From: OC GCP Questions
To: [redacted]
Subject: Documentation for off site radiology
Date: Monday, June 01, 2015 11:46:35 AM

Good morning --

Imaging scans and exams (x-ray, CT, MRI, ultrasound, nuclear medicine, etc) on research subjects and clinical trial patients should be performed in a manner consistent with the study's protocol. However, I am not aware of any FDA regulation that specifically addresses imaging. I assume documentation for imaging and testing would have to comply with state and local laws.

I did find an FDA website that discusses MRIs. See the links below.
Medical Imaging > MRI (Magnetic Resonance Imaging)
Radiation-Emitting Products

You might want to send your question to the Center for Devices (CDRH). Their email address is DICE@fda.hhs.gov

Kind regards,

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

From: [redacted]
Sent: Friday, May 29, 2015 4:16 PM
To: OC GCP Questions
Subject: Documentation for off site radiology

Hello,
What documentation is necessary when using an off-site imaging center for chest x-ray or MRI necessary for inclusion/exclusion screening in a clinical trial?

Are there specific certifications like the CAP or CLIA that are collected for clinical laboratories? Is it necessary to collect calibration records or nuclear licensing documents? What about the license & CV of the facility director?

Thank you,
[redacted]