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 : **EC4**

Submitter : Dr. Murray Reicher **Date & Time:** 09/20/2005 04:09:22

Organization : DR Systems, Inc.

Category : Health Professional

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

2005D-0195-EC4-Attach-1.DOC

2005D-0195-EC4-Attach-2.DOC

First, I support the concepts proposed in Draft Guidance Document #9, and I thank those involved in its preparation. I am providing my feedback as a diagnostic radiologist, imaging center owner (providing mammography services) and Chairman of DR Systems, a RIS/PACS vendor.

My specific input is as follows:

Page 15, Q 5: This section refers to labeling of images at the time of presentation, and I agree with the comments. You may be aware that FFDM manufacturers deal with the issue of labeling of laterality and view in various ways. One vendor I know of burns Left/Right and View markers (such as LCC) in the FFDM image, just as if the technologist used a lead marker with film (I believe you can verify that Lorad/Hologic uses this technique). Another vendor does not, but only provides the information necessary for a third party viewer to derive that data in the DICOM header field. Another vendor doesn't provide the View (cc, oblique, etc) data in a standard DICOM field, but instead it seems to provide this information in a private tag. I suggest that FFDM manufacturers should be encouraged to follow Lorad's lead and actually embed the laterality and view label in the image pixels, since this eliminates the chance of mislabeling by other viewers down the line.

Page 26, Q2: The answer seems to open the door for users to try less than 5 MP monitors, although not explicitly stated. My opinion is that readers should have the discretion to pick the monitor they desire, as long as there is some instruction or method that encourages display of every pixel so that subsampled viewing of pixels in not routinely performed inadvertently. My concern, as I have expressed before, is that current mammography soft copy viewing systems make it easy for viewers to inadvertently subsample pixels when displaying images (such as when a 4:1 format is used) without understanding what they are doing.

I would suggest you consider the following comments in preparing future Guidance documents:

With regard to all imaging but mammography, the PACS vendor's responsibility with regard to data compression is to provide labeling, but readers can elect to perform primary reading of exams (CR, CT, MRI) with lossy data compression. This is becoming a very common practice, and is supported by medical literature. There is clearly a difference between lossy data compression and perceptible visually destructive data compression. A CR image or CT image with JPEG 5:1 is lossy compressed, but not distinguishable from the original by human observers.

With regard to data compression, ODE holds device manufacturers to a different standard when it comes to mammography, and I don't fully understand what the scientific or legal basis for this different approach is. With mammography, manufacturers are required to label any lossy compressed image "NOT FOR PRIMARY READING"-or at least DR Systems does that based on our understanding of what we are required to do by ODE and MQSA. If this different approach comes from MQSA and not ODE, your input would be important. If it's coming strictly from ODE, does that mean than if ODE approves a display device that uses lossy data compression for primary mammography reading, than MQSA policy with regard to that practice immediately changes de facto?

Our pilot research seems to indicate that we can compress GE FFDM mammograms down to 300-400KB per image and Lorad/Fischer mammogramss down to under 1 MB per image without resulting in a visually detectable change in the image, and perhaps more before we would alter an ROC curve. That's a big benefit for any mammography provider with multiple sites seeking to improve their mammography by centralizing

reading to a single site where an expert mammographer interprets the exams. As you know, data shows that experts may detect as breast cancer with twice the frequency or more as compared to general radiologist readers.

The same logic applies to the need for guidance with regard to digitization of old film-screen mammograms, with discard of the original. This current guidance makes it clear that a facility may elect to digitize prior film mammograms for comparison purposes. We want to go to the next step, and allow a facility with proper quality controls to digitize the prior film and discard the original or give it to the patient. Our belief is that this will not only lower costs, but actually enhance safe storage and electronic clinical access for future comparison.

In summary, my questions with regard to both digitizing films and data compression may be condensed into one basic question: In upholding the requirement to view and store the "original mammogram", how can a facility or vendor properly demonstrate the a "non-identical" original (as a result of data compression, for example) is in fact so functionality identical to the original that it can replace the original? Of course, with regard to both printing of film and display on monitors, one must recognize the all existing systems slightly alter the "original" today, since no two printers or monitors are exactly alike. So if a provider or vendor can follow a quality process that ensures that other data-altering steps, such as data compression, functionally and visually preserves the information in the original image, why provide any barrier to that process with regard to mammography in distinction to all other forms of medical imaging?