



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

October 29, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 68

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 June 10 1993 requesting an opinion regarding compliance with the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS)) In your letter you referred to a series of communications between yourself and Dr David L. Dull of LDIAD. Specifically, you requested clarification of reporting protocols of Quality Assurance Unit (QAU) inspections.

On August 19 1993 in a telephone conversation with Steve Howie of my staff you clarified several of the issues. You explained that in your organizational structure, the laboratory Technical Director performs testing facility management functions. The Technical Director does not perform any study related activities. The Technical Director as management oversees the Study Director. The QAU which is also not involved in study related activities, submits reports to the Technical Director to fulfill requirements that it submit reports to management. You asked whether these procedures conflicted with GLPS.

One of the more important requirements of GLPS is as described at 40 CFR 160 35(a), "...[f]or any given study the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. The GLPS are flexible with regard to organizational structure as long as there are not conflicts with requirements such as those at 160.35(a).

It appears that the procedures which you described to Mr. Howie conforms with GLPS. However, please note that it is essential that these procedures be properly documented to ensure that they can at a later date be determined to have been in place and followed at the time EPA inspected your facility it was apparently unclear to the inspection team as to whether the QAU, management study activities were adequately separated from one another.

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