



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

GLP Regulation Advisory No. 20

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 398-8265 or (703) 308-8265.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dear

This is in reply to your letter of April 11, 1990, in which you requested comments concerning Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). Specifically, your letter dealt with the difficulty of assigning a single study director to one research project, as required at 40 CFR 160.33.

According to your letter, the program conducts approximately 200 research projects annually to support minor uses of pesticide. The work on a given product may be performed at several different field and/or laboratory sites, each with its own management unit. While the National Headquarters coordinates all research, it does not have direct technical control of the performance of work at any of the field or laboratory sites. You proposed that we accept a "multi-study director" concept that defines each field trial at each location with a single pesticide/commodity as a study. You would further define the analytical phase of each project as a separate study.

I believe that the Headquarters Coordinators could meet the requirements of a Study Director, and we need to explore this option rather than the multi-Study Director system that you have suggested. The latter would require reproposing and amending the GLP regulation and would, in my view, compromise one of the primary tenets of the current regulations, accountability.

The requirement at 40 CFR 160.33 states that the study director represents the single point of study control, and is responsible for the overall conducting of the study. Dividing a technical effort into multiple studies creates multiple points of control, and means that there is no individual with overall responsibility. The accountability provided by a single study director (who plans, oversees, and controls the interpretation, analysis, documentation, and reporting of the results) is one of the most important aspects of the GLP standards. In addition, the regulations define a study as a complete experimental effort.

Separate phases whether by location or type or work performed (i.e. analytical versus field) do not constitute separate studies under the current regulations.

I would see with projects, a single study director who takes overall responsibility for assuring the adequate completion of the entire research project, but who need not be directly involved in performance of on-site technical effort. Thus, for projects coordinated by the study director would oversee the performance of on-site technical directors (or assistant study directors) who are responsible for the individuals carrying out field and analytical duties.

I believe that we can resolve these issues, as you suggest, with a meeting. The Office of Pesticide Programs (OPP) has also expressed an interest in such a meeting. I understand that you also have several technical questions regarding the GLPs, and I would be willing to discuss these at our meeting. If you would please contact me at your earliest convenience, we can arrange a suitable time and place; I will coordinate with the appropriate OPP staff. I can be reached at 202-382-7825.

Sincerely yours,

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

cc: David L. Dull
Anne Lindsay
Rick Tinsworth
Penelope Fenner-Crisp
GLP File