

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

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Organization : State of Wisconsin

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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The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9 DRAFT GUIDANCE Document issued on: July 15, 2005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:

If only one pad is acceptable for multiple phantoms, I think there should be a use limit for the number of times that the same pad can be used. Think of this scenario: a facility uses the same pad for each phantom image for five years and two units. How is this pad stored between uses? Does the adhesive pick up any debris? Would this pad still be reflective of clinical use? Do the cushion pad manufacturers verify that each pad is free of any artifacts or defects, and that each batch of pads is reproducible? When a facility uses the cushion pads for the majority of mammography patients, it would be more reflective of clinical imaging if a different pad were used for each phantom. One pad may look fine on a phantom, whereas another may have an artifact. Testing a one time use pad would only indicate that the individual pad was problematic (or not) but wouldn't necessarily tell you anything about other pads. The facility should be aware if these differences exist. At the very least, there should be a use limit for the number of times a pad can be used for phantom testing. Also, even though the guidance states that the pads must be used for the phantom and dose QC testing, I think it needs to be made clearer that this includes the weekly phantom testing, as well as the annual phantom and dose testing performed by the medical physicist.

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