

FDA APPROVED ACCREDITING BODY
ARKANSAS DEPARTMENT OF HEALTH
RADIATION CONTROL

Application for Accreditation to Perform Mammography Under MOSA

FDA: Facility ID: _____ Accreditation Number: MAS
 EIN Number: _____

1. Facility Name: _____
 Mailing Address: _____

City: _____ State: AR Postal Code: _____

Physical Address: _____

City: _____ State: AR Postal Code: _____

Telephone Number: _____ Facility Contact: _____

Fax Number: _____ **Contact's email:** _____

2. This accreditation application is:	<input type="checkbox"/> New	<input type="checkbox"/> Change	<input type="checkbox"/> Renewal	<input type="checkbox"/> Reinstatement*
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** Reinstatement applications must be accompanied by a corrective action plan and \$500.00 reinstatement fee.*

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: _____
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6. Documents that must be submitted with this application for MQSA accreditation to perform mammography

- A. Supportive documentation for Radiologic Technologist(s) (including FFDM training)
- B. A copy of the Physicist's survey report (Within six months for initial accreditation and within fourteen months for reaccreditation/reinstatement)
- C. Phantom Image using average technique factors for facility (see application guide)
(use the method in which the clinical images are routinely reviewed for interpretation)
- D. Clinical Images (as indicated in the application guide) **use the method in which the Clinical images are routinely reviewed for interpretation**
- 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)
- H. Interpreting Physician approval of clinical images form.

Date: _____ Administrator's Signature: _____
 Signature name printed or typed: _____
 Title of Administrator: _____

ATTESTATION OF MAMMOGRAPHY QUALITY ASSURANCE PROGRAM

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

1. To establish and maintain a quality assurance (QA) 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

INTERPRETING PHYSICIAN APPROVAL OF CLINICAL IMAGES

As an MQSA qualified interpreting physician (IP), I have reviewed and approved these clinical images for submission for quality evaluation in accordance with the guidance outlined on the “Mammography Evaluation Form-Physician’s Review Form”.

IP Signature _____ M.D.

DENSE SUBMISSION PATIENT NUMBER _____

FATTY SUBMISSION PATIENT NUMBER _____

**Shipping address: 5800 W. 10th Street, Suite 100
Little Rock, Arkansas 72204
ATTN: Mammography Program**

**Mailing address: 4815 W. Markham, Slot 30
Little Rock, Arkansas 72205**

APPLICATION GUIDE FOR ACCREDITATION TO PERFORM 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 6** Submit supportive documentation for each physician interpreting the results of mammography examinations as follows:

Initial Training-Only for interpreting physicians new to your program

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 education in each mammographic modality used by the physician. (This may be part of the 2 months in item 2B or the 40 hours in item 3)
- Initial Training and Experience on or after 4/28/99***
1. Certificate from FDA Approved body (ACR, ABR, RCSPC) in Radiology or Diagnostic Radiology
- OR**
2. 3 months documented training in mammography
- AND**
3. 60 hrs. of Category I training in mammography with at least 15 hrs in the 3 years immediately preceding initial qualifying date
- AND**
- 4.A. Have read 240 patient exams under direct supervision in 6 month period immediately preceding initial qualifying date **or** in any 6 month period during last 2 years of residency if Board Certified at first possible opportunity
- OR**

- Item 8** Submit for the *individual providing medical physics services*, supportive documentation based on the following: **Not necessary to submit as long as all information is available for review at your facility**

Initial Requirements for Medical Physicists

- 1.A. Current Arkansas Vendor Service Card

AND IF APPLICABLE

- 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 of education in each mammographic modality used by the medical physicist. (This may be part of the 20 hours in item 3)

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 of education in each mammographic modality used by the medical physicist. (This may be part of the 40 hours in item 3)

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 9** 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 for initial accreditation, for reaccreditation or reinstatement must be within the last 14 months.

Item 10 Phantom Image(s)

1. Submit a hard copy phantom or phantom image as an electronic digital image may be submitted on CD, DVD or other media in DICOM format (**use the method in which the clinical images are routinely reviewed for interpretation**).
2. Each phantom submitted must contain technique factors utilized.
3. **ONLY SUBMIT ONE PHANTOM IMAGE PER UNIT WITH THE APPLICATION (USE THE METHOD IN WHICH THE CLINICAL IMAGES ARE ROUTINELY REVIEWED FOR INTERPRETATION). IF ADDITIONAL PHANTOM IMAGES ARE REQUIRED, THE DEPARTMENT WILL REQUEST THEM.**

4. Up to three (3) submissions, if needed, will be accepted on initial, reaccreditation and reinstatement applications.

Item 11 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 clinical images for screen film, which have been interpreted as Negative or Benign for each unit to be accredited. This can be either a hard copy image or an electronic digital image for FFDM units (**USE THE METHOD IN WHICH THE CLINICAL IMAGES ARE ROUTINELY REVIEWED FOR INTERPRETATION**). 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, reaccreditation and reinstatement applications.
 - b. Hard copy images should be original hardcopy of interpretable quality.
 - c. Electronic digital images may be submitted on CD, DVD or other media in DICOM format. Include additional programs needed to view the images. The SAR reserves the right to request hard copy images if the first and second attempts of the electronic digital images cannot be opened as submitted.
5. For facilities accrediting units for the first time, the images must be obtained during the six-month provisional usage period but should be submitted **at least 2 months** prior to the expiration of the provisional certificate. Images should be reviewed by an MQSA qualified interpreting physician whose signature is required on the application.
6. In order for a facility to image patients with a mammography unit, the following must be evaluated and approved by the State of Arkansas Mammography Accrediting Body:
 - Application completeness
 - Personnel documentation
 - An equipment evaluation within 6 months prior to the application date
 - A hard copy phantom or phantom image as an electronic digital image may be submitted on CD, DVD or other media in DICOM format (**use the method in which the clinical images are routinely reviewed for interpretation**).

REACCREDITATION:

1. Clinical images should be performed within ninety (90) 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 clinical images for screen film, which have been interpreted as Negative or Benign for each unit to be accredited. **This can be as either a hard copy image or an electronic digital image for FFDM units (USE THE METHOD IN WHICH THE CLINICAL IMAGES ARE ROUTINELY REVIEWED FOR INTERPRETATION).** 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.***
 - a. Up to three submissions, if needed, will be accepted on initial, reaccreditation and reinstatement applications.
 - b. Hard copy images should be original hardcopy of interpretable quality. Electronic digital images may be submitted on CD, DVD or other media in DICOM format. Include additional programs needed to view the images. The SAR reserves the right to request hard copy images if the first and second attempts of the electronic digital images cannot be opened as submitted.
 - c. A hard copy phantom or phantom image as an electronic digital image may be submitted on CD, DVD or other media in DICOM format (**use the method in which the clinical images are routinely reviewed for interpretation**).

Item 12 Submit the appropriate accreditation fee with the application. Applications will not be reviewed until the application fee is submitted.

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 13 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 14 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.