



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 15, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 48

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, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear

This is in reply to your letter of May 15, 1992 to Phyllis Flaherty, of my staff. Your letter referred to the requirements for studies performed in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) You specifically requested clarification regarding what the duties of the quality assurance unit (QAU) are under FIFRA GLPS and whether a person in the QAU must belong to a national quality assurance organization in order to be qualified to conduct QA audits.

The requirements for the QAU are clearly stated at 40 CFR 160.35 As this section states, there are a number of specific duties that the QAU must perform, and the QAU must be entirely separate from and independent of personnel engaged in the direction or conduct of the study This standard does not require the QAU to belong to any national quality assurance organizations.

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 Dull
GLP File