General Laboratory Equipment

A. **PURPOSE**:

There are several types of equipment used throughout the Division of Scientific Services for testing, and/or as reference materials. This equipment and reference materials may require periodic verification or calibration based on how it is used and the analytical testing needs. All instruments and reference material important to testing will be maintained in a manner to ensure proper calibration and working order.

Some equipment (instrumentation or reference material) will be calibrated internally and some externally through an approved vendor. Instrumentation specific to a Unit will have a procedure for the maintenance, upkeep and periodic check of that instrument.

B. **RESPONSIBILITY**:

Director: responsible to support the Quality System.

Deputy Director: responsible to assure that section employees follow procedural guidance and that authorized personnel conduct the required periodic checks. Additionally they are responsible to assure Maintenance and/or verification plans are met.

Administrative Manager (however titled): responsible to assure that section employees follow procedural guidance for general laboratory equipment.

Quality Section: responsible to audit the DSS to assure that periodic checks are performed and equipment is maintained properly.

Section Leads/Supervisors: are responsible to assure that equipment/reference materials used are maintained properly, and that all required periodic checks are performed and documented as required.

Analysts (however titled): are responsible to assure that the equipment/reference materials used in unit testing meet general and unit requirements and to bring issues with equipment/reference materials forward to their Leads.

Evidence Control Officers: are responsible to assure that equipment/reference materials used within the ER Unit meet the general requirements of this procedure.

C. **DEFINITIONS**:

Performance Check: a periodic in-laboratory verification of the working condition of an instrument or a reference material. The frequency of this verification is dependent on the item and the use of the item.

Calibration/Calibrated: (for the purpose of this procedure) generally performed by an approved vendor, this is a periodic check of an instrument or reference material that meets a higher level of scrutiny then a performance check. The frequency of a calibration is dependent on the item and use of the item.

Calibration definition from the VIM:

> "Operation that, under specified conditions, in a first step, establishes a relation between the **quantity values** with **measurement uncertainties** provided by **measurement standards** and corresponding **indications** with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a **measurement result** from an indication"

Approved Vendor: vendors of supplies or services whom are either:
ISO certified, or have completed a laboratory survey to demonstrate their ability to provide products or services that meet the requirements of the laboratory. (Refer to the Purchasing GL SOP for further guidance).

D. **PROCEDURE**:

Balances:
Analytical balances used for testing purposes will be calibrated annually by an approved vendor. The Quality Section is responsible to arrange for this annual service.

Performance checks of balances will be specific per Unit and will be addressed in Unit procedures. The stringency of the performance check is based on the needs of the testing.

Example:
Units using balances for non-critical weights may choose to performance check the device once per month or quarter. Units using balances for critical weights may choose a more stringent performance check of each day of use.

If an incident occurs that requires the device to be performance checked, outside of its normal schedule, (such as a significant move of the device or a failure to perform as expected) this will be performed in the following manner:

1. Using reference weights check the device at a high, mid and low level specific to that device.

2. Take and record 10 replicates at each level (record this on the 'Balance Performance Check' worksheet GL 21.1).
3. Determine the average, standard deviation and % difference.
    a. The acceptable values will be based on the use of the instrument and type.
    b. For balances with a maximum load of less than or equal to 700g, the acceptance criteria is: SD <1, %Recovery ≤2%, coefficient of variance ≤3%.
    c. For balances with a maximum load of ≥701g the acceptable criteria is: SD<1, %Recovery ≥5%, coefficient of variance ≤3%.
    d. For balances where measurements obtained are not critical (any weight load), the acceptance criteria is: SD <1, %Recovery ≤5%, coefficient of variance ≤3%.

    e. The unit Lead and Deputy Director should review the data to determine if the results are acceptable to the work being performed.
    f. If the balance does not meet the acceptance criteria inform the Quality Section. The Quality Section may choose to re-evaluate the device or to call for service.
    g. The Quality section can be consulted if guidance is needed.
4. All documentation will be filed in the maintenance binder/log for the device within the Unit.

Weights:

Traceable weights are used to verify that balances are working as expected. Different units have different requirements for the frequency of this check, based on how the balances are used. These requirements can be found in Unit specific protocols.

Weights will be sent out to an approved vendor that is ISO/IEC 17025 accredited no less than every 5 years. These will be performance checked annually. Note that weights used in Evidence Receiving for the purpose of monitoring drug cases, (weights that are not reportable) need only be checked in-house every 5 years. These need not be calibrated externally unless in-house checks give reason to doubt the validity of the weights.

Procedure to performance checks weights:

a. Weights will be checked using a calibrated analytical balance. The balance must be appropriate for the item being checked (i.e. for a 1kg weight use a balance that can achieve that weight).
b. Take a minimum of 10 consecutive weights recording the weight on the 'Weight Performance Check' form (GL 21.2).
    i. Record the balance used to perform the check, and include the serial number or other unique identifier of the weights, on the form.
    ii. Record the weights to the same level as the balance read out (e.g. if for a 1gram weight the balance reads 1.0010g record exactly that).
c. Calculate the average, Standard Deviation and Coefficient of Variation.
d. For Class A or Ultra Class weights acceptable criteria are:
    i. Weight average = <2% of the expected value based on the latest calibration certificate.
    ii. SD should be less than 1
    iii. The Coefficient of Variation should be <1% of the expected value based on the latest calibration certificate.
e. For NRA weights and no-class weights including those used in Evidence receiving.
    i. Weight average should be ≤5% of the expected value inscribed on the weight or if the weights had been sent out for calibration previously the average weight should be ≤5% of the expected value based on the latest calibration certificate.
    ii. SD should be less than 1
    iii. The % difference should be <3% of the expected value inscribed on the weight.
f. Any weight not meeting the acceptance criteria shall be marked do not use.
g. The Unit Lead is to be informed of the issue.
h. The Quality Section should be consulted. The Quality Section may re-test the weight or may replace the device if appropriate.
i. All documentation will be filed in the maintenance binder/log for the device within the Unit.

<u>Refrigerators/Freezers</u>:

Refrigerators and freezers used in the DSS, in general, do not need to be at specific temperatures. Depending on the Unit, the refrigerators and freezers may hold evidence,

reagents or reference materials. Sections/Units requiring strict temperature ranges will note those in Unit procedures.

Refrigerators: The temperature should be checked and recorded not less than once a month. Temperatures are recorded on the 'Temperature Record' form. For refrigeration units that store evidence, reference materials or critical reagents the check should be no less than weekly.

For refrigerators with set temperatures, the acceptable range should be no more than +/-3° of the set point. Units requiring specific temperatures shall outline this in Unit specific procedures.

For refrigerators that do not have set temperature features, the temperature range should be 0° – 15° C. Units requiring specific temperatures should outline this in Unit specific procedures.

Freezers: The temperature should be checked and recorded no less than once a month. Temperatures are recorded on the 'Temperature Record' form. For devices that store evidence, reference materials or critical reagents the check should be no less than weekly.

For freezers with set temperatures, the acceptable range should be no more than +/-5° of the set point. Units requiring specific temperatures should outline this in Unit specific procedures.

For freezers that do not have set temperature features the temperature range should be -5 to -15°C. Units requiring specific temperatures shall outline this in Unit specific procedures.

The form used to record the temperature ranges, 'Temperature Record' (GL 21.4), should be kept attached to the device (or in close proximity to the device) while the form is active. Once the form if completed, the form should be filed, in a logbook and maintained in the Unit. Units may use Unit specific forms; the form should include the following information (at minimum):

1. Device Name/ID
2. Acceptable temperature range
3. Section/Unit where the device is located

4. Frequency of required check
5. Place for the temperature taken, the date taken and initials for the person recording the temperature.

Section Leads are responsible to assure device monitoring occurs per the predefined interval; this is documented by initialing the monitoring form monthly.

Those performing the checks of the device must inform the Unit lead if the device is outside the acceptable range.

Thermometers:

NIST traceable thermometers, non-NIST traceable thermometers and digital thermometers that are apart of specific instruments/devices may be used depending on the need of the testing, throughout the DSS.

Thermometers are used to monitor the working condition of devices such as refrigeration units, water baths, and other unit specific devices. Thermometers used will be checked in-house annually by comparison to a NIST traceable thermometer.

NIST Traceable thermometers will be purchased from approved vendors. Sections/Units purchasing NIST thermometers are responsible to maintain the traceable certificate that is issued with the device. It is suggested that the Quality Section be forwarded a copy of the document.

NIST thermometers are appropriate for use to certify/verify other thermometers until the date listed on the traceable certificate. After that date the thermometers may be sent out to an approved vendor for re-calibration or the DSS may choose to purchase new NIST thermometers and use the old as non-traceable devices.

An exception to this is for the DNA unit; NIST thermometers are performance checked annually per FBI QAS. The procedure for this performance check is found in the DNA Unit procedures.

Non-NIST traceable thermometers shall be checked against NIST thermometers annually. Listed below is a method to perform this check. Units may make slight deviations from this based on the need of the testing performed in the Unit.

1. Place the device to be checked and the NIST thermometer in the equipment the thermometer is usually used to monitor (such as the water bath or refrigerator).
    a. For refrigerators/freezers – allow both thermometers to sit for approximately ½ hour and record the temperature reading of both devices on the 'Thermometer Check' GL 21.3 (or equivalent Unit specific form).
    b. For devices that are not always on (such as water baths) turn on the device, place both thermometers in the device. Allow the device time to reach its optimal temperature (this is specific to the instrument). Once optimal temperature is reached allow the thermometers to sit in the device for approximately ¼ hour and record both temperatures on the 'Thermometer Check' form.
    c. In general the thermometer being checked is acceptable if the reading is no more than +/-2 ° from the NIST thermometer.
        i. If the readings <u>are not</u> +/-2° place both thermometers back in the device for up to 24 hours and record the reading.
        ii. If the reading is still outside the accepted range the thermometer is to be marked do not use. Report this to the Unit Lead.
    d. All documentation will be filed in the maintenance binder/log for the device within the Unit.

E. REFERENCES:

<u>International vocabulary of metrology – Basic and general concepts and associated terms (VIM)</u>; 3rd Edition, 2008