

EXHIBIT G-5



Operating Without a Certificate

July 18, 2002

PRIVILEGED and CONFIDENTIAL • PEER REVIEW
Code of Virginia 8.01-581.17

Joanne Choy
CDRH, OHIP (HFZ-240)
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850

Subject: Baltimore Imaging Center, MAP 06468/FDA 110957

Dear Joanne:

We believe that Baltimore Imaging Center, 724 Maiden Choice Lane, Baltimore City, MD 21228, at phone number (410) 747-9303, has been conducting mammography without an MQSA certificate. The facility's recent history is as follows:

DATE	HISTORY
04/29/02	The facility was issued a clinical fail report.
05/01/02	ACR staff received a phone call from Kim asking for the status of the facility's review on their repeat cycle, she was informed that a report had been written and FedEx overnight to the facility.
05/23/02	Kim from the facility called to inform the ACR that the facility would reinstate once they received their new unit.
07/18/02	ACR staff received a phone call from the facility's lead interpreting physician Amile Korangy, M.D. Dr. Korangy inquired whether the facility needed to send clinical images to the ACR along with his reinstatement paperwork. ACR staff asked Dr. Korangy if the facility was performing mammography, he skirted the issue and stated that he just needed to know if he needed to send images with his paperwork. Again, ACR staff asked Dr. Korangy if the facility was performing mammography, he said he just wanted to send in his reinstatement paperwork. ACR staff again asked Dr. Korangy if the facility was performing mammography, he stated "No". ACR staff then inquired, "How the facility intended to submit images with its reinstatement paperwork," Dr. Korangy said he was just asking. ACR staff explained to Dr. Korangy that the facility was denied accreditation in April and that the facility has not had an active certificate to perform mammography legally since 04-29-02. ACR staff explained the reinstatement process to Dr. Korangy and reinforced that the facility could not legally perform until approved for reinstatement and they receive the interim from the FDA.
07-18-02	Due to the nature of the comments from Dr. Korangy, ACR staff called the facility number, (410) 747-9303 and asked to schedule a mammogram; the scheduler stated that the facility was booked into the latter part of August. ACR staff asked if the facility was performing now, the scheduler indicated yes and the earliest available appointment was August 13, 2002. The ACR staff member told the facility that she

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	would have to check her schedule and call back for the appointment. The ACR feels that this facility is currently performing mammography without a valid certificate.
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The ACR believes that this is an intentional disregard for the FDA regulations.

Please call me at (800) 227-6440, x-4595 if you have any questions.

Sincerely,

Pamela L. Platt, BSRT, (R),(M),(CV)
FDA Liaison
ACR, Breast Imaging Program

Enclosure(s)

cc: Priscilla F. Butler
Christine Waldrip
Facility File