FDA APPROVED ACCREDITING BODY

ARKANSAS DEPARTMENT OF HEALTH RADIATION CONTROL

Application for Accreditation to Perform Mammography under MQSA

FDA Facility ID: _____ Accreditation MAS Number: _____ 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: New_____ Change_____ Renewal_____ Reinstatement_____

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

4. Number of mammography units to receive accreditation: _____
   Machine A:
   Manufacturer: _____ Model: _____
   Date of Manufacture: _____ Operator Console Serial # _____
   Machine B:
   Manufacturer: _____ Model: _____
   Date of Manufacture: _____ Operator Console Serial #: _____

5. Medical Physicist that supplied the Annual Physicist's survey or Mammography Equipment Evaluation:
   Name _____ AR Vendor Reg. Number: _____

6. Documents that MUST be submitted with this application for MQSA accreditation to perform mammography:
   A. Supportive documentation for Radiologic Technologist(s) (including FFDM and DBT training if applicable)
   B. A copy of the Physicist's survey report (Within 6 months for initial accreditation and within 14 months for reaccreditation/reinstatement)
   C. Phantom image using average technique factors for facility (see application guide). Submit the Phantom using the method in which the clinical images are routinely reviewed for interpretation at the facility. **DBT units see Guide.**
   D. Clinical Images and the reports (as indicated in application guide). Submit the Clinical Images using the method in which they are routinely reviewed for interpretation at the facility**. DBT units see Guide.**
   E. Accreditation fee in the amount of $700 for one unit, $500 for each additional unit. Reinstatement fee $500. ***DBT units submit an additional $100 per unit for review of phantom and clinical images.**
   F. Submit signed attestation regarding QA program (page 2 of the application)
   G. Submit signed Interpreting Physician approval of Clinical Images Form (page 3 of the application)
   H. Submit documentation regarding previous accreditation(if applicable, see application guide)

Administrator's Signature: _____ Print or typed: _____

Title: _____ Date: _____

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 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

MAS_____

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.

***Room _____**

***DENSE SUBMISSION PATIENT NUMBER_____**
Date of Mammogram_____
Please send reports with the images.

***ADIPOSE SUBMISSION PATIENT NUMBER_____**
Date of Mammogram _____
Please send reports with the images.

******Total Number of Mammograms performed at the facility in the past 12 months: _____**

*************Shipping address***************

Arkansas Department of Health-Radiation Control
5800 W. 10th Street, Suite 401
Little Rock, Arkansas 72204
ATTN: MAMMOGRAPHY PROGRAM

***For initial facility accreditation only-. Enclose the first 3 months of your facility's Quality Control (QC) data to be included with your clinical image submission. If the clinical images are sent in prior to 3 months, include all QC data up to that point.**

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 pt. exams under direct supervision in 6 month period immediately preceding initial qualifying date **or** if Board Certified at first possible opportunity, or if graduated from residency in or after 2014

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)

Continuing Education

6. 15 hrs. Category 1 CME documented in past 36 months (please send only the past 12 months for interpreting physicians submitted for previous accreditation)

Continuing Experience

7. Has interpreted or multi-read at least 960 exams over a 2 year period (please send the most current 24 month period)

Item 7 Submit supportive documentation for *each Radiologic Technologist performing mammography* as follows:

Initial Requirements for Radiologic Technologists

1. Current ARRT "R" card
   AND
   Current State License
   AND
   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
   AND
5. 8 hours of education in each mammographic modality used by the technologist. (This may be part of the 40 hours in items 2 or 3)

Continuing Education

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

Continuing Experience

1. 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 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 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 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 equipment evaluation/survey report (physicist's report) for each 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 the equipment evaluation/survey report (physicist's report) for each unit being accredited must be within the last 14 months.

Item 10 Phantom Image(s)

1. Submit a hard copy phantom (film screen only) or phantom image as an electronic digital image (may be submitted on CD, DVD or other media in DICOM format). JPEG or TIFF images may be sent electronically by email.
2. **FOR DIGITAL BREAST TOMOSYNTHESIS SYSTEMS**
   Submit the DBT Phantom at the level where the elements are best seen in focus and the 2D Phantom. If unable to submit the phantom on a one slice image, then send a complete set of DBT slices and indicate the level where the elements have been scored.
3. Each phantom submitted must contain technique factors utilized.
4. **SUBMIT ONE PHANTOM IMAGE PER UNIT WITH THE APPLICATION. (ADDITIONAL IMAGE(S) FOR TOMOSYNTHESIS)**
5. 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. For a DBT unit, the 2D portion and the DBT portion must each undergo accreditation. Each mammography modality must have two clinical image cases submitted per unit for review: one set demonstrating predominately adipose tissue and one set demonstrating predominately dense tissue. The clinical image cases can only have 4 images: 2 cranio-caudad (CC) and 2 mediolateral oblique (MLO) views. The format for submission of clinical images will depend upon the modality, possible manufacturer restrictions and the facility's primary clinical protocol. ***Include a copy of the interpreting physician's report for each set of images.***

   - Film-Screen Mammography – hard copy images

   - FFDM – electronic digital images (submitted on CD, DVD or other media in DICOM format).
     - 2D (CC & MLO) or
     - Synthesized 2D (CC and MLO), or
     - 2D CC and 2D synthesized MLO, or
     - 2D synthesized CC and 2D MLO

   - DBT – without synthesized capability (submitted on CD, DVD or other media in DICOM format).
     - DBT Series (CC and MLO views).

   - DBT – with synthesized capability (submitted on CD, DVD or other media in DICOM format).
     - Synthesized 2D (CC and MLO), or
     - 2D CC and 2D synthesized MLO, or
     - 2D synthesized CC and 2D MLO

5. **For initial facility accreditation only:**
   - 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.
   - Up to three submissions, if needed, will be accepted on initial, reaccreditation and reinstatement applications.
   - Images should be reviewed by an MQSA qualified interpreting physician whose signature is required on the Interpreting Physician Approval Form.

   - Enclose the first 3 months of your facility's Quality Control (QC) data with your clinical image submission. If the clinical images are sent in prior to the end of the first 3 months of use, include all QC data up to that point.

6. **For Reaccreditation** clinical images should be performed <u>within ninety days (90) prior to the application submission date</u> when facilities are going through the reaccreditation process.

7. 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 (film screen only) or phantom image as an electronic digital image may be submitted on CD, DVD or other media in DICOM format.

FOR DIGITAL BREAST TOMOSYNTHESIS SYSTEMS

Submit the DBT Phantom at the level where the elements are best seen in focus and the 2D Phantom. If unable to submit the phantom on a one slice image, then send a <u>complete</u> <u>set of</u> DBT slices and indicate the level where the elements have been scored.

REACCREDITATION:

1. For a DBT unit, the 2D portion and the DBT portion must each undergo accreditation. Each mammography modality must have two clinical image cases submitted per unit for review: one set demonstrating predominately adipose tissue and one set demonstrating predominately dense tissue. The clinical image cases can only have 4 images: 2 cranio-caudad (CC) and 2 mediolateral oblique (MLO) views. The format for submission of clinical images will depend upon the modality, possible manufacturer restrictions and the facility's primary clinical protocol. ***Include a copy of the interpreting physician's report for each set of images.***

- Film-Screen Mammography – hard copy images

- FFDM – electronic digital images (submitted on CD, DVD or other media in DICOM format).
    - 2D (CC & MLO) or
    - Synthesized 2D (CC and MLO), or
    - 2D CC and 2D synthesized MLO, or
    - 2D synthesized CC and 2D MLO

- DBT – without synthesized capability (submitted on CD, DVD or other media in DICOM format).
    - DBT Series (CC and MLO views).

- DBT – with synthesized capability (submitted on CD, DVD or other media in DICOM format).
    - Synthesized 2D (CC and MLO), or
    - 2D CC and 2D synthesized MLO, or
    - 2D synthesized CC and 2D MLO

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

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.
4. ***DBT units submit an additional $100 per unit for review of phantom and clinical images.**

Item 13 Submit documentation regarding previous accreditation approval or denial if previously with a different accreditation body. Any previous application made to an accrediting body other than the State of Arkansas must be accompanied by FDA Facility ID# and documentation regarding approval or denial of accreditation.

Has your facility previously been accredited with an accrediting body other than the State of Arkansas**? 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.