

**Forest Service Handbook
National Headquarters - Washington Office
Washington, DC**

**Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 20 – Personnel**

Amendment: 4090.13-93-1

Effective date: November 10, 1993

Duration: This amendment is effective until superseded or removed.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Superseded Document(s):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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20.3 - Policy

Ensure that personnel are qualified to conduct studies in compliance with Good Laboratory Practices and document employee qualifications in up-to-date, detailed records of training, experience, and education (sec. 21).

20.4 - Responsibility

20.41 - Line Officers

It is the responsibility of line officers to instruct members of their staffs to report health or medical conditions that may affect the study to the Study Director.

21 - Staffing

(Sec. 01, ex. 01; 40 CFR 160.29).

21.1 - Qualifications

All individuals involved in a study, including supervisors, Study Directors, technicians, field personnel, and quality assurance staff, must have adequate training, education, and experience, or a combination thereof, to properly carry out their assigned responsibilities. Individuals involved in pesticide studies should also be trained in hazardous material recognition and should be able to read, understand, and implement the safety procedures listed on the Material Safety Data Sheet. All training should be documented in the individual's training record (sec. 22 and FSM 6141).

21.2 - Number of Personnel

Ensure that the station or laboratory is staffed with a sufficient number of trained personnel to conduct each study according to the protocols.

21.3 - Precautions to Avoid Cross-Contamination

21.31 - Attire

Dress appropriately for the duties performed. Change clothing as frequently as necessary to:

1. Ensure personal safety (FSH 6709.11, sec. 8-1).
2. Prevent test systems or test, control, and reference substances from being contaminated with microbiological, radiological, or chemical agents.

21.32 - Health

Take all health and personal sanitation precautions necessary to prevent contamination of test systems or test, control, and reference substances. (This is usually a concern only in vertebrate studies.) Exclude individuals with an illness or medical condition that could jeopardize the quality or integrity of a study from direct contact with the test systems or test, control, and reference substances.

22 - Training Records and Position Descriptions

Each field personnel office must keep accurate, current job descriptions and records of the training, education, and experience of all supervisory and technical staff involved in Good Laboratory Practice (GLP) studies. These records may be kept separate from other personnel records, such as salary and health benefits records, to make them more readily accessible to U.S. Environmental Protection Agency inspectors when requested.

Anyone working with GLP studies should maintain a current Factor IV (FSM 6151.3 and FSH 6109.15, ch. 30) or equivalent standardized training form that is updated annually and lists:

1. Education. Include degree(s) held, institution(s), and dates attended.
2. Experience. Include position(s) held and dates of employment; post-graduate training (external and in-house); promotions; special awards and honors; instrumentation capabilities; and studies performed with the accompanying area of responsibility.

A sample format for identifying training accomplishments (education and experience) of GLP staff employees is shown in exhibit 01.

22 - Exhibit 01

Sample Format for Recording Training

TRAINING RECORD FOR GOOD LABORATORY PRACTICES STAFF

Name: Jessie A. Micales

Date: 4/10/93

EDUCATION

Degrees: (Institutions and Dates)

Ph.D., Virginia Polytechnic Institute and State University, Blacksburg, VA
Major: Plant Pathology. June 1985.

B.S., Delaware Valley College of Science and Agriculture, Doylestown, PA
Major: Agronomy (summa cum laude). May 1979.

EXPERIENCE

Positions Held, Dates of Employment:

7/89 - present: Research Plant Pathologist, GS-13, Forest Products Laboratory, Madison, WI

9/85 - 7/89: Research Plant Pathologist, GS-12, Forest Products Laboratory, Madison, WI

6/84 - 9/85: Research Associate, Cornell University (stationed at USDA-ARS Foreign Disease and Weed Science Research Unit, Frederick, MD)

6/79 - 6/84: Research Assistant, Virginia Polytechnic Institute and State University, Blacksburg, VA

Post-graduate Training Courses: (External training, In-house training)

Date: August 3-4, 1992

Subject: Grammar, Writing, and Editing Workshop

Location: Careertrack Seminar, Madison, WI

Date: June 29-30, 1992

Subject: Training for Directive Authors

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Amendment: 4090.13-93-1

Effective date: November 10, 1993

Location: Information Systems Staff, Washington, DC

Date: February 2-3, 1992

Subject: Introduction to Good Laboratory Practices and Auditing

Location: International Center for Health and Environmental Education: Alexandria, VA

Date: December 7-8, 1991

Subject: Writing Standard Operating Procedures for Regulatory Compliance

Location: International Center for Health and Environmental Education: Alexandria, VA

Promotions, Special Awards, Honors: USDA Certificate of Merit, July 1992

Instrumentation Capabilities: HPLC; FPLC; scanning electron microscopes; ultracentrifuge; personal computers (IBM) - graphics, statistical, word processing, and data base software; spectrophotometers; other standard laboratory equipment.

Studies Performed and Areas of Responsibility:

CLTH 21402 - Chlorothalonil: field dissipation study. Study Director.

CLTH 21709 - Chlorothalonil: efficacy for sapstain control on lumber. Study Director.