

2005D-0195 Guidance for Industry and FDA Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System
FDA Comment Number : EC2

Submitter : Mrs. Susan Miller

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Organization : Mrs. Susan Miller

Category : Health Professional

Issue Areas/Comments

GENERAL

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My comment is regarding Docket No. 2005D-0195, CDRH 200439. The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9 DRAFT GUIDANCE. Document issued on: July 15, 2005.

Question 2: [Repeated as question 18 under Quality Assurance/Equipment/Weekly Equipment Quality Control]: We are using an FDA cleared single use cushion pad (e.g., MammoPad) when performing mammograms on some of our patients. Do we have to include the pad when performing the phantom and dose QC tests?

If you are not using a cushion pad for the majority of your patients, you do not have to include the cushion pads when performing the phantom and dose QC tests. However, if you are using a cushion pad for the majority of your patients, you must include the cushion pads when performing the phantom and dose QC tests in order to simulate as closely as possible your typical clinical conditions (21 CFR 900.12(e)(2)). If you routinely use the cushion pad on both the bucky and the compression paddle, you must use 2 layers of the cushion pad (may be achieved by folding over a single cushion pad) when performing the phantom and dose QC tests. In order to reduce expense, you may use the same cushion pad repeatedly when performing the tests. Because the phantom and dose tests are the only QC tests affected by the use of a cushion pad, the facility does not have to include the cushion pad when performing other QC tests.

My comment:

When using Kodak 2190 fast screens with Kodak 2000 film and imaging a fatty breast, I have evidence of what a Biolucent representative referred to as the large white egg effect. The facility that was performing testing using these pads showed that the same breast and view imaged with the pad showed a subtle large oval opaque density, which was eliminated upon removal of the pad. My opinion is that the pad reduces image quality by reducing the ability to obtain maximum compression, creating more distance between the breast and the image receptor showing some magnification and reducing image sharpness. Furthermore, the opaque density created by the pad could possibly obscure some types of breast tissue and prevent the diagnosis of breast cancer. FDA's approval for the device (Class 2) states that the manufacturer received a 510K based on a claim it was "substantially equivalent", to a pre-1976 device. Because mammography technology has changed dramatically since 1976, I think that this device was approved on erroneous information and should be removed from the market until it can be approved using modern technology, in particular, fast screens and digital imaging of fatty breasts. I have submitted an example to Dr. Charles Finder for his review of the large white egg effect. This comment is my personal opinion and does not reflect the opinion of any corporation or government agency.

Susan Miller, Certified MQSA Mammography Inspector #I2085
 State of Wisconsin

PO Box 2659
Madison, WI 53507-9772