UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES
June 1, 1989

MEMORANDUM

SUBJECT: OCM Policy on Interpretation of GLP Regulations

FROM: Ken Kanagalingam, Chief
Scientific Support Branch (EN-342)

THROUGH: David L. Dull, Director
Laboratory Data Integrity
Assurance Division

TO: Addressees

The community that the laboratory inspection/data audit program monitors, as well as inspectors and other interested personnel periodically raise questions related to interpretation of the GLP regulations. Often the questions are relatively simple and straight forward to which all inspectors would provide a uniform and consistent reply. However, there are instances when several interpretations are possible or clarification may be necessary. In such cases, these questions must be directed to the Policy and Grants Division for response. Only this group is authorized to provide policy interpretations.

With the new comprehensive regulations covering newer areas of study due to be promulgated soon the frequency of inquiries is likely to rise. As a standard procedure please direct the inquirers to present the questions in writing and address them to David L. Dull, Director, LDIAD, who will send the to Jack Neylan, Director, Policy and Grants Division, OCM (EN342) at headquarters.

When the Policy Division formulates its interpretation and provides replies, the response will be copied to the Director, LDIAD. We in turn will distribute the response as “GLP Regulations Advisory” to all EPA GLP inspectors.

As Advisory No. 1, I attach herewith for your information a response by Policy and Grants Division to such inquiry.

Attachment

Addressees

cc: Connie Musgrove
Jack Neylan

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Dear

I have reviewed the points that you expressed in your letter dated November 16, 1988. Please note that the responses below reflect current Agency policy in these areas.

l. Solubility.

As you pointed out, section §160.135 of the 1987 proposed FIFRA Good Laboratory Practice (GLP) standards does not distinguish between organic solvent and water solubility studies. Since there is no distinction in the regulations, you must assume that any solubility study, including organic solvent solubility, is subject to the full regulations.

2. Identification of Impurities.

Section §160.105(a) of the GLPs require adequate test, reference, and control substance characterization to be performed and documented before study initiation. "Adequate" characterization, e.g., specific level of impurities, is study specific and hence not defined further in the GLPS. It is appropriate to consult with the Office of Pesticide Programs (OPP) to determine if there are characterization requirements beyond those that your laboratory believes are sufficient. A decision to reject a study may be made by OPP independently of GLP compliance. Documentation as to when the levels of impurities were identified should be included in your submission to OPP.

3. Computer Validation of Analytical Results.

Design and use of an automated data collection system falls under GLPs if the system is used in the generation of raw data as defined in §160.3 and/or in the conduct of the study as addressed in §160.130(e). In such cases, the equipment must be of "appropriate design and adequate capacity" as specified in §160.61, and be adequately tested, calibrated and/or standardized, maintained, and records kept for, as specified in §160.63. Written SOPs are required for this equipment. No distinction is made between the automated data collection equipment and other analytical instrumentation, so the same standards must be interpreted to apply to both.

As long as the data capture system meets these criteria, there is latitude in its design. Again, the testing facility will be expected to provide documentation in the form of SOPs and other written records to support the validity of the system however it is designed.

I hope this provides adequate clarification to enable you to proceed with the development of your GLP compliance plan. Should you have further questions about these or other GLP concerns, please contact me.

Sincerely,

/s/Phyllis E. Flaherty
Acting Director
Policy and Grants Division

cc: John J. Neylan III