



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

November 1, 1991

MEMORANDUM

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

GLP Regulations Advisory No. 37

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 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This letter is in response to your October 29, 1991 letter to me requesting a waiver of the GLP requirement to retain the original container of metam sodium which will be used in a worker exposure study. In your letter you state that the original container will be a railroad car or a large tanker truck. The test material will be pumped from the tanker trucks directly to nurse tanks for application. To further clarify this point, you stated to Dan Helfgott of my staff in a telephone conversation on October 30, 1991, that the material is going directly from the railroad car or tank truck to the application device and that there will be no intermediate storage of the product.

If there will be no intermediate storage of the test substance, N will not be required to meet the requirement of 40 CFR 160.105(c) which states that storage containers shall be assigned to a particular test substance for the duration of the study. However, the Statement of Compliance required by 40 CFR 160.12, which must be submitted with the study, must reflect this deviation from the GLPs. It would also be beneficial to include an explanation of why you were unable to meet this requirement.

In lieu of the requirement of 40 CFR 160.105(c), you will need to take additional steps to document that the substance used in the study was the material delivered from the rail car or tank truck. Therefore, ~ must maintain as raw data the records of delivery, and the identity and net contents of the material delivered. Such documentation may be in the form of a the bill of lading or carrier bills, and a copy of the pesticide label. The use of photographs of the railroad car or tanker trucks, as you suggested in your letter, is also a good idea.

Sincerely yours,

/s/ John J. Neylan III, Director,
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull