Forest Service Handbook
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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 10 – Compliance with Good Laboratory Practices

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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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11 - Applicability of Good Laboratory Practices

(Sec. 01, ex. 01; 40 CFR 160.1, 160.10, and 160.135). Good Laboratory Practices (GLPs) specify how to collect, store, and present data to regulatory agencies in a standardized manner that allows effective auditing and evaluation. Good Laboratory Practices do not regulate the experimental design of a study or address issues of worker safety. For direction on worker safety, see:

1. The Health and Safety Code Handbook, FSH 6709.11;

2. Section 55.21 of this Handbook for direction on writing safety-related Standard Operating Procedures; and

3. Other related documents, such as Station or Regional Safety Plans.

11.1 - Types of Studies Requiring Good Laboratory Practices

Any Forest Service study on pesticides that is performed with the intention of submitting the data to the U.S. Environmental Protection Agency in support of a research or marketing permit must be conducted under Good Laboratory Practice (GLP) standards. This includes research on microbial pesticides used for biological control, and pesticide-related laboratory and field studies concerned with any of the following:

1. Health effects.

2. Environmental effects.

3. Chemical fate.

4. Chemical and physical properties.

5. Residue chemistry.

6. Epidemiology.

11.2 - Types of Studies Not Requiring Good Laboratory Practices

11.21 - Studies Not Submitted to the U.S. Environmental Protection Agency

Pesticide-related studies that are not intended to be submitted to the U.S. Environmental Protection Agency (EPA) do not need to be conducted under Good Laboratory Practice (GLP) standards. A disclaimer should be added to the study plans or to the project record stating:

> This study/project involves the use of pesticides, but the findings are not intended to be submitted to the U.S. Environmental Protection Agency in support of a research or

marketing permit. This research is therefore not covered by the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practices regulations.

The results of such a study may not be accepted by the EPA if the study is submitted to EPA at a later date.

11.22 - Development of New Pesticides and Testing Procedures

The initial phases of research, including pesticide development and establishment of testing methodology, do not fall under Good Laboratory Practices (GLPs). Such basic exploratory studies are not subject to GLP regulations unless the data generated during the study would be submitted to the U.S. Environmental Protection Agency in support of a research or marketing permit.

11.23 - Efficacy Tests

Most efficacy tests, which comprise the bulk of Forest Service pesticide studies, are designed to compare a number of registered chemicals to determine which ones are best for a given forest management situation. Efficacy testing does not currently require Good Laboratory Practice (GLP) compliance if the study is not intended for submission to the U.S. Environmental Protection Agency (EPA). However, efficacy tests must conform to GLP standards if test results are to be submitted to the EPA in support of registration or reregistration. If a study is eventually submitted to the EPA, a compliance statement must be included, even if GLPs were not required or followed when the study was conducted (sec. 12.2).

11.3 - Types of Studies That Allow More Relaxed Good Laboratory Practice Standards

Certain types of studies can be conducted using more relaxed Good Laboratory Practice standards (sec. 01, ex. 01; 40 CFR 160.135; and 40 CFR 792.232) when studies involve:

1. Physical and chemical characterizations of a compound.

2. Pest management alternatives with pesticide-like materials or techniques. These include the use of pest baits, parasites, and predators; the monitoring of traps or trap crops; and the release of sterile male pests.

12 - Aspects of Compliance

12.1 - Applicability

(Sec. 01, ex. 01; 40 CFR 160.10). Conduct all studies under Good Laboratory Practices (GLPs) that are intended for submission to the U.S. Environmental Protection Agency (EPA) in support of research or marketing permits. Ensure that any study, or portion of a study, intended for submission to the EPA that is performed under contract by independent consulting laboratories, contractors, or grantees is conducted in compliance with GLP standards.

12.2 - Statement of Compliance

(Sec. 01, ex. 01; 40 CFR 160.12). Include one of the following statements of compliance with each study submitted to the U.S. Environmental Protection Agency (EPA):

1. The study was conducted in accordance with Good Laboratory Practice (GLP) regulations with no deviations from the protocol.

2. The study was conducted in accordance with GLP regulations, but with deviations. Describe in detail all of the differences between the practices used in the study and those required by the GLP regulations.

3. The person was not a sponsor, did not conduct the study, and does not know whether the study was conducted in compliance with GLP regulations. Such a submission may result in rejection of the study.

The applicant, the sponsor, and the Study Director are each responsible for signing the compliance statement. Signing a statement of compliance must be taken very seriously. The EPA officials can prosecute anyone under Title 18, United States Code, section 1001 for knowingly and willfully falsifying information in the compliance statement (sec. 12.4).

12.3 - Inspections

(Sec. 01, ex. 01; 40 CFR 160.15). Allow authorized representatives of the U.S. Environmental Protection Agency (EPA) to inspect field unit facilities (sec. 93). These inspections are conducted to determine whether Good Laboratory Practices and other Federal Insecticide, Fungicide, and Rodenticide Act regulations are being properly followed and that data are available to support the study. Allow inspectors access to the facility and to all records and materials required to be maintained for the study (sec. 72); otherwise, the EPA may not consider the data reliable for purposes of supporting an application for a research or marketing permit. Refusing an EPA inspection can invalidate a study and may result in cancellation, suspension, or modification of a research or marketing permit (sec. 93.1).

12.4 - Effects of Noncompliance

(Sec. 01, ex. 01; 40 CFR 160.17). The U.S. Environmental Protection Agency (EPA) may invalidate or refuse to consider any study submitted to them that does not follow Good Laboratory Practice (GLP) regulations.

The deliberate falsification of data, records, and reports, or the refusal to maintain or submit required records can lead to the imposition of civil penalties or criminal prosecution. In addition, the applicant, sponsor, and Study Director who fraudulently sign the compliance statement can be civilly liable.

To avoid penalties, accurately and completely list all non-GLP portions of a study in the compliance statement. Penalties are not assessed for submitting non-GLP studies to the EPA; but penalties can be assessed for affirming that studies follow GLP regulations when they do not.