Sections in This Document

1. Purpose 1
2. Scope 1
3. Responsibility....2
4. Background....2
5. References 2
6. Procedure 2
   - 6.1. Overview 2
   - 6.2. Logbook Sections....3
     - 6.2.1. The following information may be included:....3
     - 6.2.2. Operating Instructions....3
     - 6.2.3. Calibration and Verification 3
   - 6.3. Maintenance....4
   - 6.4. Repair....5
   - 6.5. Non-Conformances 5
   - 6.6. Software Record and Calibration 5
   - 6.7. Manufacturer's Instructions 5
7. Glossary/Definitions....5
8. Records 5
9. Supporting Documents 6
10. Document History 6
11. Change History 6
12. Attachments....6

1. Purpose

This procedure provides guidance for ISO/IEC 17025:2017 record requirements for laboratory testing equipment in the Office of Regulatory Science (ORS) laboratories.

2. Scope

These procedures apply to equipment maintenance, performance checks, calibration, and verification records of the ORS laboratories.

3. Responsibility

A. ORA laboratories ensure that laboratory testing equipment is maintained, monitored, calibrated, and verified properly before and/or during use.

B. Laboratory Management ensures that the equipment record requirements outlined in this procedure are adhered to.

4. Background

ISO/IEC 17025:2017 requires records to be retained for equipment which can influence laboratory activities. ORS laboratories maintain equipment records electronically, in logbooks, or other kinds of record files for equipment calibration, verification, service, and other maintenance.

Records include equipment related information such as descriptions of operation, preventive maintenance, repairs, calibrations and verifications. Volume II, Section 2, ORA-LAB.5.5 Equipment provides guidelines on equipment performance measures and maintenance.

Periodic review of equipment records, included as part of the laboratory's audit procedure, is essential.

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

6. Procedure

6.1. Overview

A. The instrument or equipment records are compiled and required information maintained in a readily accessible manner. There is no requirement that the records be kept in a bound notebook or binder. Records may be kept electronically. For electronic records, local work

instructions state where these records are located and how they can be accessed.

B. The records are kept in a secure, accessible place in the laboratory.

C. The records for similar instruments may be kept together if they are clearly identified and separated. For example, records for multiple balances may share a single location.

D. The records are maintained for a period determined in each laboratory's record and data management procedure and in accordance with agency record management policies.

6.2. Logbook Sections

6.2.1. The following information may be included:

A. description of the instrument critical accessories and software/firmware version;

B. manufacturer's name, type, serial number, and/or other unique identification (i.e. FDA number);

C. its current location, and

D. Evidence of verification that equipment conforms with specified requirements, including installation qualification (IQ), operational qualification (OQ) records; and

E. other related material such as instrument service and repair, warranty information, service contract conditions and specifications, and equipment manufacturer representatives' names and telephone numbers.

6.2.2. Operating Instructions

Each piece of equipment has step-by-step operating instructions, including starting and shutting down the instrument. This may be addressed in manufacturer's manuals or per laboratory procedure.

6.2.3. Calibration and Verification

A. All measuring equipment has an established schedule specifying performance checks, including the testing frequency and acceptable performance specifications. These performance checks ensure the equipment is operating properly and consistently prior to analysis.

B. Records will include calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or calibration interval.

C. Laboratory equipment may have peripheral equipment that affects their performance. In these cases, systematic checks are also specified to ensure that the peripheral equipment is functioning properly. For example, tests of voltage regulators ensure voltage stability of automatic samplers for consistent sample delivery.

D. The performance check includes a description of the performance check, the date and analyst name, the determined value compared to a target value or specification, and any information to aid in equipment assessment.

E. Quality control procedures monitoring test validity and calibrations connected to a particular sample are generally recorded on the worksheet or electronically. For example, system suitability test results performed as part of sample analysis are submitted with the worksheet.

F. For equipment performance checks where traceability to primary standards is needed, a certificate or record establishing traceability or information about the properties or characteristics of the reference material is kept on file.

G. When contract calibration or verification services are used, the vendor should provide the following information (if not proprietary):

1. Description of work performed,
2. Test method,
3. Test data,
4. Traceability of standards used,
5. Date vendors test equipment or standards were last certified,
6. Performance versus the acceptance criteria, and
7. Certificate of conformance.

6.3. Maintenance

A. Service contract or in-house preventive maintenance is recorded. This includes all maintenance, except for routine cleaning.

B. The records include:

1. description of the maintenance;
2. date it was done; and
3. name of the service representative and company, or name of the analyst if maintenance provided internally.

6.4. Repair

A. Equipment repairs are recorded.

B. The records include:

1. Initials of the analyst, and the date the problem was observed,
2. Description of the problem;
3. Date and initials of the analyst or service representative performing the repair;
4. Synopsis of the repair; and
5. Additional optional information like cost of repair, work order, copy of the invoice, etc.

6.5. Non-Conformances

Equipment non-conformances are recorded according to the procedures for Control of Nonconforming Work (ORA-LAB.4.9).

6.6. Software Record and Calibration

Software calibration certificates provided by the manufacturer are kept on file by the laboratory.

6.7. Manufacturer's Instructions

Manuals provided by the equipment manufacturer may be included in the logbook if they are very brief, significant, and readily accessible. Otherwise, logbooks should include references to the manuals' location.

---

7. Glossary/Definitions

None

---

8. Records

A. Laboratory equipment records for maintenance, performance checks, calibration and verification

B. Laboratory equipment service and repair records

C. Records providing evidence of conformance to specifications

D. Primary standard certificates

E. Software calibration and version records

---

9. Supporting Documents

A. ORA Laboratory Manual, Volume II, ORA-LAB.5.5, Equipment

B. ORA Laboratory Manual, Volume II, ORA-LAB.4.13, Record and Data Management

C. ORA Laboratory Manual, Volume II, ORA-LAB.4.11, Corrective Action Procedure

D. ORA Laboratory Manual, Volume II, ORA-LAB.4.9 Control of Nonconforming Work

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	11/16/05	LMEB	LMEB
1.3	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

None