Forest Service Handbook
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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 40 – Equipment

Amendment: 4090.13-93-1

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Duration: This amendment is effective until superseded or removed.

Approved by: David G. Unger, Acting Chief

Date approved:

Responsible Staff:

Last Change:

Superseded Document(s):

POSTING NOTICE. Amendments are numbered consecutively by Handbook number and calendar year. Post document in numerical order of chapters (1109.12, sec. 4.32, ex. 01). Remove entire national text of the Handbook and replace with this amendment. DO NOT REMOVE SUPPLEMENTS OR INTERIM DIRECTIVES. Retain this transmittal as the first page of this document.

Digest: Following is an explanation of the changes throughout the directive by section.

This Handbook provides direction on the principles and requirements of Good Laboratory Practice (GLPs) for Forest Service management and technical personnel. Any study that is performed with the intention of submitting the data to the U.S. Environmental Protection Agency or the U.S. Food and Drug Administration in support of a research or marketing permit must follow GLP standards.

01 - 06.5: Sets forth Authority (sec. 01), Policy (sec. 03), Responsibility (sec. 04), Definitions (sec. 05), and References (sec. 06) in the zero code chapter for the new Handbook on Good Laboratory Practices.

11 - 12.4: Establishes a new chapter that provides direction on the applicability of Good Laboratory Practices (GLPs) (sec. 11) and aspects of compliance (sec. 12).

20.3 - 22: Establishes a new chapter that provides direction on staffing requirements and training for personnel conducting, or involved with, Good Laboratory Practices.

30.3 - 35: Establishes a new chapter that provides policy and direction to determine requirements for test system care facilities (sec. 31); test system supply facilities (sec. 32); facilities for handling test, control, and reference substances (sec. 33); laboratory facilities (sec. 34); and archiving facilities (sec. 35) where Good Laboratory Practices are conducted or stored.

40.3 - 42.3: Establishes a new chapter that provides direction on equipment requirements including equipment design (sec. 41) and calibration and maintenance (sec. 42) for studies complying with Good Laboratory Practices.

50.3 - 55.33: Establishes a new chapter that provides direction on facility operations required for Good Laboratory Practices, including preparation of master schedule (sec. 51); standard operating procedures (sec. 52); reagents and solutions (sec. 53); test system care (sec. 54); and characterization, handling, and mixing with carriers of test, control, and reference substances (sec. 55).

61 - 62.32: Establishes a new chapter that provides direction on the preparation of protocols and collection of raw data for Good Laboratory Practices.

70.4 - 73.3: Establishes a new chapter, Records, Reports, and Archiving that provides direction on reporting study results (sec. 71), archiving (sec. 72).

80.1 - 81.2: Establishes a new chapter that provides direction on the requirements and duties of local and national Quality Assurance Units in support of Good Laboratory Practices.

90.1 - 93.38: Establishes a new chapter that provides direction on inspections conducted by local and national Quality Assurance Units (sec. 91 and 92) and the U.S. Environmental Protection Agency (sec. 93) in conjunction with Good Laboratory Practices.

This Handbook is now available electronically in the National Information Center in the same format as the paper copy. Henceforth, amendments to this Handbook will be issued to Forest Service units electronically on a document basis.

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40.3 - Policy

All equipment used to conduct Good Laboratory Practices shall:

1. Be properly designed and suited for its purpose.

2. Be calibrated to known standards.

3. Have updated calibration, maintenance, and repair records that are available at study sites and retained in the archives.

4. Have written Standard Operating Procedures (SOPs) (sec. 42.2 and 52) that outline procedures for the use, calibration, and maintenance of the equipment. The SOPs should contain contingency plans in case of equipment malfunction or breakdown during the course of a study.

41 - Equipment Design

(Sec. 01, ex. 01; 40 CFR 160.61). Use only properly designed equipment that is capable of fulfilling its function, as detailed in the experimental protocol, including the equipment used for the generation, measurement, or assessment of data, as well as that used to regulate the environment of the testing facility. Keep equipment accessible and suitably located for proper operation, inspection, cleaning, and maintenance. Identify all equipment with a unique number, such as an inventory number, for correlation with the calibration, maintenance, and repair records.

42 - Calibration and Maintenance

(Sec. 01, ex. 01; 40 CFR 160.63).

42.1 - General Considerations

Adequately inspect, clean, and maintain all equipment. Test, calibrate, and/or standardize equipment used for the generation, measurement, or assessment of data. Frequently used equipment, such as balances and pH meters, should be standardized daily or before each use if used periodically. Most modern balances are calibrated by internal electronics and should be recalibrated daily and after a power failure. Periodically verify the calibration of balances with standard laboratory weights. Calibrate pH meters with known buffers before each use. In field studies, calibrate sprayers before the application of test, control, or reference substances to the test system. Recalibrate sprayers between applications, or as often as needed to avoid errors due to calibration changes. Some types of laboratory equipment, such as graduated cylinders and volumetric flasks, are precalibrated and do not need to be recalibrated. Uniform volumes can sometimes be obtained only by repeated use of a particular measuring device. For example,

use the same type of syringe to inject reference standards and test samples into a gas chromatograph during chemical characterization studies.

42.2 - Standard Operating Procedures

Have written Standard Operating Procedures (SOPs) in place which adequately describe the procedures, materials, and schedules for routine equipment inspection, cleaning, maintenance, testing, calibration, standardization, or use of equipment. Ensure that these SOPs specify options in event of equipment failure in order that equipment may be fixed and to ensure the timely and adequate completion of the study. Ensure that these SOPs designate the persons and their positions who are responsible for the performance of each operation. This designation may refer to a service department or to the contracting of service personnel in event of equipment failure. See section 52 for further guidance on preparing SOPs.

42.3 - Documentation

Maintain written records of all inspection, maintenance, testing, calibration, and/or standardizing operations in equipment logs. Maintain equipment logs for all laboratory and field equipment, including pH meters, balances, centrifuges, freezers, microscopes, spectrophotometers, autoclaves, hygrothermographs, sprayers, helicopters, generators, insect traps, air samplers, pheromone dispensers, and any other piece of equipment used in a study. Clearly identify the log by equipment name and dates covered. Include the following information in the log:

1. Dates the equipment is in operation.

2. Dates and results of inspections.

3. Maintenance, including cleaning procedures. Describe whether maintenance was routine and followed written Standard Operating Procedures.

4. Testing, calibration, and/or standardization operations.

5. Service and repair events. Record the nature of the failure or malfunction, how and when it was discovered, and any remedial action taken.

6. Changes in configuration and addition of options.

Store all written records or equipment logs in the archives when they are no longer kept in the laboratory or field station (sec. 72 and 73). Each log should be adequately identified as to the piece of equipment and dates covered by the log. See exhibit 01 for a sample format for an equipment log.

42 - Exhibit 01

Sample Format for an Equipment Log

Equipment: Mettler Balance PE160
Location: Biodeterioration RWU, Building 1, Room 153
Dates Covered by Log: January 1, 1993 - present
Identification Number: RWU4502-001

Calibration Records

Date	Deviation from Standard Weight?			Balance Recalibrated?	Written SOPs Followed? (Initial)
	1g	10g	100g		
1/2	no	no	no	no	yes JAM
1/3	1.005	10.004	100.708	yes	yes JAM
1/5	no	no	no	no	yes JAM
1/6	no	no	no	no	yes JAM
1/7	0.996	9.997	99.993	yes	yes JAM
1/8	0.998	9.994	99.992	yes	yes JAM
1/9	no	no	100.002	no	yes JAM

Routine Maintenance Log

Date & Initials	Maintenance Performed	Remarks	Date of Next Scheduled Maintenance
1/7 JAM	cleaned and recalibrated		2/17/93
1/8 JAM	cleaned due to chemical spill	pan dropped on floor	2/17/93
2/17 JAM	cleaned and recalibrated		3/17/93
2/18 JAM	no power; fuse replaced	worked OK w/new fuse	3/17/93
2/19 JAM	no power; fuse replaced	maintenance called	3/17/92
2/20 JAM	repaired; recalibrated		3/17/92

42 - Exhibit 01--continued

Equipment: Mettler Balance PE160
Location: Biodeterioration RWU, Building 1, Room 153
Dates Covered by Log: January 1, 1993 - present
Identification Number: RWU4502-001

Nonroutine Maintenance Log

Date: February 20, 1993

Name (Initial/signature): Jessie A. Micales

Description of the problem:

Bad integrated circuit caused power surge.

How was the problem corrected?

Board replaced.

Who corrected the problem?

Forest Products Laboratory electrical repair shop.

What studies could have been affected? (Give experiment numbers and dates.)

CLTH 21402 and CLTH 21709; February 17 - 19, 1993

How could the studies have been affected?

Data may have been inaccurate due to a bad integrated circuit. Samples were reweighed. Results were not significantly different from the original readings.