SOP: 6.4 Rev 1

EFFECTIVE DATE: September 10, 2024

AUTHOR(S): Wilfredo Robles, Edwin Barbosa, and Bill Barney

APPROVED BY: see cover page

TITLE: **Standardization and Maintenance of Instruments and Gauges**

PURPOSE: Provide guidelines to ensure that instruments and gauges used to generate GLP data are standardized and maintained to give accurate readings.

SCOPE: Applies to all field trials in the Minor Use Foundation's magnitude of pesticide residue studies.

PROCEDURES:

1. Ensure that all instruments used in GLP trials are kept clean at all times and are properly calibrated in accordance with the applicable procedures.
2. Instruments used in GLP field research should be tested to determine that they are accurate to meet the data-recording requirements of professional scientific methods utilized in GLP-regulated studies. At a minimum, standardize each environmental testing instrument once per year. Testing should be completed under conditions similar to those under which the instrument will be used.

3. Testing can include standardizing instruments with comparison to two other like instruments; they should test out at ±5% of the average of all (except wind speed indicators, which will be at ±10%). If one of them is more than 5% different (or 10% for wind meters) than the average, that instrument will not be used and is to be replaced. Standardizing instruments against known constants (e.g., thermometers in ice water slurry, stainless steel weights, etc.) or through certification may also be used for testing the accuracy of instruments and gauges.

4. New instruments are considered calibrated for the period of one year unless the manufacturer specifies another date. Regardless of the accuracy-testing method, document the date of standardization, the equipment identification number of the instrument involved, and the results of the tests. Unless otherwise noted, instruments that have been

standardized are considered to have had adequate maintenance. Any instrument that uses batteries should be replaced annually, or earlier, if needed. When a new instrument is purchased, issue a new ID number for it and mark this number on the instrument.

5. All documentation that has been produced by the standardization and maintenance of these instruments will be recorded in a log, and copies placed in the field data notebook, where applicable.

6. NIST Thermometer

   The NIST mercury-in-glass thermometer is a reference thermometer used when standardizing temperature recording devices, such as a soil or air thermometer. It is used for comparison only and is not used when calculating the average of the temperature recording devices. Other standardizing equipment may be used as long as it is calibrated against a traceable standard and has a valid calibration certificate.

7. Soil and Water Thermometers

   Soil and water temperature are usually measured using a digital thermometer. Standardization is conducted by immersing the probes of at least three digital thermometers in the same container of water and recording temperatures after about two minutes. Include a NIST-certified thermometer for comparison. Results should be within 5% of the average of all thermometers. The NIST thermometer reading is not used when calculating the average; it is used for comparison only but must be within 5% of the average of the digital thermometers. It is recommended to standardize the thermometers under conditions that generally reflect the conditions in which the thermometers will be used. For example, standardize the thermometers in both cold water (e.g., 35 to 45° F) and in warm water (e.g., 65 - 75° F).

8. Instrument for measuring air temperature, relative humidity, and wind speed

   a. A popular instrument used to measure air temperature, relative humidity, and wind speed is a digital Kestrel 3000 or another model by Nielsen-Kellerman. Other instruments are acceptable. Standardization is accomplished by comparing readings from the three like instruments (e.g., three Kestrels) while under the same conditions.

b. To standardize for air temperature and relative humidity, line up the instruments on the same surface, at the same level, under the same conditions. After about 15 minutes, take readings from all instruments for each environmental parameter (i.e., air temp, RH). Results should be within 5% of the average of all three instruments. Instruments should be standardized in the approximate range of the temperatures likely to occur in the field.

c. To standardize for wind speed, align the instruments next to each other on the same surface, aiming them all in the same direction. Conducting the standardization indoors with a fan directed towards the meters facilitates the standardization process. Read all three instruments concurrently and document. Results should be within 10% of the average of all three instruments. It is recommended to standardize the instrument under a range of wind speeds. For example, for a given standardization, altering the distance from the fan that the instruments are placed will give different wind speeds.

9. <u>Temperature-recording devices for Freezers and Test Substance storage and transport</u>

a. It is recommended to use electric temperature recording devices, such as a HOBO, with a temperature range appropriate for warm, cool, or frozen conditions. Use a NIST mercury-in-glass thermometer for comparison. If a HOBO temperature datalogger is not available, a min/max thermometer must be set up within each cabinet and freezer. The temperatures reported from the min/max thermometer will be recorded regularly throughout the trial period.

b. Before use, visually inspect the datalogger for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries should be replaced when the power indicator light does not blink while the unit is on). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used as raw data.

c. All dataloggers will be identified with a unique number or code. The identification number or code will be placed on the measuring device such that it can easily be cross-referenced to calibration log records.

d. Data logger(s) to be calibrated and the reference thermometer will be read side by side under conditions appropriate to the intended use.

e. Examples of temperature ranges to test may include:
    i. room temperature (approx. 22°C)
    ii. ice slush (approx. 0°C)

f. Water baths will be contained in a pan or beaker deep enough for adequate immersion of the instrument. The ice bath should be made with chopped ice in water to form a tightly packed slush.

g. The data logger (s) and the reference thermometer will remain in the calibrating environment until a constant reading is reached. When the analyst feels confident that reading is constant, the values will be recorded in the log. The following information will be documented in the log:
    i. date of calibration
    ii. initials of person doing calibration
    iii. reference thermometer reading
    iv. the datalogger temperature reading
    v. identification (ID) or code number of the datalogger being calibrated

h. Temperature reading taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2ºC, the recorded value will be 38ºC).

i. Data from temperature data loggers will be downloaded regularly. The downloaded data will be saved electronically and printed out (hard copy). This data will be retained in an electronic and a copy file as raw data. The following information will be included in the files:
    i. ID code number of the device
    ii. Date
    iii. Routine Maintenance check (satisfactory or not satisfactory)
    iv. Measurements units
    v. Initials of person downloading the data

j. Units will be appropriately maintained. If the unit fails, it will be discarded and replaced by a new one. The only exception is

the changing of batteries and charts or the adjustment of sensor arms during calibration.

10. Balance Calibration
    a. For balances used to weigh a test substance dry formulation, it is recommended that professional calibration and maintenance be performed and certified every year for accuracy.
    b. Adjustments for accuracy can be made by an accredited company certified with the National Institute of Standards and Technology (NIST). The calibration by use of "Known Weights" is acceptable before weighing test substance for the application. Documentation of calibration will be kept on file.
    c. To calibrate
        i. Clear the unit to the point at which the readout is at zero.
        ii. Center the calibration weight on the weighing platform or pan. If adjustments are allowed, adjust the balance until the readout is within +/- 2% of the declared value of the calibrated weight.
        iii. Annotate values on a log for retention in raw data. If recalibration is required and operator-level adjustments are available, it should be done, and the weights remeasured.
        iv. If operator-level recalibration is either not available or not adequate, the unit should be routed for maintenance by a properly trained technician.

Approved by:



October 5, 2026

Anna Gore, Executive Director
Minor Use Foundation

Date