



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

NFI-35
10/23/97
ef

98-PHI-01

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

October 23, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James E. Bauer, M.D.
President
A.V. Medical Imaging & Radiation Oncology, Inc.
415 Fourth Ave.
Tarentum, PA 15084

Dear Dr. Bauer:

Your facility was originally a certified mammography facility operating under an FDA Certificate identified by your facility ID number 100149 with an expiration date of June 12, 1997. You applied to the ACR for reaccreditation, however their review was not completed as of June 12, 1997. On June 26, 1997 you applied to FDA for an Interim Notice which would allow you to legally provide mammography services while you were waiting for ACR to complete their review of your reaccreditation application. FDA sent you this Interim Notice on July 10, 1997.

This letter is to inform that your facility operated without a Certificate or Interim Notice from FDA for the time period from June 13, 1997 through July 9, 1997. On October 7, 1997 we visited your facility and determined that you performed mammography services on the dates of 6/13,16,17,18,20,23,24,25,226,27,30/97 and 7/1,2,3,7,8,9/97 without a valid certificate from FDA.

You are advised that performing mammography without a certificate issued by the Food and Drug Administration is unlawful under regulations promulgated under the Mammography Quality Standards Act of 1992 (MQSA). These regulations may be found under Title 21 of the Code of Federal Regulations, Part 900.11(a). Among other things, a facility may be subject to civil money penalties up to \$10,000 for failure to obtain a certificate [42U.S.C.263b(h)(2)(A)].

It is understood that you are presently operating under a valid FDA certificate identified as a "6 Month Provisional Certificate", "Reinstated facility undergoing accreditation" with an expiration date of February 15, 1998.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to assure that in the future your facility will only perform mammography services when you are in possession of a valid FDA certificate. Also, describe the steps you will take if you do not have a valid FDA certificate or Interim Notice from FDA to perform mammography services.

Please send your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

If you have any questions regarding this matter, please call Mr. Davis at 412-644-3394.

Sincerely,



Diana Kolaitis
District Director
Philadelphia District

cc: Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

Michael Huskuliak
PA Dept. of Environmental Protection
Bureau of Radiation Protection
400 Waterfront Drive
Pittsburgh, PA 15222-4745

bcc: HFA-224 HFR-MA150 HFR-MA25 (Rourke) HFZ-240
HFC-210 (CFN: 2530254) HFR-MA100 HFR-MA1515 (Davis) EF (PGH-RP)
Warning Ltr File (HFR-MA140)
Warning Ltr Book (HFR-MA140)
HFI-35 (redacted copy for public display)