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 they are used and 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 either internally or through an external vendor. Additionally, some equipment requires periodic calibration. Calibrations are performed by external authorized venders (refer to GL-6). 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 direct 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, performance checks and/or verification plans are met.

Assistant Director of the State Forensic Science Laboratory: 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 Supervisors and Leads: responsible to ensure that equipment/reference materials (as well as all applicable documentation) are maintained properly, and that staff conducts required periodic performance checks to ensure the functionality of their Units.

Analysts (however titled): responsible to ensure that the equipment/reference materials used in Unit testing meet General Laboratory and Unit requirements. Additionally bring forward issues with equipment and/or reference materials related to quality, casework and relevant matters to their Supervisor.

Evidence Control Officers: responsible to ensure that equipment/reference materials used within the ER Unit meet the General Laboratory requirements of this procedure.

C. **DEFINITIONS**:

Performance Check: verification of the working condition of an instrument or a reference material. The frequency of this verification is dependent on the purpose of its use and may vary. Performance checks may be performed by DSS personnel or through an approved vendor.

Calibration/Calibrated: (for the purpose of this procedure) is a periodic check or adjustment 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. The interval of calibration will be defined based on 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**:

Equipment which can influence the performance of laboratory activities includes, but may not be limited to, instruments, reagents, reference standards, and measurement standards.

1. Equipment will be handled, stored and transported in a manner to ensure its integrity. This includes ensuring proper function and the prevention of contamination.
2. Equipment will demonstrate the ability to meet the requirements of the DSS prior to being put into service.
3. Equipment that affects the measurement accuracy or measurement uncertainty will be calibrated, or performance checked on a defined schedule.

4. Equipment will be calibrated and/or have performance checks performed when required to establish the metrological traceability of the reported results, based on defined intervals.
5. Equipment will have a defined schedule for performance checks and/or calibration, as appropriate. This schedule will be such to maintain confidence in the performance of the equipment. The schedule should be reviewed and may be adjusted when it is needed to maintain confidence in the equipment.
6. The schedule for equipment calibration and/or performance checks will be defined in Unit procedures. These SOPs will include evaluation criteria that need to be met for acceptance of the calibration and/or performance check and will include the interval of these activities.
7. 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).
8. 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'.
9. Guidance for the calibration of and/or the performance checks of some equipment that is common to multiple Units within the DSS is listed below.

Balances: Balances will be maintained in a manner to ensure accuracy. Balances should be stored on a bench top and in a manner to avoid unintended jarring. Balances should not be transported and put into service without conducting a performance check to verify its appropriate working condition.

a. Analytical balances used for testing purposes will be calibrated annually by an approved vendor.
    i. The Quality Section is responsible to arrange for the annual service.
    ii. Calibration of balances will be such that the traceability is maintained by using an appropriate vendor. (See GL-6 "Purchasing for guidance).
    iii. The 'as found' data and 'as left' data (however labeled) and device uncertainty will be part of the calibration documentation (calibration certificate).
    iv. In cases were the 'as found' data is not acceptable a QAR may be initiated depending on the use of the device.
    v. A copy of the calibration record will be maintained in the logbook for the device.
    vi. The vendor will minimally label the balances with calibration date and next calibration due date.

b. If an incident occurs that requires a balance to be performance checked outside of its normal schedule, (such as a significant move of the device or a failure to perform as expected) the following will be performed:
    i. Using traceable reference weights check the device at a high, mid and low level within the limits of 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, percent recovery, and coefficient of variation.
        a. The acceptable values will be based on the use of the instrument and type.
            i. For balances with a maximum load of less than or equal to 700g, the acceptance criteria is: SD < 1, Recovery ≤ 2%, coefficient of variation ≤ 3%.
            ii. For balances with a maximum load of ≥701g the acceptable criteria is: SD < 1, Recovery ≤ 5%, coefficient of variation ≤ 3%.
            iii. For balances where measurements obtained are not critical (any weight load), the acceptance criteria is: SD <1, Recovery ≤ 5%, coefficient of variation ≤ 3%.
        b. The Unit Lead/Supervisor or Assistant Director or Deputy Director will review the data to determine if the results are acceptable to the work being performed.
        c. If the balance does not meet the acceptance criteria inform the Quality Section. The Quality Section will work with the appropriate section Manager to determine whether to re-evaluate the device or to call for service.
        d. All documentation will be filed in the maintenance binder/log for the device within the Unit.
    iv. Note: The Auto Cal function on the balance will not be used on DSS balances. The use of this may invalidate the traceable calibration certificate for the device. If this is accidently done report this to your Assistant Director or Deputy Director so appropriate action can be taken.

Weights: Traceable weights are reference materials used to perform periodic performance checks of balances to demonstrate that they are working as expected. In general the DSS uses class A or Ultraclass weights for performance checks when a balance is used for an action that is part of measurement uncertainty.

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). Weights will be performance checked annually by the Quality Section or designee. Performance checks are not required in the calendar year that the weights are sent out for calibration.
b. The vendor will place a calibration sticker on the proximal container for the weights with minimally the calibration date, calibration due date and initials of the person performing the check.
c. Calibration certificates must contain the uncertainty, 'as found' and 'as left' data.
d. In cases where the 'as found' data is not acceptable a QAR may be initiated depending on the use of the weights.
e. Weights will be stored in a manner to protect their integrity. In general storage will be within a case designed for the weight, within the assigned Unit. At any time when an issue occurs to a weight that brings into question the suitability of the reference material the Unit Lead/Supervisor will be notified. The Quality Section should be notified to arrange for a performance check of the item.
f. Procedure for the performance check of 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 are generally performed by the Quality Section but can be performed by anyone that is authorized to use 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 identifier, and include the serial number or other unique identifier of the weights, on the form.
        b. Record the weights to the level of digits the balance allows.
        c. Calculate the average, standard deviation and coefficient of variation.
        d. For Class A or Ultraclass weights acceptable criteria are:

i. Weight average ≤2% of the expected value based on the latest calibration certificate.
ii. Standard deviation must be less than 1.
iii. The Coefficient of Variation should be < 1% of the expected value based on the latest calibration certificate.

e. For other classes of weights the weight average must be ≤ 5% of the expected value based on the last calibration certificate.
f. The storage container(s) of weights meeting the acceptance criteria will be marked appropriately (date of performance check, the expiration date and the initials of the person performing the verification).
g. Any weight not meeting the acceptance criteria shall be marked out of service or will be removed from the laboratory workspace.
h. The Unit Lead/Supervisor is to be informed of any failures.
i. The Quality Section will be notified. The Quality Section may re-test the weight on a 2nd balance or may replace the weight if appropriate.
j. The Quality Section maintains the records of the annual performance checks. If a periodic check is performed within a Unit, that Unit will maintain the records.

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 their procedures.

a. Refrigerators: The temperature should be checked and recorded not less than once a month. Temperatures are recorded on the 'Temperature Record' form (GL-21.4 or Unit specific). 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° C of the set point. Units requiring specific temperatures shall list these values in their specific procedures.

   For refrigerators that do not have set temperature features, the temperature range should be 0° – 15° C. Units requiring specific temperatures shall list these values in their 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 shall list these values in their 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 list these values in their specific procedures.

c. Either the form 'Temperature Record' (GL 21.4) or a unit-specific form can be used to record temperatures. These should be kept attached to the device (or in close proximity to the device) while the form is active. Once the form is completed the form should be filed in a logbook and maintained in the Unit (or maintained as per Unit guidance). Unit specific forms should include the following information (at minimum):
   i. Device Name/ID
   ii. Acceptable temperature range or set point (as applicable)
   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/Supervisors are responsible to ensure 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/Supervisor if the device is outside the acceptable range. The Lead/Supervisor will consult the Section Manager to determine appropriate follow-up.

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

a. NIST traceable thermometers (digital or liquid in glass) will be maintained to execute performance checks of commonly used thermometers.
   i. Commonly used thermometers may or may not be NIST traceable. (e.g. expired NIST traceable thermometers).

ii. The Quality Section maintains a set of NIST thermometers for in-house checks.

iii. NIST traceable thermometers that are used for verification of non-critical thermometers are appropriate for use for 5 years from the date on the calibration certificate.

a. After that date the devices may be sent out for re-calibration or be put in general use as a non-traceable devise.

iv. The DNA Unit maintains NIST thermometers for use with their equipment; refer to Unit specific SOPs for guidance on these devices. The DNA Unit SOPs provide guidance on the acceptance of NIST traceable thermometers.

v. NIST traceable thermometers used for performance checks of other thermometers will be stored and handled in a manner to protect their integrity.

vi. If a NIST thermometer is found where the column of fluid is separated this will be taken out of use.

b. 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.

c. Thermometers used to monitor the working condition of equipment shall be checked against NIST traceable thermometers annually. Listed below is a method to perform this check. Units may make slight variations from this based on the need of the testing performed in the Unit.

i. Place the thermometer to be checked and the NIST traceable thermometer in the type of 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. Note it is acceptable to put multiple thermometers into one device (such as a refrigerator) with the NIST thermometer to verify multiple thermometers at one time.

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 ½ 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 traceable 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 out of service. Report this to the Unit Lead or Supervisor. The Unit Lead or Supervisor will report this to the appropriate Manager and/or Quality Section to determine if follow-up is required.
d. All documentation will be filed in the maintenance binder/log for the device within the Unit.

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

a. Units requiring the use of hygrometers will ensure the device is NIST traceable.
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 by a vendor that meets the needs of a calibration vendor as defined in GL-6 "Purchasing".

<u>Pipettes</u>: Mechanical pipettes will be calibrated annually by an approved vendor. The Quality Section will arrange for this service. The level of calibration will be determined by how the device is used.

a. Pipettes used for critical measurements, include but may not be limited to those used in the DNA Unit and in the Toxicology Unit. For Units where pipettes are part of the consideration for the uncertainty budget, the calibration company will be informed that the calibration certificate is required to contain the device uncertainty, 'as found' and 'as left' data. For Units where uncertainty is not a concern, the calibration company will be informed that minimally the calibrations certificates will require 'as found' and 'as left' data as part of the calibration certificate. Unless specified in a Unit specific procedure the calibration should be to the pipette manufacturer's specification for the specific device.

i. When 'as found' data determines that the device is out of expected tolerance a QAR will be initiated (an exception being if the device was already taken out of service).

b. Pipettes used for non-critical purposes may have a lower level calibration performed requiring only the 'as found' and 'as left' data to be present on the calibration certificate.

c. Calibration stickers will be placed on the device by the vendor. At minimum these will list the calibration date and the due date.

d. Calibration certificates will be disseminated by the Quality Section to be maintained by each Unit as appropriate.

b. Pipette in-house check/verification – in the event a pipette needs to be checked to verify the continued working condition the following should be considered.

a. If the pipette is a variable volume device, is it used and dedicated to 1 level or is it used at multiple levels?

Note that some Units may have their own procedure for the verification of pipettes to meet the specific needs of the work within the area.

c. For fixed volume pipette or variable volume pipettes dedicated to 1 volume:

a. Tare a weigh boat on a calibrated analytical balance.

b. Using the pipette to be verified draw up and dispense 10 volumes of room temperature DI water onto the weigh boat.

c. Record the value after each weight on to form GL-21.5. See figure 1 below for expected weight.

d. Calculate the average, % recovery, standard deviation (sd) and coefficient of variation following the guidance on the Gl-21.5 form.

e. Acceptable parameters:

i. % Recovery 98% - 102%

ii. sd <1

iii. Coefficient of variation <3%

d. For a variable volume pipette:

a. Follow the steps for a fixed volume pipette but test the device at the low medium and high volumes. For example a pipette with a range of 10ul to 100ul check at 10ul, 50ul and 100ul.

e. If a pipette does not meet the acceptable parameters mark the device as out of service (or similar wording) and report the issue to you Supervisor.

Figure 1:

Volume of DI water	**Expected weight**
1 ml	1.00 g
0.5 ml	0.500 g
100ul	0.100g
50ul	0.05g
10ul	0.01g

Note: Adjustments should not be made to calibrated pipettes as this may invalidate the traceable calibration certificate.

E. REFERENCES:

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