INTRODUCTORY MEMORANDUM

TO: New Mammography Facilities

FROM: Theresa Branham, BSRS
       Director, Mammography Accreditation Program

SUBJECT: ACR Mammography Accreditation Program

The ACR is happy to announce that beginning July 29, 2013 applications for Mammography Accreditation are available in our ACRedit database, online. The ACR Mammography Accreditation 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 Jean M. Weigert, M.D., FACR. Please review the ACR Mammography Program Requirements before submitting your online application.

What you need to do:

1. 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.)

2. New facilities will complete an online application here: https://acredit.acr.org. If your facility has an existing online accreditation account, you may log in, and create your new facility. If you have never logged into the ACRedit database for other modalities, click “Register” to create a new account. You may start the application two weeks prior to your expected submission date in order to gather information and signatures.

3. The application includes:
   a. Basic facility, equipment, and personnel information entered online
   b. Legal agreements with appropriate signatures (electronic signatures are accepted, or documents may be printed and faxed from inside the online application)
      i. Mammography Accreditation Survey Agreement
      ii. MQSA Information Release Authorization
   c. The medical physicist’s Mammography Equipment Evaluation summary showing that all FDA-required tests have passed (this can be uploaded in the online application)
      i. MQSA Requirements for Mammography Equipment checklist
      ii. Medical Physicist’s Mammography QC Test Summary form

4. Submit the application materials with an application fee of $1700 for the first mammography unit (and $1500 for each additional unit) to the ACR at:
5. If you are accrediting a mobile mammography unit, call the ACR for specific instructions.

6. If you are using both screen-film and computed radiography on the same x-ray units, you must accredit each unit as 2 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.

7. 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 notification that your online testing package for each unit is available.
- Provide you with:
  - The ACR Digital Mammography Quality Control Manual.
  - Barcoded labels for images and documents, if submitting hard copy images.

IMPORTANT: You must download the Personnel, Testing Package documents here: http://www.acraccreditation.org/Modalities/Mammography and follow all instructions carefully.

- 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 ([https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm)).

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 visit our website at [http://www.acraccreditation.org/Modalities/Mammography](http://www.acraccreditation.org/Modalities/Mammography) or 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.**