



3978 '00 MAR 13 AM 11:47

614 Main Street
Dunedin, Florida 34698
Ph. (727) 734-6067
Fx. (727) 733-5471

February 28, 2000

Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

RE: CFR900.12 (B)(8)(I)

To Whom it May Concern:

The recent requirement for fine adjustment compression control for mammography machines is wrongheaded and self-serving to one or two companies that manufacture such equipment. This regulation, which requires fine adjustable compression control knobs on both sides of the patient has no practical use and will not result in better films or more breast cancers diagnosed.

New equipment that incorporates this change would be very expensive and units that are otherwise perfectly satisfactory would become non-compliant. Since these machines cost over \$75,000 a piece, such cost is not justified for a very questionable benefit.

In drafting the final regulations I would urge that this particular requirement be scrapped.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Weiss", is written over a large, faint watermark of the signature.

BARRY WEISS, M.D.
Chairman, Diagnostic Mammography Committee
Morton Plant Mease Health Care

DICT: 02/25/2000
TRANS: 02/28/2000
BW:lo

cc: Mary Swain, M.D.
Radiology Associates of Tallahassee
1623 Medical Drive.
P.O. Box 12219
Tallahassee, FL 32317-2219

99D-4910

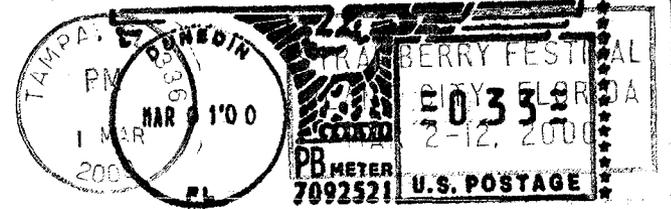
C18



FLORIDA
COMMUNITY
CANCER CENTERS

FLORIDA
COMMUNITY
IMAGING CENTERS

614 Main Street
Dunedin, Florida 34698



Division of Management Systems and
Policy
Office of Human Resources and
Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)

Rockville, MD 20852