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.

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 equipment that is appropriate to the procedure, that the equipment has been validated and is in service, and that documentation regarding such validation is kept up to date.

D. **PROCEDURE**:

All pipettes should be marked with a unique identifier (e.g., CS-1, CS-2, CS-3)

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.

a. All pipettes will be calibrated by an appropriate outside vendor according to General Laboratory (GL) policy. The Quality Section will facilitate this process and will ensure that the vendor will be appropriately accredited (i.e., ISO certified or equivalent). The certificate of calibration will be maintained within the Quality section and copies may be maintained within the Unit.
    i. Pipettes that are calibrated by an outside vender may be verified in-house prior to casework.
        (a) The vendor's certificate will be reviewed by a supervisor or members of the Quality section 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, no further checks will be required and the section supervisor or a member from the Quality section will initial and date the certificate. A sticker will be attached to the pipette indicating that can be used for casework.
        (c) If the "as found" condition was unacceptable, but the pipette was able to be remediated, a supervisor or a member of the Quality section will be informed. Based on the nature of the issue and how the pipette was used (i.e., quantitative, qualitative), a QAR may be required to determine if any cases need to be re-evaluated.
        (d) If the "as left" condition is unacceptable, the pipette will be taken out of service, a supervisor or a member of the Quality section will be informed, and any pipette documentation paperwork will be updated.

b. Pipette check: If a pipette is calibrated by an outside vendor, an in-house check may also be performed in order to verify the calibration, but it is not required.
    i. Using an appropriate, certified balance, pipette and weigh 10 portions of room temperature water using a specific volume. Record the weights (e.g., 'Pipette Calibration Check' form (CS-6.1)).
    ii. Complete the 'Pipette Calibration' form and associated values. When possible, weights should be recorded to the thousandths place (i.e., 3 decimal points).

c. 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.

2. Masses/Weights:

   All masses/weights will be calibrated by an appropriate outside vendor according to General Laboratory (GL) policy. The Quality Section will facilitate this process and will ensure that the vendor will be appropriately accredited (i.e., ISO certified or equivalent). The certificate of calibration will be maintained within the Quality section and copies may be maintained within the Unit.

   a. The acceptable range for masses used in the daily check are based on the mass corrections listed on the calibration report. Upper and lower uncertainty values are used to calculate the acceptable range, which is -1% of the lower reported value and +1% of the upper reported value.

   b. If new masses are purchased, the calibration documentation provided with the masses is used to determine the working ranges for the masses. Acceptable masses/weights will be listed within General Laboratory (GL) policy.

3. Thermometers:

   a. Thermometers are used for refrigerator/freezer functionality.

   b. Thermometers will be checked based on DSS laboratory procedure.

   c. A sticker will indicate that a thermometer has been checked.

4. Refrigerators:

   a. 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.

   b. Temperatures of refrigerators/freezers will be monitored (e.g., once per work week) and will be recorded on the temperature record log form (CS-6.3). At the end of each calendar year the log for that year will be filed (e.g., in the 'validation of miscellaneous equipment' notebook) and a new logbook will be established for the next calendar year.

5. 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, will be no less than once a year, and can be part of the yearly audit.

6. Equipment Failure:

a. 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.

b. 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, if needed.

c. 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.

7. Records:

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

E. **CALCULATIONS**:

The calculations listed below can be performed through an Excel spread sheet. (See cs-6:1)

1. Standard Deviation

$$\sigma = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \mu)^2}, \quad \text{where} \quad \mu = \frac{1}{N}\sum_{i=1}^{N} x_i.$$

2. Percent Recovery: $100 - \left[\frac{|\text{Theoretical Value} - \text{Average Value}|}{\text{Theoretical Value}} * 100 \right]$

3. Coefficient of Variation (aka: RSD): CV = %RSD = (σ / Average Value)*100

Rev. #	History
3	Changed title. General verbiage changes throughout document. Section B: Changed 'Variance' to 'Coefficient of Variation' and removed 'Average Deviation.' Section D: Made in-house validation of equipment optional, re-worded procedure that GL policy will be followed for equipment calibrations, and clarified responsibilities. Section E: corrected calculation equations.