

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

**Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 90 – Inspections and Audits**

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Duration: This amendment is effective until superseded or removed.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Superseded Document(s):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

Contents

90.1	Authority
90.3	Policy
90.4	Responsibility
90.41	Deputy Chiefs for Research, State and Private Forestry, and the National Forest System
90.42	National Quality Assurance Unit Manager
90.43	Regional Foresters, Station Directors, Area Director, Director of the Forest Products Laboratory, and Institute Director
90.44	Local Quality Assurance Unit Manager
91	Quality Assurance Unit Inspections
91.1	National Quality Assurance Unit Inspections
91.2	Local Quality Assurance Unit Inspections
91.3	Inspection Records
92	Forest Service Reviews
92.1	Management and Activity Reviews
92.2	Supervisory Reviews
93	U.S. Environmental Protection Agency Inspections
93.03	Policy
93.1	Refusal of Inspection
93.2	Types of U.S. Environmental Protection Agency Inspections
93.3	Inspection Process
93.31	Notification
93.32	Preparation
93.33	Opening Conference
93.34	Facility Inspection
93.35	Study (Data) Audit
93.36	Closing Conference
93.37	Post-inspection Activities
93.38	Routes of Appeal