



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

May 26, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 47

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



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Dear

This is in response to your letter of February 11, 1992, to Dr David Dull, which was referred to my office for reply. In your letter you requested clarification on self-carbonized paper and whether carbonized copies (i.e., second and third copies on carbonized paper) would suffice for the raw data. The letter stated that the carbonized pages are "exact, and stamped as such.

Under 40 CFR 160.195(i) exact copies, which could be carbon copies, can be used to meet certain Good Laboratory Practice (GLP) data archiving requirement. For example, such exact copies may suffice for audit purposes, or for meeting data archiving time constraints. However, original records (top original) must be kept to meet the Federal Insecticide, Fungicide and Rodenticide Act section 8 books and records requirements as stated at 40 CFR 169.2(k). These regulations require the producer/sponsor to maintain all underlying raw data, which means that originals must be kept.

If you have any questions, 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

cc: David Dull
GLP File