

**FDA APPROVED ACCREDITING BODY
ARKANSAS DEPARTMENT OF HEALTH
RADIATION CONTROL**

Application for Accreditation to Perform 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 Contact: _____

Fax Number: _____ Contact's email: _____

2. This accreditation application is:	New	Change	Renewal	Reinstatement*
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3. Name(s) of all Interpreting Physician(s): _____

<p>4. Number of mammography units to receive accreditation: _____</p> <p>Machine A. _____</p> <p>Machine Manufacturer: _____</p> <p>Machine Model: _____</p> <p>Serial Number: _____</p> <p>Date of Manufacture: _____</p> <p>Reciprocating Grids 18 X 24 24 X 30</p>	<p>5. Name of the Medical Physicist that supplied the Mammography Equipment Evaluation or the annual physicist's survey:</p> <p style="text-align: center;">Name: _____</p> <p>Arkansas Vendor Registration Number: _____</p>
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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. Phantom Image using average technique factors for facility (see application guide)
 - D. Clinical Images (as indicated in the application 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 and \$500. 00 reinstatement fee.**

Date: _____ Administrator's Signature: _____

Signature name printed or typed: _____

Title of Administrator: _____

**GUIDE FOR APPLICATION 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 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

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 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

- 4.B. Presently reading under direct supervision of qualified interpreting physician

Continuing Education

5. 15 hrs. Category 1 CME documented in past 36 months

Continuing Experience

6. Has interpreted or multi-read at least 960 exams over a 2 year period

Item 6B Submit supportive documentation for each Radiologic Technologist performing mammography as follows:

Initial Requirements

1. Current ARRT "R" card

AND

Current State License

Initial Training before 4/28/99

2. 40 hours of documented mammography training or equivalent

OR

Current ARRT "M"

Initial Training on or after 4/28/99

3. 40 hours of documented mammography training which includes:

Breast Anatomy

QA/QC Techniques

Physiology

Imaging of patients with Breast Implants

Positioning and compression

AND

4. Performed at least 25 mammography exams under direct supervision of a MQSA qualified individual

Continuing Education

5. 15 hrs. CEU documented in past 36 months – Copies of certificates

Continuing Experience

6. Documentation of the number of patient exams performed in the past 24 months (200 exams / 24 months) please send a summary document on the facility's 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 (**STATE REQUIREMENT**)

AND

- 1.B. Board Certification (ABR or ABMP)

OR

- 1.C. Licensure from any State

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)

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)

Continuing Education

5. 15 hrs. CME documented in past 36 months – Copies of certificates

Continuing Experience

6. 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 equipment evaluation/survey report (physicist's report) for each mammography 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 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 MAMMOGRAPHY 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 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 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.
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
 - A mammography equipment evaluation within 6 months prior to the application date
 - A phantom image

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 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, 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