



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 28, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 62

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, D.C. 20460

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Dear

This is in response to your letter of January 22, 1993, to Dr. David Dull, in which you requested clarification of guidelines concerning retention of test substances. You stated several questions had arisen concerning disposition of empty test material containers and the use of surplus test substance. Your letter was referred to my office for reply.

Specifically, you asked three questions: (1) Can surplus test material and test substance containers be returned to the sponsor or to your permanent facility or must they remain on site until the completion of the study? (2) After completion of the field portion of the study, or upon completion of the entire study, can surplus test substances be utilized elsewhere? (3) Is storage data (temperature, etc.) required for surplus test substances after completion of the field portion of a study? Although not stated in your letter, Steve Howie, of my staff verified during a telephone conversation with you on February 17 that your request for clarification was in reference to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) at 40 CFR Part 160.

Under GLPs, test substance containers must be retained for the duration of a study. Th necessary to comply with the provisions of, 40 CFR 160.105(c), which states in part that "...storage containers shall be assigned to a particular test substance for the duration of the study." To comply with this, the test substance storage containers must be kept until the study is completed. Note that it is not necessary for the containers to be kept at a particular location, except that they must be available for inspection upon request. It would be necessary to maintain records or the location of the containers if such containers are not kept at the testing site or facility.

Surplus test substance which is left over from a study need not be retained until the study is over. It may instead be used for other purposes. If the product is a registered pesticide, it may be disposed of by use in a manner consistent with its labeling, or by appropriate disposal in accordance with applicable labeling and local, State and Federal laws. However, it is necessary in any

event that the receipt and distribution (including use or disposal) be documented as is required at 40 CFR 160 107. It is also necessary in the case of a study of more than 4 weeks duration to assure that a reserve sample of each batch of the test control and reference substance is retained as required at 40 CFR 160 105(d). Note that these samples must be retained for the period of time given at 40 CFR 160 195. Note that any test substance storage container which held test substance actually used in a study must be retained until the study ends; if surplus material in the container is used for other purposes or disposed of the container must still be retained.

Finally with one exception once material is no longer needed for a study it is not necessary to assure its continued physical integrity (i.e., temperature logs etc.). The exception would be in the case of the reserve sample retained for a study of greater than 4 weeks duration Such samples must be stored in archives under conditions which minimize deterioration as stated at 40 CFR 160 190(b). Documentation such as temperature logs or other records must be kept as necessary to support the claim that the archives were in compliance with this section

If you have any questions concerning this response please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

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

cc: David L. Dull
GLP File