



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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

July 24, 2012

Dear Stu:

Thank you for your letter of July 18, 2012. In this letter you inquired about the scope of EPA Advisory 83. You also wanted me to confirm that the new interpretations of the GLP regulations expressed in Advisory 83 regarding raw data apply equally to all paper records described in 40 CFR part 160.195(i), namely that they need only be retained as true copies and no longer must the original paper also be retained.

You specifically mentioned paper Quality Assurance records that could be converted into appropriate true copy e-records, and after verification and documentation of each e-record as a true copy, the original paper record may be discarded.

The Agency's position on copies versus originals of data and other records in the context of GLP is set forth in the regulations and in Advisory 83. When copies are relied upon, rather than originals, they need to be true copies. EPA Advisory 83 also applies to all paper records described in 40 CFR 160.195.

Please do not hesitate to contact me whenever you have additional questions arising from this letter.

Thank you for your continuous support of the EPA GLP program.

Sincerely,

A handwritten signature in blue ink, appearing to read "Francisca E. Liem".

Francisca E. Liem

Director, GLP Program