



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 6, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 56

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 (703) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of September 17, 1992, in which you requested an exemption for the TSCA Good Laboratory Practices (GLP) requirement at 40 CFR 792.105(c) for a two-year inhalation study with the hydrochlorofluorocarbon HCFC-124. In that letter you explained that due to the large quantity of test material (73,000 kg), and the large size and high cost of the four ISO containers to be used, the laboratory would incur a substantial financial burden if required to assign each container to the test substance for the duration of the study. Instead, you plan to recycle the containers during the course of the study to reduce storage costs, that is, the test facility would have two containers on-site, a supply container of test material, and a recovery container of spent material which when full would be returned to the material supplier for recycling. The empty supply container would then serve as the replacement recovery container, and a recycled supply container would be shipped to the facility from the supplier. Based on this description, EPA assumes that the 4 ISO containers would be dedicated to this study, and that no material other than HCFC-124 or the material recovered from its use would be stored in the containers.

You have proposed to keep the following documentation with the study records to track the movement of the ISO containers:

- (1) Receipt documents for each ISO container including the bill of lading and carrier bill.
- (2) Test material tracing form.
- (3) Shipping documents for return of each ISO container to the supplier, including the shipping request, bill of lading, and carrier bill.

The assignment requirement at §792.105(c) is important and normally poses no significant burden. However, given the cost information provided in your letter, and the large volume of material you plan to use, we believe that an exemption is warranted in your case. In granting previous exemptions, EPA has established stringent record keeping requirements as an alternate method of

assigning storage containers in lieu of compliance with §792.105(c). In addition to the documentation you have proposed to maintain in your study records, this exemption from the requirements for the subject study is conditional on the following:

- (1) The receipt documents for the ISO containers shall be signed and dated by the responsible parties;
- (2) Retain signed and dated records of the origin and final destination of the ISO containers, such as receipts from the supplier, recycler, or reclaimer;
- (3) For this study, include a statement under 40 CFR 792.12(b) explaining that this exception to the regulations is in accordance with the conditions of this letter;
- (4) Within two weeks of receipt of this letter, report to the following person the identity and locations of (1) the facilities storing the test material, (2) the facility storing empty containers prior to recycling or return to the supplier, and the recycling or supplier's facility, (3) the facility maintaining the records of shipment, and (4) the test facility using the substance in the study:

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

As a reminder, this letter applies only to the assignment requirement, not to the other requirements of 40 CFR 792.105(c), and it does not supersede other Federal, state, or local laws which may apply, nor shall it apply to any other study.

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

Please contact Mr. Cary Secrest of my staff at (202) 260-8660 if you have any questions regarding the rules or this letter.

Sincerely,

/s/ John J. Neyland, Director

Policy and Grants Division
Office of Compliance Monitoring (EN-342)

cc: Mike Wood, CD
David L. Dull, LDIAD
Francisca E. Liem, LDIAD
Scott Garrison, OE