

STANDARD OPERATING PROCEDURE
Archiving Study Data, Records, and Other Documents

KEY WORDS

Archivist, quality assurance, SOP, Project Leader, Check-in, Check-out, GLP

APPROVALS

APPROVED BY: **Original Signed by:** _____ DATE: **3/6/97**
John S. Sanders, Ph. D.
Environmental Monitoring Branch Management

APPROVED BY: _____ DATE: **3/5/97**
Heinz L. Biermann, Ph.D.
Environmental Monitoring Branch Senior Scientist

APPROVED BY: _____ DATE: **2/26/97**
Randy Segawa
Environmental Monitoring Branch Quality Assurance Officer

PREPARED BY: _____ DATE: **2/24/97**
Adrian Bradley
Environmental Research Scientist

Environmental Monitoring Branch organization and personnel, such as management, senior scientist, quality assurance officer, project leader, etc., are defined and discussed in SOP ADMN002.

STANDARD OPERATING PROCEDURE
Archiving Study Data, Records, and Other Documents

1.0 INTRODUCTION

1.1 Purpose

This Standard Operating Procedure (SOP) describes the archiving procedures for all records and data associated with studies conducted by the Environmental Hazards Assessment Program (EHAP), Department of Pesticide Regulation, California Environmental Protection Agency. This SOP should be followed for the archiving of all study data.

1.2 Definitions

Archivist is the individual responsible for maintaining the archives.

Project leader is the individual responsible for the overall conduct of a study.

Study file is the file containing all of the records and data for a study.

Study number is the unique identification number assigned to each study.

2.0 MATERIALS

none

3.0 PROCEDURES

3.1 Archived study files shall consist of all raw data, field notes, protocols, interim reports, and a master copy of the final report. Correspondence and other documents relating to interpretation and evaluation of data must also be included in the study file if they are not included in the final report. Raw data results will in most cases consist of the original chain of custody with the analytical result and chemist signature (white copy).

3.2 Study files will be retained by the project leader until the final report is approved. At that point, the project leader will give the study file to the archivist. During the period between initiation of the study and final report approval, the archivist will include the location of the study file in the archives index.

STANDARD OPERATING PROCEDURE
Archiving Study Data, Records, and Other Documents

3.3 Archiving of study files must be done only by the archivist. The project leader must organize the study file so that information is readily retrievable from within the file.

3.4 The project leader shall provide the archivist with an electronic copy of the final report. For studies conducted under Good Laboratory Practices, additional requirements will apply (U.S. EPA, 1992), including the following:

3.4.1 Photocopied material shall not be included in the study file.

3.4.2 All field notes, data records, etc. must be in ink.

3.5 The archivist shall be the only individual with access to the archives. The archivist will designate an alternate when he/she is absent.

3.6 The study files shall be filed numerically by study number. The project leader must request a study number prior to the beginning of the study. Each protocol must have a study number for approval.

3.7 An index of the archived study files shall be kept by the archivist. Other individuals may have copies of this index upon request.

3.7.1 The index shall list the study files numerically by study number.

3.7.2 Each entry on the index shall list the study number, the date the study file was archived, and the title of the study.

3.7.3 The index shall list the location of files for studies still in progress, as stated in section 3.2

3.8 Requests for information contained in archived files will be made to the archivist. Check-in/out procedures are as follows:

3.8.1 Archivist retrieves study file.

3.8.2 The study file number is recorded on the check-in/out log. The check-out date will be recorded, and the archivist and requestor will initial it.

3.8.3 No alterations or additions shall be made to the files while in the borrower's

STANDARD OPERATING PROCEDURE
Archiving Study Data, Records, and Other Documents

possession.

3.8.4 The study file shall be returned to the archivist by the same individual who checked it out. The file shall be returned in the same organized manner as it was checked out. The check-in date will be recorded in the log and the archivist and the borrower shall initial it.

3.8.5 The archivist is responsible for refiling the study file in the archives.

3.9 A check-in/check-out log will be kept by the archivist. This log shall contain the following information:

3.9.1 The study number.

3.9.2 The name of the borrower.

3.9.3 The check-out date.

3.9.4 The check-in date.

3.9.5 Spaces for the archivist and borrower to initial both the check-in and check-out dates.

3.10 Electronic copies of final reports will be stored indefinitely in a manner that prevents deterioration and insures that copies are easily accessible by the archivist. It is the responsibility of the archivist to manage these files, updating electronic format when appropriate. When updates are necessary, the archivist will state the type of change on the archive index, initial, and date the entry.

3.11 Study files will be retained for a minimum of five years. After that time, the archivist may continue storage of files, or transfer to another location. In all cases, study file transfers or disposals will be noted in the archives index.

STANDARD OPERATING PROCEDURE
Archiving Study Data, Records, and Other Documents

4.0 REFERENCES

U.S. Environmental Protection Agency. 1989. Federal Insecticide Fungicide, and Rodenticide Act (FIFRA); Good Laboratory Practice Standards; Final Rule.

U.S. Environmental Protection Agency. 1992. Federal Insecticide Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) Questions and Answers. Office of Prevention, Pesticides, and Toxic Substances.