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

Re.: Docket Number 2005D-0195

GE Healthcare Technologies offers the following comments on the document “The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9”:

**Recordkeeping**

**Citation:**

*900.12(c)(4)(i),(ii): Recordkeeping.*

**Question 4:**

We are quite surprised by FDA’s intention to delete the phrase “of primary interpretation quality” from the description of the hardcopy films considered suitable for purposes of transferring films from the facility to another medical institution, physician, healthcare provider, patient, or patient’s representative. The cited Quality Mammography Standard states that the facility must forward “original mammograms.” Understandably, for digital mammography systems, there may be some uncertainty regarding what constitutes the original mammogram.

It seems reasonable to expect that whatever mammogram is transferred, it should have been determined, for example, through clinical studies, that such mammograms are not inferior to original mammograms produced by screen-film image receptor systems for purposes of clinical interpretation. Such mammograms, whether hardcopy or softcopy may then be identified as “for primary (or final) interpretation.” To maintain accord with the Quality Mammography Standard, the Guidance should retain the qualifier “for primary (or final) interpretation.” Deleting the qualifier is contrary to the intent expressed in the Standard and can result in the transfer of a mammogram of inferior quality and indeterminate utility.

## Mammographic Image Identification

### Citation:

900.12(c)(5)(i),(ii),(iii),(iv),(v),(vi),(vii): *Mammographic image identification.*

### Question 5:

We agree that it will be helpful for FDA to provide clarification regarding the expected labeling of digital mammograms. However, we found that this Question and Answer introduced additional uncertainty. The question explicitly cited the case of displaying an image “for final interpretation.” But the answer referred to “each mammographic image.” Particularly for the case of digital mammographic systems, it is possible to display many forms of the mammographic image, but only certain of those may be classified as “for final interpretation.”

In general, we recognize that there is value in consistency of labeling among the various presentations of a mammogram. However, in some circumstances, providing all of the labeling specified in the Quality Mammography Standard may become problematic. For example, when multiple images are printed on a single sheet of film, it may become difficult to include all of the required information at a size that remains legible yet does not obscure the clinical information. Presentation of all of the specified information at the acquisition workstation might not be considered essential since there is little uncertainty regarding the identity of the facility, the view and laterality, the mammography unit, etc.

The examples cited above represent cases where the image is not intended for final interpretation. Recognizing that there may be other images generated by a digital mammographic system for various purposes other than final interpretation, we suggest that consistency of labeling be advised and that FDA recommend through Guidance that it be applied where practical. We suggest that the “mammographic image” specified in the Standard be identified in the PGHS as the mammogram for final interpretation and that the strict interpretation of the Standard should be limited to images intended for final interpretation. We observe that this interpretation would be consistent with the Note following Question 2 under **Other Modalities Quality Control Tests** in the subject document where FDA states:

“Note: Each softcopy and hardcopy mammographic image used for final interpretation must indicate identifying information (view and laterality, technologist identification, patient name, etc.) (21 CFR 900.12(c)(5)).”

## Dosimetry – Annual Quality Control Test

### Citation:

900.12(e)(5)(vi): *Dosimetry.*

### Question 2:

We are in agreement with FDA’s recommendation to include a cushion pad when performing the phantom image quality and dose QC tests. To make this limitation clear we recommend editing the last sentence of the proposed Guidance as follows:

~~\*+Because the phantom and dose tests are the only QC tests affected by the use of a cushion pad,\*- ^+It is recommended that^- the facility \*+does\*- not \*+have to\*- include the cushion pad when performing other QC tests.~~

Deletion of the first clause is recommended because the pads might affect other tests, particularly automated flat field and automatic exposure control tests intended to be performed under pre-defined conditions. The second clause is re-written to emphasize that the facility should not use the pads for any other tests. We also suggest that FDA include the recommendation that if either of the included tests fails with the pad in place that the pad be removed and the test repeated to determine if the pad is affecting the outcome of the test.

We recommend that FDA reconsider its Guidance suggesting that the pads may be re-used to reduce expense. Considering that the pads are intended for single use, multiple use may lead to degradation that is not typical of a pad used only once. Repeated compression of the pad against the sharp-edged, incompressible phantom may lead to a change of its characteristics that do not represent the conditions when applied to the breast. Thinning of the pad after multiple compressions might lead to a lower estimate of the dose than is characteristic of a new pad when used with an automatic exposure control system that uses compressed breast thickness as a dose control parameter. However, at present we have no data to demonstrate effects on the outcome of the QC tests due to multiple use of these pads.

**Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs**

While we agree with FDA's addition of the item "Slower screen speed with significant dose increase," the inclusion of this item might lead to confusion regarding the previous item, "Different screen speed." The Medical Physicist Involvement for the former is "MP conducts evaluation in person" while that for the latter is "MP oversight." Since "slower" is also "different," there is the possibility for misunderstanding of the level of medical physicist involvement. We recommend that "Different" be changed to "Faster," which leads to three unambiguous categories—same, faster, and slower.

An ambiguity that remains is the meaning of "significant" with regard to the dose increase. We recommend that FDA provide a guide as to what it considers a "significant" dose increase. Since FDA has accumulated data on the spread of dose measurements in clinical practice, perhaps these data could be used to provide such a guide.

While FDA has not proposed a change for the item "Manufacturer's software modifications," we recommend that this entry be modified to include a reference to the alternative standard "Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicist Oversight," which was approved on 31 May 2002 and is included in the PGHS. This alternative standard specifies conditions under which the mammography equipment evaluation (MEE) may be performed under medical physicist oversight instead of an in-person evaluation. We recommend that FDA suggest that the facility ask the manufacturer if the alternative standard applies to a software upgrade since the level of medical physicist involvement in the MEE can affect the cost to the facility and the amount of time the mammography unit is out of service.

We agree with FDA's recommendations regarding FFDM repairs as included in the table.

**Quality Assurance Records****Citation:**

900.12(d)(2): *Quality assurance records.*

**Question 9:**

Although the question deals primarily with digitizing paper QC records, in Note 2 FDA introduces the situation where the test data might be stored electronically by the mammography unit or the QC test equipment. In such a circumstance, there might never have been a paper record of the results of the measurements. Could FDA please clarify if conditions 1, 2, 3, and 5 listed in the answer to the question apply equally to the case of digitizing paper records as to the case where a paper QC record might never have existed?

We greatly appreciate FDA's consideration of these comments and suggestions.

Sincerely,

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Imaging Physicist