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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Docket No. 1538; Policy Guidance Help System #9

To whom it may concern:

The American College of Radiology has provided the attached comments of the FDA's Policy Guidance Help System #9. Thank you for the opportunity to review this important guidance. If you have any questions, please contact me at (800) 227-6440, x-4389.

Sincerely,



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cc: Charles Finder, M.D.
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2005D-0195

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**MQSA FINAL REGULATIONS
MODIFICATIONS AND ADDITIONS TO POLICY GUIDANCE
HELP SYSTEM #9**

Comments from the American College of Radiology

General

The ACR believes that the proposed guidance helps clarify a number of important points for mammography facilities. In particular, the guidance regarding HIPAA is necessary and welcome. We commend the FDA for taking a reasonable and clinically relevant approach to this guidance.

Mammographic Modality

Page 7, Question 5.

The term, “coned views” is outdated. We suggest replacing this with “is limited to only a portion.”

Regarding the sentence, “SFDM is considered a subpart of the Full Field Digital Mammography (FFDM) mammographic modality.” In what sense is SFDM considered a subpart of FFDM? They are entirely different devices used for mostly different purposes. This should be explained further.

Recordkeeping

Page 13, Question 4.

The guidance states that “the facility must maintain, in retrievable form, either the original or lossless compressed full field digital data or hardcopy films for the “specified periods of time.” For clarity, we recommend that the FDA either state these periods or provide a reference to the place in which these regulations are stated.

The ACR believes that transferred hardcopy images should be of “primary interpretation quality” and recommends that this deletion be removed.

Page 13, Question 5.

The answer says that a copied or digitized film mammogram cannot be used for retention or final interpretation because “such images are not produced through radiography of the breast” and hence are not considered to be mammograms. Yet hardcopy FFDM images are acceptable (see the answer to question 4). This seems contradictory. Better justification should be provided. If quality (i.e., loss of data or information) is the issue, then this should be stated.

Mammographic Image Identification

Page 16, Question 5.

The answer states that the usual identifying information must be indicated on each mammographic image (i.e., acquisition or review workstations), not just on the hardcopy films. Many radiologists find this distracting on the digital image during aspects of interpretation. We recommend that the FDA allow this information to be “toggled” on or off the displayed image as necessary.

Personnel – Interpreting Physician – Interpreting Physician Alternative to Board Certification

Page 20, Question 3.

The answer states that the initial experience and initial medical education must be obtained within the specified timeframes of the person’s starting date (21 CFR 900.12(a)(1)(i)(C)-(D)). Physicians will *not* have the patience to look up this regulation after they have already taken the time to find this guidance. We suggest that the FDA make this guidance more user-friendly by spelling out this important regulation in this question.

Page 22, Question 4.

The answer states that if the facility has FFDM, the non-US or Canadian-trained interpreting physician would have to obtain “8 hours of training in that mammographic modality prior to interpreting examinations produced by the facility’s FFDM unit.” We suggest that the FDA further clarify this by adding that these hours may be obtained as part of the physician’s initial formal training in mammography or CME (i.e., it is not required that they be in addition to them).

G. Quality Assurance/Equipment

Page 24, Question 2.

If the cushion pad is used for the majority of the facility's patients, the medical physicist should also perform part of the artifact test using a pad.

Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs (pages 24 – 26)

Bucky replacement – FFDM detector not replaced: Since this may have an impact on the detector position relative to the chest wall edge of the bucky (and thus may result in missed breast tissue), we suggest the medical physicist conduct an evaluation in person.

Cassette replacement – different screen speed: Since changing screen speeds would change the dose and may impact image quality, we suggest that the medical physicist conduct an evaluation in person.

Collimator replacement or reassembly with blade replacement: We do not believe that these should constitute “major repairs”. These functions can easily be evaluated by the medical physicist via films sent to him or her by the service personnel. We suggest that these repairs be changed to “MP oversight.”

Film type change: Shouldn't this be “film speed” change? If so, we suggest that the medical physicist conduct an evaluation in person for the same reasons as specified with the screen speed change above.

Manufacturer's software modifications: The table states that these are “major repairs” and require the medical physicist to evaluate the change in person before the facility may use the x-ray unit to examine patients. Many of these upgrades, especially for FFDM systems, are ***not*** major repairs. They fix minor problems or improve efficiencies, and do not impact patient dose or image quality. We suggest that the in-person evaluation only be required when the upgrade is a major repair that may impact dose or image quality. This information should be provided to the facility by the manufacturer.

H. Quality Assurance/General

Page 28, Question 9 (#4).

Some facilities have invested in special software to help expedite the mammography QC process. Consequently, their QC data will be saved in a digital file rather than a paper chart or record. If this is the facility's normal practice, we strongly recommend that the FDA not require them to produce paper copies for the on-site MQSA inspections.