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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

Subject: Docket No. 1435; Policy Guidance Help System #6

To whom it may concern:

The American College of Radiology has the attached comments to the FDA's Policy Guidance Help System #6 draft that covers the testing of mammography automatic exposure control systems. Thank you for the opportunity to review this important guidance. If you have any questions, please contact me at (800) 227-6440, ext. 4141.

Sincerely,

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cc: Charles Finder, M.D.
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MQSA FINAL REGULATIONS
MODIFICATIONS AND ADDITIONS TO POLICY GUIDANCE
HELP SYSTEM #6

Comments
American College of Radiology

General

The ACR believes that the proposed guidance helps clarify a number of important points for medical physicists and mammography facilities. We commend the FDA for taking a reasonable and clinically relevant approach to this guidance.

AEC Performance Testing – Annual Physics Survey and Mammography Equipment Evaluation

Page 4, Question 1.
We suggest clarifying the definition of "Mean Optical Density" further by adding the following italicized phrase since later discussions relate Mean Optical Density to a specific equipment configuration:

"Mean Optical Density (MOD) is defined as the average of the optical densities measured on the images produced during the AEC performance test using phantom thicknesses of 2, 4, and 6 centimeters *(for a given equipment configuration)."*

Page 4, Question 1.
We suggest removing "target-filter" combinations from the examples of "equipment configuration" and including

1. image receptor size (18 cm x 24 cm vs. 24 cm x 30 cm) and
2. screen (or film) type (e.g., Kodak 2000 vs. Kodak 2190 screens)

as examples of "equipment configurations." The AEC should be calibrated for target-filter combination changes and therefore should be capable of achieving ±0.15 optical density. Conversely, it is unreasonable to expect the AEC system to compensate for cassette-to-cassette changes in screen speed or size-to-size variations in film emulsion speed.

Page 5, Question 3, Step 2.
Since this guidance will be issued well past October 28, 2002, we suggest simplifying the guidance by removing any reference to the AEC performance criteria that was in effect before October 28, 2002. This comment also applies to Pages 6, 7 and 9.

Page 8, Question 7.
We recommend that image receptor size be considered an "equipment configuration." The testing guidance provided in Question 7 would be more consistent with the testing instructions

provided in Question 4. We also agree with the FDA's recommendation here that the large image receptor be tested annually as described in this paragraph. This would be consistent with the instructions provided in the *1999 ACR Mammography Quality Control Manual.*

Page 9, Question 8.
The guidance for equipment evaluations in the second paragraph ("if designed to operate outside that range [2-6 cm], the unit should meet the manufacturer's specifications over such additional ranges") may conflict with the guidance for annual surveys provided in the first paragraph ("FDA recommends that a technique chart be developed showing appropriate techniques...for the different breast thicknesses and compositions so that optical densities (OD) within ±0.15...of the MOD under AEC testing conditions can be produced"). In both cases we recommend following the *1999 ACR Mammography Quality Control Manual* recommendation that "the AEC should be able to maintain constant film optical density to within ±0.30 of the average [now defined as the MOD] over the phantom thicknesses...tested."

Page 10, Question 15.
We agree with the guidance provided in this paragraph about not displaying the size of the AEC detector on the paddle for some systems. However, it would be helpful to provide a common example, such as the GE 2000D full-field digital mammography unit, for clarification.

Phantom Images Exposed in a Fully Automatic AEC Mode, if that is the clinically-used Technique

Page 15, Question 10.
One of the ACR's committee members wrote the following about phantom testing in the Full-Auto AEC Mode:

"This always causes problems. I always tell the technologists to shoot the phantom just as they would do clinically, but the problem comes in when using the Auto programs in that the kVp might go up just because the phantom is not exactly in the same position. A prime example is the GE 800T in which the switch between 25 and 26 kVp usually occurs at just over 4 cm. One day you can make an exposure in the Contrast mode and get 25 kVp and some mAs. This would be the norm. then on another day one gets 26 kVp and an obviously lower mAs. Thus your mAs plot looks like there is something wrong. What I tell them to do when this happens is to repeat the phantom and set the kVp to 25 and use AEC (auto time) and then use this for the right mAs. The OD will come out okay either way."

This is a very common problem with modern equipment and is time consuming and frustrating for the QC staff. Because the noted artificial variations are primarily caused by the slight positioning differences of the phantom, it has no relevance to image quality. In the past, we have suggested that a manual kVp be allowed for this test. If this is not possible, we would suggest including guidance, such as that presented above, to help facilities understand how they can better deal with this issue and that it has the "blessing" of the FDA.

We hope these suggestions are helpful. Thank you for the opportunity to review this important guidance.