A. **PURPOSE**:

Several types of general or routine laboratory equipment are integral parts of the testing process. These include items such as analytical balances, manual and automated pipettes. Other equipment however; may only require monitoring (e.g. refrigerator temperature).

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; the square root of the variance of a normally distributed variable, utilized as a measure of the dispersion of a particular variable.
4. Percent Recovery; a measure of the difference between a determined value, and its target value.
5. Variance; measure of the statistical dispersion of a normally distributed variable
6. Average Deviation: a measure of the deviation of values in a data set from a given point of that data set, (e.g. the mean value).

C. **RESPONSIBILITY**:

All analysts (however titled) assigned to the section must assure that they are using equipment that is proper to the procedure.

D. **PROCEDURE**:

Analysts using equipment as part of sample analysis must ensure that the items that they are using are appropriately validated as functional for use. It is also the responsibility of the analysts to ensure that documentation regarding such validation is kept up to date.

a. Repeat Pipette Validation:

All pipettes are marked with a unique identifier: CS-1, CS-2, CS-3 etc…

i. Note: Class A Volumetric Pipettes need not be validated. However, such pipettes shall be discarded if the tips are cracked, chipped or otherwise broken or damaged.

b. The laboratory will have an outside vendor perform the annual validation/calibration. The vendor must be an ISO certified company or equivalent. The certificate of validation/calibration will be maintained within the laboratory section.

   i. Pipettes that are validated/calibrated by an outside vender will also be verified in-house prior to casework as detailed below in step e.

      (a) The vendors certificate will be reviewed by the section Supervisor or 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.

            1. This review will be annotated by initialing and dating the certificate.

      (b) If the "as found" condition was acceptable and the as left condition was acceptable, the Pipette Check listed in step e below will be used however; the pipette check need only be performed at the mid-point of the pipettes range. If the pipette is primarily dedicated to a specific volume the check will be performed at that volume. The acceptance criteria are as listed on worksheet CS-6.1.

      (c) If the "as found" condition was unacceptable, the Section Supervisor or Deputy Director will be so informed. Based on the nature of the issue and how the pipette is used (quantitative v. qualitative) a QAR may be required to determine if any case findings need to be re-evaluated.

      (d) If the "as left" condition is unacceptable, the pipette shall be marked as "out of service" or disposed, with that process annotated on pipette documentation.

c. Pipette check: Once a pipette is calibrated by the vendor, an in house check will be performed to verify the calibration.

   i. Using an appropriate, certified balance, pipette and weigh 10 portions of room temperature D.I. water, of the target validation volume. Record the weights on a "Pipette Calibration Check" form (CS-6.1).

   ii. Complete the "Pipette Calibration" form and calculate the % Recovery, Standard Deviation, Coefficient of Variation, Average Deviation and Pipette Accuracy.

      (a) Weights should be recorded with a minimum of 3 decimal points when possible so that the needed calculations can be effective.

d. If performance of the pipette is acceptable, The Pipette Calibration form must be reviewed and signed by a second analyst, and a validation sticker will be attached to the pipette.

i. The validation sticker will have the date of check, the pipette number, the initials of the person performing the validation; and (in cases were only a specific volume is validated) the volume that the pipette is validated.

ii. The validation paperwork will be filed in the appropriate section of the 'validation of miscellaneous equipment' notebook.

2. Masses:

a. Masses used as the basis for daily weight checks will be calibrated annually by an ISO/IEC accredited vendor (or equivalent). The calibration paperwork will be filed in the 'validation of miscellaneous equipment' notebook. The calibration laboratory must follow ISO/IEC 17025 standards.

i. The acceptable range, for masses used in the daily check, are based on the mass corrections listed on the calibration report. For this the 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.

ii. If new masses are purchased the calibration documentation provided with the masses is used to determine the working ranges for the masses. Only NIST traceable masses will be considered as acceptable for use in the CS laboratory. Class 1 and Ultra Class masses are acceptable.

3. Thermometers:

a. The thermometers used in this laboratory are used only for non-essential temperatures such as for recording refrigerator temperatures. Current procedures have no specific temperature ranges which must be maintained.

b. Thermometers will be verified annually as described in 3.c.i.(a), below. The reading will be recorded on the Annual Thermometer Check worksheet (CS-6.2). The records are maintained within the section.

c. The manufactures serial number is used to identify the thermometer when possible. This designation will be written on a sticker on the thermometer itself or on the container directly related to the thermometer.

i. Thermometers used in refrigerators or freezers:

(a) Using a NIST traceable thermometer (with valid certification) place both the NIST traceable thermometer and the one to be checked into a refrigerator for ~1/2hour. The reading of both will be taken and recorded on the annual Thermometer Validation' worksheet (CS-6.2). The thermometer is acceptable for use if the thermometer being

validated is +/-2° of the reference thermometer. Note: for freezers the reference thermometer will be in a range appropriate for the device.

(i) NIST traceable thermometers are considered valid for 5 years.

(b) A green validation sticker will be placed on the thermometer once verified. The sticker will have at minimum the date validated and the initials of the analyst.

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 failure.

      i. Temperatures of refrigerators will be monitored a minimum of once per work week this will be recorded on the temperature record log form (CS-6.3) attached to specific unit. At the end of each year the log will be filed in the 'validation of miscellaneous equipment' note book.

5. Controls:

   a. The paperwork generated by the above processes will be periodically reviewed to verify compliance with the procedures. Review will be no less than once a year as part of the yearly audit.

6. Equipment Failure:

   a. Any equipment which fails a validation procedure or in the case of refrigerators starts to work outside of normal working parameters will be immediately reported to the section supervisor or designee.

   b. The section supervisor (or designee) will take needed steps to correct any instrument failures or take the equipment out of use. Major equipment failures need to 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 as "out of use" or similarly to assure it is not used for analysis.

7. Records:

   a. Validation records: forms completed to document the validation of any miscellaneous equipment will be filed in the appropriate log book within the section. These records will be maintained for a minimum of ten years.

E. **CALCULATIONS**:

It is suggested that the calculations listed below be performed through an Excel spread sheet. (See cs-6:1)

1. Standard Deviation

$$\sigma = \sqrt{\mathrm{E}((X - \mathrm{E}(X))^2)} = \sqrt{\mathrm{E}(X^2) - (\mathrm{E}(X))^2}$$

2. Accuracy: 100 - % recovery

3. Percent Recovery: $\frac{\text{(expected value – average value)}}{\text{(expected value)*100}}$

4. Variance: V = (σ / average value)*100

5. Average Deviation: $\frac{1}{n}\sum_{i=1}^{n}|x_i - \overline{x}|$