



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

April 12, 1990

MEMORANDUM

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

GLP Regulation Advisory No. 12

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 January 18, 1990, requesting clarification of your obligations regarding archiving of raw data. In your letter you stated that you are a contract laboratory, and that many of your clients prefer to archive original data generated by you. You asked whether you were required to archive authenticated copies. You explained that, due to the large amount of data often generated, it becomes difficult to archive data immediately at the completion of a study, and you asked whether it would be acceptable to archive within 30 days of report completion.

Under the federal insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs), there must be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports (40 CFR 160.190(b)). Further, the study director is required to assure that all such records are transferred to the archives during or at the close of the study (40 CFR 160.33(f)). This ensures that data are fully accounted for at the completion of the study. This must be completed prior to the signing of the compliance statement by the study director.

There is flexibility in the location of the archives of raw data and specimens. At 40 CFR 160.190(b), the GLPs state that retention of records at alternate locations is acceptable, provided that there is specific reference to those locations in the archives. Such off-location archives must still meet the full requirements of 40 CFR 160.190. Whether records are archived at the registrant's facility, at a contractor's central location, or at separate contractors' locations, the study director must assure that all raw data and specimens have been archived before the study report is signed. If the study director cannot assure that records at a particular location are archived correctly, he cannot sign a compliance statement that indicates that this standard has been met.

The sponsor is ultimately responsible for the raw data supporting the study (40 CFR 169.2(k)) and may require archived records to be shipped to the sponsor's archives at some date following a study. Alternatively, a testing facility may wish to consolidate archives at one location during or after a study. Such

transfers of archives do not present a problem if the records are properly accounted for and the testing facility maintains records of the archive location(s) at all times.

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, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull
GLP File