A. **PURPOSE**:

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

Some equipment requires periodic performance checks which may be performed internally or through an external vendor. Additionally some equipment requires periodic calibration. Calibrations are performed by external authorized venders. Equipment specific to a Unit will have a procedure for the maintenance, upkeep and periodic check of that equipment. Unit documentation will include a schedule for performance checks and/or calibrations as applicable to the equipment.

B. **RESPONSIBILITY**:

Director: responsible to support the Quality System.

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

Scientific Services Administrative Manager: responsible to ensure that section employees follow procedural guidance for general laboratory equipment.

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

Section Leads/Supervisors: are responsible to ensure 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 ensure 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 ensure 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 (International Vocabulary of Metrology):
> "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. An approved vendor will have an ISO accreditation appropriate to the task to be performed. (Refer to GL-6 "Purchasing" for further guidance).

Traceability or Metrological Traceability (this will be used to mean the same thing):
definition from the VIM: Metrological Traceability: "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty**".**

D. **PROCEDURE**:

a. Equipment which can influence the correct performance of laboratory activities includes but may not be limited to instruments, reagents, reference standards and measurement standards.
   i. Equipment will be handled, stored and transported in a manner to ensure its integrity. This includes ensuring proper function and the prevention of contamination.
   ii. Equipment will demonstrate ability to meet the requirements of the DSS prior to being put into service.
   iii. Equipment that affects the measurement accuracy or measurement uncertainty will be calibrated on a defined schedule.
   iv. Equipment will be calibrated if the calibration is required to establish the metrological traceability of the reported results.

b. Equipment will have a defined schedule for performance checks and/or calibration as appropriate. This schedule will be such to maintain confidence in the working condition of the equipment. The schedule should be reviewed and may be adjusted when it is needed to maintain confidence in the equipment.
    i. Equipment that affects the measurement accuracy or measurement uncertainty will be calibrated on a defined schedule.
    ii. Equipment will be calibrated if the calibration is required to establish the metrological traceability of the reported results.
    iii. The schedule for equipment calibration and/or performance checks will be defined in Unit documentation. These SOPs will include any special specification to be met for the calibration. SOPs providing guidance on performance checks will include the interval of the check and the acceptance criteria for performance check.
c. Equipment will be labeled or identified in a manner to allow the user of the equipment to readily identify the status of the item (calibrated or performance checked).
d. Documentation of calibrations and performance checks shall be maintained as per Unit guidance. These documents will be maintained as per guidance of GL-11 'Control of Records'.

1. Guidance for the calibration of and/or the performance checks of some devices common to multiple Units of the DSS is listed below.

2. Balances: Analytical balances will be maintained in a manner to ensure the validity of the results. Balances should be stored on a bench top and in a manner to avoid unattended jarring. Analytical balances should not be transported and put into service without performing a performance check to verify its appropriate working condition.

a. Analytical balances used for testing purposes will be calibrated annually by an approved vendor. Calibration of balance will be such that the traceability is maintained. The Quality Section is responsible to arrange for this annual service. A copy of the calibration record will be maintained in the logbook for the device. The vendor will minimally label the balances with calibration date.
b. Performance checks of balances, when required, 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. The Unit SOP will define the acceptability requirements for the performance check and what to do if the check is outside the accepted parameters.
    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.

c. 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:
   i. Using traceable reference weights, check the device at a high, mid and low level specific to that device.
   ii. Take and record 10 replicates at each level (record this on the 'Balance Performance Check' worksheet GL 21.1).
   iii. 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 Assistant or 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.
   iv. All documentation will be filed in the maintenance binder/log for the device within the Unit.

3. Weights: Traceable weights are reference materials are used to perform periodic performance checks of balances, to demonstrate that they are working as expected. In general the DSS uses class A or Ultra class weights when a balance is used for an action that is part of measurement uncertainty (for example the weight of drugs in the controlled substance Unit).

a. Weights will be calibrated by an approved vendor that is ISO/IEC 17025 accredited no less than every 5 years. Calibration will be performed to maintain the traceability of the weights. Generally the Quality Section is responsible to arrange for this

calibration. Refer to GL-6 Purchasing for guidance on approved vendors. These will be performance checked annually.

b. Weights will be stored in a manner to protect their integrity. In general this will be within a case designed for the weight, within the assigned laboratory. At any time when an issue occurs to a weight that brings into question the suitability of the reference material the Quality Section should be notified to arrange for a performance check of the item.

c. Procedure to performance checks weights:
   i. 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).
   ii. Performance checks of weights can be performed by anyone that uses balances as part of their normal testing processes.
   iii. Take a minimum of 10 consecutive weights recording the weight on the 'Weight Performance Check' form (GL 21.2).
      a. Record the balance used to perform the check, and include the serial number or other unique identifier of the weights, on the form.
      b. 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. Weights meeting the acceptance criteria will have the outside container housing the weight labeled with the date of performance check and the initials of the person performing the verification.
      f. Any weight not meeting the acceptance criteria shall be marked out of service or will be removed from the laboratory workspace.
      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.

4. Refrigerators/Freezers: 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 provide guidance in Unit procedures.

a. 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.

b. 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 C or colder. Units requiring specific temperatures shall outline this in Unit specific procedures.

c. 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):
   i. Device Name/ID
   ii. Acceptable temperature range
   iii. Section/Unit where the device is located

iv. Place for the temperature taken, the date taken and initials for the person recording the temperature.

d. Section Leads are responsible to assure device monitoring occurs per the predefined interval; this is documented by initialing the monitoring form monthly.
e. Those performing the checks of the device must inform the Unit lead if the device is outside the acceptable range.

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

a. NIST traceable thermometers will be maintained to execute performance checks of commonly used thermometers.
    i. Commonly used thermometers may or may not be NIST traceable.
    ii. The Quality Section maintains the NIST thermometers for the Identification and Chemistry sections.
    iii. NIST thermometers obtained that are for verification of non-critical thermometers will be calibrated or removed from use five years from the date on the traceability certificate.
    iv. The FB/DNA Unit maintains NIST thermometers for use with their equipment; refer to Unit specific SOSs for guidance on these devices.
    v. NIST Thermometers used for performance checks of other thermometers will be stored and handled in a manner to protect their integrity.
b. 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.
c. 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.
d. For the Identification and Chemistry Sections, NIST thermometers are appropriate for use to certify/verify other thermometers until 5 years from 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.

i. For the FB/DNA Section; NIST thermometers are performance checked annually per FBI QAS. The procedure for this performance check is found in the FB/DNA Section procedures.

e. Thermometers used to monitor the working condition of equipment 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.

i. Place the thermometer to be checked and the NIST thermometer in the equipment the thermometer is usually used to monitor (such as the water bath or refrigerator). If the device to be checked cannot accommodate 2 thermometers the check can be performed in another device operating in the range of the thermometer.

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 or Supervisor. The Unit Lead or Supervisor will report this to the appropriate Manager to determine if follow-up is required.

d. All documentation will be filed in the maintenance binder/log for the device within the Unit.

6. <u>Hygrometers</u>: Hygrometers are used to measure the humidity level in a chamber or oven.

a. Units requiring the use of hygrometers will assure the device is NIST traceable or has been checked against a NIST traceable device annually.

b. NIST Traceable devices can be used without an annual check until the expiration date as listed on the certificate of calibration.

c. NIST Traceable Hygrometers will be taken out of service after the date on the traceable certificate and replaced or sent for re-calibration.

E. REFERENCES:

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