

EQUIPMENT POLICIES AND PROCEDURES

General Policies:

1. Required testing and reference equipment and measurement standards shall be calibrated, standardized, checked, or maintained at specified intervals following the general procedures described below. Hereafter in this document, “calibration” and “calibrated” represent all four of the preceding activities just mentioned; and “equipment” includes testing equipment, reference equipment, and measurement standards.
2. Equipment that becomes suspect of defect shall be removed from service and shall not be used until the required corrective actions have been taken.
3. Equipment that may be affected by moving it to a new location or environment shall be calibrated at its new location before being placed in service.
4. Newly acquired equipment that is not affected by being moved to a new location and that does not come with a calibration record, shall be calibrated before being placed into service. Newly acquired equipment that is potentially affected by being moved to a new location, shall be calibrated in the laboratory before being placed into service, even if it comes with a calibration record.
5. Equipment that has not been calibrated within the applicable frequency, because it has been removed from service, shall be calibrated before being returned to service.
6. Calibrations of reference equipment and measurement standards shall be performed by a calibration service provider that is accredited to ISO/IEC 17025 for this service.

General Procedures:

1. The [Quality Manager] is responsible for ensuring that calibration activities are performed and that records are maintained. He shall maintain a file for each piece of equipment requiring calibration. The file for each piece of equipment shall contain detailed records of calibration work performed in chronological order and shall be kept [in the Quality Manager’s office].
2. The [Quality Manager] shall maintain a set of 12 labeled folders in his office—one for each month of the year. Each month’s folder shall contain a partially completed calibration record form for each piece of equipment requiring calibration during the month indicated on the folder’s label.
3. During the first week in each month, the [Quality Manager] shall remove the partially completed record forms from the current month’s folder and instruct the appropriate staff

to perform the necessary calibration work within the next week and return the completed record forms.

4. The [Quality Manager] shall prepare partially filled out record forms for each piece of equipment calibrated that month—identifying the equipment and the next date that calibration work is required (month, day, and year)—and file each partially filled out form in the appropriate monthly folder.
5. The [Quality Manager] shall file each of the completed record forms in the appropriate equipment record file in chronological order.
6. Calibrations of reference equipment and measurement standards shall be performed by a calibration service provider that is accredited to ISO/IEC 17025 for this service.
 - a. Prior to scheduling an appointment to calibrate reference thermometers, the [Quality Manager] will ensure that the calibration agency selected for this service meets these requirements. The following list is a collection of websites for examples of US agencies that accredit calibration service providers, and these websites may be consulted to determine whether the selected calibration agency is accredited:
 1. www.a2la.org
 2. www.anab.org
 3. <https://www-s.nist.gov/niws/index.cfm?event=directory.search#no-back>
 4. <http://www.pjlabs.com/>
 5. <https://www.iasonline.org/>
 - b. The [Quality Manager] will ensure that the calibration records issued by the accredited calibration agency will include detailed results of the calibrations as well as estimates of measurement uncertainty.
7. Newly acquired equipment that does not come with a record of calibration from the manufacturer shall be calibrated before being placed into service (see also No. 8 below). The record of calibration shall be placed into a file that has been newly created for that piece of equipment and Step 4 above shall be completed.
8. Equipment that may be affected by moving it to a new location or environment shall be calibrated at its new location before being placed in service. This requirement also applies to such newly acquired equipment, even if it comes with a calibration record (see No. 7 above). Examples of equipment that may be affected by a move include, but are not limited to, balances, compression machines, mechanical compaction equipment, and sensitive measurement equipment.

9. When any of the laboratory's equipment is overloaded, mishandled, damaged, malfunctioning, giving results that are suspect, or is not meeting specification tolerances, the [Quality Manager] shall remove it from service and clearly mark it by attaching a red ribbon or tape. Corrective action shall begin with a root cause analysis and the following steps shall be followed:
 - a. All work will be halted until corrective actions have been completed and documented.
 - b. The results of previous tests performed using this equipment shall be reviewed to detect any possible negative impact that may have been caused by the defective equipment, and to evaluate the significance of this impact. Records for all tests completed since the time of the last satisfactory calibration will fall under this evaluation.
 - c. If the corrective action investigation determines that any inspection or test results were affected, the client, and any other party as required by the contractual agreement, shall be immediately notified in writing.
 - d. The equipment shall be returned to service only after appropriate repairs are made; calibration confirms that the equipment functions satisfactorily and meets specification tolerances; and any and all other corrective actions have been completed and documented.
 - e. Steps 4 and 5 above shall be completed.
 - f. Records of any malfunction, damage, or repair shall also be maintained and placed in chronological order with the other calibration records for that equipment.