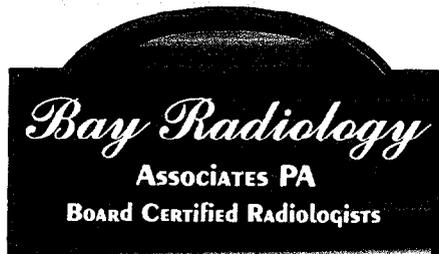


D. H. ANDERSON, M.D.  
J. B. HARBISON, M.D.  
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G. A. PRESSER, M.D.



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March 2, 2000

Docket No.99D-4910. Dockets Management Branch  
Division of Management Systems & Policy  
Office of Human Resources & Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Md. 20852

RE: CFR 900.12(b)(8)(i)

Dear Sirs:

I would like to speak against the requirement for fine adjustment compression controls operable from both sides of the patient.

Many mammographic machines that otherwise comply with all FDA regulations would have to be removed from service if this requirement goes into effect. I believe this is an onerous requirement.

A simple add on device is not available to allow for otherwise adequate machines to be included in this proposal.

The cost of replacing otherwise compliant machines with a new machine would be in excess of \$80,000 and particularly onerous to small private medical practices.

The increasing regulation and liability associated with mammography is decreasing the availability of mammography in many sections of the country. This onerous regulation could further limit timely access to mammography. This requirement seems to be contrary to the goals of the MQSA.

Please feel free to contact me if there is any question. Also, I would like to be notified of the ultimate regulation.

Sincerely yours,

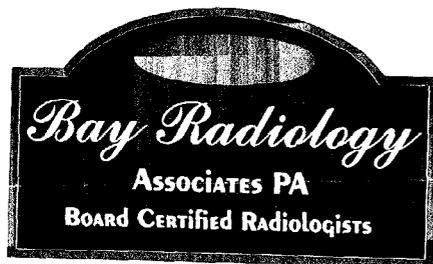
A handwritten signature in black ink, appearing to read "Joe B. Harbison".

Joe B. Harbison, M.D.  
Senior Radiologist, Bay Radiology Associates, Panama City

JBH/js

99D-4910

C5



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Docket No.99D-4910. Dockets Management Branch  
Division of Management Systems & Policy  
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