Forest Service Handbook
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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 30 – Facilities

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Approved by: David G. Unger, Acting Chief

Date approved:

Responsible Staff:

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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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30.3 - Policy

1. Do not violate protocols because of inadequate space, poor design, or other physical factors.

2. Ensure that all studies not conducted within a controlled environment are suitably located. For example, do not evaluate pesticide efficacy at an experimental location unsuited to the host or pest species.

3. Design facilities to allow separation of operations that could adversely affect the study if conducted close together.

31 - Test System Care Facilities

(Sec. 01, ex. 01; 40 CFR 160.43). Test system care facilities include greenhouses, field plots, growth chambers, or any other facility in which test systems are housed.

1. Plant, insect, and pathogens. Only those requirements that pertain to plant, insect, or pathogen studies are discussed in this Handbook, since these are the test systems most frequently used in Forest Service studies.

2. Animal, fresh water, and marine organisms. Facility requirements for other test systems, including animal, fresh water, and marine organisms are set forth in Title 40, Code of Federal Regulations, section 160.43 (40 CFR 160.43).

31.1 - Separation of Species

Provide separate rooms for housing different species for studies that use vertebrates as test systems. Separation of species can be accomplished by using separate aquariums in tests with aquatic animals. Separate housing is not required in studies using plants, insects, or pathogens so long as the species are adequately separated and identified to prevent a mix-up or cross-contamination. For example, in a field nursery test plant only a single tree species in a single subplot. Separation of species is not required if the protocol specifies the simultaneous exposure of two or more species in the same chamber or area.

31.2 - Biohazard Facilities

Provide separate rooms or chambers for those studies which require isolation due to the use of certain test, control, or reference substances that are known to be biohazardous. This would include highly toxic pesticides and other volatile materials, such as aerosols, radioactive materials, and infectious agents. This requirement is necessary for safety and to prevent cross-contamination of the test systems. Separate field plots adequately to prevent cross-contamination and drift. If test systems cannot be separated, list procedures in the protocol that describe safety measures and show how cross-contamination can be prevented.

31.3 - Collection and Disposal of Contaminated or Hazardous Materials

Make proper provisions for the collection and disposal of contaminated water, soil, or hazardous and other waste material (FSH 6709.11, sec. 8-3, 9-3, 9-4, 9-10; FSH 2109.12, ch. 40). Ensure that disposal facilities prevent the transmission of plant pathogens, environmental contamination, and health hazards, and the escape of quarantined pests.

31.4 - Regulation of the Environment

Greenhouse and laboratory facilities must have provisions to regulate environmental parameters, such as temperature, humidity, and photoperiod, specified by the protocol. Backup systems should be available, or other contingencies should be made, to prevent the disruption of the study in case of equipment failure. This requirement refers only to greenhouse and laboratory studies and cannot be applied to field tests.

32 - Test System Supply Facilities

(Sec. 01, ex. 01; 40 CFR 160.45).

32.1 - Storage Areas

Provide storage areas for test system supplies, including diet ingredients, containers, cages, nutrients, soil, bedding, supplies, and equipment. Position storage areas away from areas where the test systems are located. Store perishable items, such as diet ingredients, culture media, nutrients, or fertilizers, properly to prevent decomposition.

32.2 - Facilities for Plant Growth

Separate facilities should be available for plant growth prior to exposure to the test, control, or reference substances. These facilities can include greenhouses, growth chambers, light banks, or field plots.

33 - Facilities for Handling Test, Control, and Reference Substances

(Sec. 01, ex. 01; 40 CFR 160.47). Provide separate facilities to prevent the contamination or mix-up of test, control, and reference substances during their receipt, mixing, and storage. For example, store pesticides separately from diluents, adjuvants, and other chemical reagents. These materials may be used in a single room if there are separate areas with adequate space, equipment, and ventilation to prevent contamination or mixing of substances. A separate storage locker for pesticides within a larger storage area can also provide adequate separation. Separate storage areas from areas housing plants, insects, or other test systems. Ensure that environmental conditions of storage facilities are adequate to preserve the identity, strength, purity, and stability of the substances and mixtures. Direction on the storage of hazardous materials is provided in FSH 2109.12, chapter 10 and FSH 6709.11, section 9-10.

34 - Laboratory Facilities

(Sec. 01, ex. 01; 40 CFR 160.49). When appropriate, make separate laboratory space available for the performance of all routine and specialized procedures specified in the protocol.

35 - Archiving Facilities

(Sec. 01, ex. 01; 40 CFR 160.51). Provide adequate space to store and retrieve from archiving all raw data, specimens, samples, and documentation from completed studies (sec. 72).