. Thermometers are used for refrigerator/freezer functionality and for some experiments (e.g., derivatization, hydrolyzation). They are not used for reportable, measured purposes.
2. Thermometers will have been checked based on the appropriate DSS laboratory [GL] procedure.
3. An indicator that a thermometer has been checked for quality will be applied (e.g., a sticker).

D. Balances:

1. Balances used on any given day for casework that involve critical measurments (e.g., those mesurements that would significantly affect the outcome of a result of an examination) should be checked for accuracy with at least one (1) NIST traceable mass/weight.
2. Each day a balance is used for a critical measurment it should be checked with at least one calibrated mass/weight. The check is logged into a log book located near the balance. Complete the form as appropriate. The mass/weight that is used to check the balance must give a weight that is ±1% of its reported value. If the measurement is outside the acceptable ±1% limit, then the balance should not be used until either a Lead Examiner or Deputy Director is notified and the issue is resolved. The analyst should select a mass/weight that is appropriate to the material that is to be weighed.

E. Refrigerators:

1. Refrigerators are used to store some standards, reagents, and biological evidence. The temperatures are monitored to ensure that there is not a gradual temperature drift which may indicate refrigerator/freezer failure.
2. Temperatures of refrigerators/freezers will be monitored at least weekly and will be recorded on an appropriate form. At the end of each calendar year log books (or records) will be filed (e.g., in the 'validation of miscellaneous equipment' notebook) appropriately and a new logbook (or records) will be established for the next calendar year.

F. Review:

The paperwork generated within this procedure will be periodically reviewed in order to verify compliance with the procedures. Reviews will be the responsibility of the Lead Examiner (or designee), will be performed annually, and can be part of the yearly audit.

G. Equipment Failure:

1. Any equipment which fails a validation procedure or starts to operate outside of normal working parameters (e.g., refrigerator/freezer temperature ranges) will be immediately reported to a lead Examiner, a section supervisor, or to the Quality section.
2. The section supervisor (or designee) will take steps to correct the problem or will take the equipment out of use. Major equipment failures should be reported to the Deputy Director so that replacements can be arranged, as needed.
3. Any equipment that is not acceptable for use will be marked appropriately (e.g., "out of use, do not use for casework" or similar verbiage) and should include the date and person's name who is taking the equipment out of service.

H. Records:

Validation records/forms completed which document the validation of any miscellaneous equipment should be filed in an appropriate log book. These records should be maintained for a minimum of ten (10) years.

Rev. #	History
3	Changed title. Significant format and verbiage changes throughout document. No longer a requirement to revalidate pipettes after they are calibrated by an ISO-accredited vendor. In general, followed the CS 6 procedure. Weights/masses are calibrated and performance checked according to GL SOP (timeframe changed). 'Principle' section renamed to 'Purpose.' Removed 'Variance' and 'Average Deviation' sections. Added a 'Responsibility' section. Removed 'Automated Pipettes' section. Updated the 'Masses' and 'Thermometers' sections to follow GL SOP. Updated the 'Balances' section. 'Controls' section renamed to 'Review.' Removed sentence regarding sending equipment out of the laboratory to be repaired in the 'Equipment Failure' section.