INSTITUTE FOR MAMMOGRAPHY RESEARCH, INC.

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29 August 2000

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1350 Piccard Drive
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RE: Compliance Guidance issued July 18, 2000
MQSA Final Regulations, Document #3

Dear Doctor Finder:

I saw the announcement on the Internet that the MQSA compliance guidance is on the agenda for the September 28, 2000 meeting of the NMQAAC. This letter is to alert the committee to inconsistent and impractical answers in Document #3 under section 21 CFR 900.12 (e)(2).

The problem:
A): At the top of page 21, in response to a question regarding what film should be used for the weekly phantom QC test, the answer given is ....."It is recommended that the phantom image evaluation test be performed using films from the box currently being used to produce clinical mammograms....."

B): Page 22 contains answers to questions for situations when the OD at the center of the phantom image falls below the required minimum of 1.20, and when the OD for the weekly phantom test changes by more than +/- 0.20 from the established operating level. The answers given for each situation contain a five step procedure, step #3 of which states that the facility should... "Check the function of the mammography unit by comparing the mammography units's current mAs output with values obtained for previous phantom images (**assuming that the facility** has been tracking mAs and **has been using the same** kVp and **film emulsion** /screen combination)...." (emphasis added by me).

Step #3 is inconsistent with the answer under A). This is because a box of clinical film can easily be used up in a week or two (and sometimes in a day). Therefore, notwithstanding that the answer under B) is hedged by parenthesis, it is unrealistic to expect that the same box of film, **i.e. the same emulsion**, could be used for more than two or three weekly phantom tests.

Further evidence of this inconsistency is found on page 21:..."FDA realizes that, due to **differences in emulsion batches**, a phantom image test with films **from a new box** may show variance in optical density and density difference greater than the allowed limits (when measured against the operating level established with film from the previous box)...."

Therefore, since steps #4 and #5 of B) depend on step #3, the guidance is impractical.

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Comment:
Some members of the committee may be under the impression that the questions asked under B) are new because they are being addressed in this latest version of the guidance. Actually, the problem created by the use of different emulsions for phantom image tests was investigated over a decade ago, and a method for overcoming it was reported and patented in 1991 and 1994 (1-2). The method is simple, quick, and requires no additional expensive equipment. Unlike the guidance, it is also very practical. A license for its use can be obtained by any mammography facility from the Institute for Mammography Research, Inc. (IMR) for a small fee.

If you or any member of the committee would like more information about this, please contact me.

Very truly yours,

Benjamin M. Galkin, CRP, FACR
President

1. Galkin BM, Method and Apparatus for Testing Radiographic Film Processors, U.S. Patent No. 5,063,583, Nov 1991.
2. Galkin BM, Method and Apparatus for Standardizing and Monitoring Image Quality in Mammography, U.S. Patent No. 5,276,726, Jan 1994.