

INTRODUCTORY MEMORANDUM

TO: New Mammography Facilities

FROM: Marion Boston, R.T.(R)(M)
Manager, Mammography Accreditation Program

SUBJECT: ACR Mammography Accreditation Program

Thank you for your recent inquiry regarding the American College of Radiology's Mammography Accreditation Program. This unique program offers radiologists an opportunity for review and evaluation of their mammography facility, personnel qualifications, image quality, quality control procedures, and dose through a peer review mechanism. The program is consistent with all Food and Drug Administration (FDA) regulations under the Mammography Quality Standards Act (MQSA) and is administered by the ACR Committee on Mammography Accreditation under the direction of Debra L. Monticciolo, M.D. Please review the enclosed Overview before completing the application form.

What you need to do:

- Have your medical physicist conduct a Mammography Equipment Evaluation on *each mammography unit at your facility* to ensure that all FDA requirements are met. This should be done *at least 1 week before "applications" training* to allow time for corrective action of potentially non-compliant tests. (This is important because "applications" training usually involves imaging human subjects.)
- Complete a copy of the enclosed *Entry Application*. Be sure to include the *results of your units' Mammography Equipment Evaluation*; your medical physicist must complete the enclosed forms:
 - MQSA Requirements for Mammography Equipment checklist
 - Medical Physicist's Mammography QC Test Summary form
- Submit the application materials with an *application fee* of \$1325 for the first mammography unit (and \$1175 for each additional unit) to the ACR at:

Mammography Accreditation Program
American College of Radiology
1891 Preston White Drive
Reston, VA 20191

- If you are accrediting a *mobile mammography unit*, call the ACR for specific instructions.
- If you are using both screen-film and computed radiography (Fuji FCRm) on the same x-ray units, *you must accredit each unit as two separate units*. Because computed radiography is considered full-field digital mammography, the image quality, QC, and personnel requirements are different. Therefore, the ACR must accredit these systems separately.
- Contact your *state radiation control agency* for any state-specific requirements.

What ACR will do:

- Review your application for completeness and to make sure that all equipment problems identified by your medical physicist *have been corrected*.
- *Notify the FDA (or state certifier)* within 2 business days of receiving the *complete* application materials that your facility has an application in process, provided that you have met all requirements.
- Send you a *full application and testing materials* for each unit.
- Send you a copy of the *1999 ACR Mammography Quality Control Manual*.
- Once you pass accreditation, send you a final report, an accreditation certificate, and a decal for each passing unit at your facility. Your facility's *accreditation will expire 3 years from the date of the final report*.
- *Notify the FDA* of your facility's successful accreditation.
- List the name of your accredited facility on the ACR website (www.acr.org).

What FDA (or your state certifier) will do:

- Fax your facility either a *provisional certificate or an "interim notice"* allowing you to lawfully provide mammography services. (The certificate or "interim notice" will be faxed to you within 2 business days of receiving the notification from the ACR. If you do not receive it, please contact the ACR at the number below.)
- *Mail you a provisional certificate* that allows you 6 months to complete the accreditation process.
- Once you pass accreditation, *send you a new 3-year MQSA certificate* that has the ACR listed as your accrediting body.
- List the name of your accredited and certified facility on their website (www.fda.gov/cdrh/mammography/index.html).

The Committee on Mammography Accreditation recognizes that the accreditation process involves a significant investment in time and effort on the part of your facility. Thank you for demonstrating your interest in providing quality mammography services by accrediting with the American College of Radiology. Please call the Mammography Accreditation Program at (800) 227-6440 if you have any questions.

Your facility must have a current and valid MQSA certificate (or interim "notice") before you may perform mammography. Any facility performing mammography without this certificate is subject to sanctions under MQSA.