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Discussion on the retention of original record

>>> COMMENT>>>

I like to know if the retention of original electronic record is required in the following case.

- 1) Measuring the absorbance by the endpoint method using UV.
- 2) The absorbance is just a number and no dynamic data is required. In other words, the reprocessing of the data is never be done.
- 3) The measured absorbance and required meta data such as operator information, time/date, wave length and sample ID are printed out, and the printout is retained as a CGMP paper record.
- 4) The printout is signed and dated by the operator.
- 5) Then the second person reviews the printout and the related audit trail in the UV, and the test is authorized by this second person's review.
- 6) However, the electronic data of the UV is not backed up. This means that the audit trail is not guaranteed to be retained for years and years in case of such as HDD crash.

I think that the paper record without audit trails is sufficient and the retention of original electronic record with audit trail information is not required in the above case. The reason is;

- A) No dynamic data is required since the reprocessing the data is never be

done.

B) The second person has checked the audit trail and authorized the test

C) So the retention of audit trail may not be mandatory

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