

**FDA APPROVED ACCREDITING BODY
 ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES
 RADIATION CONTROL**

Application for Accreditation to Perform Full Field Digital Mammography Under MQSA

FDA: Facility ID: _____ Accreditation Number: _____

1. Facility Name: _____

Mailing Address: _____

City: _____ State: AR Postal Code: _____

Physical Address: _____

City: _____ State: AR Postal Code: _____

Telephone Number: _____ Facility EIN: _____

Fax Number: _____ Facility Contact: _____

| | | | | |
|--|-----|--------|---------|----------------|
| 2. This accreditation application is : | New | Change | Renewal | Reinstatement* |
|--|-----|--------|---------|----------------|

3. Name(s) of all Interpreting Physician(s): _____

| | |
|---|---|
| 4. Number of mammography units to receive accreditation: _____ Machine A. _____ Machine Manufacturer: _____ Machine Model: _____ Serial Number: _____ Date of Manufacture: _____ Reciprocating Grids 18 X 24 24 X 30 | 5. Name of the Medical Physicist that supplied the Mammography Equipment Evaluation or the annual physicist's survey: Name: _____ Arkansas Vendor Registration Number: _____ |
|---|---|

6. Documents that must be submitted with this application for MQSA accreditation to perform mammography
- A. Supportive documentation for Interpreting Physician(s), Radiologic Technologist(s) and Medical Physicists.
 - B. A copy of the Physicist's report (Annual Survey or Mammography Equipment Evaluation)
 - C. Hard Copy Phantom Image at average technique factors for facility (see guide)
 - D. Hard Copy Clinical Images (as indicated in the guide)
 - E. Accreditation fee in the amount of \$700.00 for one unit, \$500.00 for each additional unit
 - F. Submit documentation regarding previous accreditation (if applicable) (see application guide)
 - G. Submit signed attestation regarding QA program (Attestation is the last page of application guide)

*** Reinstatement applications must be accompanied by a corrective action plan.**

Date: _____ Administrator's Signature: _____

Signature name printed or typed: _____

Title of Administrator: _____

APPLICATION GUIDE FOR ACCREDITATION TO PERFORM FULL FIELD DIGITAL MAMMOGRAPHY UNDER MQSA

- Item 1** Specify the name, address, telephone number and facsimile number of the facility that will be responsible for ensuring that the mammography program complies with MQSA Final regulations (21 CFR Parts 16 and 900) as set forth in the October 28, 1997, issue of the Federal Register.
- Item 2** Self-explanatory.
- Item 3** Name or names of the individuals that will be actively interpreting mammography exams for your facility.
- Item 4** Self-explanatory.
- Item 5** Self-explanatory.
- Item 6A** Submit supportive documentation for each physician interpreting the results of mammography examinations as follows:

Initial Training

1. Current Arkansas Medical License
- Initial Training and Experience before 4/28/99***
- 2.A Certificate from FDA Approved body (ACR, AOBR, RCSPC) in Radiology or Diagnostic Radiology
- OR**
- 2.B. 2 months documented training in mammography
- AND**
3. 40 hrs. of training in mammography
- AND**
- 4.A. Have read 240 patient exams (directly supervised if done after 10/1/1994) in any 6-month period
- OR**
- 4.B. Presently reading under direct supervision of qualified interpreting physician
- AND**
5. 8 hours of FFDM specific education
- Initial Training and Experience on or after 4/28/99***
- 2.A. Certificate from FDA Approved body (ACR, ABR, RCSPC) in Radiology or Diagnostic Radiology
- OR**
- 2.B. 3 months documented training in mammography
- AND**
3. 60 hrs. of Category I training in mammography with at least 15 hrs

letterhead, which lists the number of patient exams performed per technologist.
DO NOT SEND PATIENT LISTS OR COPIES OF THE PATIENT LOG BOOK.

Item 6C Submit for the *individual providing medical physics services*, supportive documentation based on the following:

Initial Requirements

- 1.A. Current Arkansas Vendor Service Card
AND IF APPLICIBLE
- 1.B. Board Certification (ABR or ABMP)

AND

Option 1 - Master's Degree or Higher

- 2. M.S. or Ph.D in a Physical Science (w/20 semester hr. in physics)

AND

- 3. 20 Contact Hours Training in Surveys

AND

- 4. Experience in Conducting Surveys (1 facility & 10 units - supervised)

AND

- 5. 8 hours training specific to FFDM

Option 2 - Bachelor's Degree (Must meet all requirements on or before 4/28/99**)**

- 2. B.S in a Physical Science (w/10 semester hr. in physics)

AND

- 3. 40 Contact Hours Training in Surveys (after B.S. degree)

AND

- 4. Experience in Conducting Surveys (1 facility & 20 units - supervised)
(after B.S. degree)

AND

- 5. 8 hours training specific to FFDM

Continuing Education

- 6. 15 hrs. CME documented in past 36 months – Copies of certificates

Continuing Experience

- 7. Documentation of the number of facilities and units surveyed by the physicist in the past 24 months (Must be at least 2 facilities and at least 6 mammography units).

Item 6D Submit a copy of the FFDM equipment evaluation/survey report (physicist's report) for each FFDM unit being accredited. This report must be dated within six (6) months prior to submission of the application.

Item 6E Phantom Image(s)

1. Submit an original hard-copy phantom film demonstrating appropriate technique factors for a 4.5 cm thick compressed breast.
2. Each phantom submitted must contain technique factors utilized and an optical density measurement in the image.
3. **ONLY SUBMIT ONE PHANTOM IMAGE PER FFDM UNIT WITH THE APPLICATION. IF ADDITIONAL PHANTOM IMAGES ARE REQUIRED, THE DIVISION WILL REQUEST THEM.**
 - a. Up to three (3) submissions, if needed, will be accepted on initial and reaccreditation applications.
 - b. Up to two (2) submissions, if needed, will be accepted on reinstatement applications.

Item 6 F Clinical Images

INITIAL ACCREDITATION:

1. **PATIENTS CANNOT BE IMAGED AT A NEW FACILITY UNLESS THE FACILITY HAS OBTAINED A FDA PROVISIONAL CERTIFICATE.**
2. A new facility beginning operations is eligible to apply for a provisional certificate which will enable it to perform mammography and thus obtain the clinical images needed to complete the accreditation process.

When a facility submits the required accreditation information and the State of Arkansas verifies that the information is complete, the FDA will issue a provisional certificate to the facility upon determination that the facility has satisfied the requirements of 21CFR section 900.11(b)(2)(i).

3. A provisional certificate shall be effective for up to 6 months from the date of issuance.
4. The facility should submit two (2) sets of original hard copy FFDM clinical images, which have been interpreted as Negative or Benign for each unit to be accredited. One set should demonstrate imaging of fatty breasts (75% adipose tissue) and one set should demonstrate imaging of dense breasts (75% glandular tissue). **ONLY SUBMIT ONE SET OF FATTY BREAST IMAGES AND ONE SET OF DENSE BREAST IMAGES WITH THE APPLICATION. IF ADDITIONAL FILMS ARE REQUIRED, THE DEPARTMENT WILL REQUEST THEM.**
 - a. Up to three submissions, if needed, will be accepted on initial or reaccreditation applications.

- b. Up to two submissions, if needed, will be accepted on reinstatement applications.
5. For facilities accrediting FFDM units for the first time, the images must be obtained during the six-month provisional usage period.
6. In order for a facility to image patients with a FFD mammography unit, the following must be evaluated and approved by the State of Arkansas Mammography Accrediting Body:
 - Application completeness
 - Personnel documentation
 - An FFDM equipment evaluation within 6 months prior to the application date
 - An FFDM phantom image

REACCREDITATION:

1. Clinical images should be performed within thirty (30) days prior to the application submission date when facilities are going through the reaccreditation process.
2. The facility should submit two (2) sets of original hard copy FFDM clinical images, which have been interpreted as Negative or Benign for each unit to be accredited. One set should demonstrate imaging of fatty breasts (75% adipose tissue) and one set should demonstrate imaging of dense breasts (75% glandular tissue). **ONLY SUBMIT ONE SET OF FATTY BREAST IMAGES AND ONE SET OF DENSE BREAST IMAGES WITH THE APPLICATION. IF ADDITIONAL FILMS ARE REQUIRED, THE DEPARTMENT WILL REQUEST THAT THEY BE SUBMITTED.**
 - c. Up to three submissions, if needed, will be accepted on initial or reaccreditation applications.
 - d. Up to two submissions, if needed, will be accepted on reinstatement applications.

Item 6G Submit the appropriate accreditation fee with the application. Applications will not be reviewed until the application fee is submitted.

Fees:

1. First mammography unit (tube) - \$700 to be collected at the beginning of each three (3) year accreditation period.
2. Each additional mammography unit (tube) - \$500 to be collected at the beginning of each three (3) year accreditation period.
3. Each additional view of clinical images and phantoms - \$100 to be collected at the time of submission of additional clinical images and phantoms except that the maximum annual cost for additional review of clinical images and phantoms shall not exceed \$300.

Item 6H Submit documentation regarding previous accreditation approval or denial. Previous application made to the American College of Radiology must be accompanied by FDA Facility ID# and documentation regarding approval or denial of accreditation.

Has your facility previously been accredited with the American College of Radiology?

If so, what was your FDA ID# _____

Item 6I The MQSA Final regulations (21 CFR 900.12) as set forth in the October 28, 1997, issue of the Federal Register requires any facility performing mammography services under MQSA to establish and maintain a quality assurance program. **Sign and submit the attached ATTESTATION OF MAMMOGRAPHY QUALITY ASSURANCE PROGRAM.**

PLEASE SIGN AND DATE THE APPLICATION. APPLICATIONS WILL BE RETURNED IF THEY ARE NOT SIGNED.

ATTESTATION OF MAMMOGRAPHY QUALITY ASSURANCE PROGRAM

As a FDA Certified Mammography Facility accredited by Arkansas Department of Health and Human Services, Division of Health, Radiation Control, the Facility acknowledges and affirms:

1. To establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility in accordance with 21 CFR 900.12(d) and (e);
 - a. Responsible Individuals assigned and identified
 - b. Quality assurance records will be maintained and updated
 - c. Standard Operating Procedures for Quality Control tests will be established and maintained and procedures will be performed as required
 - d. Technique tables and charts will be maintained and updated
 - e. Standard Operating Procedures for Infection Control will be established and followed
 - f. Written procedures for handling Consumer Complaints will be established

2. To establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings in accordance with 21 CFR 900.12(f).

Date

Facility Administrator