



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

January 21, 1992

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulation

GLP Regulations Advisory No. 41

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at FTS-398-8265 or (703) 308-8265.

Attachment

cc: M. Stahl
C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dear

This is in response to your letter of November 20, 1991. In that letter you described an ongoing oncogenicity study, sponsored by the Isoprene Toxicology Working Group. As you have indicated, the study will require the maintenance of a fairly large number of isoprene cylinders. The Good Laboratory Practices (GLP) regulations (40 CFR §792.1 et seq) require, among other things, that each storage container for a test, control, or reference substance be assigned to a particular substance for the duration Or the study (40 CFR section 792.105(c)).

EPA believes that the provision for the assignment of storage containers for the duration of a study is a logical and necessary provision of the GLP regulations. In most cases this requirement provides accountability of test material in a manner which poses no unusual burden. However, due to unstable and potentially hazardous nature of the substance in question (isoprene), this GLP requirement may present an unusual burden to the laboratory as well as a potentially hazardous situation.

In granting previous exemptions to this provision of the GLP regulations, EPA has established stringent record keeping requirements as an alternate method of accounting for the storage containers in lieu of actual storage for the duration of the study. For the purposes of exemption from the assignment requirements for this study, EPA will require that the following documentation be retained for the duration of the study: 1) purchase and shipping receipts for all isoprene storage containers received at the laboratory (certified copies dated and signed by responsible persons will be considered adequate); and 2) records of the final destination of the storage containers such as receipts from the recycler or reclaimer (again, dated and signed certified copies will be adequate).

Additionally, this exemption from the assignment requirements for the above study is conditional on the following:

- 1) for this study, a statement shall be included with the statement of compliance or noncompliance required at 40 CFR

section 792 12(b) explaining that this exception to the Good Laboratory Practices regulations is in accordance with the requirements provided in this letter;

2) an inventory shall be prepared of all empty containers before disposal, including sufficient information to uniquely identify containers This inventory shall be maintained in an up-to-date manner, recording all shipments Of empty containers and their disposal. This record shall be maintained for the duration of the study;

3) identification of the locations of the facilities where test material is stored, where empty containers are stored prior to disposal or recycling, where records of shipment of containers are maintained, and where the test substance is used in the study (i.e., testing facility) Within two weeks of receipt of this letter, the location of each of these facilities shall be reported to

David L. Dull, Director
Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Office of Pesticides and Toxic Substances
U. S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Should these conditions not be fully met, the provisions of 40 CFR §792.105(c) shall apply.

In addition, N is reminded that storage, disposal or recycling of containers must bo done in a manner pursuant to all applicable Federal, State, County or local laws

Sincerely yours,

/s/John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

cc: Connie Musgrove, IO
David L. Dull, LDIAD
Francisca E. Liem, LDIAD
Scott Garrison, OE