



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 28, 1991

MEMORANDUM

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

GLP Regulations Advisory No. 31

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: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of December 11, 1989, to Dr. David Dull regarding Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA) Good Laboratory Practice (GLP) standards. That letter was transmitted to my office for reply.

In your letter you raised questions regarding: (1) the time frame allowed for archiving raw data at the close of studies; (2) EPA's interpretation of the meaning of "four week duration," in reference to sections 160.105(d) and 792.105(d); and (3) what EPA's plans are concerning making compilations of interpretations and clarifications available to the public.

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 signing the compliance statement.

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 a 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. In the case that 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 (e.g., 40 CFR 169.2(k)), and may request

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.

Please note that this position regarding archiving also applies to the TSCA GLP standards at 40 CFR Part 792.

As you indicated in your letter, the term "four week experimental duration" is tied to the experimental start and termination dates. This is clarified in the preambles to the August 17, 1989 rules amending the FIFRA GLPs (54 FR 34052, 34061) and the TSCA GLPs (54 FR 34034, 34040). These dates are clearly defined, and are not limited to the period of administration of the test substance.

Finally, EPA is preparing a question and answer document to improve communication of interpretations regarding GLPs to the regulated community.

If you have any questions concerning this response, please call 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

cc: David Dull
GLP File