

<b>STANDARD OPERATING PROCEDURE</b>		
SOP NO.: GLP-DA-02		Page No.: 1 of 4
Title: <b>AUDITING ECOTOXICOLOGY STUDIES</b>		
Revision: Original	Replaces: N/A	Effective: 06/08/99

## 1. **PURPOSE**

This Standard Operating Procedure (SOP) has been developed to provide guidance in conducting data audits of ecotoxicology studies intended to be submitted to the Environmental Protection Agency (EPA) to assure compliance with the GLP Standards (40 CFR Part 160 [FIFRA] and 40 CFR Part 792 [TSCA].

## 2. **SCOPE**

This SOP should be used when conducting ecotoxicology data audits to ensure that applicable study records are fully reflected in the final report. The scope of this SOP entails verification of the data integrity and reconstruction of the study. Adherence to this SOP will also ensure proper documentation and presentation of the audit observations.

## 3. **OUTLINE OF PROCEDURES**

- ! Pre-audit Preparation
- ! Conduct of the Data Audit

## 4. **REFERENCES**

- 4.1 40 CFR § 160 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards; Final Rule, August 17, 1989.
- 4.2 40 CFR § 169 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Books and Records of Pesticide Production and Distribution; August 15, 1980.
- 4.3 40 CFR § 792 Toxic Substance Control Act (TSCA) Good Laboratory Practice Standards; Final Rule, August 17, 1989.
- 4.4 EPA OPPTS Test Guidelines Series 870: Health Effects, U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS), Washington, D.C.

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- 4.5 Good Laboratory Practice Standards Inspection Manual, EPA 723-B-93-001, September 1993 and EPA 723-K-96-001, May 1996.
  - 4.6 Determining Compliance of Audited Studies with GLP Standards Requirements, LDIB SOP-C-02
  - 4.7 Evidence Requirements for Documenting GLP Standards and Study Audit Deficiencies, LDIB SOP-S-02

## 5. AUDIT PROCEDURES

### 5.1 PRE-AUDIT PREPARATION

The final study report is supposed to be a true reflection of the original study records. This needs to be verified during the audit. As a preliminary step before the audit, a copy of the final report provided by EPA should be reviewed for general content ( i.e., GLP elements, consistency of the information presented, agreement of results and conclusions with the tables and/or charts). The auditor should review the compliance statement in the final report to determine:

- ! If the compliance statement states that the study was conducted in accordance with the GLP regulations, then a complete GLP data audit should take place.
- ! If the compliance statement states that the study was not conducted in accordance with the GLP regulations, then a Books and Records inspection should be conducted under 40 CFR 169.2 (k), (Reference 4.2).

A number of organisms, parameters, and data points should be selected for a random evaluation and/or verification against the raw data. The auditor should compile a list of personnel that may be identified in the report for a review of their training records, also compile a list of equipment used on the study to review the use, maintenance and calibration records.

### 5.2 CONDUCT OF THE AUDIT

#### 5.2.1 General Procedure

The documentation and records pertaining to the study will be reviewed. The laboratory and/or field procedures will be reviewed to assess their adherence to the GLP standards. Any audit observations will be discussed with the study director or facility staff member(s) involved with the study.

To support the audit observations, all evidence will be collected and documented according to the guidelines in SOP No. GLP-S-02.

### 5.2.2 Audit Types

There are approximately 18 to 20 types of ecotoxicology studies that are requested by EPA:

- Daphnid acute & chronic toxicity tests
- Mysid shrimp acute & chronic toxicity tests
- Oyster acute toxicity test
- Oyster bioconcentration test
- Oyster shell growth test
- Penaeid shrimp growth test
- Acute fish test (cold & warm water) fresh & salt water
- Fish bioconcentration tests (fresh water)
- Fish early life stage test (fresh & salt water)
- Avian dietary & single-dose tests
- Avian reproduction test (mallard, bobwhite quail)
- Wild mammal toxicity tests (skunks, wolves, foxes, rodents)
- Special avian & mammalian tests
- Algal acute toxicity tests
- Seed germination/root elongation toxicity tests
- Plant uptake & translocation tests
- Small pen/field studies

### 5.2.3 Study Records

The auditor will check the study records for their completeness, accuracy, and consistency in the raw and calculated data, then verify the final report and its results and conclusions against the study data. Adherence to the study performance requirements specified in the protocol, methods, and SOPs will also be checked. Special attention will be paid to correspondence and work performed by subcontractors and consultants. Look for altered data, omitted data, or manufactured data. Collect all evidence to support your observations in the audit report. The following general items will be routinely audited:

- Study protocol including amendments and deviations.
- Training records of study personnel and consultants.
- Current and/or historical SOPs used for the study
- Maintenance, calibration, & use logs of equipment used in the study to generate a numerical value (weight, temperature, etc.) that is used to make a conclusion or present a result in the final report.

- QA inspection/audit records for the study and subcontractors.
- Archival procedures for the study records, retention samples and/or specimens.
- Test substance characterization.
- Test substance receipt, handling, distribution, and accountability records.
- Test system receipt, acclimatization, identification, and housing records.

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Date

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