

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question regarding certification of EMR
Date: Friday, November 03, 2017 10:39:20 AM

Good morning –

Please see the cleared response (in red) from FDA's Office of Medical Policy. Thank you for your patience.

Kind regards,

The OGCP Group

From: [REDACTED]
Sent: Tuesday, October 24, 2017 11:53 AM
To: OC GCP Questions
Subject: Question regarding certification of EMR

To whom it may concern:

Certification of EMR printouts when read only access cannot be granted to monitors appears to be interpreted by institutions/sites/investigators within many differing details. I have 2 questions about certification.

- Some institutions do not certify their printed EMR stating they provide over the shoulder viewing by the monitor, auditor, inspector upon request. Does this policy meet the regulatory requirements for complete access to source (EMR)?

Yes. It is not necessary to make certified paper copies of original electronic records if the original electronic record is available and accessible for viewing by the monitor, auditor, or inspector upon request.

- Sites who utilize the EPIC EMR system, however, cannot provide read only access to monitors, auditors, inspectors, print EMR with the a footer that shows the name of the person who accessed the system and printed the copy, the date of printing, the page number, and the time stamp. Does a statement of certification also need to be included on these print outs with an initial and date?

Yes, certification is needed when making copies of paper or electronic documents. Certified paper copies of electronic documents should be generated through a validated process or verified (e.g., by a dated signature) as an exact copy having all of the same attributes and information of the original documents, including any associated metadata (e.g., units of the data, date and time stamps, data originator, and other audit trail information associated with the data). If screenshots or paper printouts of an EMR are used to serve as a paper record and that record fails to capture important metadata and audit trail information that are recorded in the electronic system, such paper records would be regarded as incomplete unless the accompanying metadata and audit trail information are included. FDA would require access to the electronic system used to produce those data to review

the complete record (see 21 CFR 312.58, 312.68, 812.140, and 812.145).

- If a staff member is delegated to certify EMR, does a statement of certification, in addition, to the initial and date of the designee need to be added to the printed EMR copies?

See above response.

Thank you for your response

Best Regards,

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]