Forest Service Handbook
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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 70 – Records, Reports, and Archiving

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Duration: This amendment is effective until superseded or removed.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Superseded Document(s):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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70.4 - Responsibility

70.41 - Line Officers

The line officers of each Station, laboratory, or other facility must appoint an individual to be in charge of the archives.

70.42 - Study Director

It is the responsibility of the Study Director to transfer all raw data, documentation, protocols, specimens, and final reports to the archives during or at the completion of the study.

71 - Reporting Study Results

(Sec. 01, ex. 01; Title 40 CFR 160.185).

71.1 - Format and Content of the Final Report

Summarize the results of each study in a final report. These results can also be published in scientific journals; however, journal articles cannot substitute for a final report. The final report must include, but is not necessarily limited to, the following information:

1. Compliance statement (sec. 12.2).

2. Name and address of the facility performing the study.

3. Study initiation and termination dates (month, day, year).

4. Experimental start and termination dates (month, day, year). This information is not required under Good Laboratory Practice (GLP) regulations but can be included for thoroughness.

5. Objectives and procedures stated in the approved protocols, including any protocol amendments or deviations.

6. Characteristics of the test, control, and reference substances including:

    a. Name of chemical compounds (when known).

    b. Chemical abstracts service (CAS) numbers or code numbers.

    c. Strength, purity, composition, and any other important characteristics that are known.

7. Stability and, when relevant to the study, solubility of the test, control, and reference substances under conditions of administration. This information is needed to ensure that the proper amount of test substance was delivered to the test system.

8. Description of the dosage, dosage regimen, method of administration, and duration of dosage.

9. Description of the test system.

10. Description of any circumstances, mistakes, or events which could have affected the quality or integrity of the data.

11. Statistical methods used for analyzing the data.

12. Summary and analysis of the data, including statistical analysis and any transformations, calculations, or operations performed on the data. Data Reporting Guidelines can be obtained from the Office of Pesticide Programs of the U.S. Environmental Protection Agency (EPA). These address scientific issues rather than GLP standards.

13. Statement of conclusions drawn from the data analysis.

14. Names of the supervisors, Study Director, and any other scientists or professionals involved in the study. The names of technicians and other support staff may be included but are not required by the regulations.

15. Signed and dated reports of all scientists involved in the study describing their contribution. This includes work performed at contract laboratories or by consultants, including statisticians.

16. Location of archives (sec. 72).

17. Quality assurance compliance statement (sec. 80.44).

71.2 - Approval

The final report must be signed by the Study Director. This action officially terminates the study. Any revisions made after this time must take the form of official amendments (sec. 71.3). The final report should be thoroughly reviewed by the Study Director, Quality Assurance Unit Manager, and the sponsor before it is signed to avoid unnecessary revision.
Exhibit 01 sets forth a sample checklist for approving the final report, and exhibit 02 provides a sample concurrence format for approving the final report.

71.2 - Exhibit 01

Sample Checklist for Approval of Final Report

Name of Study: Chlorothalonil: Field dissipation

Study Number: CLTH 21402 Study Director: Jessie A. Micales

Initiation Date: April 10, 1993

Information Included:	YES	NO	NOT APPLICABLE
1. Compliance statement		X	
2. Time and place			
a. Name of testing facility		X	
b. Address of testing facility		X	
c. Dates of study initiation and Termination	X		
d. Dates of experimental start and Termination	X		
3. Approved protocol			
a. Objective		X	
b. Changes in original protocols		X	
4. Statistical procedures used		X	
5. Test and control substance identification			
a. Name, chemical abstract number, or code	X		
b. Strength (concentration)		X	
c. Purity		X	
d. Composition		X	
e. Other characteristics		X	
6. Stability of test and control substances	X		
7. Methods used		X	
8. Test System			
a. Number			X
b. Species			X

71.2 - Exhibit 01--continued

Information Included:	YES	NO	NOT APPLICABLE
8. Test System			
c. Subspecies			X
d. Cultivar or strain			X
e. Source of supply			X
f. Age			X
g. Method of identification			X
9. Dosage			
a. Concentration		X	
b. Frequency		X	
c. Method of application		X	
d. Duration of treatment		X	
10. Any circumstances affecting the quality or integrity of the data?		X	
11. Data			
a. Calculations, transformations, or other operations performed			X
b. Summary of data		X	
c. Analysis of data		X	
d. Conclusions		X	
12. Personnel			
a. Study Director		X	
b. Other scientists or professionals		X	
c. Supervisory personnel			X
13. Reports of other scientists or professionals (reports attached, signed, and dated)	X		
14. Location of specimens and raw data		X	
15. Quality assurance compliance statement		X	
16. Study Director's signature and date		X	

Reviewer's Comments:

71.2 - Exhibit 01--continued

1. No information was provided on the test system (field 8).

2. Data transformations were not discussed even though demonstrated in figure 12 (field 11a).

3. Supervisory personnel were not listed (field 12c).

4. The QA compliance statement is missing (field 15).

71.2 - Exhibit 02

Sample Concurrence Format For Protocol Approval

Study Director: Jessie A. Micales

Title of Study: CLTH 21402 Chlorothalonil: Field Dissipation Study

Review of Rough Draft:

Name	Title	Draft Date	Signature	Signature Date
Jessie Micales	Study Director	4/12/93	/s/Jessie Micales	4/12/93
Carolyn Boyle	Quality Assurance Unit Manager	4/17/93	/s/Carolyn Boyle	4/21/93
Others:				
M. F. Maury (peer review)	Microbiologist	4/19/93	/s/M. F. Maury	4/24/93
Carolyn Boyle	Quality Assurance Unit Manager	5/1/93	/s/Carolyn Boyle	5/3/93
John Pelham	Sponsor Representative	5/5/93	/s/John Pelham	5/6/93
Jessie Micales	Study Director	5/10/93	/s/Jessie Micales	5/10/93

71.3 - Amendments

Corrections and additions can be made to the final report after it is signed, even after submission to the U.S. Environmental Protection Agency (EPA). This is done in the form of an amendment, which is made by the Study Director. Amending a final report should be a rare event. The amendment must clearly define which section of the final report is being changed and must list the reasons for such a change. The amendment must be signed and dated by the Study Director and the person responsible for the change. An amendment is not required when reformatting is necessary to bring the report into compliance with EPA submission requirements. If resubmission to the EPA is necessary, the amended final report should be resubmitted in its entirety, not just the affected sections.

71.4 - Retention

The testing facility and sponsor must retain a copy of the final report, including any amendments, for the time period specified in FSH 6209.11.

72 - Archiving

(Sec. 01, ex. 01; 40 CFR 160.190 and 160.195). Ensure that all raw data, specimens, and reports associated with a study are archived. Inspectors from the U.S. Environmental Protection Agency should examine the archives during each inspection. Use care to ensure that all study materials and information are saved and properly preserved (sec. 73).

72.05 - Definitions

72.1 - Materials to be Maintained

Store all raw data produced during a study in their original form except where copies are specifically required. If copies are used, state the location of the original records. Apply these requirements to all laboratory worksheets, records, notes, memoranda, magnetic media, microfilm, microfiche, photographs, software, videotapes, computer printouts, and instrument outputs. Data that are stored in computers should be archived in hard copy form to prevent the loss of information due to computer problems and to guarantee that raw data can be retrieved from outdated hardware and software systems. Outmoded versions of software should also be kept if data are stored electronically. Data stored on magnetic tape should be transferred to fresh magnetic tape every 2 years to prevent loss due to deterioration of the tape. Password protection is not sufficient to ensure the integrity of raw data stored electronically. Use "read only" programs that allow data to be accessed but not altered.

Retain all documentation; records; protocols; specimens; samples of test, control, and reference substances; and the final report generated during a study. This includes all correspondence and documents concerning the interpretation and evaluation of data, even if such information is not included in the final report. Archive this information for all test

substances in a study, even if only one compound is eventually registered. Archive all records and reports on equipment calibration, maintenance, and inspection. Records at test facilities may be kept as originals, photocopies, microfilm, microfiche, or other accurate methods of reproduction. Write the statement "Exact copy of original data" on all copies. Do not destroy original copies. The purpose of copies is to provide on-site records and to ensure the integrity of degradable media records. It is the responsibility of the applicant to keep the original records.

Certain types of specimens, such as soil, water, plant parts, and biological fluids, cannot be retained for long periods of time due to their fragile nature and rapid rate of decomposition. Keep such specimens until the Quality Assurance Unit (QAU) determines that discarding the material does not affect the integrity of the study (sec. 80.44).

The QAU must keep copies of the current master schedule, the protocols, and the records of quality assurance inspections for the time periods specified in section 73.1. Retain summaries of training, experience, and job descriptions for the time periods specified (sec. 73.1).

72.2 - Facilities

Certain conditions must be met to fulfill archiving requirements. Conditions of storage must be adequate to minimize deterioration or chance of loss. It may be necessary to separate reports and written information from samples and chemicals. Each archive area must be provided with adequate security, including fire prevention, pest control, and an evacuation plan. Each test, control, and reference standard must be stored properly (FSH 2109.12, ch. 10).

The archives must be indexed to allow orderly storage and expedient removal of the documents and specimens. Materials can be checked out of the archives on a limited basis. However, it is recommended that these materials not be removed from the archives. Access to the archives must be limited and restricted to authorized personnel.

72.3 - Archiving Methods

Archiving can become an expensive requirement if a large number of studies are being conducted under Good Laboratory Practice regulations. Field units have several options: in-house archives and contract archives.

72.31 - In-house Archives

A station or other facility with a small number of Good Laboratory Practice (GLP) studies should normally not need an extensive archiving facility. A locked file cabinet can serve as an archive under these conditions. More extensive archiving facilities are required if a larger number of GLP studies are being conducted. In this case, archives should be in a separate room or rooms with restricted access.

72.32 - Contract Archives

The field unit can contract its archiving responsibilities. Commercial archives can serve as a repository for storage of all required materials. Alternatively, the field unit can store final reports and other paperwork in its archives and contract for storage of specimens and chemicals. In this case, the archives of the field unit must contain a specific reference to the location of the material stored off-site.

72.4 - Archiving Subcontracted Material

At the termination of a study, the Study Director should retrieve all raw data and reports, or exact copies, produced by independent consulting laboratories, grantees, or other contractors involved with the study. This material should be stored in either Forest Service in-house or contracted archives.

73 - Retention of Specimens and Records

(FSH 6209.11, sec. 44).

73.1 - Duration

73.11 - Fragile Specimens

Retain wet specimens, samples of test, control, or reference substances, and specially prepared, fragile specimens that deteriorate with time only for as long as their quality allows evaluation. Ensure quality assurance verification is obtained before any material is discarded (sec. 80.44).

73.12 - All Other Materials

Retain all materials, other than fragile specimens, for the time periods set forth in FSH 6209.11, section 44.

73.2 - Elimination of Requirement

Material need not be archived after the Forest Service receives written notification from the U.S. Environmental Protection Agency that the information is no longer required. This may occur after a facility inspection and data audit. See FSH 6209.11, section 44 for direction on the disposition of records. However, most private companies prefer to retain the information in their archives in case of legal challenges.

73.3 - Transfer of Archives

If a contract laboratory or archiving facility goes out of business, retrieve any raw data or other materials stored by the facility and place them in the unit's archives or at another contract facility. Notify the U.S. Environmental Protection Agency in writing of this transfer.