

## **Mammography Equipment Evaluation Summary** *(new and relocated units only)*

*Your medical physicist must complete:*

1. *MQSA Requirements for Mammography Equipment checklist*
2. *Medical Physicist's Mammography QC Test Summary form*

### **WHEN CAN MY FACILITY LEGALLY START USING A NEW UNIT TO EXAMINE PATIENTS?**

Facilities with a current MQSA certificate - **only after** the medical physicist passes the Mammography Equipment Evaluation **and** you send all above requested materials to the ACR; for **digital units**, in order to assure reimbursement by the Center for Medicare and Medicaid Services (CMS):

- Fax the above materials to the ACR at (703) 648-9176, and
- After 3 business days, call the ACR to confirm that the new unit information was sent to the FDA
- **Do not** submit your mammography claims for 14 days (as recommended by CMS) to ensure that your local payer has the most current MQSA file.

### New Unit at Accredited Facility -Before You May Examine Patients

- Call ACR for appropriate application materials
- Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
- Facility must send ACR the application, fees and Equipment Evaluation Pass/Fail results
- Facility does not have to wait for a response from ACR to use the new unit for mammography
  - Facility already has a current MQSA certificate
- Beware if you have digital, CMS will not reimburse if they don't have notification from FDA that you are approved for digital
  - Call ACR to be sure we have received your FFDM application and transmitted it to the FDA before using

### ACR's Current FFDM QC Requirements are the same as FDA's

- ACR suggests using mfr's data forms
- Medical physicist must complete ACR's summary forms
  - MQSA Requirements for Mammography Equipment (checklist)
  - Medical Physicist's Mammography QC Test Summary form
  - Available on ACR website in Excel
- Forms provides ACR with essential pass/fail information
  - If medical physicist passes test, ACR accepts it
  - If he/she fails test, ACR requests corrective action
  - If he/she writes "N/A" "See comments" (or anything other than pass or fail), ACR will follow-up and accreditation will be delayed

### Medical Physicist's Mammography QC Test Summary Forms

- Use for both Equipment Evaluations and Annual Surveys
- Addresses 900.12(e) of the FDA regulations
- All have been revised to further streamline
- Excel format
  - Built-in P/F drop-down boxes
- Use the one for your digital unit manufacturer
  - General Electric/Fischer
  - Lorad/Siemens
  - Fuji
- Check version of manufacturer's QC manual used
- Single overall review workstation assessment