

From: OC GCP Questions
To: [REDACTED]
Subject: Part 11 application to the True Copy Process - Including Signature and newly-created Electronic Copy
Date: Wednesday, January 25, 2017 10:43:00 AM
Attachments: [REDACTED]

Good morning –

Please see the Center for Drugs (CDER) Office of Medical Policy (OMP)'s response to your email.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Here is our cleared response:

Question 1: I am attempting to write an SOP for an organization that wishes to create certified electronic copies of original, hardcopy documents that are governed by the Predicate Rules. The organization will then destroy the hardcopy documents. Procedurally, the person will transform the hardcopy document (required by predicate rules) into an electronic file/record, then they will review it to assess its accuracy, completeness, etc. Is the storage/management of the newly-created electronic copy subject to 21 CFR Part 11?

Response: Yes, part 11 requirements apply to electronic records and electronic signatures and to the electronic systems that are used to create, modify, maintain, archive, retrieve, or transmit them.

Question 2: The person reviews the electronic copy, then they will either (preferred)

- a) Affix a signature/date to the copy by using an electronic/digital signature.
 - Is this signature-affixing process (that certifies this predicate-rule-required document as a true copy) subject to Part 11?

Response: Yes, Part 11 requirements would apply to electronic signatures that are used for electronic records that fall under the scope of the Part 11 regulations.

- b) Create/sign a second document that certifies this newly created copy is a true copy
 - If this second document is kept/signed electronically, is it subject to Part 11?

Response: Yes, Part 11 requirements would apply to electronic signatures that are used for electronic records that fall under the scope of the Part 11 regulations.

Question 3: I recognize that the FDA does not want to be prescriptive, but if the answer to any of these questions is “Yes”, then is there some scenario to create certified electronic copies of predicate-rule documents that will not necessitate Part 11?

Response: FDA permits the interchangeable use of electronic records and paper records for the archiving and protection of records provided that recordkeeping and retention requirements are met (see 21 CFR 56.115, 312.57, 312.62, and 812.140).

If the sponsor or other regulated entity intends to use an electronic copy in place of the paper source data (i.e., intends to destroy the paper source data), then part 11 regulations would apply to the electronic system used to create the copy (see §§ 11.10 and 11.30)). A process should be in place to certify that the electronic copy is an accurate representation of the original paper document. The copy of the original record should be verified as having all of the same attributes and information as the original record and it should be certified as indicated by a dated signature. Sponsors and other regulated entities should have written procedures to ensure consistency in the certification process.

Part 11 regulations would not apply if you plan to retain your hard copy (i.e., not destroy the paper source data) and rely on the paper hard copy to perform your regulated activities. In such cases certification of an electronic copy would not be necessary because you are retaining and maintaining the paper source data.

From: [REDACTED]
Sent: Thursday, January 12, 2017 2:19 PM
To: OC GCP Questions
Subject: Part 11 application to the True Copy Process - Including Signature and newly-created Electronic Copy

Good afternoon,

I am attempting to write an SOP for an organization that wishes to create certified electronic copies of original, hardcopy documents that are governed by the Predicate Rules. The organization will then destroy the hardcopy documents.

Procedurally, the person will transform the hardcopy document (required by predicate rules) into an electronic file/record, then they will review it to assess its accuracy, completeness, etc.

- Is the storage/management of the newly-created electronic copy subject to 21 CFR Part 11?

The person reviews the electronic copy, then they will either:

1. (preferred) Affix a signature/date to the copy by using an electronic/digital signature.
 - Is this signature-affixing process (that certifies this predicate-rule-required document as a true copy) subject to Part 11?
2. Create/sign a second document that certifies this newly created copy is a true copy
 - If this second document is kept/signed electronically, is it subject to Part 11?

I recognize that the FDA does not want to be prescriptive, but if the answer to any of these questions is “Yes”, then is there some scenario to create certified electronic copies of predicate-rule documents that will not necessitate Part 11?

Kind regards,

[REDACTED]
[REDACTED]