

From: OC GCP Questions
To: [REDACTED]
Subject: Certified Copy of Medical Records
Date: Thursday, May 11, 2017 8:55:00 AM
Attachments: [REDACTED]

Good morning –

Below is the cleared response from FDA's Office of Medical Policy (OMP):

In order to answer your question more fully, we would need more information on how you plan to use the printed copies of the EMR. In general, for inspection purposes, if simple screenshots or paper printouts of the EMR fails to capture important metadata (e.g., the data originator and the audit trail of the data) that are recorded in the electronic system, then such paper records would not be regarded as certified copies of the originals and would be considered incomplete unless the accompanying metadata are included. FDA would require access to the EMR used to produce those data to review the complete record (see 21 CFR 312.58, 312.68, 812.140, and 812.145). Please let us know if you have additional questions.

Kind regards,

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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.

From: [REDACTED]
Sent: Monday, May 08, 2017 2:43 PM
To: OC GCP Questions
Subject: Certified Copy of Medical Records

Hello,

I have a question regarding certified copy of records. Per ICH E6(R2) it is a copy of the original record that has been verified by a dated signature or by generation through a validated process.

If a site is printing the record directly from the validated EMR system and that record has a date and time stamp on it, would that be considered "generation through a validated process?"

Thanks

[REDACTED]