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

RE: Docket No. FDA-2011-N-0053

Dear Directors,

I have been servicing medical equipment for 29 years. I am a Certified Biomedical Equipment Technician and In 1990 I became the 105th Certified Radiological Equipment Specialist Internationally. I retired from Federal Government with 27 years' service, 21 of which were servicing radiation machines and components. I am self-employed and provide physicians' office medical equipment repairs since 1987.

You need to be aware of a radiation safety issue which affects the general population of the U.S. and the world. Simply, it is a matter of certain CR digital imagers replacing film processors throughout the U.S.

In 2005 I designed a research project for under-graduate students in chemistry at Catawba College in Salisbury, NC, where I live. The research plotted sensitometric testing of x-ray film in a dedicated film processor, against visual images on film of a radiographic image resolution phantom which I designed. This phantom is equivalent in radiation density to 23cm of water which is the national average NEXT survey projection of 23cm AP L/S Spine. The phantom contains resolution objects to be identified by the user.

The research shows that visual changes in objects within the phantom on film are just as sensitive to changes with sensitometric testing in film. This research demonstrates that there is a direct relationship in resolution properties of x-ray film and digital imaging by use of a phantom image.

In the field, CR digital imagers are replacing x-ray film processors. This is occurring in general practitioners' offices throughout the U.S. Observing the phantom images in the field reveals that certain CR imagers, which replaced a film processor in a general practitioners office produces poorer image quality than film and requires more radiation dose to obtain the same image.

General practitioners, however, do not realize this change as it is not apparent the resolution that is missing in the images. The only way to know is having a phantom image showing the resolution objects which could be visualized using the film processor they no longer have, compared to the CR digital imager they now have.

In 1995 when MQSA was implemented, I personally took two (2) mammography machines to the local scrap yard and had them crushed into scrap metal because the x-ray tube in the mammography machine would not meet the MQSA Standard for focal spot size. This Standard was chosen by knowledgeable professionals who determined that a .6 focal spot size was not small enough for the resolution needed for breast imaging.

Now, 15 years later, we all know that ionizing radiation causes cancer in humans. Cancer doesn't discriminate. There are CR imagers that are replacing film processors in the U.S. which cause increased radiation dose to the general public and the general practitioners and the general population doesn't know it. Some CR imagers have poorer image resolution than the film processor it replaced and the physicians don't know because they can't see what is missing from the image.

There should be a Standard resolution phantom image for general radiography just like mammography. This Standard must apply to both film screen radiography and CR digital imaging alike. Maximum radiation dose and minimum image resolution quality is determined with a phantom image. Systems which cannot meet the Standard are not allowed. Just like in 1995. Time is now. Mitigate the damages now.

Sincerely,

Steve Arey, CRES, CBET
Manager
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