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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 28, 1991

MEMORANDUM

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

GLP Regulations Advisory No. 34

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 is in response to your letter of July 18, 1990, regarding questions on Federal Insecticide, Fungicide, and Rodenticide Act, Good Laboratory Practice standards (GLPs). Your questions restated and answered below:

l.a. Where a subcontractor with an independent quality assurance unit is performing work and generating a report for a sponsor, is a compliance statement required for the analytical report?

Response: Under GLPs there is no requirement to have a compliance statement in each subunit of the overall study such as an analytical report. However, assurance of compliance may be needed by the sponsor or study director, so that they can truthfully sign the compliance statement. Arrangement for such assurances must be worked out between the subcontractor, the study director and the sponsor.

l.b. Do the GLPs mandate that the quality assurance inspections conducted at the subcontractor's facility be reported to both the study director and the "management"? Should management include management at both the sponsor and subcontractor facilities?

Response: The GLPs require at 40 CFR 160.35(b)(4) that status reports be periodically submitted to both the study director and management. "Management" refers to testing facility management, i.e., the person whose responsibilities are stated under 40 CFR 160.31. It is not necessary under GLPs for the QAU to submit multiple management reports, i. e., to both the sponsor and subcontractor management, as long as reports are submitted to the correct person to discharge the duties specified at 40 CFR 160.31.

2. The preamble of the GLPs regulations states at 160.35(b)(3) that each study, no matter how short, must be inspected at least once while in progress. To what extent would the following fulfill this requirement: a) a protocol audit; b) a raw data audit; or c) a draft report review including confirmation the report reflects the raw data?

Response: All of these types of audits may be useful. But please note that there must be enough coverage for a given facility during all audits and inspections so that all aspects of testing are covered. As stated at 40 CFR 160.35(a), the coverage must include facilities, equipment, protocols, personnel, methods, practices, records, and controls. It is not necessary to separately address all of these aspects for each study, as long as overall coverage, that is, the sum of all inspections, is balanced to include all aspects. Therefore, protocol audits, raw data audits, and draft report reviews must not be the sole focus of inspections.

If you have any further questions please give Steve Howie of my staff a call at (202) 308-8290.

Sincerely yours,

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

cc: David Dull, EPA
GLP File