UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

July 16, 1990

MEMORANDUM

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

GLP Regulation Advisory No. 15

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-475-9864.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in response to your letter of May 14, 1990, to Mr. A. E. Conroy II in which you requested a opinion regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). Your letter was referred to me for reply.

Specifically, you requested clarification regarding the duties of the Quality assurance unit (QAU) and the study director under GLPs in the situation where contract laboratories are cooperating on studies. You suggested that a study director employed by a competitor with whom you are cooperating on a GLP study would be in a position to gain access to confidential business information. This would occur through QAU reports as required by GLPs and through inspections by such study director of your facilities. You also suggested that practical difficulties that arise in gaining timely approvals of procedure changes by off-site study directors, and that the involved nature of field studies makes it impossible for one person to be completely responsible for such studies. You proposed that these problems could be solved by transferring study director oversight responsibilities to on-site principal investigators.

The GLPs require at 40 CFR 160.35(b)(3) that the QAU bring to the attention of the study director and management any problems which are likely to affect the integrity of the study. At 40 CFR 160.35(b)(4), the QAU is further required to submit written status reports to the study director, noting problems and corrective actions. Since these reports need only contain study-performance information, our office does not believe that they involve confidentiality issues, and thus must be submitted to the study director as required.

The GLPs do require at 40 CFR 160.33 that there be one study director to provide assurance that certain tasks are properly performed. As you pointed out, the study director must authorize deviations in standard operating procedures and must sign protocol revisions. While such approvals should be done as early as possible, conduct of the study is not required to cease before the approval action. Consequently, these requirements are not in conflict with having an off-site study director. Further, the study

director has no explicit site-inspection duties under the GLPs. While the study director must maintain overall responsibility, delegation of the practical oversight of technical efforts is not prohibited by the regulation. This allows necessary technical duties to be assigned to on-site individuals (e.g., to principal investigators) and should relieve your concerns regarding the presence of persons who may be security risks. Please note that the study director must sign the compliance statement for the study.

It is our opinion that there is no inherent conflict with GLPs when more one contracting facility and/or location is involved in a study. 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: Connie Musgrove
David L. Dull
GLP File