Sections in This Document

1. Purpose

This procedure specifies the schedule and requirements for maintenance, performance, calibration, and verification of laboratory testing equipment to ensure compliance with ISO/IEC 17025:2017 and AOAC requirements. Meeting the criteria in this procedure demonstrates control of the equipment maintenance and calibration parameters needed to achieve accurate test results.

2. Scope

These procedures apply to the analytical testing equipment used by the Office of Regulatory Science (ORS) laboratories.

3. Responsibility

A. Laboratory Management

1. Ensures the laboratory is equipped with equipment that meets the specifications of the analytical methods used.
2. Ensures equipment maintenance and calibrations are conducted.
3. Provides support for arranging non-routine instrument repair and ordering replacement instrument parts.
4. Designates equipment monitors.

B. Assigned Monitors

1. Maintains equipment logbooks
2. Performs periodic equipment checks
3. Ensures equipment is maintained in accordance with their respective requirements.

C. The Quality Management System Manager

1. Ensures monitoring of equipment records.
2. Ensures laboratory equipment is calibrated and maintained in accordance with accreditation requirements.

D. Staff

1. Verifies equipment conforms to specifications prior to use.
2. Completes the record of this verification.
3. Adheres to written equipment operation procedures.

4. Background

None

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories Section 6.4

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements,

and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

C. FDA Staff Manual Guide (SMG) 2620.2, Procedure for surplus equipment

6. Procedure

6.1. Equipment Identification and Records

A. All equipment in the FDA equipment inventory system is labeled with a unique identification number (e.g. FDA bar code number). Generally, equipment not bar coded under the FDA-wide inventory system is identified under the laboratory's own unique numbering system.

B. Each laboratory maintains an inventory of its major equipment used to perform regulatory testing. This inventory contains the following information:

1. Item and its software version,
2. Manufacturer and model,
3. Serial number or other unique identification, and
4. Location

C. The label or tag found on or near the equipment contains the following information:

1. FDA bar code or unique identification number,
2. Date of last calibration, and
3. Date of the next calibration.

D. Equipment that is scheduled to be calibrated daily or with each use, is tagged as above, except that instead of the calibration dates, it is annotated as such (e.g. calibrated daily or calibrated with each use).

E. Small items with insufficient space to record the information on the label (e.g. thermometers) need only be identified with their unique identification number for traceability to their associated records.

F. Detailed guidance on equipment records is provided in ORA-LAB.5.5.1. Equipment Records.

6.2. Equipment Qualification

A. When new equipment is installed, laboratories may elect to purchase Installation Qualification (IQ) and Operation Qualification (OQ) from the manufacturer or installer. This information is kept with the equipment records.

B. Alternatively, for new equipment the laboratory may determine independently that quality assurance specifications have been met.

C. Equipment is not used until it has been qualified and users have been trained in its operation.

6.3. Equipment Maintenance and Intermediate Performance Checks

A. Laboratory equipment maintenance and intermediate performance checks are conducted on a scheduled basis. A schedule, identifying and eliminating potential sources of problems, is established for the servicing of laboratory equipment.

Note: Intervals of intermediate performance checks should be shorter than the time the equipment has been found to take to drift outside acceptable limits.

B. Such maintenance and performance checks are recorded to demonstrate that the program is being followed according to schedule.

C. Manufacturer's instructions are used for guidance in performing equipment maintenance. In the absence of manufacturer's instructions, instructions are provided in the equipment operation procedure.

D. The maintenance and performance checks records may be maintained in a logbook, log sheet, or electronically.

E. Attachment A provides information on minimum maintenance requirements for equipment according to AOAC-International. ORS laboratories are responsible for developing comparable maintenance schedules for equipment not listed in this table.

F. Preventative maintenance procedures, other than basic cleaning, are developed for each equipment item, unless they are already described elsewhere (e.g. the instrument manual).

G. General Service equipment is typically maintained only with cleaning and safety checks.

H. Use of outside contractors to perform repairs or maintenance is at the discretion of local laboratory management.

6.4. Equipment Calibration or Verification

A. A calibration or verification procedure is prepared by the testing laboratory for all critical laboratory equipment where laboratory personnel perform the testing. If the procedure is described in an operators manual or a test procedure, this can be referenced in lieu of preparing a separate procedure.

B. Calibration or verification records are maintained. See ORA-LAB.5.5.1.

C. Minimum calibration or verification schedules according to AOAC International for the most common types of laboratory equipment are found in Attachment A. For analytical equipment not listed, the laboratory must develop a comparable schedule.

D. Generally, laboratory equipment is categorized as follows:

1. General service equipment such as blenders, ovens, hotplates, furnaces, stirrers;
2. Volumetric equipment such as Class A glassware, mechanical and automatic pipettes and burets; Note: A manufacturer's certificate of graduation accuracy for Class A glassware may be accepted. Other volumetric equipment, including mechanical and automatic pipettes and burets, are calibrated by the laboratory's procedure.
3. Measuring instruments such as balances, chromatographs, spectrometers, thermometers; and
4. Physical standards such as reference weights and reference standards.

E. Data acquired on equipment which fails a parameter are investigated to include items between the failing assessment date and the last successful calibration or verification date. The problems and investigation are conducted according to the laboratory's procedures for managing nonconforming work and corrective actions.

6.5. Out of Service Equipment

A. Equipment that is not in use, and therefore has not been calibrated, verified, or not operating properly must be clearly tagged out of service.

B. Out of service equipment must be calibrated or verified prior to use.

C. Equipment is not returned to service until performance checks and verification have been performed and recorded. An exception may be made if the equipment failure is not directly related to its analytical function, such as a problem with peripheral equipment. For example, if

a printer or computer attached to a chromatographic system is out of order, performance checks and verification for the chromatograph may not be needed following repair.

6.6. Equipment Leaving Direct Control of the Laboratory

A. When, for whatever reason, i.e. repair or calibration, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment and its software are checked and shown to be satisfactory before the equipment is returned to service.

1. For equipment returned after repair, the performance checks and calibration identified in Attachment A are conducted prior to use and recorded to be within specifications.
2. For equipment returned after calibration, the contractor/vendor calibration certificates are reviewed for the following to ensure the calibration status:
    a. A statement of conformity to relevant specification after calibration/verification, Note: such as the manufacturer's specifications
    b. Item name, type, or description,
    c. Identification number,
    d. Location,
    e. Calibration interval,
    f. Calibration procedure used,
    g. Calibration source (both the standard used and the lab providing the service),
    h. Date of calibration,
    i. Corrections, conditions of use (including environmental conditions) necessary to achieve the required performance,
    j. Specific results of each calibration, prior to adjustment or repair, if the item was found out of tolerance,
    k. Details of any maintenance such as servicing, adjustments, repairs or modifications carried out,
    l. Any limitations on use,
    m. Identification of person(s) performing the calibration,

n. Where the accuracy of an item is described in a calibration report or certificate, there must be a means of traceability between that item and the report or certificate.

NOTE: The records may be maintained by approved calibration suppliers as part of their services but must remain accessible upon request. Electronic records may be used in lieu of paper calibration certificates.

3. Additionally, any equipment returned after calibration must be checked for functionality by performing a check of the operation of the equipment. For example, a pipette check would be to demonstrate that the pipette draws up a volume of water. This check must be recorded.

6.7. Handling, Use, Storage and Transport of Equipment

A. Laboratory procedures define the handling and use of the equipment. Each piece of equipment has step-by-step instructions for its start-up, operation and shutdown described in manufacturer's manuals or per laboratory procedure. Equipment is operated by authorized personnel identified by their respective laboratory.

B. The location of equipment in active use is specified in the laboratory equipment inventory. Equipment not in use is tagged per instructions in Section 6. Procedures, Part 6.5, Out of Service Equipment.

C. Surplus equipment instructions are found in the Staff Manual Guide 2620.2; surplus equipment is recorded on FDA Form HHS-22, Request for Property Action.

D. Transport or move sensitive equipment according to manufacturer's instructions. Transportation or moving equipment may be performed by the manufacturer or other service provider. Equipment is not returned to service until performance checks and verification have been performed and recorded.

E. ORS laboratories are secure. Only authorized personnel are permitted in the laboratory; non-authorized personnel are escorted. Computer software is write-protected and, in most cases, password protected to prevent unauthorized program adjustments. These measures safeguard the equipment, sample security and computer software.

7. Glossary/Definitions

A. Calibration – Calibration is the set of operations, under specified conditions, establishing the relationship between values of quantities by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realized by standards.

B. Certified reference material (CRM) – A CRM is a reference material, whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or documentation issued by a certifying body.

C. General service equipment – General service equipment is laboratory equipment that is not used for measuring but that can affect the results of an analysis. Examples include grinders, blenders, ovens, furnaces, hotplates, stirrers, non-volumetric glassware used for approximate volume measurements (e.g. measuring cylinders), laboratory heating, and ventilation systems.

D. Installation qualification (IQ) – This is the identification of all system elements, electrical or otherwise. This identification and the subsequent documentation for each installed item details normal operating instructions, routine user maintenance, preventive maintenance and cleaning procedures.

E. Measuring instruments – This includes balances, chromatographs, spectrometers, thermometers, timers, viscometers, electrochemical meters.

F. Operational qualification (OQ) - OQ is generally described as commissioning. It includes calibration and critical instrument test parameters defined for the use and purpose of the instrument, and may include the definition of upper and lower tolerances.

G. Performance qualification (PQ) - PQ relates to the daily use of the instrument and is designed to measure routine performance. Details of work instructions and specifications are included.

H. Physical standards – Physical standards includes reference weights and reference thermometers.

I. Reference Standard – A reference standard usually has the highest metrological quality found at a given location in a given organization, from which measurements made there are derived. Generally, this refers to recognized national or international traceable standards such

as National Institute of Standards and Technology (NIST) thermometers and weights.

J. Traceability – Traceability is the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties (VIM: 1999-6.10).

K. Verification Confirmation - Verification confirmation is through the provision of objective evidence that specified requirements have been fulfilled. (ISO 9000: 2000 3.8.4)

NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision to restore in service, perform adjustments or repair, downgrade or declare the equipment obsolete. In all cases, written traceability of the verification performed is kept on the measuring instrument's individual record.

8. Records

A. Equipment maintenance and performance checks records

B. Calibration records

C. Installation and operation qualification records obtained from equipment manufacturer or installer

D. Equipment inventory

E. Equipment software master list

9. Supporting Documents

None

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	6/22/05	LMEB	LMEB
1.3	R	11/16/05	LMEB	LMEB
1.4	R	11/15/07	LMEB	LMEB
1.5	R	10/30/08	LMEB	LMEB
1.6	R	06/07/10	LMEB	LMEB
1.7	R	09/23/13	LMEB	LMEB
1.8	R	05/08/14	LMEB	LMEB
02	R	06/06/2019	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.

12. Attachments

List of Attachments

Attachment A - Equipment Requirements

Equipment/System	Parameter	Frequency
Autoclaves	Accuracy of temperature sensing system	Calibrate at installation (or initial use)
		Verify annually
	Maximum temperature achieved	Verify each day
	Performance	Verify weekly with biological sterility indicator
	Uniformity [1]	Conduct an initial mapping of chamber at installation & annually thereafter
	Stability of temperature	At installation and annually as needed[2]
Automated colony chambers	Accuracy	Verify annually with manual count
Balances	Mass measurement	Verify daily when in use with internal calibration or with a working weight
	Calibrate[3]	Annually When moved to a different location or after repair
Chromatographic systems (GC, IC, LC) See additional requirements below for dietary supplements	Detector response	Verify for the analytical methods at least once with each batch.[4]
Dispensing equipment & vial fillers used in Microbiology	Mass measurement/volume	Verify at installation & daily when in use at each volume dispensed
Freeze dryers, vacuum ovens	Ability to achieve & sustain vacuum; vacuum gauges verified	Verify at installation and annually thereafter

Equipment/System	Parameter	Frequency
	against calibrated gauge	
Hydrometer, reference	Specific gravity	Calibrate every 2 years
Hydrometer, working	One-point comparison to reference hydrometer	Verify Annually
Microscopes used for measuring	Length	Calibrate stage micrometer at installation or initial use
pH meters ion selective, & related conductivity equipment[5]	Calibrate against reference buffer[5] or reference solution at level of use or bracketing range of use	Each day of use
Temperature controlled chambers used for storage (e.g. refrigerators and freezers)	Verify temperature	Frequency is dependent upon mechanism of monitoring[6]
	Uniformity of temperature by mapping the chamber	At installation (or initial use) and after nonroutine maintenance[7]
Temperature controlled chambers used for testing (e.g. ovens, furnaces, incubators, water baths)	Verify temperature	Check daily am and pm when in use with at least 4 hours between verifications
	Uniformity of temperature[1] by mapping the chamber	At installation (or initial use) and after nonroutine maintenance[7]
Temperature sensing devices/systems, reference (thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.)	Calibrate temperature to the appropriate traceable standard	Every 2 years
Temperature sensing devices/systems, working (thermometers,	Verify temperature against reference device	Annually

Equipment/System	Parameter	Frequency
thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.)		
Timers & internal timing devices[8]	Time	Verify working device annually against reference or against NIST time clock[9]
UV/Vis spectrophotometer	Blank reading	Verify daily when in use
	Wavelength	Verify at installation & annually
Volumetric delivery devices: mechanical pipets, micropipettes, mechanical burets, & liquid dispensers	Accuracy & precision using mass of water at a known temperature or by spectrophotometric method	Verify upon receipt (manufacturer's Certificate of Accuracy may be accepted) Minimum every 6 months
Volumetric delivery devices: positive displacement syringes used for volumetric delivery	Accuracy	Verify upon receipt: (manufacturer's Certificate of Accuracy may be accepted)
Volumetric glassware, non-class A (pipets, burets, & volumetric flasks)	Accuracy using mass of water at a known temperature or by spectrophotometric method	Verify upon receipt
Water activity meter	Water activity of known solutions	Verify daily when in use[5]
Water, used in all analyses to meet method requirements	Method specific water quality attributes	Minimally every month
Water, used for microbiological analyses	Acceptable levels of chlorine and aerobic plate count	Monthly

Equipment/System	Parameter	Frequency
Water used for pharmaceutical analyses	The eight types of water are as follows: 1. Nonpotable 2. Potable (drinkable) water 3. USP purified water 4. USP water for injection 5. USP sterile water for injection 6. LUSP sterile water for inhalation 7. USP bacteriostatic water for injection 8. USP sterile water for irrigation	Meet FDA Inspection Technical Guide Requirements: https://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072925.htm
Weights, reference	Mass	Calibrate every 5 years[3]
Weights,working	Mass	Verify against reference weight annually

NOTES:

1. Uniformity may not be needed for low-capacity equipment such as small chambered autoclaves, incubators, ovens, & refrigerators; circulating water baths; muffle furnaces; & freezers based on use or design. In these cases, the laboratory should have reasonable justification and document the justification for not determining uniformity and suitability.

2. Autoclaves equipped with a calibrated temperature sensing device that provides a record of temperature are considered to meet this requirement.

3. All weights & balances shall be calibrated traceable to recognized national or international units (NIST, BIPM, OIML, or equivalent traceable weights). They must be calibrated by an ISO/IEC 17025accredited calibration laboratory.

4. For quantitative methods, an analytical standard at the mid-range or lower of the calibration curve can verify detector response. For qualitative assessments, the appropriate response material must be used.

5. When pH or water activity results are reported to the customer or may be a significant component of overall uncertainty of the measurand, the reference material (e.g. buffer or water activity analytical standard) must satisfy the requirements for metrological traceability. Buffers used for this purpose must be obtained from an ISO 17034-accredited manufacturer.

6. The intent is the laboratory must be able to verify that samples were stored at the proper temperature for the duration of storage. Continuous monitoring with a calibrated and validated system meets this

requirement. A min/max data logging thermometer would require verification at a frequency dependent upon the amount of data it can store.

7. When determining mapping schedules, attention should be paid to extremes in laboratory ambient conditions (such as those brought on by seasonal changes) that can influence the performance of the equipment. Initial and nonroutine maintenance monitoring can be done with no load.

8. Timers and internal timing devices only need to be verified when time is a critical factor in the test method. Time may not be a critical factor when time is not the reported result or a precise time is not required for the test method.

9. Accrediting bodies may require Initial calibration by an ISO 17025 accredited calibration laboratory.