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Title: <b>INSTRUMENT AND EQUIPMENT DOCUMENTATION AND RECORDS</b>		Effective Date: 10-01-03 Revised: 11/10/05	

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|--------------------------------|--|
| <b>1.<br/>Purpose</b>          | <hr/> <p>This procedure provides guidance for the International Organization for Standardization (ISO) 17025 documentation requirements for laboratory testing equipment in the Food and Drug Administration /Office of Regulatory Affairs (FDA/ORA) laboratories.</p> <hr/>   |
| <b>2.<br/>Scope</b>            | <hr/> <p>These procedures apply to equipment maintenance, performance checks, calibration, and verification documentation of the FDA/ORA laboratories.</p> <hr/>   |
| <b>3.<br/>Responsibilities</b> | <hr/> <p>ORA laboratories ensure that laboratory testing equipment is maintained, monitored, calibrated, and verified properly before use.</p> <hr/>   |
| <b>4.<br/>Background</b>       | <hr/> <p>ISO/IEC17025 requires laboratory equipment documentation. Although not required, it is often convenient to maintain these documents and records in a logbook. FDA/ORA laboratories may elect to maintain the records otherwise, or use a combination of logbooks and other kinds of document files. It is suggested if some of the records are maintained outside a logbook, the logbook contain a reference to their location.</p> <p>The term logbook is used throughout this procedure. Logbook refers to the documents and records under discussion, regardless of whether they are compiled in a single book.</p> <p>The logbooks include instrument 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 instrument and equipment performance measures and maintenance.</p> <hr/> |

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

## 5. References

International Organization for Standardization and International Electrotechnical Commission. *International Standard (ISO/IEC) 17025 General requirements for the competence of testing and calibration laboratories* (Section 5.5 Equipment). Geneva, Switzerland: ISO Committee on Conformity Assessment.


## 6. Procedure

### A. Overview

1. The instrument or equipment logbook is compiled, required information maintained in a readily accessible manner. Although the term logbook is used throughout this procedure, each laboratory can establish their own record system to contain all needed information. 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, how they can be accessed, and authorized personnel.
2. The logbooks are kept in a secure, accessible place in the laboratory.
3. The logbooks may contain tabbed sections for ease of use. Not all of the sections found in Part 6., Procedures B. are necessary. At the discretion of the laboratory, the logbook sections may be combined, subdivided, or moved to a different section if it is more convenient. The logbook sections may be arranged in any order and a table of contents may precede them.
4. The records for similar instruments may be kept in the same logbook if they are clearly identified and separated. For example, multiple balances may share a single logbook.
5. The records are maintained for a period determined in each laboratory's record and data management procedure.

### B. Logbook Sections

1. The following records may be included in the logbook sections, equipment records containing:

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- description of the instrument, critical accessories and software;
- manufacturer's name, type identification and serial number;
- FDA number;
- installation qualification (IQ) and operational qualification (OQ) records obtained from the installer or manufacturer; and
- other related material such as instrument service and repair, warranty information, service contract conditions and specifications, and equipment manufacturer representatives names and telephone numbers.

## 2. Operating Instructions

Each instrument or 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.


## 3. Calibration and Verification

- a. Each instrument has an established schedule specifying performance checks, including the testing frequency and acceptable performance specifications. These performance checks ensure the instrument is operating properly and consistently prior to analysis.
- b. Instruments may have peripheral equipment that affect 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.
- c. The performance check includes a description of the

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performance check, the date and analyst name, the determined value compared to a target value or specification, and any information to aid in instrument assessment. Each laboratory may develop forms capturing this information for each instrument.

- d. For equipment that has scheduled daily or with-use verifications, the records may be maintained on a log sheet kept with the equipment. These log sheets, as well as calibration and verification records, control charts, and other records associated with an instrument may be attached to the logbook when they are complete.
- e. Quality control procedures monitoring test validity and calibrations connected to a particular sample are generally recorded on the worksheet, and do not need to be retained in the logbook. For example, system suitability test results performed as part of sample analysis are submitted with the worksheet.
- f. For instrument performance checks where traceability to primary standards is needed, a certificate or documentation 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):
  - Description of work performed,
  - Test method,
  - Test data,
  - Traceability of standards used,
  - Date vendors test equipment or standards were last certified,

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- Performance versus the acceptance criteria, and
- Certificate of conformance.

#### C. Maintenance


1. Service contract or in-house preventive maintenance is documented. This documentation is required for annual maintenance. Maintenance performed at other times, with the exception of routine cleaning, is documented.
2. The documentation includes:
  - description of the maintenance;
  - date it was done; and
  - name of the service representative and company, or name of the analyst if maintenance provided internally.

#### D. Repair

1. Instrument and equipment repairs are documented.
2. The documentation includes:
  - initials of the analyst, and the date the problem was observed,
  - description of the problem;
  - date and initials of the analyst or service representative performing the repair;
  - synopsis of the repair; and
  - cost of repair, copy of the invoice and any additional information (not required).

#### E. Non-Conformances

1. If limits or specifications are exceeded, explanatory documentation is required. Documentation includes the limit of specification that was exceeded, and the probable cause and

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resolution.

2. Non-conformances are handled by the laboratory's corrective action procedure, See Volume II, Section 1, ORA-LAB.4.10 Corrective Action Procedure.

F. Software Record and Calibration

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

G. Manufacturer's Instructions

Manuals provided by the equipment manufacturer may be included in the logbook if they are very brief, significant, and readily accessible.

**7.**

**Definitions**

None

**8.**

**Records**

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

Laboratory equipment service and repair records

Installation qualification (IQ) and operational qualification (OQ) records obtained from the manufacturer


Primary standard certificates

Software calibration records

**9.**

**Supporting Documents**

*ORA laboratory manual of quality policies and procedures*, Volume II, Section 2, ORA-LAB.5.5 Equipment  
 Laboratory record and data management procedure  
 Laboratory corrective action procedure

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