

INSTITUTE FOR MAMMOGRAPHY RESEARCH, INC.

35 IVY LANE, CHERRY HILL, NEW JERSEY 08002

856-667-2053 FAX 856-482-8435

7 January 2000

Charles A. Finder, MD
Center for Devices and Radiological Health (HFZ-240)
Food and Drug Administration
1350 Piccard Dr.
Rockville, MD 20850

Dear Doctor Finder:

The announcement of the forthcoming meeting of the National Mammography Quality Assurance Advisory Committee says that the committee will discuss the establishment of a proposed demonstration project to assess the efficacy of less than annual inspections as described in the Mammography Quality Standards Reauthorization Act of 1998.

The committee may recall that, at its last meeting, I pointed out a potential problem with this program, namely, the poor sensitivity of the current phantom-disc image quality test. I suggested there was a need for a study to determine the extent to which changes in imaging parameters and patient dose go undetected, and changes in equipment go uncorrected. At that time I suggested that the committee should recommend funding for this type of study. The committee took no action on my recommendation.

I think the committee may be interested to learn that such a study is currently underway. The enclosed preliminary report may be of interest to the members in their discussions on this subject.

If you or any member of the committee have any questions about this study, please call me at 856-667-2053.

Best wishes for the New Year.

Sincerely,


Benjamin M. Galkin, CRP, FACR
President
enc.



Thomas
Jefferson
University
Hospital

Department of Radiology
Breast Imaging Center

Philadelphia, PA 19107
(215) 955-

THE TECHNICAL QUALITY OF MAMMOGRAPHY AT FACILITIES ENROLLED IN A MOCK MQSA DEMONSTRATION PROGRAM

Benjamin M. Galkin, MS,* and Andrew D. Maidment, PhD**

Introduction:

The Mammography Quality Standards Reauthorization Act of 1998 (MQSRA) provides for the establishment by the FDA of a demonstration program under which inspections of selected mammography facilities that are substantially free of incidents of noncompliance with MQSA standards, are conducted less frequently than annually. This report describes an ongoing study to determine if past compliance with MQSA regulations is an adequate criterion for ensuring quality mammography at facilities that are eligible for the demonstration program.

Description of the mock MQSRA program:

A group of 80 mammography facilities from 37 states, having 129 mammography units of different makes, is currently enrolled in this program. The study is designed to determine the extent to which changes in exposure and dose are not detected under current MQSA regulations over a period of a year. Each facility performs the required daily processor control test and weekly phantom-disc image quality test, and retains the films and test results for its own records. The facility also obtains a weekly Mammography System Test (MST)# film using the same image quality test technique. Each MST film contains an image of the phantom-disc combination, an image of a Mammography Beam Quality Monitor (MBQM)# alongside the phantom, and a sensitometric strip along an edge that is shielded during the x-ray exposure#. The MST films are coded to preserve confidentiality, labeled with the technical factors used, and mailed to us for evaluation. Optical density measurements of the phantom-disc combination serve as the control to monitor compliance with the regulations. Optical density measurements of the MBQM and sensitometric strip are used to monitor the reproducibility of kVp, mAs, HVL, and dose and to determine if image quality changes are caused by the x-ray unit or film processor. The MBQM is known to be sensitive to very small changes in these parameters.##

Results:

Preliminary results indicate that facilities can remain in compliance with the regulations, and thus eligible to participate in the demonstration program, even though they are not able to detect large changes in equipment performance that could compromise patient care. This suggests the need to reevaluate the criterion on which to base a program of less than annual inspections.

Conflict of interest statement: # U.S. Patents by BMG. Proprietary interest in these patents are held by Thomas Jefferson University, Philadelphia, PA, (TJU) and The Institute for Mammography Research, Inc., Cherry Hill, NJ. (IMR).

Reference: BM Galkin, AD Maidment, FP Moyer, Radiology 205(P) 303,1997.

* BMG: Professor Emeritus of Radiology, Jefferson Medical College, TJU
President, IMR

** ADM: Assistant Professor of Radiology, Jefferson Medical College, TJU