

Helping Grow Your Business with Good Science & Compliance

**PEAK Quality Consulting, Inc.**

113 McIntire Lane  
Cary, NC 27513-4019  
Cell 919-602-8568  
Email [stu@peakqc.com](mailto:stu@peakqc.com)

July 18, 2012

Francisca Liem, Director  
GLP Program  
Email Letter

Dear Francis,

In my GLP training and consulting activities, I have had inquiries regarding the scope of the new EPA Advisory No. 83. I am writing to you seeking additional confirmation and clarification based on your experience with this new guidance document.

Will you please confirm that the new interpretations of the GLP regulations expressed in EPA Advisory No. 83 regarding raw data apply equally to all paper records described in 40 CFR Part 160.195, namely that they need only be retained as true copies [§195(i)]. No longer must the original paper also be retained.

For example, facility management desires to use an appropriate electronic record (e-record) format to: reduce paper storage space in GLP Archives and QA files/Archives, provide for more rapid access to view and produce copies of records (including during an Agency inspection), transfer records (e.g., §195.3(g)), and provide protection from data loss due to fire and/or natural disasters. The new interpretations may be applied to all paper QA records required to be retained by §195(d-e), including letters or signed/dated printouts of emails used to issue inspection reports.

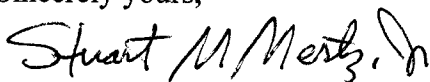
Specifically, a facility may convert their paper QA records into appropriate “true copy” e-records. Then after verification and documentation of each e-record as a “true copy” and e-record “true copy” backup, the paper record may be discarded. All other requirements and guidance identified in Advisory No. 83 pertaining to e-records apply here as well. The GLPS Oct 1989 Preamble section H.3.ii.Response §195(i) gives additional guidance on verification of the authenticity of the copies.

Your confirmation that the new interpretations expressed in EPA Advisory No. 83 apply equally to all paper records described in 40 CFR Part 160.195 will be greatly appreciated.

I desire to submit the content of this letter and your reply as an article in the QA section of a future NAICC Newsletter (and maybe the SQA Newsletter too) because there is value to all in the EPA GLP community. I hope this will be acceptable to you.

Thank you so very much for your assistance in this matter.

Sincerely yours,



Stuart M Mertz, Jr. PhD  
President, RQAP-GLP