UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

May 5, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 46

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

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Dear

This is in response to your letter of March 3, 1992 in which you requested clarification of certain issues covered by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). You requested clarification regarding the definition of a testing facility as described at 40 CFR 160.3, and the responsibilities of the testing facility management as described at 40 CFR 160.31.

You stated that your company oversees a number of field trials which involve a number of independent contractors in different locations around the country. Your company coordinates between subcontractors and the sponsor. The tasks performed by individual contractors is limited to cover application of test .substances, sample collection, and sample shipment. Separate analytical laboratories are responsible for analyzing samples. Each contractor employs a principal investigator who reports to the Study Director, who is usually an employee of your company designated by your management.

There were several questions which you asked in relation to the above scenario. These questions concerned determination of who is the "testing facility" and who is "testing facility management" when actual use of the test substance in the test system is by field cooperators, while facility management responsibilities as defined at 40 CFR 160.31 are assumed by your company and/or by the study sponsor. You asked: (1) whether actual conduct of the study at the field cooperators is consistent with "testing facility management" being at your company; (2) it management duties at 40 CFR 160.31 could be performed in part by the sponsor (such as designating the study director) and in part by your company; (3) whether the "testing facility" is only the field cooperator when management duties are carried out elsewhere; (4) how can management duties at 40 CFR 160.31 be performed in the case of field cooperators being “testing facilities”; (5) whether all field cooperators are ~testing facilities" or whether your company should be defined), the testing facility; and (6) whether it is necessary for copies of the final report to be maintained by each field cooperator.

These questions are largely answered by understanding that

there is only one "testing facility" for any given study regardless of how many organizational subunits, i.e., subcontractors, are involved in its performance. Hence, if a study's performance involves your company and several subcontractors, all of the portions of the different organizations which perform study activities are considered together to be the testing facility The address of the testing facility in such a situation is assumed to be the address where testing facility management and overall study coordination is located. Note that since there is only one “testing facility" it is not necessary for each subcontractor involved in a study to retain a copy of the final report.

"Testing facility management" consists simply of the organizational entity or subunit(s) which provides the assurances required at 40 CFR 160 31. It is not at all inconsistent for testing facility management responsibilities to be centralized at your company while technical performance is conducted by a number of field cooperators. Note, however, that the GLPS clearly state that certain tasks such as designation of the study director are responsibilities of the testing facility management. Therefore, the sponsor could designate the study director only if acting in the role of testing facility management.

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 Dull
GLP File