



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

May 1, 1990

MEMORANDUM

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

GLP Regulation Advisory No. 13

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 Liem at FTS-475-9864.

Attachment

cc: C. Musgrove



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Dear

This is in reply to your letter of March 21, 1990, in which you requested clarification regarding the Good Laboratory Practice standards (GLPs). Specifically, you requested guidance regarding Quality Assurance Unit (QAU) inspections, and what inspectional frequency would be considered to be "adequate to insure the integrity of the study, "when a study involves multiple sites, narrow crop windows, and field cooperators that have no QAUs. Since your letter referenced field studies and crops, this reply is being made in the context of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) GLPs.

The GLPs state at 40 CFR 160.35(a) that a testing facility shall have a QAU that shall monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the GLPs. The GLPs further state at 40 CFR 160.35 (b)(3) that the QAU shall inspect each study at intervals adequate to ensure the integrity of the study.

Clearly, the QAU must conduct inspections adequate to provide the assurances required at 40 CFR 160.35(a) and, in the course of so doing, must inspect each study at least once. All parameters must be verified adequate for each site, but it is acceptable to use inspections conducted during other studies to provide necessary assurances. It is also acceptable to use inspections conducted when no study is in progress to assure that methods, personnel, etc. at a particular site are in conformance with GLPs. However, acceptability of such inspections is contingent on assuring that the facilities, personnel, methods, etc., which are inspected are representative of those used in the study. Please note that it is necessary to reinspect facilities periodically to account for changes in personnel, equipment, etc.

Finally, no matter how complete QAU inspectional coverage is regarding the sites involved in a study, it is still necessary to conduct at least one inspection of study activities while the study is in progress.

If you have any questions concerning this response, please contact Steve Howie of my staff at (202) 475-7786.

Sincerely yours,

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

cc: David L. Dull
GLP File