



Mammography Accreditation Approval Report

November 22, 2002

PRIVILEGED and CONFIDENTIAL - PEER REVIEW
Code of Virginia 6.01-581.17

Amile Korangy, M.D.
Baltimore Imaging Center
724 Maiden Choice Lane
Baltimore, MD 21228

SUBJECT: MAP ID# 06468, Baltimore Imaging Center, Unit # 03

Dear Dr. Korangy:

This letter is an addendum to the report you received dated April 29, 2002 and contains the results of your unit's testing after REINSTATEMENT.

The American College of Radiology's Committee on Mammography Accreditation is pleased to inform you that the above-named mammography unit has been **GRANTED ACCREDITATION** for a period of three years.

Accreditation is granted if your facility has met all of the testing criteria established by the ACR Committee on Mammography Accreditation for 1) clinical image quality, 2) phantom image quality, 3) average glandular dose and 4) processor quality control. Your mammography unit's results are presented in the following table:

MAP ID/Unit #: 06468-03		Unit Year & Manufacturer: 2002 LoRad			
	Clinical Image Quality	Phantom Image Quality	Average Glandular Dose	Processor Quality Control	Overall Accreditation Outcome
ACR Performance Criteria:	Meet criteria for positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and labeling	See at least: 4.0 Fibers 3.0 Specks 3.0 Masses	≤ 300 mrad for a phantom comparable to a CC view of an average (4.2 cm) compressed breast	≤ 3 data points outside of control limits without corrective action	ACCREDITATION GRANTED
Your Unit's Results:	See comments, if applicable	Fibers = 4.50 Specks = 3.50 Masses = 3.50	170ad	See comments, if applicable	
Evaluation:	ACCEPTABLE	ACCEPTABLE	ACCEPTABLE	ACCEPTABLE	

Standardized scoring procedures were used in the review of all images and data submitted for evaluation:

- 1) The clinical mammograms must be passed by two radiologist reviewers in order to receive accreditation. During the review, eight image quality categories are scored for each case. Additional comments may be provided by the reviewers to further improve image quality; they are recorded in the clinical image reviewer section of this report.
- 2) The phantom image must be passed by two medical physicists and must show an average of at least 4.0 fibers, 3.0 speck groups and 3.0 masses. See the *1999 ACR Quality Control Manual* for the evaluation criteria used by the reviewers. If additional comments are provided by the reviewers to improve image quality, they appear in the phantom image reviewer comments section of this report.
- 3) The average glandular dose may be no more than 300 millirads (mrad) per exposure for a single cranio-caudal view of an average (4.2 cm) compressed breast as measured by the dosimeter on the mammographic phantom.
- 4) The processor quality control chart may not have more than three occurrences of mid-density, density difference or base-plus-fog outside control limits without corrective action. The chart must show corrective action documented in the "Remarks" section of the control chart and a new data point plotted that falls within control limits. In addition, the film used for processor quality control and the clinical film must be the same.

Requirements for Maintaining Accreditation

- Please post the enclosed ACR Accreditation Certificate in a location visible to patients and affix the Accreditation Decal to the mammography unit.
- Please remember that the FDA requires you to have a current MQSA certificate in order to lawfully conduct mammography. Your approved accreditation status has been transmitted to the FDA.
- All ACR accredited mammography facilities are required to comply with the Quality Standards described in Section 900.12 of the FDA's Quality Mammography Standards; Final Rule that went into effect April 28, 1999. You must maintain this compliance throughout the duration of your 3-year accreditation. Under the FDA's Final Rules, the lead interpreting physician has the overall responsibility for the facility's quality assurance program.

We strongly recommend that you review your quality assurance and personnel qualification logs periodically with your QC mammography technologist to verify that you meet these requirements.

- ACR accredited mammography facilities must also comply with all applicable federal, state and local laws and regulations. (Please note that under MQSA, state mammography laws and regulations are permitted to be stricter than federal MQSA regulations.)
- You must notify the ACR in writing as soon as possible of any change in supervising radiologist (i.e., lead interpreting physician), total radiology group, all mammography technologists, facility owner or facility address.
- You must call the ACR to notify us of any change (either addition or replacement) of mammography units as soon as possible so that we may advise you of the appropriate required testing to maintain accreditation and your MQSA certificate.
- You must notify the ACR in writing as soon as possible if the facility is closing.
- MQSA and the ACR Mammography Accreditation Program require that you participate in an annual update. Each year, on approximately the anniversary of your accreditation, we will send you a copy of your facility's Full Application data to update with any changes in address or certain personnel. You will also be requested to submit a copy of your most recent medical physicist's report summary.
- Approximately 8 months prior to the expiration of your accreditation, we will send you a package to begin the accreditation renewal process. The entire process should take approximately six months so it will be important to return these completed materials in a timely manner so that your FDA (or state) certification does not expire.
- The ACR Mammography Accreditation Program is required by the FDA to conduct a random review of facilities to validate the accreditation process. It is expected that your facility will continue to maintain the demonstrated level of quality. If requested by the ACR, you must participate in either a mailed review of image quality or an on-site survey by an ACR team.
- Although you may advertise the ACR accreditation status of your mammography equipment, the ACR logo may not be used in your advertisements. "ACR" is a registered trademark and service mark of the American College of Radiology.

Your state or local division of the American Cancer Society will be notified of your accreditation.

Amile Korangy, M.D.

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The ACR's Committee on Mammography Accreditation sincerely hopes you will find the enclosed report helpful in improving image quality at your facility. Please call the ACR Breast Imaging Accreditation Information Line at 800-227-6440 if you have any questions.

Finally, we hope you proudly display your new ACR Accreditation Certificate so that it is visible to all of your patients. It signifies that your facility provides this essential service to your community at the highest standards of the radiology profession.

Sincerely yours,



Judy M. Destouet, M.D.

Chairman, Committee on Mammography
Accreditation



Mammography Accreditation Failure Report

April 29, 2002

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

Amile Korangy, M.D.
Baltimore Imaging Center
724 Maiden Choice Lane
Baltimore, MD 21228

SUBJECT: MAP ID# 06463-02, Baltimore Imaging Center, Unit # 2

Dear Dr. Korangy:

This letter is an addendum to the report you received dated March 05, 2002 and contains the results of your unit's REPEAT testing.

The American College of Radiology must FAIL your mammography unit at this time due to one or more deficiencies.

Accreditation is only granted if your facility has met all of the testing criteria established by the ACR Committee on Mammography Accreditation for 1) clinical image quality, 2) phantom image quality, 3) average glandular dose and 4) processor quality control. Your mammography unit's results are presented in the following table:

MAP ID/Unit #: 06463-02 Unit Year & Manufacturer: 1997 - Instrumentarium Imaging Corp.					
	Clinical Image Quality	Phantom Image Quality	Average Glandular Dose	Processor Quality Control	Overall Accreditation Outcome
ACR Performance Criteria:	Meet criteria for positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and labeling	See at least: 4.0 Fibers 3.0 Specks 3.0 Masses	≤ 500 mrad for a phantom comparable to a CC view of an average (4.2 cm) compressed breast	≤ 3 data points outside of control limits without corrective action	ACCREDITATION NOT GRANTED
Your Unit's Results:	See comments, if applicable	Not Applicable	0 mrad	Not Applicable	
Evaluation:	NOT ACCEPTABLE	not tested	not tested	not tested	

Standardized scoring procedures were used in the review of all images and data submitted for evaluation:

- 1) The clinical mammograms must be passed by two radiologist reviewers in order to receive accreditation. During the review, eight image quality categories are scored for each case. Additional comments may be provided by the reviewers to further improve image quality; they are recorded in the clinical image reviewer section of this report.
- 2) The phantom image must be passed by two medical physicists and must show an average of at least 4.0 fibers, 3.0 speck groups and 3.0 masses. See the *1999 ACR Quality Control Manual* for the evaluation criteria used by the reviewers. If additional comments are provided by the reviewers to improve image quality, they appear in the phantom image reviewer comments section of this report.
- 3) The average glandular dose may be no more than 300 millirads (mrad) per exposure for a single craniocaudal view of an average (4.2 cm) compressed breast as measured by the dosimeter on the mammographic phantom.
- 4) The processor quality control chart may not have more than three occurrences of mid-density, density difference or base-plus-fog outside control limits without corrective action. The chart must show corrective action documented in the "Remarks" section of the control chart and a new data point plotted that falls within control limits. In addition, the film used for processor quality control and the clinical film must be the same.

How to Proceed after Notification of Failure

Because this is your unit's second unsuccessful attempt at attaining accreditation, it is regarded as a FAILURE. ACR strongly recommends that you cease conducting mammography with this unit upon receipt of this letter. As an FDA-approved accrediting body, the ACR is required to notify the FDA of this failure and the FDA will officially notify you to discontinue mammography with this unit. Continuing to conduct mammography with this unit may result in official sanction and fines from the FDA. Please note that this will not be an order to permanently cease mammography. A process is in place to allow you to resume mammography under specific conditions. The ACR will work with your facility through this process to help you improve image quality and patient care so that accreditation can be achieved.

After a FIRST FAILURE you have two options available to continue the accreditation process on this unit: you may either REINSTATE or APPEAL the failure. You may also WITHDRAW this unit from the accreditation process.

- 1) **REINSTATE** - We strongly recommend that you reinstate at this time so that you may continue providing mammography services with minimum interruption. In order to reinstate you must submit and implement a detailed corrective action plan (along with supporting documentation) for those areas marked NOT ACCEPTABLE. After your corrective action plan (and other requested materials) have been reviewed and approved by the ACR, we will reinstate your unit and notify the FDA of its acceptance so that you may resume mammography. The FDA will send you an interim notice permitting you to resume conducting mammography with this unit. Shortly after that you will receive a new six (6) month provisional reinstatement MQSA certificate that should allow adequate time for your facility to submit all areas of testing to the ACR to complete the accreditation process.

After the ACR has reinstated your unit, we will send you a Full Application to complete with the appropriate testing materials. In order to initiate the reinstatement process you must return the following materials (attached) to the ACR:

- Accreditation Options form - this needs to be completed and signed by the supervising radiologist and returned to ACR within thirty (30) days of the date on this letter.
- Reinstatement application - use this to outline your corrective action plan. Carefully review this report, take steps to effectively correct those areas that are NOT ACCEPTABLE and document this on the reinstatement application. You must also provide supporting documentation (e.g., training certificates, service tickets, etc.) to show that these corrections have been completely implemented. If possible, return these materials to us within thirty (30) days of the date on this letter. If this is not feasible, please notify ACR of the status of your corrective action plan implementation.
- Entry Application - return this with your reinstatement application.
- Mammography Survey Agreement - return this with your reinstatement application.
- MQSA Information Release Authorization - return this with your reinstatement application.
- Invoice and fees - return this with your reinstatement application.

Please note that we will NOT reinstate your facility until all corrective action has been completed, supporting documentation has been received, we have approved your corrective action and have received the appropriate fees.

It is important to note that if this unit receives additional deficiencies after the testing materials are reviewed following your reinstatement, the unit FAILS again and you will be required by the FDA to discontinue conducting mammography. After a second FAILURE, the ACR will require that you take extensive corrective action and participate in a Scheduled On-Site Survey in order to resume mammography and re-enter the accreditation process. The Scheduled On-Site Survey is conducted so that an ACR review team (consisting of a radiologist, a medical physicist and a mammography technologist who is a member of the ACR staff) can review your facility's progress and provide on-site training in areas where you may need help. However, this process is time-consuming and the facility is responsible for payment of a base site visit fee in addition to all travel expenses incurred by the ACR team.

- 2) **APPEAL** - In order to appeal the decision of the ACR reviewers, you must submit your request in writing by completing the enclosed Accreditation Options form and returning the film(s) resulting in the NOT ACCEPTABLE decision to the ACR as soon as possible (but no later than 30 days from the date on this letter). Only the original films resulting in the NOT ACCEPTABLE decision will be accepted.

Your images will be reviewed by an ACR reviewer who did not participate in the initial review. We will notify you of the results of the appeal as soon as possible.

In the event that your unit is denied accreditation after the appeal process is complete, your facility may request an appeal directly from the FDA. However, please be advised that an appeal to the FDA precludes further action on your application by the ACR until the FDA renders a determination in your appeal. If you appeal to the FDA, your accreditation records will be forwarded to them as part of the appeal process. You need to be aware that this process takes time and may not be completed before the expiration of your MQSA certificate. Furthermore, you may not lawfully conduct mammography if your MQSA certificate expires.

- 3) **WITHDRAW** - You may withdraw the mammography unit from the accreditation process if you choose not to appeal or take corrective action and reinstate. If you choose to withdraw, complete the enclosed Accreditation Options form, sign it and return it to the ACR as soon as possible. Please note that if you withdraw, you may no longer conduct mammography on this unit. If you choose to cease mammography permanently you must also remove the ACR accreditation certificate from public display.

Please remember that your facility cannot legally conduct mammography after receiving notification to cease from the FDA. Should you continue to conduct mammography without legal certification, your facility will not be eligible for reimbursement by Medicare or Medicaid for services provided during that time, and your facility could be subject to sanctions or fines from the FDA.

The ACR's Committee on Mammography Accreditation sincerely hopes you will find the enclosed report helpful in improving image quality at your facility. The ACR Breast Imaging Accreditation Information Line in Reston, VA is staffed by radiologic technologists with advanced certification in mammography who can help you complete the accreditation process. Please call them at 800-227-6440 if you have any questions.

Sincerely yours,



Judy M. Destouet, M.D.

Chairman, Committee on Mammography
Accreditation

SUMMARY OF REVIEWER COMMENTS

I. Clinical Image Reviewer Comments:

A. General

Review the "Clinical Image Evaluation" section of the 1999 ACR Mammography Quality Control Manual for additional information on specific comments.

Clinical Image Reviewer Comments:

Fatty Dense Clinical

ATTRIBUTE	PROBLEM(S) NOTED	POSSIBLE CAUSE(S)
A. Positioning	<input type="checkbox"/> MLO: Poor visualization of posterior tissues <input checked="" type="checkbox"/> MLO: Sagging breast <input type="checkbox"/> MLO: inadequate amount of pectoral muscle <input type="checkbox"/> CC: Poor visualization of posterior tissues <input checked="" type="checkbox"/> CC: Excessive exaggeration <input checked="" type="checkbox"/> Portion of breast cut off <input checked="" type="checkbox"/> Skin folds <input type="checkbox"/> Other body parts projected over breast <input type="checkbox"/> Non-standard angulation <input type="checkbox"/> Posterior nipple line on CC not within 1cm of MLO <input checked="" type="checkbox"/> Breast positioned too high on image receptor	<input checked="" type="checkbox"/> Technologist technique <input type="checkbox"/> Inappropriate mammographic projections <input checked="" type="checkbox"/> Wrong size recording system <input type="checkbox"/> Uncertain Additional Comments: Markers overlap the breasts; Skin folds- axillary on CCs and abdomen on RM/LC; RCC- excessive exaggeration
	Other:	
B. Compression	<input type="checkbox"/> Poor separation of parenchymal densities <input checked="" type="checkbox"/> Non-uniform exposure levels <input type="checkbox"/> Patient motion Location of deficiency:	<input type="checkbox"/> Under compression by technologist <input type="checkbox"/> Unsuitable compression device <input checked="" type="checkbox"/> Technologist positioning of compression device <input type="checkbox"/> Uncertain
	Other:	
C. Exposure Level	<input type="checkbox"/> Generalized underexposure <input type="checkbox"/> Generalized overexposure <input type="checkbox"/> Inadequate penetration of dense areas <input type="checkbox"/> Excessive penetration of lucent areas	<input type="checkbox"/> incorrect manual timing <input type="checkbox"/> Film development <input type="checkbox"/> Under compression with photo timing <input type="checkbox"/> Radiologist preference <input type="checkbox"/> Phototimer variability <input type="checkbox"/> Uncertain
	Other:	
D. Contrast	<input type="checkbox"/> Inadequate contrast <input type="checkbox"/> Excessive contrast	<input type="checkbox"/> Film development <input type="checkbox"/> Improper kVp <input type="checkbox"/> Excessive scatter <input type="checkbox"/> Underexposure <input type="checkbox"/> Uncertain
	Other:	

<p>E. Sharpness</p>	<input type="checkbox"/> Poor delineation of linear structures <input type="checkbox"/> Poor delineation of feature margins <input type="checkbox"/> Poor delineation of microcalcifications Location of deficiency:	<input type="checkbox"/> Patient motion <input type="checkbox"/> Poor screen contrast <input type="checkbox"/> Film-screen selection <input type="checkbox"/> Uncertain
	Other:	
<p>F. Noise</p>	<input type="checkbox"/> Visually striking mottle pattern <input type="checkbox"/> Noise limited visualization of detail	<input type="checkbox"/> Film development <input type="checkbox"/> Recording system speed <input type="checkbox"/> Improper kVp <input type="checkbox"/> Uncertain
	Other:	
<p>G. Artifacts</p>	<input checked="" type="checkbox"/> Punctate or lint <input checked="" type="checkbox"/> Scratches or pickoff <input type="checkbox"/> Roller marks <input type="checkbox"/> Grid related artifacts <input type="checkbox"/> Hair, deodorant, etc <input type="checkbox"/> Film handling <input type="checkbox"/> Film fogging <input type="checkbox"/> Poor screen/film alignment	<input checked="" type="checkbox"/> Poor screen maintenance <input checked="" type="checkbox"/> Development related <input type="checkbox"/> Unsuitable grid or Bucky <input type="checkbox"/> Film exposed to light <input type="checkbox"/> Lack of patient preparation <input type="checkbox"/> Poor cassette closure <input type="checkbox"/> Damaged cassette <input type="checkbox"/> Uncertain
	Other: RCC-finger print	
<p>H. Exam ID</p>	<input checked="" type="checkbox"/> Patient and additional patient identifier <input checked="" type="checkbox"/> Facility name and location (city, state and zip) <input type="checkbox"/> Date of examination <input type="checkbox"/> View and laterality <input type="checkbox"/> Unit identification (if more than one) <input checked="" type="checkbox"/> Technologist identification <input type="checkbox"/> Cassette/screen identification	<input type="checkbox"/> Technologist error <input checked="" type="checkbox"/> Missing or non-standard labeling method <input checked="" type="checkbox"/> Improper positioning of label <input type="checkbox"/> Uncertain
	Other: Partially obscured	
<p>I. Additional Recommendations</p>	<input type="checkbox"/> Recommend reviewing 1999 ACR QC Manual for MQSA film labeling requirements <input type="checkbox"/> Recommend sending technologist to a hands-on positioning course <input type="checkbox"/> Excessive collimation: recommend coning to size of film to reduce viewbox glare <input type="checkbox"/> Check optimal film development conditions with film manufacturer <input type="checkbox"/> Physician should review Clinical Image Evaluation section of 1999 ACR QC Manual	
<p>J. Additional Comments:</p>		

SUMMARY OF REVIEWER COMMENTS

I. Clinical Image Reviewer Comments:

A. General

Review the "Clinical Image Evaluation" section of the 1999 ACR Mammography Quality Control Manual for additional information on specific comments.

Clinical image Reviewer Comments:

Fatty Dense Clinical

ATTRIBUTE	PROBLEM(S) NOTED	POSSIBLE CAUSE(S)
A. Positioning	<input type="checkbox"/> MLO: Poor visualization of posterior tissues <input type="checkbox"/> MLO: Sagging breast <input type="checkbox"/> MLO: Inadequate amount of pectoral muscle <input type="checkbox"/> CC: Poor visualization of posterior tissues <input type="checkbox"/> CC: Excessive exaggeration <input type="checkbox"/> Portion of breast cut off <input type="checkbox"/> Skin folds <input type="checkbox"/> Other body parts projected over breast <input type="checkbox"/> Non-standard angulation <input type="checkbox"/> Posterior nipple line on CC not within 1cm of MLO <input type="checkbox"/> Breast positioned too high on image receptor Other:	<input type="checkbox"/> Technologist technique <input type="checkbox"/> Inappropriate mammographic projections <input type="checkbox"/> Wrong size recording system <input type="checkbox"/> Uncertain Additional Comments:
B. Compression	<input type="checkbox"/> Poor separation of parenchymal densities <input type="checkbox"/> Non-uniform exposure levels <input checked="" type="checkbox"/> Patient motion Location of deficiency: RMLO Other:	<input checked="" type="checkbox"/> Under compression by technologist <input type="checkbox"/> Unsuitable compression device <input type="checkbox"/> Technologist positioning of compression device <input type="checkbox"/> uncertain
C. Exposure Level	<input type="checkbox"/> Generalized underexposure <input type="checkbox"/> Generalized overexposure <input type="checkbox"/> Inadequate penetration of dense areas <input checked="" type="checkbox"/> Excessive penetration of lucent areas Other:	<input type="checkbox"/> Incorrect manual timing <input type="checkbox"/> Film development <input type="checkbox"/> Under compression with phototiming <input type="checkbox"/> Radiologist preference <input checked="" type="checkbox"/> Phototimer variability <input type="checkbox"/> Uncertain
D. Contrast	<input type="checkbox"/> Inadequate contrast <input type="checkbox"/> Excessive contrast Other:	<input type="checkbox"/> Film development <input type="checkbox"/> Improper kVp <input type="checkbox"/> Excessive scatter <input type="checkbox"/> Underexposure <input type="checkbox"/> Uncertain

<p>E. Sharpness</p>	<input checked="" type="checkbox"/> Poor delineation of linear structures <input checked="" type="checkbox"/> Poor delineation of feature margins <input type="checkbox"/> Poor delineation of microcalcifications Location of deficiency: MLOs, RMLQ>LMLO	<input checked="" type="checkbox"/> Patient motion <input type="checkbox"/> Poor screen contact <input type="checkbox"/> Film-screen selection <input type="checkbox"/> Uncertain
	<p>Other:</p>	
<p>F. Noise</p>	<input type="checkbox"/> Visually striking mottle pattern <input type="checkbox"/> Noise limited visualization of detail	<input type="checkbox"/> Film development <input type="checkbox"/> Recording system speed <input type="checkbox"/> Improper kVp <input type="checkbox"/> Uncertain
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	<p>Other:</p>	
<p>H. Exam ID</p>	<input type="checkbox"/> Patient and additional patient identifier <input checked="" type="checkbox"/> Facility name and location (city, state and zip) <input type="checkbox"/> Date of examination <input type="checkbox"/> View and laterality <input type="checkbox"/> Unit identification (if more than one) <input checked="" type="checkbox"/> Technologist identification <input type="checkbox"/> Cassette/screen identification	<input type="checkbox"/> Technologist error <input checked="" type="checkbox"/> Missing or non-standard labeling method <input checked="" type="checkbox"/> Improper positioning of label <input type="checkbox"/> Uncertain
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