



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. 19

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



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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Dear

This is in response to your letter of March 2, 1990 to Phyllis Flaherty, of my staff. In your letter, you requested clarification regarding thirteen area of concern that your notes from the January 8, 1990 FIFRA GLP Workshop suggested were under review at this time, or would require follow-up.

Your questions covered programmatic issues, such as scheduling of laboratory audits, and policy issues, such as interpretation of the GLPS. Our office has responded in writing to persons asking questions concerning several of these issues.

I have enclosed copies of such letters that relate to the policy issues that you identified in your letter, including: routine analyses (question 3); revision of policies regarding penalties (question 4); subdivision of studies (question 5) and; inspection of studies (question 6); timing of transfer to archives (question 8); and documentation of characterization (question 13). The issue of test article container assignment has been handled on a case-by-case basis (question 9).

The other policy issues that you identified in your letter are still under review, and may be addressed in a question-and-answer document that our office is currently preparing. 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

Enclosures

cc:: David Dull (letter only)  
GLP File (letter only)