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## ***I. FFDM Phantom Image Reviews***

### **Phantom Image Criteria**

Each new, reaccreditation, and reinstatement application must include one original hard-copy phantom image for each unit being accredited, using the phantom recommended by that unit's manufacturer. Each phantom submitted must contain technique factors utilized and an optical density measurement of the image.

The phantom image passes the evaluation process when the phantom image is evaluated and passes by two approved SAR phantom image reviewers and meets or exceeds the minimum manufacturer requirements:

**Lorad Selenia:** requires at least 5 fibers, 4 speck groups, and 4 masses. However, the score of 4.5 fibers, 4.0 speck groups, and 3.5 masses is acceptable provided that both SNR and High Contrast Resolution of the system exceed recommended criteria.

**General Electric Senographe Systems:** require at least 4 fibers, 3 speck groups, and 3 masses.

The phantom image fails the evaluation process when the phantom is scored with less than the minimum manufacturer requirements.

New and reaccreditation applications are allowed three (3) submissions of phantom images, while reinstatement applications are only allowed two (2) submissions.

### **Phantom Image Review**

The reviews of the phantom image are documented on the Phantom Image Reviewer's Form, which are maintained in the facility's "Yellow" file along with the original phantom image. The overall results of the phantom image review are also documented on the Facility Accreditation Tracking Form and in the Mammography Database (tables: "phantom eval" and "phantom scores"). The Facility Accreditation Tracking Form is shown on the next page.

Phantom Image Reviewers perform the Phantom Image Review using the following evaluation method adapted from the MQSA inspection procedure.

**Phantom Information:** the following information about the phantom is documented on the Phantom Image Reviewer's Form:

1. Facility Name
2. Date of the Phantom
3. Name of the Reviewers
4. Date of the Review
5. Type of Review
6. Background Density
7. Object scores
8. Number and type of artifacts
9. Pass/Fail for each object and overall

**Background Density:** the background density is measured using a densitometer that has been calibrated by the FDA. The measured background density must be greater than or equal to 1.2 for screen-film systems under MQSA. For hard copy images, consult the FFDM system's QC manual.

**Scoring the phantom:** Scoring the phantom involves determining the number of fibers, speck groups, and masses visible on the phantom image. The following conditions are maintained when scoring the phantom:

1. The phantom is scored using a view box with masking to the phantom size.
2. The ambient light in the room where the phantom is scored is kept very low.
3. A magnifying glass is used to evaluate artifacts and score the speck groups.

**Fiber Scoring:** fibers are counted from larger to smaller (left to right). A fiber receives a score of 1.0 when the entire length of the fiber is visualized and is in the correct location and orientation on the phantom image. A fiber is given a score of 0.5 if more than half of its length is visible. The score is zero if less than half of the fiber is visible. Fibers will be counted until a fiber receives a score of less than 1. At that point no other fibers will be counted. Once the number of fibers is tabulated, the number of fiber-like artifacts is subtracted (note: amount subtracted must be 0, 0.5, or 1) from the number of fibers. This gives the total score for the phantom's fibers.

**Speck Group Scoring:** Speck groups are scored from the most prominent to the least prominent (starting at the middle of the second row to the middle of the third row moving from left to right.). When scoring the speck groups, a magnifying glass is used. A speck group may be counted as a full point if four or more of the six specks are visible at the correct location and orientation. A score of 0.5 may be given to a speck group if at least two or three of the six specks are visible. If fewer than two specks in a group are visible, the score is zero. Speck groups are counted until a speck group receives a score of less than 1. Once the number of speck groups is determined, the number of speck-like artifacts is subtracted from the number of specks in the last speck group (note: the number subtracted must be less than or equal to the number of specks in the last speck group).

After the speck-like artifacts are subtracted the score is determined by the number of specks that are left in that speck group using the same method as was used to determine the number of speck groups. If the number of speck-like artifacts are equal to or greater than the number of specks in the last speck group the score for that group is 0. If the number of speck-like artifacts is less than the number of specks in the last group the score is based on the difference between the number of specks in the last group and the number of speck-like artifacts. This gives the total score of the speck groups.

**Mass Score:** Masses are counted from larger to smaller (masses are counted from left to right beginning at the right edge of the third row of objects and proceeding to the fourth row of objects). A mass receives a score of 1.0 when a density difference is seen at the correct location and at least 3/4 of the circular border visualized. A mass receives a score of 0.5 when a density difference is seen at the correct location and at least 1/2 of the circular border is visualized. Density differences with less than 1/2 of the circular border visualized receive a score of zero. Masses are counted until one receives a score of less than 1. At that point no other masses will be counted. Once the number of masses is tabulated, the number of mass-like artifacts is subtracted from the number of masses (note: amount subtracted must be less than or equal to the score of the last mass (0, 0.5, and 1.0)). This gives the total score for the phantom's masses.

The form used for phantom image review is listed on the next page.

**Phantom Image Review Form**

Name of Reviewers:	<input type="text" value="Reviewer 1"/>	and	<input type="text" value="Reviewer 2"/>	
Tie Breaker:	<input type="text"/>	Date Reviewed:	<input type="text"/>	
Facility Under Review:	<input type="text"/>			
Accreditation Number:	<input type="text"/>			
Phantom Image Date:	<input type="text"/>			
Type of Review:	<input type="text"/> (Initial Review, Reaccreditation, Adding a new unit, Annual Submission)			
Background Density:	<input type="text"/>			

**Phantom Scores**

	<input type="text" value="Reviewer 1"/>	Scores	<input type="text" value="Reviewer 2"/>	Scores
Fibrils:	<input type="text"/>		<input type="text"/>	
Fibril Artifacts:	<input type="text"/>		<input type="text"/>	
Amount Subtracted:	<input type="text"/>		<input type="text"/>	
Fibril Total:	<input type="text"/>		<input type="text"/>	
Speck Groups:	<input type="text"/>		<input type="text"/>	
Specks in Group:	<input type="text"/>		<input type="text"/>	
Raw Speck Score	<input type="text"/>		<input type="text"/>	
Speck Artifacts:	<input type="text"/>		<input type="text"/>	
Amount Subtracted:	<input type="text"/>		<input type="text"/>	
Speck Total:	<input type="text"/>		<input type="text"/>	
Masses	<input type="text"/>		<input type="text"/>	
Mass artifacts	<input type="text"/>		<input type="text"/>	
Amount Subtracted:	<input type="text"/>		<input type="text"/>	
Mass Total:	<input type="text"/>		<input type="text"/>	

**Pass or Fail**

Fibrils:	<input type="text"/>		<input type="text"/>	
Speck:	<input type="text"/>		<input type="text"/>	
Mass:	<input type="text"/>		<input type="text"/>	
Overall:	<input type="text"/>		<input type="text"/>	
Tie Breaker Needed	<input type="text"/>			

The consensus of two MQSA certified inspectors with a minimum of 8 hours FFDM training is required to either pass or fail a phantom image. If the initial two reviewers are in disagreement or the total score of an object group differs by more than 0.5, a third reviewer (tiebreaker) is used. Currently the reviewers are Melinda Davis (#2345) and Sherry Davidson (#2344). These individuals will serve as initial reviewers.

If a tie-breaking reviewer is needed the phantom image label will be masked and another MQSA qualified phantom reviewer will then evaluate the phantom image or an Arkansas Registered Medical Physicist qualified to provide mammography medical physics. Approved Medical Physicist must be:

1. An MQSA qualified Medical Physicist, and
2. An Arkansas registered Medical Physicist, qualified to provide mammography medical physics services with the State of Arkansas.

Kaye Goss-Terry, of the State of Texas Mammography Accreditation Program, has volunteered to act as a tie-breaking reviewer. The current medical physicists who have volunteered to act as tie breaking reviewers are Paul Beck, M.S., Tom Bennett, M.S., and Chris Killgore, B.S.

Phantom image review is completed prior to the issuance of a 6-month Provisional Certificate for either new facilities or for new units at existing facilities. Phantom review for reaccreditation applications is typically performed within two weeks of receipt of the application.

### **Notification of Phantom Image Results**

The results of the phantom image review are communicated to the facilities by letter. If the phantom image has passed review the letter states: "Phantom Image dated (Month/Day/Year) was found to be adequate." This is included as part of the accreditation letters. If the phantom image failed review, the phantom score assigned by the reviewers as well as the required passing score is included along with the reasons for phantom failure. Specific deficiencies such as roller marks, excessive dust/lint artifacts, and mass-like artifacts are documented in the letter of notification. Improper positioning of the phantom is an automatic failure. If failure of the phantom is due to improper positioning, proper positioning of the phantom is discussed in the notification letter. An example of the form letter used to notify a facility of the phantom failure is listed on the next page.

DATE OF LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

RE: ACCREDITATION NO: ACCREDITATION NUMBER

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Arkansas Department of Health has completed the initial review of FACILITY NAME's Accreditation Application to Perform Mammography under MQSA. During the review the phantom image was found to be deficient and failed the review process.

NUMBER OF REVIEWERS colleagues from the Arkansas Department of Health reviewed the phantom image submitted with the application. The details of this review are as follows:

The phantom image dated: **DATE OF PHANTOM**

Overall Evaluation: **FAIL**

Reviewer Object Scores:

Reviewer 1 Scores

Reviewer 2 Scores

Reviewer 3 Scores

Fibers:

Fibers:

Fibers:

Specks:

Specks:

Specks:

Masses:

Masses:

Masses:

**Reason For Failure:** EXPLANATION OF THE FAILING SCORE (we are including the state's phantom scoring method to serve as a guide for your next phantom submission). The following scores are required for the phantom objects: fibers: 4, specks: 3, masses: 3.

**Secondary Findings and Comments:** EXPLANATION OF SECONDARY FINDINGS (artifacts, background density, etc.)

In order to proceed with your application, a second phantom image should be submitted for review. It should be noted that applications are allowed three (3) film submittals for phantom image review. Your first submission has failed phantom image review; therefore, you have two submissions remaining. As noted under Item 6G of the Application Guide, each additional review of clinical and phantom images requires an additional fee of \$100. **Please submit a second phantom image and check for \$100 made out to Arkansas Department of Health, Radiation Control Section.**

The failure of a phantom image, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a second phantom image submission.

If you have any questions regarding the accreditation process or we can be of any assistance with your mammography program, please contact this office at (501) 661-2301. Please address correspondence to ***Mail Slot #30***.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

DATE OF LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

RE: ACCREDITATION NO: ACCREDITATION NUMBER

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Arkansas Department of Health has completed the review of FACILITY NAME's second phantom image submission. During the review the phantom image was found to be deficient and failed the review process.

NUMBER OF REVIEWERS colleagues from the Arkansas Department of Health reviewed the phantom image submitted with the application. The details of this review are as follows:

The phantom image dated: **DATE OF PHANTOM**

Overall Evaluation: **FAIL**

Reviewer Object Scores:

Reviewer 1 Scores

Reviewer 2 Scores

Reviewer 3 Scores

Fibers:

Fibers:

Fibers:

Specks:

Specks:

Specks:

Masses:

Masses:

Masses:

**Reason For Failure:** EXPLANATION OF THE FAILING SCORE (we are including the state's phantom scoring method to serve as a guide for your next phantom submission). The following scores are required for the phantom objects: fibers: 4, specks: 3, masses: 3.

**Secondary Findings and Comments:** EXPLANATION OF SECONDARY FINDINGS (artifacts, background density, etc.)

In order to proceed with your application, a third phantom image should be submitted for review. It should be noted that applications are allowed three (3) film submittals for phantom image review. Your second submission has failed phantom image review; therefore, you have one submission remaining. As noted under Item 6G of the Application Guide, each additional review of clinical and phantom images requires an additional fee of \$100. **Please submit a second phantom image and check for \$100 made out to Arkansas Department of Health, Radiation Control Section.**

The failure of a phantom image, like any other adverse accreditation decision, can be appealed. If after further review, you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and you wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a third phantom image submission.

If you have any questions regarding the accreditation process or we can be of any assistance with your mammography program, please contact this office at (501) 661-2310. Please address correspondence to ***Mail Slot #30***.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

DATE OF LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

RE: ACCREDITATION NO: ACCREDITATION NUMBER

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Arkansas Department of Health has completed the review of FACILITY NAME's third (final) phantom image submission. During the review the phantom image was found to be deficient and failed the review process. Unfortunately, this application to add the new unit to your facility's certificate has been denied. This denial is based on the failure of the three phantom images that were submitted. The results of the final review are listed below.

NUMBER OF REVIEWERS colleagues from the Arkansas Department of Health reviewed the phantom image submitted with the application. The details of this review are as follows:

The phantom image dated: **DATE OF PHANTOM**

Overall Evaluation: **FAIL**

Reviewer Object Scores:

Reviewer 1 Scores

Reviewer 2 Scores

Reviewer 3 Scores

Fibers:

Fibers:

Fibers:

Specks:

Specks:

Specks:

Masses:

Masses:

Masses:

**Reason For Failure:** EXPLANATION OF THE FAILING SCORE (we are including the state's phantom scoring method to serve as a guide for your next phantom submission). The following scores are required for the phantom image objects: fibers: 4, specks: 3, masses: 3.

**Secondary Findings and Comments:** EXPLANATION OF SECONDARY FINDINGS (artifacts, background density, etc.)

During the accreditation process you are allowed three submissions phantom images (Application Guide Item 6F). Since all three submissions of phantom images have failed, your accreditation application dated DATE OF APPLICATION is denied.

In order to resume performing mammography your facility must be reinstated. The reinstatement process involves several steps, which are detailed below.

- A. First, a Corrective Action Plan (CAP) must be submitted. This plan should detail the actions that will be taken to address the clinical image deficiencies noted by the CIRC. This CAP should also document the estimated completion date for each of the corrective actions. This corrective action plan should include the following:
  1. ACTION ONE THAT SHOULD BE TAKEN
  2. ACTION TWO THAT SHOULD BE TAKEN
  3. ACTION THREE THAT SHOULD BE TAKEN
  
- B. Along with the Corrective Action Plan, your facility should submit an accreditation application. This application must include a current physicist survey (within 6 months), one phantom image, and \$500 application fee and any updates to the personnel documentation for the Interpreting Physicians, Radiologic Technologist, and Medical Physicist. Once this information is received and reviewed a colleague from the Arkansas Department of Health and Human Service's Mammography Accreditation Program will inform you that you have been approved for reinstatement and the information will be forwarded to the Food and Drug Administration and your facility will be given a 6-month Provisional Reinstatement of the unit.

For your convenience, I am including a blank application form.

### **RIGHT TO APPEAL**

If you feel that the decisions regarding your facility were inaccurate and/or did not warrant failure, you may appeal the decision. This process is outlined on the Appeal Procedure, which is included.

If you have any questions regarding the accreditation process or we can be of any assistance with your mammography program, please contact this office at (501) 661-2301. Please address correspondence to ***Mail Slot #30***.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

## ***II. FFDM Qualifications for Phantom Image Reviewers.***

### **Initial Training:**

All Phantom Reviewers for the State of Arkansas' Accreditation Body (SAR) are either Certified MQSA inspectors with a minimum of 8 hours training specific to FFDM or MQSA qualified/SAR registered Medical Physicists with a minimum of 8 hours FFDM training.

To act as a primary reviewer for the SAR, the phantom image reviewer must review at least 20 phantom images under the direct supervision of one of the current phantom image reviewers.

Prior to independently reviewing phantoms, new reviewers must watch the FDA's CDRH TV Video, Phantom Image Scoring with Stephanie Belella and Thomas Clarida.

### **Continuing Experience/Education:**

Each reviewer must review at least 20 phantom images per year as part of the Accreditation Process and/or during MQSA inspections.

Each reviewer must watch the FDA's CDRH TV Video, Phantom Image Scoring with Stephanie Belella and Thomas Clarida at least once a year.

To ensure that all reviewers meet these continuing education/experience requirements, annually the SAR will hold a PIR training session, in which 20 phantom images will be reviewed and discussed. In conjunction with this training session, the FDA's CDRH TV Video, Phantom Image Scoring with Stephanie Belella and Thomas Clarida will be reviewed and discussed.

Each reviewer must maintain his or her certification as an MQSA Inspector or MQSA qualified/SAR registered Medical Physicist.

### **Phantom Image Reviewers Performance Audit.**

The performance of the Phantom Image Reviewers is reviewed annually. This is done as part of the Accrediting Body Annual Performance Evaluation. Statistics for each reviewer and the SAR as a whole are evaluated. The primary measure is the agreement rate. This is calculated using the following formula.

Agreement rate = [(Total Number of reviews – Number of Tie breaking reviews) / Total Number of reviews] \* 100

### ***III. Use of FFDM Phantom Image Scores***

**Accreditation:** During the Accreditation Process phantom images are used as an indicator of the system image quality of a facility. The FFDM phantom image is generated and submitted by the staff of the facility. The phantom image is reviewed and must receive a passing score before a facility can image patients. ***All images submitted for FFDM accreditation are to be hard copy originals.***

**Correction of Deficiencies:** If during any part of the accreditation process, random clinical image review, or additional medical review it is noted that the system image quality is not optimal, the SAR may require that the facility submit weekly phantom images for review. During this process the SAR will give weekly feedback to the facility via telephone communications and will give written feedback upon completion of the corrective action.

### ***V. FFDM Clinical Image Review***

#### **Film Review Process**

When the accreditation staff receives clinical images, the films are logged into the Image Review Log. The Clinical Image Review Log is used for accreditation/reaccreditation, random review, on-site review and AMR films. Each type of review has its own section in the Image Review Log. In addition to the Image Review Log, the results of the Clinical Image Reviews are maintained in a Microsoft Access based Mammography Database.

The Clinical Image Review Log Form is listed on the Next Page.

**CLINICAL IMAGE REVIEW LOG**

Accreditation Number and Facility Name					
Date Received					
Patient ID # and Date of Films					
<b>Label Review (P/F)</b>					
1st Reviewer ID # and Date Mailed					
<b>Date Received from 1st Reviewer</b>					
Results of 1st Review (P/F)					
2nd Reviewer ID# and Date Mailed					
<b>Date Received from 2nd Reviewer</b>					
Results of 2nd Review (P/F)					
<b>3rd review needed?</b>					
3rd Reviewer ID # and Date Mailed					
<b>Date Received from 3rd Reviewer</b>					
Results of 3rd Review (P/F)					
Pathology Suspected? (Y/N)					
Date ADH/Facility Notified					
Date Films/Letter Mailed Back To Facility					

COMMENTS:

As noted on the Image Review Log, the next step of the procedure is the film labeling review. The criteria for this review are noted below under the **Film Labeling** section. Clinical images, which do not meet the film labeling criteria, are FAILED by the accreditation staff, are not submitted to the Clinical Image Review Committee (CIRC) for review, and are considered one submission of clinical images.

### **Film Labeling Review**

Each clinical image label must contain the facility name and location (with postal code), patient name, patient identifier (patient ID/Social Security number/date of birth), date of exam, technologist identification, and unit number (if applicable).

Each film must also contain a marker indicating laterality (Right or Left) and projection/view (MLO or CC) placed nearest to the axilla of the breast imaged. The technologist may be identified with these markers.

Reviewer's Evaluation of Film Labeling form is listed on the next page. The film labeling review form is performed by the accreditation staff, who are Certified FDA MQSA Inspectors.

### Evaluation of Film Labeling

Review Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_  
 Facility Under Review: \_\_\_\_\_  
 Accreditation Number: \_\_\_\_\_  
 Mammogram ID Number: \_\_\_\_\_  
 Mammogram Date: \_\_\_\_\_  
 Dense or Fatty: \_\_\_\_\_

**Passed Evaluation  
(Yes/No)**

Facility Name and Location (Name, City, State, and Zip)  
 Patient Name  
 Patient Identifier  
 Date of Examination  
 Projection/view (Labeled correctly and properly positioned)  
 Technologist (Name or Initials)  
 Unit ID Number (If more than one unit at facility)  
 Overall


Type of Review (Initial Review, Reaccreditation, Reinstatement)

--

**Comments:**


Clinical images, which PASS the film labeling review, are then prepared for submission to the first reviewing member of the CIRC. Staff members complete the applicable sections of the Mammography Evaluation Form - Physician's Review Form. This information includes the Facility Under Review, which is only identified by the state accreditation number (MAS0000), the type of film review (initial, reaccreditation, random), a film tracking number, breast type as stated by the facility (dense or fatty), and film technical factors.

### **Determination of Breast Type**

Prior to the evaluation of film quality, the clinical image reviewer must determine if the clinical image demonstrates imaging of the indicated breast type. Although the application guide states that a facility should select images that demonstrate imaging of breasts that are 75% glandular tissue for dense submissions and 75% adipose tissue for fatty submissions, the clinical image reviewer will decide based on clinical experience. The guide for this determination is whether the submission is predominately glandular tissue for examples of imaging dense breasts or predominately adipose tissue for examples of imaging fatty breasts.

If the initial reviewer determines that a set of images does not represent the indicated breast type, this is reflected on the evaluation form and a review of film quality is not performed. This is not considered a clinical image review failure. The facility will be instructed that the images did not represent the indicated breast type and an additional set will be requested.

If the initial reviewer determines that a set of clinical images represents the indicated breast type and the second reviewer indicated that they do not, the set of clinical images will be sent for a tie-breaking review. If after the tie-breaking review, the set of clinical images is determined not to represent the indicated breast type the facility will be informed that the images did not represent the indicated breast type and an additional set will be requested. If, however, the tie-breaking reviewer determines that the images do represent the indicated breast type the results of the evaluation will be used as the second evaluation of film quality.

### **Film Quality Evaluation by Clinical Image Reviewers**

The State of Arkansas accreditation body shall use the following attributes for all clinical image reviews; the criteria listed on the evaluation forms are based on these attributes:

- *Positioning.* Sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning.
- *Compression.* Compression shall be applied in a manner that minimizes the potential obscuring effect of overlying breast tissue and motion artifact.
- *Exposure level.* Exposure level shall be adequate to visualize breast structures. Images shall be neither underexposed nor overexposed.
- *Contrast.* Image contrast shall permit differentiation of subtle tissue density differences.

- *Sharpness*. Margins of normal breast structures shall be distinct and not blurred.
- *Noise*. Noise in the image shall not obscure breast structures or suggest the appearance of structures not actually present.
- *Artifacts*. Artifacts due to lint, processing, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present.

These attributes are listed on the Mammography Evaluation Form-Physician's Review Form. In addition to the attributes the State of Arkansas Accreditation body has developed specific primary [indicated with an asterisk (\*)] and secondary criteria for each attribute. A deficiency of a primary criterion can be justification for failure of a set of clinical images, while deficiencies of three secondary criteria is justification for failure of a set of clinical images.

The Mammography Evaluation Form- Physician's Review Form is shown on the next pages.

**Mammography Evaluation Form - Physician's Review Form**

---

Reviewing Physician:		
Facility Under Review:		
Type of Review:		
Film Identification:		
Date of Images		
Mammo. Unit Identification		

Film Technique Factors

VIEW	kVp	mAs	Compression (mm)

Film type as stated by the facility under review:  (Fatty, Dense, or Choice)

Actual Breast Type as determined by the Clinical Image Reviewer

<input type="text"/> 1- Fatty	<input type="text"/> 3-Moderately Dense
<input type="text"/> 2-Average	<input type="text"/> 4-Dense

Fatty Enough for Evaluation? \_\_\_\_\_ YES \_\_\_\_\_ NO

Dense Enough for Evaluation? \_\_\_\_\_ YES \_\_\_\_\_ NO

\*\*If "NO" Films will not be evaluated - No further review is required\*\*

---

**I. POSITIONING**

**MLO Views**

**Please circle the view(s) that had the deficiency.**

\*  Pectoral Muscle not well-visualized or does not extend to or below the nipple line.

RMLO	LMLO	Both
------	------	------

Inframammary fold not open.

RMLO	LMLO	Both
------	------	------

\*  Low axilla not included.

RMLO	LMLO	Both
------	------	------

\*  Retroglandular fat not visible behind glandular tissue.

RMLO	LMLO	Both
------	------	------

Other.

RMLO	LMLO	Both
------	------	------

**I. POSITIONING (Continued)**

**Comments on the Positioning of the MLO Views**

**CC Views**

**Please circle the view(s) that had the deficiency.**

Posterior Nipple line should not be less than 1.0 cm from MLO.

RCC	LCC	Both
-----	-----	------

\* All breast tissue not visualized (excluding the axillary tail).

RCC	LCC	Both
-----	-----	------

Nipple was not centered.

RCC	LCC	Both
-----	-----	------

Other.

RCC	LCC	Both
-----	-----	------

**Comments on the Positioning of CC Views**

**General Positioning**

- Nipple not in profile on at least one view.
- Skin folds.
- Other body parts projected over the breast image.
- Other.

**I. POSITIONING (Continued)**

**Comments on General Positioning**

**Positive Aspects of Positioning (Bonus)**

- Pectoral Muscle Visualized on the CC views.
- Excellent Patient Positioning by the Technologist.

**Most likely causes of the positioning deficiencies.**

- Inappropriate mammographic projections.
- Technologist's positioning technique.
- Unsuitable Mammographic Equipment.
- Wrong size recording system.
- Other.

**II. Compression**

**Please circle the view(s) with deficiency**

\*  Poor separation of parenchymal densities.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

\*  Patient motion.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

Non-uniform exposure levels or detail.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

Other.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

**II. Compression (Continued)**

**Most likely cause of compression deficiencies:**

Undercompression by the technologist.

Unsuitable compression device.

Other.

**Comments on Compression**

---

**III. Exposure**

Overexposed (dark/overpenetrated).

\* Underexposed (light)/underpenetrated).

Other.

**Most likely cause of exposure deficiencies**

Improper manual timing.

Improper technique factors.

Inadequate film processing (over-or-underdeveloped).

Other.

**Comments on Exposure**

**IV. Spatial Resolution/Sharpness**

Please circle the view(s) with deficiency

\*  Poor delineation of linear structures.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

\*  Poor delineation of tissue margins.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

\*  Poor delineation of microcalcifications.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

Other.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

**Most likely cause of exposure deficiencies**

Undercompression.

Screen/film-screen contact.

Motion Blur.

Other.

**Comments on Spatial Resolution/Sharpness**

**V. Contrast**

\*  Inadequate contrast ("gray", "flat", "low contrast").

Other.

**Most likely cause of contrast deficiencies**

Improper tube kVp.

Film or film development.

Excessive Scatter.

**V. Contrast (Continued)**

**Comments on Contrast**

**VI. Noise**

- \*  Visually striking mottle pattern. (n/a for digital films)
- \*  Noise-limited microcalcification detection.
- \*  Noise-limited tissue characterization.
- \*  Other.

**Comments on Noise**

**VII. Artifacts**

**Please circle the view(s) with deficiency**

- \*  Roller Marks.(n/a for digital films)

RMLO	LMLO	LCC	RCC
------	------	-----	-----

- Punctate artifacts/pick-off.  
(n/a for digital films)

RMLO	LMLO	LCC	RCC
------	------	-----	-----

- Scratches.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

- Lint.

RMLO	LMLO	LCC	RCC
------	------	-----	-----

**VII. Artifacts(Continued)**

<input type="checkbox"/> Chemical Stains. (n/a for digital films)	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
<input type="checkbox"/> Grid-related artifacts.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
<input type="checkbox"/> Patient-related artifacts.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
* <input type="checkbox"/> Film-handling artifacts/fingerprints. (only applicable to wet processing)	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
* <input type="checkbox"/> Fog. (only applicable to wet processing)	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
* <input type="checkbox"/> Film exposed light.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
<input type="checkbox"/> Linear artifacts.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
* <input type="checkbox"/> Film bend/tear.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
* <input type="checkbox"/> Discolored.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		
<input type="checkbox"/> Other.	<table border="1"><tr><td>RMLO</td><td>LMLO</td><td>LCC</td></tr></table>	RMLO	LMLO	LCC
RMLO	LMLO	LCC		

**Most likely cause of artifact deficiencies**

- Poor screen maintenance.
- Processing related (Development, Fixation, or mechanical damage on wet processed film).
- Unsuitable grid or bucky.
- Poor film storage or outdated film.
- Lack of patient preparation.
- Other.
-

### Overall Film Quality

<b>Pass</b>	<input type="checkbox"/>
<p>A deficiency in any single aspect denoted by an asterisk (*) will be sufficient Cause for failing the patient image quality review. Three or more deficiencies In any other aspect is also cause for failure.</p>	

<b>Fail</b>	<input type="checkbox"/>
<p><i>If the images fail, please choose one of the following:</i></p>	
<b>Images fail, but are of diagnostic quality</b>	<input type="checkbox"/>
<b>Images fail to the extent that there is potential to adversely affect diagnostic capacity of images produced at this facility.</b>	<input type="checkbox"/>

**Suspicion of pathology: Please review the film quality as usual**

**Additional comments regarding the clinical image review/suspected pathology:**

--

Reviewing Physician's Signature: \_\_\_\_\_

Name Printed or typed: \_\_\_\_\_

Date of film Review: \_\_\_\_\_

The CIR process is a “blind” review. In order to assure that there is no bias or “actual or real” conflict of interest, the films are masked. Blackened strips of x-ray film are taped over all film identification labeling, with the exception of the projection/view. The accreditation staff labels the films with the state accreditation number, the film identification number, and whether the examination is of fatty or dense breasts. This type of masking allows the films to be unmasked at the end of the CIR process and returned to the facility in the same condition in which they were received.

After masking the films, the SAR staff must then determine to which reviewer the images will be submitted. As noted in the initial Accrediting Body (AB) application, volunteer members of the CIRC are located throughout the State of Arkansas. The CIR is a “blind” process. However, to assure that a clinical image reviewer does not have a financial interest in the facility whose images he or she is reviewing, the SAR endeavors to assure that the reviewer will not conduct reviews of facilities within 50 miles of their primary practice location. Typically reviewers do not conduct reviews of facilities within 75-100 miles of their primary practice location. In addition, the SAR maintains a list of all facilities at which reviewers have a financial interest, perform services, or are otherwise associated.

After selecting a reviewer for the films, the Mammography Evaluation Form - Physician’s Review Form and the Image Review Log are completed. The films are transferred to the reviewers by one of three methods:

1. Local reviewers (Little Rock area) are hand-delivered the films by members of the staff. The transfer of films from the SAR to reviewer and reviewer to SAR is documented on the Acknowledgment Receipt of Patient Films Notebook. The SAR keeps this notebook with the Clinical Image Review Log Book.
2. Films are mailed to regional reviewers using Federal Express, and are returned via Federal Express second day delivery.
3. Films needing immediate review are sent Federal Express next day delivery. The SAR maintains a copy of the FedEx Sender’s Copy.

Upon return of the films from the first reviewer, the results are logged in the Clinical Image Log Book and the Facility Accreditation Tracking form. The Mammography Evaluation Form - Physician’s Review Form is placed into the facility’s “Yellow” folder, which is used for all documentation regarding clinical image review and phantom image review.

Following the procedures outlined above, the films would be submitted to a second reviewer, reviewed and returned to the SAR. If necessary, a third review of the films would be conducted by a tiebreaker.

At the present time, the SAR typically completes the CIR process within thirty (30) days of receipt of the films. If necessary, due to impending expiration of a facility’s current FDA Certificate to Perform Mammography, the SAR may elect to accelerate the CIR process by the use of local reviewers or Overnight FedEx. The acceleration of the CIR process is not, however, a SAR policy and is used at the discretion of accreditation staff based on the timeliness of the application submission.

**Suspicious for Pathology**

If a member of the CIRC notes “suspicious for pathology” on the clinical images which were submitted to the SAR as negative or benign, the reviewer notes the questionable or suspected pathology under the comment section of the Mammography Evaluation Form - Physician’s Review Form. Upon return of the films to the SAR, the facility will be immediately, within one working day of receipt by accreditation staff, notified via telephone of the findings. A letter notifying the facility of the suspected pathology is then mailed to the facility. This letter requires the facility to respond in writing to the SAR within ten (10) days, concerning the patient follow-up of the suspected pathology

The suspicious for pathology letter is sent on ADH letterhead. An example of this letter is shown on the next page.

**Certified Mail**

DATE OF THE LETTER

FACILITY CONTACT

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

As discussed during our telephone conversation, the Clinical Image Review Committee noted the following suspicious pathology on the clinical images submitted to us.

Patient I.D. XXXXX- There was a suspicious area in the (RIGHT or LEFT) Breast. This patient needs further evaluation or our Department needs verification that the suspicious area has been evaluated in the past.

**Please submit follow-up evaluation plans to this office within ten (10) days of receipt of this letter.**

The aforementioned patient films are enclosed.

If you have any questions or concerns please call this office at (501) 661-2301. Please address correspondence to me at Mail Slot # H-30.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

## **Selection of Clinical Images for Review**

*Accreditation:* the staff of the facility that is seeking accreditation selects and submits the clinical images that are used during the accreditation process. The facility must submit one set (4 images RCC, RMLO, LCC, and LMLO) of images demonstrating imaging of fatty breasts and one set of images demonstrating imaging of dense breasts. The application guide states that a facility should select images that demonstrate imaging of breasts that are predominantly glandular tissue for dense submissions and predominantly adipose tissue for fatty submissions.

SAR reserves the right to grant an extension of the prescribed timeframe for image selection in the event that a facility has extenuating circumstances which would hinder the selection of images meeting the criteria stated above. An example of this would be a mammography program operated in a retirement center or a community comprised of predominately retirement age individuals or in the case of facilities with low patient volume. In this event, the facility shall notify SAR and alternative clinical image selection methods will be outlined which do not compromise image quality.

*Random Clinical Image Review:* To ensure that the sample is random, each facility is assigned a number from 1 to the total number of facilities accredited by the SAR. This number is currently 60 (July 1, 2007). Then, using a Microsoft Excel based random number generator, a number is selected. Reviews are performed on the facility that corresponds to the number that is selected. If a facility is selected and it has gone through a random clinical image review within the preceding 6 months, the accreditation process within the preceding 6 months or has received notification of the need to begin the accreditation renewal process, the random clinical image review will not be requested and an additional facility will be selected.

The staff of the facility is given written notification that is used during the random review. The facility must submit two sets of dense images, two sets of fatty images, and one set that demonstrates the large image receptor size. The SAR will perform Random Clinical Image Review on at least 3% of the facilities that it accredits annually.

An example of the letter sent requesting random clinical images is listed on the next page (printed on ADH letterhead).

## DATE OF THE LETTER

Facility Contact, Contact Title

Facility Name

Address 1

Address 2

City, AR, Postal Code

RE: MAS0XXX

Dear Contact Greeting:

As part of our continuous quality improvement assessment, your facility has been randomly selected to submit clinical images. We request that your facility submit five (5) mammography studies (per mammography unit) that were performed within the last 90 days, and are not waiting to be read by a radiologist. These films must have been interpreted as negative or benign. Please submit the following five (5) sets:

- 2 - mammography studies that demonstrate imaging of patients with fatty breasts.
- 2 - mammography studies that demonstrate imaging of patients with dense breasts.
- 1 - study your choice

One of the five sets must be on 24 X 30 film. **All images submitted must be hard copy originals. Please remember all mammography studies submitted must be negative or benign.**

If you have any questions regarding this matter please contact our office at 501-661-2301. The mammogram films should be mailed to **Mail Slot #30.**

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

The results of a passing the random clinical image review will be sent using the letter shown on the next page (printed on ADH letterhead).

**Certified Mail**

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the random clinical images, submitted on DATE SUBMITTED. It is required that at least 60% of the five mammography studies submitted, pass the review. NUMBER OF PASSING SETS OF IMAGES of the submitted sets of images (PASSING PERCENTAGE) were found to be adequate by members of the Clinical Image Review Committee (CIRC).

The results of the random image review and comments made by the CIRC are listed on the attached page. Please look over the comments and make appropriate changes as needed.

Thank you for responding to the request for submission of random clinical images. Should you have any questions or concerns regarding this film review and/or your mammography program, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

## Clinical Image Review Results

For the purpose of Clinical Image Review the following criteria is used: *a deficiency in any single aspect denoted with an asterisk (\*) will be sufficient cause for failing the patient film quality review. Three or more deficiencies in any other aspect are also cause for failure.*  
Please note: Reviewers comments next to each check-off criterion.

### Set 1

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

### Set 2

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

### Set 3

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

**Set 4**

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

**Comments:**

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

**Set 5**

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

**Comments:**

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

If a facility fails a random clinical image review, the SAR will request a limited Additional Mammography Review (specified timeframe and at least three sets of clinical images), and an accreditation onsite visit will be performed. This review is requested in the random clinical image notification letter. This letter is shown on the next page.

**Certified Mail**

DATE OF THE LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the random clinical images, submitted to us on DATE IMAGES SUBMITTED. It is required that at least 60% of the sets pass the review. NUMBER OF SETS OF IMAGES THAT PASSED of the five submitted sets of images (PERCENTAGE OF PASSING IMAGES) were found to be adequate by members of the Clinical Image Review Committee (CIRC).

Unfortunately, your facility has failed the initial random clinical image review. As a result the State of Arkansas Accreditation Program (SAR) will set up an accreditation on-site visit. During the on-site visit a representative from the SAR will select three additional sets of clinical images for review.

If the second submission of clinical images fails, the Food and Drug Administration will be notified of the failure. Depending on the severity of the deficiencies, your facility may be required to temporarily terminate mammography services or may have its accreditation revoked. Your facility will also have to submit a corrective action plan, which addresses the deficiencies noted during the random clinical image review.

The results of the random image review and comments made by the CIRC members are on the attached pages. Please review the deficiencies and address them immediately. The accreditation on-site visit will be set up within the next 30 days.

Should you have any questions or concerns regarding this film review and/or the second submission of random clinical images, please contact Sherry Davidson or me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

## Clinical Image Review Results

For the purpose of Clinical Image Review the following criteria is used: *a deficiency in any single aspect denoted with an asterisk (\*) will be sufficient cause for failing the patient film quality review. Three or more deficiencies in any other aspect are also cause for failure.* Please note: Reviewers comments next to each check-off criterion.

### Set 1

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

### Set 2

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

### Set 3

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

### Set 4

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

#### Comments:

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

**Set 5**

Patient Films ID: ID NUMBER, dated DATE OF IMAGES – (Pass or Fail)

**Comments:**

**MLO:** COMMENTS MLO VIEWS

**CC:** COMMENTS CC VIEWS

**Other:** OTHER COMMENTS

If the second submission of clinical images fails the clinical image review process, the Food and Drug Administration will be notified of the failure. Along with the notification the SAR will submit a draft of the correspondence that will be sent to the facility outlining the actions that should be taken by the facility and any other recommendations of the SAR.

Depending on the severity of the deficiencies, the facility may be required to temporarily terminate mammography services or may have its accreditation revoked.

At a minimum the facility will have to complete the following steps:

- Submit a corrective action plan, which addresses the deficiencies noted during the clinical image reviews within 10 business days of the notification
- Complete the actions specified in the Corrective Action Plan within three months
- Submit five additional sets of clinical images following the completion of the actions specified in the Corrective Action Plan.

At the completion of the Corrective Action Plan, the submitted images fail the clinical image review process the facility's accreditation will be revoked.

As with all decisions made by the State of Arkansas Accreditation Body the facility has the right to appeal. Along with the letter informing the facility of the deficiencies, a copy of the appeal procedure will be sent.

*Additional Mammography Review:* Additional Mammography Review is used only in cases where the quality of images produced at the facility is suspected to have been compromised. As such, the quantity and selection of the clinical images will be determined on a case-by-case basis. The selection process and the number of films selected will be based on information obtained from a "For Cause" onsite accreditation visit. This visit may be initiated by consumer complaint, MQSA annual inspection, onsite visit, or a failing random clinical image review.

## **VI. *FFDM Clinical Image Reviewers Qualifications***

### **Initial Training:**

Members of the Clinical Image Review Committee are required to meet the initial qualifications and continuing experience and education requirements of 21 CFR 900.12(a)(1).

Documentation regarding compliance with the continuing requirements is on file at the Arkansas Department of Health.

Initial training of reviewers is conducted prior to their evaluating clinical images independently. Eklund, G.W., Cardenosa, G., and Parsons, W.: Assessing Adequacy of Mammographic Image Quality, RAD 190:2 297-307 is distributed to each reviewer and a meeting is held to discuss the “Criteria for Good Quality Mammograms”.

In addition to the initial training, new reviewers must complete the mentoring process and meet at least one of the following additional requirements.

Additional requirements: certified by the American Board of Radiology, member of the American College of Radiology, completion of a specialty fellowship in mammography, published articles on breast imaging or related subjects, read at least 1500 mammography studies per year, participate in activities which promote breast cancer awareness or education, and demonstrate a dedication to providing outstanding mammography services to the women of Arkansas.

### **Mentoring Process:**

The process of mentoring will be achieved by first submitting Clinical Images to the New Clinical Image Reviewers for evaluation. Once this has been accomplished the images will be sent to the mentor along with a form that will denote whether or not the mentor agrees with the evaluation of the New Reviewer. If the mentor does not agree with the evaluation or has additional comments they should document this on the form, and contact the new reviewer to discuss the evaluation.

The Clinical Image Reviewer Mentor Form is listed on the next page.

# Clinical Image Reviewer Mentoring Form

1. Results of the Clinical image Review performed by the New Reviewer:

I agree with the results

I disagree with the results

2. Overall film quality:

PASS

FAIL

3. Mentoring Clinical Image Reviewer:

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

4. Additional Comments (If Mentor disagrees with the results):

---

---

---

---

---

5. New Clinical Image reviewer contacted by mentor to discuss comments (if any):

YES

NO

If new clinical image reviewers have questions regarding the review process they should contact their mentors.

The mentoring process will last for five evaluations of clinical images.

A contact list will be generated and sent to each of the clinical image reviewers to facilitate communication between the members.

**Continuing Education:**

Continuing training is conducted at least annually during the CIRC meeting. Regulation changes and relevant subjects are presented to and discussed by members of the Committee. If necessary, meetings may be held at greater than annual frequency to conduct required business and training.

To ensure consistency among the reviewers, an audit of the CIR results is conducted annually. This information is presented to the members during the annual meeting. Based on the outcome of the audit, members discuss issues relevant to the findings. If significant inconsistencies are noted, a member of the SAR staff notifies the CIRC chairman. The chairman discusses the inconsistency with the reviewer in question.

## ***VII. FFDM Additional Mammography Reviews***

Additional Mammography Review (AMR) is used only in cases where there are significant indications that the quality of images produced at the facility has been compromised. As such, the quantity and selection of clinical images will be determined on a case-by-case basis.

There are two types of additional mammography reviews. The first is a Limited AMR, which will consist of the review of at least three sets of clinical images. This type of review may be initiated by consumer complaint, MQSA annual inspection, onsite visit, recommendations for an additional mammography review by a clinical image reviewer, or a failing random clinical image review.

The second type of AMR is a Full AMR. This type review is initiated to evaluate problems that have or may have the potential to adversely affect the diagnostic capacity of the images produced and/or evaluated at a facility. A minimum of 30 clinical images will be selected by the SAR staff and reviewed by two senior members of the Clinical Image Review Committee (CIRC). In addition to the standard review, the reviewer will be asked to determine, based on the quality of clinical images, whether or not there is a significant health risk associated with the lack of image quality. The two reviewers will agree to consult together to reach one conclusion as to this finding. If the assessment is that there is not a significant health risk, the statement will be forwarded to the Food and Drug Administration (FDA). If the assessment concludes that there is a significant health risk, then a statement documenting this finding will also be forwarded to the FDA.

### **The following points will be used as guidelines when deciding how and when an AMR should be performed:**

1. Limited AMR consists of at least 3 cases.
2. Full AMR consists of 30 cases.
3. While impossible to achieve complete randomization, cases shall be selected in such a manner as to minimize the possibility of facility bias. For a Limited AMR, these cases may be selected by the facility's Lead Interpreting Physician or by a colleague from the SAR. In the event of a Full AMR, these cases will be selected by a colleague from the SAR.
4. A senior clinical image reviewer will be needed to conduct an AMR.
5. The SAR will gather as much information as possible with respect to the reasons for the AMR and whether there are questions about the quality of interpretation. Individual reviewers will be blinded to information (e.g., fraud) that is not directly needed for the evaluation so as to avoid biasing the review.
6. Each case will be evaluated first on the image label review. Should the images fail the label review, this will be considered a failure and the images will not be sent to the CIRC for further review. Provided the label review passes, the images will be

evaluated on the 7 attributes listed on the Clinical Image Review Forms and there will be a pass/fail assessment for each case.

7. Additional Mammography Reviews can be used to evaluate interpretation quality.
8. Unless there are other indications of quality problems, the fact that a facility fails an AMR would not automatically require that AMRs be done at other facilities where those same personnel work.
9. The SAR will provide the FDA with an overall assessment for the entire Full AMR. This will be based on the clinical image reviewer's written statement with regard to his or her professional expert judgment evaluating the global assessment of risk.
  - a. For limited AMRs the possible overall assessments are:
    - i. Pass
    - ii. Deficiency-needs corrective action
    - iii. Deficiency – needs full AMR
  - b. For full AMRs the possible overall assessments are:
    - i. Pass
    - ii. Deficiency – needs corrective action
    - iii. Fail– serious risk to human health
10. Post AMR actions
  - a. Pass
    - i. Close out letter from SAR and/or FDA
  - b. Deficiency – needs corrective action
    - i. SAR develops corrective action plan (CAP)
    - ii. SAR instructs facility to complete CAP
    - iii. Facility continues to operate while under the CAP
    - iv. Facility completes the CAP to the SAR's satisfaction
    - v. SAR sends close-out letter
    - vi. Limited post CAP AMR performed
  - c. Deficiency (in a limited AMR) – needs full AMR
    - i. Full AMR performed
  - d. Fail (in a full AMR)- serious risk to human health
    - i. SAR suspends/revokes accreditation (SAR under State regulations, may take further actions)

- ii. FDA evaluates the entire situation and in most cases takes action to ensure facility stops performing (FDA will declare certification “no longer in effect” for those facilities whose accreditation has been revoked)
  - iii. FDA evaluates the entire situation and in most cases will require the facility to perform patient/physician notification (depends on situation but can be retroactive to two years)
  - iv. SAR develops corrective action plan (CAP)
  - v. SAR instructs facility to complete CAP
  - vi. Facility completes the CAP to the SAR’s and FDA’s satisfaction
  - vii. SAR and FDA reinstate facility
  - viii. Full post CAP AMR performed
11. Corrective Action Plans will include remediation for both the technologist(s) and physician(s) when there are quality issues with the clinical images.

**For a Limited AMR, the SAR will utilize the following Limited AMR Image Review Form in lieu of the standard Clinical Image Reviewers Form. Additionally, the overall assessment form LIMITED ADDITIONAL MAMMOGRAPHY REVIEW EVALUATION FORM will be used. These forms appear on the following pages.**

**LIMITED ADDITIONAL MAMMOGRAPHY ASSESSMENT FORM**

Facility ID: \_\_\_\_\_

Please categorize the overall assessment for the Limited AMR in one of the following three categories:

- Pass (A majority of the clinical images had few and/or minor deficiencies)
- Deficiency, needs corrective action (A majority of the images had significant and/or numerous quality deficiencies, but they were still adequate for diagnosis)
- Deficiency, needs Full AMR (Diagnostic quality compromised and overall lack of quality exists)

Number of Passing Reviews: \_\_\_\_\_

Number of Failing Reviews: \_\_\_\_\_

Reviewer : \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**LIMITED AMR PHYSICIANS REVIEW FORM**

Case#	Tracking#	P/F	Positioning	Compression	Exposure	Sharpness	Contrast	Noise	Artifacts	Comments
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										

**Certified Mail**

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Limited Additional Mammography Review. These images were submitted on DATE SUBMITTED. NUMBER OF PASSING SETS OF IMAGES of the submitted (NUMBER) sets of images were found to be adequate by a member of the Clinical Image Review Committee (CIRC).

The overall assessment of this Additional Mammography Review is: PASS.

The results of the Additional Mammography Review and comments made by the reviewer are listed on the attached page. These comments are included as a means to help you improve your program.

Thank you for your cooperation during this review of your facility's mammography program. Should you have any questions or concerns regarding this film review and/or your mammography program, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

### Limited Additional Mammography Review Results

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Should a Limited Additional Mammography Review result be "Deficiency", the SAR will notify the facility of the required corrective action to be taken. An example of the letter used for this notification follows.

**Certified Mail**

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Limited Additional Mammography Review. These images were submitted on DATE SUBMITTED. NUMBER OF PASSING SETS OF IMAGES of the submitted (NUMBER) sets of images were found to be adequate by a member of the Clinical Image Review Committee (CIRC).

Unfortunately, your facility was found to have areas of deficiency that are in need of correction. The Department's recommendations for this Corrective Action Plan are included with this letter, as are the results of the Limited Additional Mammography Review, and comments made by the reviewer. These comments are included as a means to help you improve your program.

Please notify our office within ten (10) days of receipt of this letter as to your facility's intentions to carry out Corrective Action. This plan should include steps to be completed within ninety (90) days of receipt of this letter.

Thank you for your cooperation during this review of your facility's mammography program. Should you have any questions or concerns regarding this film review and/or your mammography program, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

## Corrective Action Plan

Your facility's plan for corrective action is to include:

Limited Additional Mammography Review Results

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
4				
5				
6				
7				
8				
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10				
11				
12				
13				
14				
15				

If the overall assessment of a Limited Additional Mammography Review is deficiency in need of full AMR, SAR will conduct a full Additional Mammography Review.

**Certified Mail**

DATE OF THE LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Limited Additional Mammography Review. These images were submitted on DATE SUBMITTED. . NUMBER OF SETS OF IMAGES THAT PASSED of the submitted (NUMBER) sets of images were found to be adequate by a member of the Clinical Image Review Committee (CIRC).

Unfortunately, the Limited Additional Mammography Review has produced a result of "Deficiency, Needs Full Additional Mammography Review". The comments made by the reviewer are included on the attached pages. As a result of this deficiency, the State of Arkansas Accreditation Program (SAR) will conduct a Full Additional Mammography Review. An appointment to initiate this process will be requested within the next 30 days.

Your facility will be required to complete a Corrective Action Plan (CAP), as outlined by the Department. This CAP will address the deficiencies noted during the Limited Additional Mammography Review. A copy of this Corrective Action Plan is included with this correspondence.

Should this Review reveal further deficiencies, the Food and Drug Administration will be notified. Depending on the severity of the deficiencies, your facility may be required to temporarily terminate mammography services or may have its accreditation revoked.

**RIGHT TO APPEAL**

If you feel that the decisions regarding your facility were inaccurate or did not warrant failure, you may appeal the decision. This process is outlined on the Appeal Procedure, which is included.

Should you have questions regarding this notification, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

**Limited Additional Mammography Review Results**

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
4				
5				
6				
7				
8				
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13				
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15				

### Corrective Action Plan

Your facility's plan for corrective action is to include:

**For a full AMR, the SAR will utilize the following AMR Image Review Form in lieu of the standard Clinical Image Reviewers Form. Additionally, the overall assessment form ADDITIONAL MAMMOGRAPHY REVIEW EVALUATION FORM, appears on the following pages.**

**FULL AMR PHYSICIANS REVIEW FORM**

Case#	Tracking#	P/F	Positioning	Compression	Exposure	Sharpness	Contrast	Noise	Artifacts	Comments
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										

Case#	Tracking#	P/F	Positioning	Compression	Exposure	Sharpness	Contrast	Noise	Artifacts	Comments
28										
29										
30										

**ADDITIONAL MAMMOGRAPHY REVIEW EVALUATION FORM**

Facility ID: \_\_\_\_\_

Please categorize the overall assessment for the AMR in one of the following three categories:

- Pass (A majority of the clinical images had few and/or minor deficiencies)
- Deficiency, needs corrective action (A majority of the images had significant and/or numerous quality deficiencies, but they were still adequate for diagnosis)
- Fail, will recommend Patient/Physician notification by FDA (Diagnostic quality compromised and overall lack of quality represents a serious human health risk)

Number of Passing Reviews: \_\_\_\_\_

Number of Failing Reviews: \_\_\_\_\_

Reviewer: \_\_\_\_\_

Reviewer: \_\_\_\_\_

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Form letters for communicating the results of a full AMR are shown on the following pages.

**Certified Mail**

DATE OF THE LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Additional Mammography Review. These images were submitted on DATE SUBMITTED.

The overall result of this Review is a passing score. The comments made by the Clinical Image Review Committee member, regarding each mammographic study, are included on the attached pages. These comments are included in an attempt to help you improve the quality of mammographic images produced at your facility.

The Food and Drug Administration will be notified of these results.

Thank you for your cooperation during this review of your facility's mammography program. Should you have questions regarding this notification, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosure: AMR Facility Results Form

**Full Additional Mammography Facility Results Form**

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
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20				
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22				
23				
24				
25				

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
26				
27				
28				
29				
30				

**Certified Mail**

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Additional Mammography Review. These images were submitted on DATE SUBMITTED.

Unfortunately, your facility was found to have areas of deficiency that are in need of further correction. The Department's recommendations for this Corrective Action Plan are included with this letter, as are the results of the Additional Mammography Review and comments made by the Clinical Image Reviewer. These comments are included as a means to help you improve your program.

Please notify our office within ten (10) days of receipt of this letter as to your facility's intentions to carry out Corrective Action. This plan should include steps to be completed within ninety (90) days of receipt of this letter.

The results of this Additional Mammography Review will be communicated to the Food and Drug Administration.

Thank you for your cooperation during this review of your facility's mammography program. Should you have any questions or concerns regarding this film review and/or your mammography program, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures: Corrective Action Plan, Full AMR Facility Results Form

## Corrective Action Plan

Your facility's plan for corrective action is to include:

**Full Additional Mammography Review Facility Results Form**

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
4				
5				
6				
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25				

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
26				
27				
28				
29				
30				

**Certified Mail**

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

RE: MAS0XXX

Dear CONTACT GREETING:

The Department has completed the review of the clinical images, submitted for Additional Mammography Review. These images were submitted on DATE SUBMITTED.

Unfortunately, the assessment of this review indicates that, because of the lack of quality of the images reviewed, diagnostic quality has been compromised. This lack of quality may represent a serious risk to the health of your patients. Attached please find a review form with comments regarding each set of clinical images reviewed.

The results of this review have been communicated to the Food and Drug Administration.

Please be aware that in accordance with the State of Arkansas Accreditation Program, the following actions will be taken (OUTLINE STATE RESPONSE). Also, be advised that the Food and Drug Administration will likely take further action as to patient and referring physician notification.

**RIGHT TO APPEAL**

If you feel that the decisions regarding your facility were inaccurate or did not warrant failure, you may appeal the decision. This process is outlined on the Appeal Procedure, which is included.

Thank you for your cooperation during this review of your facility's mammography program. Should you have any questions or concerns regarding this film review and/or your mammography program, please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures: Full AMR Facility Results Form, Appeal Procedure

**Full Additional Mammography Review Facility Results Form**

Case#	Patient ID	P/F	Reason for Failure	Reviewer Comments
1				
2				
3				
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27				

<b>Case#</b>	<b>Patient ID</b>	<b>P/F</b>	<b>Reason for Failure</b>	<b>Reviewer Comments</b>
28				
29				
30				

### ***VIII. FFDM Onsite Visit***

#### **Focus of Onsite Visits:**

The focus of an accreditation onsite visit is to identify areas that can be improved and reinforce best practices utilized at facilities. The SAR performs onsite visits to assist facilities before problems arise that could escalate into regulatory non-compliances and to verify that the facilities that are accredited by the SAR are providing patients with high quality mammography services.

#### **Selection of facilities for onsite visits:**

Onsite visits are performed on a selected sample of facilities as specified by the FDA. The SAR will perform onsite visits on at least five percent of the facilities it accredits. As required in the final regulations the State will perform onsite visits to a minimum of five facilities, with at least 50% of those facilities being randomly selected.

To ensure that the sample is random, each facility is assigned a number from 1 to the total number of facilities accredited by the SAR. This number is currently 60 (July 1, 2007). Then using a Microsoft Excel based random number generator a number is selected. Random onsite visits are performed at facilities that correspond to the numbers that are selected.

Facilities that have received notification of the need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous six months will not be selected for random onsite visits.

#### **Selection of facilities for “For Cause” onsite visits:**

“For Cause” onsite visits may be initiated by consumer complaint, MQSA annual inspection, onsite visit, recommendation for an additional mammography review by a clinical image reviewer, a failing random clinical image review, or any other information in the possession of the SAR, MQSA inspectors or FDA.

#### **Qualifications of individuals making the onsite visits:**

Individuals that perform onsite visits must be MQSA Certified Inspectors or meet the following alternative requirements:

- Have at least two years experience performing x-ray or radioactive material compliance inspections.
- Have at least 40 hours of training specific to Mammography.
- Registered as a Radiologic Technologist.
- Performed at least two onsite visits under the direct supervision of an MQSA Certified Inspector.

**Performing Onsite Visit:**

Each onsite review consists of an evaluation of the following aspects of the facility's Mammography Program:

(A) Assessment of overall clinical image QA activities of the facility. This includes the following: personnel responsibilities and procedures for QA/QC testing. Other QA-related written policies, procedures, and records required by the regulations such as those relating to infection control, breast implants, and consumer complaints.

(B) Review of facility documentation to determine if appropriate mammography reports are sent to patients and physicians as required. This must include the following:

Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible. In addition, the facility must communicate the mammography results to health care providers when the patient has a referring health care provider or the patient has named a health care provider. This communication must include a written report of the mammography examination, including the items required by the MQSA Final Rule, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination. Also, if the assessment is "Suspicious" or "Highly suggestive of malignancy," the facility must make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(C) The SAR will select a sample of clinical images for clinical image review by the SAR's Clinical Image Review Committee. Three sets of films will be selected at the time of the onsite visit. If two of the three sets of images fail clinical image review, the SAR will initiate a Limited AMR of five sets of clinical images selected by the facility within a prescribed timeframe determined by the SAR.

(D) In the case of a "For Cause" On-site visit, the Clinical Image Review will be conducted as a Limited AMR. (See section VII)

(E) The SAR will select a sample of clinical images for clinical image review by the SAR's Clinical Image Review Committee. Three sets of films will be selected at the time of the onsite visit. If two of the three sets of images fail clinical image review, the SAR will initiate a "For Cause" clinical image review of five sets of clinical images selected by the facility within a prescribed timeframe determined by the SAR.

(F) Verification that the facility has a medical audit system in place and is correlating films and pathology reports for positive cases. Each facility must establish and maintain a system to track positive mammographic findings and to correlate such

findings with the biopsy results. The facility must perform this analysis on an annual basis. At a minimum, the system must track "positive mammographic findings," which refers to mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy." This system must include a set of procedures to track positive mammograms, determine whether biopsies were done on patients, determine (at a minimum) whether the biopsy specimen was benign or malignant, and report this information back to the interpreting physician. The system may be manual or computerized. Facilities must also include in their audit any patients that they become aware of who were subsequently found to have cancer that was not detected through their mammogram. The audit analysis must be initiated within 12 months after the date the facility becomes certified. The audit analysis must then be completed within an additional 12 months with subsequent audit analyses to be conducted at least once annually (Every 12 months). The analyses are to be reviewed by an "audit interpreting physician" appointed by the facility. The "audit interpreting physician" has multiple

responsibilities listed in 21 CFR Part 900.12(f)(3) of the Quality Mammography Standards; Final Rule that must be covered in the facility's audit program. The individual conducting the onsite visit will examine the audit system for the inclusion of the above items, ascertain how biopsy results are obtained, and request to see examples of biopsy results that the facility has obtained. If biopsies were recommended but no results were obtained, the facility must provide documentation of attempts to get this information.

- (G) Verification that personnel (Lead Interpreting Physician, Medical Physicist, Audit Review Physician, Q.C. Technologist, Interpreting Physician(s), and Mammography Radiologic Technologist(s)) specified by the facility are the ones actually performing designated personnel functions as required by 21 CFR Part 900.12 of the Quality Mammography Standards; Final Rule.
- (H) Verification that equipment specified by the facility is the equipment that is actually being used to perform designated equipment functions.
- (I) Verification that a consumer complaint mechanism is in place and that the facility is following their procedures. The facility's consumer complaint mechanism must meet the following criteria:
- (1) Establish a system for collecting and resolving consumer complaints. The system should include written standard operating procedures for addressing consumer complaints and a method for documenting consumer complaints.
  - (2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received.
  - (3) Provide the consumer with adequate directions for filing serious complaints with the SAR if the facility is unable to resolve a serious complaint to the consumer's satisfaction.
  - (4) Report unresolved serious complaints to the SAR within 30 days of the date that it was determined that the facility was unable to resolve the complaint. Resolution of consumer complaints should not exceed 60 days from the date that the complaint was received. In other words, if the complaint has not been resolved within 60 days it must be reported to the SAR.

- (J) Review of all factors related to previously identified concerns or concerns identified during the current visit.

The results of the onsite visit will be documented using an “Onsite Evaluation” form. An example of the Onsite Evaluation form is shown on the next two pages.

**Arkansas Department of Health & Human Services On-site visit form**

**Date of Visit:**

**Performed by:**

**Facility:**

**Accreditation Number:**

**Yes/No**

**Assessment of QA activities**

Are QA Personnel Assigned?

Are personnel specified by the facility actually the ones performing their designated functions?

Are Phantoms done weekly?

Are Phantoms scored correctly?

Are Processor strips run daily? (wet processing)

Is the above information Documented?

Comments:

**QC evaluation**

Were there any other Printer QC problems? (if yes explain)

Comments:

Were there any problems Noted with Phantom QC? (if yes explain)

Comments:

**Medical Audit:**

Does the facility have a medical audit system?

Are all positive mammograms tracked?

Are pathology reports obtained (attempted to obtain)?

Comments:

**Consumer Complaint Mechanism**

Does the facility have a written system?

Do they maintain documentation for three years?

Do they provide adequate directions to the consumer for filing serious complaints with their accreditation body if the facility is

unable to resolve a serious complaint to the consumer's satisfaction?

Comments:

Did the facility address all factors related  
To previously identified concerns?

Did the facility address all factors  
Related to concerns identified  
During this visit?

Comments:

**Equipment Verification**

Manufacturer of the Mammography Unit:

  

Mammography Unit Model Number:

Does the equipment match the equipment listed on the Accreditation?

**Clinical Image Samples**

In what time period should the films be selected?

From:

To:

Comments:

Overall Assessment:  (Excellent, Good, Poor, Inadequate)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

The written documentation is sent to the facility regarding the results of the onsite visit using the form letter entitled “Onsite Letter”. This letter gives an overall assessment along with individual assessments of Mammography Quality Assurance, Mammography Quality Control, Mammography Medical Audit, and Mammography Consumer Complaint Mechanism. Also, if there is sufficient cause, the SAR will use the letter to request additional clinical images, detail areas that need improvement, and specify corrective actions.

An example of the Onsite letter is shown on the next three pages.

## DATE OF THE LETTER

Facility Contact  
Facility Contact Title  
Address 1  
Address 2  
City, AR Postal Code

Accreditation No: MAS0XXX

Dear Contact Greeting:

Mammography activities conducted under Accreditation Number: MAS0XXX were evaluated by ONSITE EVALUATOR of the Arkansas Department of Health, on DATE OF VISIT. At the conclusion of the On-site visit our findings were discussed with you. The purpose of the On-site visit is to identify problems and/or potential problems that may cause non-compliance during future MQSA inspections and compromise the quality of the facility's mammography services.

**Results:**

1. Overall Assessment: **(inadequate – excellent)**
2. Mammography Quality Assurance: **(inadequate – excellent)**
3. Mammography Quality Control: **(inadequate – excellent)**
4. Mammography Medical Audit: **(inadequate – excellent)**
5. Mammography Consumer Complaint Mechanism: **(inadequate – excellent)**
6. Mammography Clinical Images: **(Pass or Failed)**

**Areas that need Improvement:** (description of specific areas that need to be enhanced to ensure that the quality of mammography services provided by the facility is not compromised).

**Actions:** (description of the actions that are needed in order to address the areas that need improvement).

We appreciate your time and assistance during the On-site visit. If you have any questions concerning this inspection or if we can be of assistance to you, please call this office at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

**Random Clinical Image Review**

For the purpose of Clinical Image Review the following criteria is used: *a deficiency in any single aspect denoted with an asterisk (\*) will be sufficient cause for failing the patient film quality review. Three or more deficiencies in any other aspect are also cause for failure.* Please note: Reviewers comments next to each check-off criteria.

**Set 1**

Patient Films ID: XXX, dated XX/XX/XXX – (Pass or Fail)

**Comments:**

**MLO:** (Comments about the MLO Views)

**CC:** (Comments about the CC Views)

**Other:** (All other comments)

**Set 2**

Patient Films ID: XXX, dated XX/XX/XXX – (Pass or Fail)

**Comments:**

**MLO:** (Comments about the MLO Views)

**CC:** (Comments about the CC Views)

**Other:** (All other comments)

**Set 3**

Patient Films ID: XXX, dated XX/XX/XXX – (Pass or Fail)

**Comments:**

**MLO:** (Comments about the MLO Views)

**CC:** (Comments about the CC Views)

**Other:** (All other comments)

If a facility fails the clinical image review portion of the on-site visit, the SAR will request a minimum of five additional sets of clinical images and will follow the procedure for following up on a failing random clinical image review (See Section V.).

***IX. FFDM Mammography Equipment Evaluations and Annual Physicist's Surveys.***

All FFDM Mammography Equipment Evaluations and FFDM Medical Physicist's Surveys will be evaluated directly or under the direct supervision of a MQSA Certified Inspector.

SAR shall require that all facilities undergo an annual survey to ensure continued compliance with the standards referenced in paragraph (b) of 21 CFR 900.4(e)(2) as well as compliance with all standards for test procedures and action limits established in the FFDM *Manufacturer's Quality Control Manual*. Should any FFDM equipment fail to meet such standards, the facility will be required to provide a copy of all corrective action taken as well as results from the subsequent testing. The goal of the SAR is to provide continued oversight of facilities' quality control programs as they relate to FDA and manufacturer standards. SAR shall require for all facilities that:

- Such surveys be conducted annually;
- Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and
- Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.

SAR staff members shall review the required information and use it to identify necessary corrective measures for facilities and to determine whether facilities should remain accredited by the body. Annual physicist surveys shall be available for review at the time of the annual MQSA inspection.

- **New Facilities or Adding New Units at Existing Facilities.**

When a facility initially submits an application for accreditation or submits an application to add a new FFDM unit, the SAR requires that the facility submit an FFDM Mammography Equipment Evaluation. The equipment evaluation is reviewed to ensure it complies with all required tests as described in 21 CFR Part 900.12(b) and (e) of the Quality Mammography Standards; Final Rule as well as the FFDM manufacturer's quality control manual. Once the equipment evaluation is reviewed, the results are documented on the FFDM Mammography Equipment Evaluation Form. The FFDM Mammography Equipment Evaluation will be reviewed and approved prior to allowing the facility to perform mammography with the unit. All problems documented by the medical physicist shall be corrected before the new equipment is put into service for patient examinations.

- **Reaccreditation or Accrediting Body Changes of Previously Accredited Facilities**

When a facility submits an application for Reaccreditation or change of Accrediting Body, the SAR requires that the facility submit a copy of the current FFDM Medical Physicist's Survey. The survey must have been performed within the last six months. The survey is reviewed to ensure it complies with all required tests as described in 21 CFR 900.12(e)(2), (e)(5), and, if applicable, (e)(6) of the Quality Mammography Standards; Final Rule, as well as the FFDM manufacturer's quality control manual. Also the Medical Physicist must document that he/she evaluated the adequacy of the results of all tests conducted by the facility in accordance with 21 CFR 900.12(e)(1) through (e)(7). Once the survey is reviewed, the results are documented on the FFDM Medical Physicist's Survey Form.

The FFDM Mammographic Equipment Evaluation Forms are shown on the following pages.

**LORAD FFDM MAMMOGRAPHY EQUIPMENT EVALUATION**

Initial accreditation \_\_\_ Reaccreditation \_\_\_ Adding a New Unit to Existing Accreditation \_\_\_

FACILITY \_\_\_\_\_ MAS \_\_\_\_\_ Model \_\_\_\_\_ Room \_\_\_\_\_

Survey Date \_\_\_\_\_ Within 6 months? \_\_\_ PASS/FAIL? \_\_\_\_\_ Signed by: \_\_\_\_\_

Lorad QC Manual Version at facility \_\_\_\_\_

- 1) **Mammographic Unit Assembly Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
Autodecompression can be overridden to maintain compression (and status displayed)  
Manual emergency compression release can be activated in the event of a power failure  
Performs according to 1999 ACR Mammo QC Manual
- 2) **Collimation Assessment** Yes \_\_\_\_\_ No \_\_\_\_\_  
Deviation between X-ray field and light field is  $\leq 2\%$  of SID  
X-ray field does not extend beyond any side of the IR by more than 2% of SID and must cover all the IR on chest wall side  
Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% SID or appear on image
- 3) **Artifact Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
Artifacts were not apparent or not significant
- 4) **kVp Accuracy and Reproducibility** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured average kVp within  $\pm 5\%$  of indicated kVp  
kVp reproducibility coefficient of variation  $\leq 0.02$
- 5) **Beam Quality Assessment (HVL) Measurement** Yes \_\_\_\_\_ No \_\_\_\_\_  
HVL is within acceptable upper and lower limits at all kVp values tested as stated in applicable Selenia QC manual
- 6) **Evaluation of System Resolution** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured performance within acceptable limits as stated in applicable Selenia QC manual
- 7) **AEC Function Performance** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured performance within acceptable limits as stated in applicable Selenia QC manual
- 8) **Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose** Yes \_\_\_\_\_ No \_\_\_\_\_  
Average Glandular Dose for average breast is  $\leq 3$  mGy (300 mrad) \_\_\_\_\_ mrad  
Coefficient of Variation for either exposure (R) or mAs shall not exceed 0.05
- 9) **Radiation Output Rate** Yes \_\_\_\_\_ No \_\_\_\_\_  
Radiation Output Rate is  $\geq 800$  mR per second (28 kVp, MoMo) \_\_\_\_\_ mR/sec  
or  $\geq 230$  mR/sec (28 kVp W/Rh) \_\_\_\_\_ mR/sec
- 10) **Phantom Image Quality Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
5 largest fibers, 4 largest speck groups and 4 largest masses are visible\*  
Phantom Image Quality scores: Fibers \_\_\_\_\_  
Specks \_\_\_\_\_  
Masses \_\_\_\_\_
- 11) **Signal-To- Noise Ratio and Contrast-To-Noise Ratio Measurement** Yes \_\_\_\_\_ No \_\_\_\_\_  
SNR must be equal to or greater than 40 SNR \_\_\_\_\_  
CNR should not vary by more than  $\pm 15\%$  of the aim value CNR \_\_\_\_\_
- 12) **Viewbox Luminance and Room Illuminance** Yes \_\_\_\_\_ No \_\_\_\_\_  
Mammographic viewbox is capable of a luminance of at least 3000 nit  
Room illuminance (viewbox surface as seen by observer) is 50 lux or less  
Room illuminance (monitor surface) is:  $\leq 20$  lux \_\_\_ for soft copy reading
- 13) **Diagnostic Review Workstation**  
White level performance Yes \_\_\_\_\_ No \_\_\_\_\_  
Black level performance (N/A for LCD displays) Yes \_\_\_\_\_ No \_\_\_\_\_  
Quality level performance Yes \_\_\_\_\_ No \_\_\_\_\_  
Uniformity performance (N/A for LCD displays) Yes \_\_\_\_\_ No \_\_\_\_\_

\*Due to phantom variations, a score of 4.5 fibers, 4.0 specs and 3.5 masses may be acceptable under certain circumstances.

**Note:** SAR acknowledges amended Alternative Standard #9 approved by the FDA, however, SAR requirements dictate that all equipment failures be corrected prior to accreditation or reaccreditation approval.

**General Electric FFDM MAMMOGRAPHY EQUIPMENT EVALUATION**

Initial accreditation \_\_\_ Reaccreditation \_\_\_ Adding a New Unit to Existing Accreditation \_\_\_

FACILITY \_\_\_\_\_ MAS \_\_\_\_\_ Room \_\_\_\_\_ Model \_\_\_\_\_

Survey Date \_\_\_\_\_ Within 6 months? \_\_\_\_\_ PASS/FAIL? \_\_\_\_\_ Signed by: \_\_\_\_\_

GE QC Manual at facility \_\_\_\_\_

**Applicable to ALL GE Systems:**

- 1) **Flat Field and Image Quality Checks** Yes \_\_\_\_\_ No \_\_\_\_\_  
All Flat Field checks must pass, including brightness, HFM, Pixel Uniformity, ROT, SNR  
AWS \_\_\_\_\_ RWS-L\* \_\_\_\_\_ RWS-R\* \_\_\_\_\_ Printer \_\_\_\_\_  
Fibers \_\_\_\_\_  
Specks \_\_\_\_\_  
Masses \_\_\_\_\_  
Requires 4 largest fibers, 3 largest speck groups, and 3 largest masses. (\*N/A for Seno Advantage WS)
- 2) **MTF Measurement (CNR for Seno DS)** \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_
- 3) **AOP Mode and SNR Check** Yes \_\_\_\_\_ No \_\_\_\_\_
- 4) **Collimation Assessment** Yes \_\_\_\_\_ No \_\_\_\_\_  
Deviation between X-ray field and light field is less than 2% of SID  
X-ray field does not extend beyond any side of the IR by more than 2% of SID and covers all the IR on the chest wall side  
Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% SID
- 5) **Evaluation of Focal Spot Performance** Yes \_\_\_\_\_ No \_\_\_\_\_  
Meets Manufacturer's specifications
- 6) **Breast Entrance Exposure, Average Glandular Dose and Reproducibility** Yes \_\_\_\_\_ No \_\_\_\_\_  
Maximum acceptable coefficient of variation (mAs and air kerma) is 0.05  
Mean glandular dose  $\leq$  3mGy or 0.3Rads per view \_\_\_\_\_ mRad
- 7) **Artifact Evaluation and Flat Field Uniformity** \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_  
Artifacts were not apparent or not significant
- 9) **kVp Accuracy and Reproducibility** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured average kVp within  $\pm$  5% of indicated or selected kVp  
kVp reproducibility coefficient of variation  $\leq$  0.02
- 10) **Beam Quality Assessment (HVL) Measurement** Yes \_\_\_\_\_ No \_\_\_\_\_
- 11) **Radiation Output Rate** Yes \_\_\_\_\_ No \_\_\_\_\_  
Radiation Output Rate is  $\geq$  800 mR per second \_\_\_\_\_ mR/sec
- 12) **Mammographic Unit Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
System meets requirements for motion of tube-image receptor assembly  
System meets requirements for compression paddle decompression

**Applicable to 2kD, 2kDM, and Seno Adv:**

- 13) **Viewing Conditions Check and Setting** Yes \_\_\_\_\_ No \_\_\_\_\_
- 14) **Analysis of Workstation Screen Uniformity** Yes \_\_\_\_\_ No \_\_\_\_\_  
(required for MEE and as necessary)
- 15) **Monitor Calibration and Display Device Calibration** Yes \_\_\_\_\_ No \_\_\_\_\_
- 16) **Image Quality-SMPTE Pattern** Yes \_\_\_\_\_ No \_\_\_\_\_

**For 2kD, 2kDM, DS:**

- 17) **Filmless measurement of subsystem resolution** Yes \_\_\_\_\_ No \_\_\_\_\_

\*Note: SAR acknowledges Alternative Standard #10 approved by the FDA, however, SAR requirements dictate that all equipment failures be corrected prior to accreditation or reaccreditation approval.

**FUJI COMPUTED RADIOGRAPHY FOR MAMMOGRAPHY (FCRm)  
MAMMOGRAPHY EQUIPMENT EVALUATION (MEE)**

Initial Accreditation \_\_\_ Adding New Units to Existing Accreditation \_\_\_

FACILITY \_\_\_\_\_ MAS \_\_\_\_\_ Model \_\_\_\_\_ Room \_\_\_\_\_

MEE Date \_\_\_\_\_ Within 6 months? \_\_\_ PASS/FAIL? \_\_\_ Signed by \_\_\_\_\_

QC Manual Version at facility \_\_\_\_\_

- 1) **Contrast-To-Noise Ratio (CNR) (Tech weekly test)**  
CNR must not vary by more than  $\pm 20\%$  of baseline Yes \_\_\_ No \_\_\_
  
- 2) **Imaging Plate Fog (Tech Semi-Annual Test)**  
Coin not visible on image Yes \_\_\_ No \_\_\_
  
- 3) **Viewing and Viewing Conditions** Yes \_\_\_ No \_\_\_  
Room illuminance (monitor surface) is:  $\leq 20$  lux or the limit set by the monitor manufacturer (if less than 20 lux, for soft copy reading)
  
- 4) **Printer Quality Control:** Follows Manufacturer Specification, if available. Yes \_\_\_ No \_\_\_  
If Manufacturer does not provide QC procedures, use specifications provided in Fuji FCRm QC Manual 3rd addition, page 69
  
- 5) **Monitor Quality Control:** Follows Manufacturer Specification, if available. Yes \_\_\_ No \_\_\_  
If Manufacturer does not provide QC procedures, use specifications provided in Fuji FCRm QC Manual 3rd addition, page 71
  
- 6) **S Value Confirmation** Yes \_\_\_ No \_\_\_  
Corrected S Value should not exceed the range of  $120 \pm 20\%$
  
- 7) **Evaluation of System Resolution** Yes \_\_\_ No \_\_\_  
Measured performance  $8 \pm 2$  lp/mm, both scan directions
  
- 8) **CR Reader Scanner Performance** Yes \_\_\_ No \_\_\_  
"T" test image smooth and sharp
  
- 9) **Mammographic Unit Assembly Evaluation** Yes \_\_\_ No \_\_\_  
Follows Mammographic Unit Assembly Evaluation Form shown below:
 

1. Free-standing unit is mechanically stable	Y----	N----
2. All moving parts move smoothly, without obstructions to motion	Y----	N----
3. All locks and detents work properly	Y----	N----
4. Image receptor holder assembly is free from vibrations	Y----	N----
5. Image receptor slides smoothly into holder assembly	Y----	N----
6. Image receptor is held securely by assembly in any orientation	Y----	N----
7. Compressed breast thickness scale is accurate to 0.5 cm & reproducible to 2 mm	Y----	N----
8. Patient or operator is not exposed to sharp or rough edges, or other hazards	Y----	N----
9. Operator technique control charts are posted	Y----	N----
10. Operator protected during exposure by adequate radiation shielding	Y----	N----
11. All indicator lights working properly	Y----	N----
12. Auto decompress can be overridden to maintain compr. with cont. display of override status	Y----	N----
13. Manual emergency compression release can be activated during power failure	Y----	N----
  
- 10) **Collimation Assessment** Yes \_\_\_ No \_\_\_  
Deviation between X-ray field and light field is  $\leq 2\%$  of SID  
X-ray field does not extend beyond any side of the IR by more than 2% of SID and must cover all the IR on the chest wall side  
Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% SID or appear on image
  
- 11) **AEC System Performance Assessment** Yes \_\_\_ No \_\_\_  
Measured performance within acceptable limits as stated in the applicable QC Manual.  $\Delta$  mAs/density step; within 5-15%, COV reprod.  $\leq 0.05$ , use baseline

CNR level for 4 cm as 100%, then relative CNR level for 2 cm  $\geq$  100%, and relative CNR level for 6 cm  $\geq$  75%

- 12) **System Artifact Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
Examine images for artifacts. No objectionable artifacts on image
- 13) **Phantom Image Quality Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_  
4 largest fibers, 3 largest speck groups and 3 largest masses are visible  
**Phantom Image Quality scores:**
- |                  |                             |                                    |
|------------------|-----------------------------|------------------------------------|
| <b>Hard Copy</b> |                             | <b>Soft Copy</b>                   |
| Fibers _____     | Background OD (>1.20) _____ | S value: baseline $\pm$ 20%        |
| Specks _____     | OD $\pm$ 0.20 _____         | mAs (optional): baseline $\pm$ 15% |
| Masses _____     | DD $\pm$ 0.05 _____         |                                    |
- 14) **Dynamic Range** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured performance within acceptable limits. Exposures with acrylic thicknesses of 0 cm, 2 cm, & 6 cm are discernible
- 15) **Primary Erasure** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured performance within acceptable limits. No significant artifacts observed
- 16) **Inter-Plate Consistency** Yes \_\_\_\_\_ No \_\_\_\_\_  
Variation of mAs must be within  $\pm$  10%  
Variation of SNR must be within  $\pm$  15%
- 17) **kVp Accuracy and Reproducibility** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured average kVp within  $\pm$  5% of indicated kVp  
kVp reproducibility coefficient of variation  $\leq$  0.02
- 18) **Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose** Yes \_\_\_\_\_ No \_\_\_\_\_  
Average Glandular Dose for average breast is  $\leq$  3 mGy (300 mrad) \_\_\_\_\_ mrad  
Coefficient of Variation for either R or mAs shall not exceed 0.05
- 19) **Beam Quality Assessment (HVL) Measurement** Yes \_\_\_\_\_ No \_\_\_\_\_  
HVL meets minimum specifications in the applicable QC manual.  
HVL (mmAl)  $\geq$  kVp/100 for Mo/Mo & Std. Breast
- 20) **Radiation Output Rate** Yes \_\_\_\_\_ No \_\_\_\_\_  
Radiation Output Rate is  $\geq$  800 mR per second @28 kVp (Mo/Mo) for 3 seconds

**FUJI COMPUTED RADIOGRAPHY FOR MAMMOGRAPHY (FCRm)  
Annual Survey Report for Reaccreditation**

FACILITY \_\_\_\_\_ MAS \_\_\_\_\_ Model \_\_\_\_\_ Room \_\_\_\_\_

Survey Date \_\_\_\_\_ Within 14 mo. of prior survey? \_\_\_\_\_ PASS/FAIL? \_\_\_\_\_ Signed by \_\_\_\_\_

QC Manual Version at facility \_\_\_\_\_

**1) Physicist's Review of QC Technologist Tests**

Weekly

- CNR Test** Yes \_\_\_\_\_ No \_\_\_\_\_
- Phantom Image Test** Yes \_\_\_\_\_ No \_\_\_\_\_
- Printer QC Test** Yes \_\_\_\_\_ No \_\_\_\_\_
- Monitor QC Test** Yes \_\_\_\_\_ No \_\_\_\_\_

Monthly

- Visual Checklist** Yes \_\_\_\_\_ No \_\_\_\_\_

Quarterly

- Repeat Analysis** Yes \_\_\_\_\_ No \_\_\_\_\_

Semi-annually

- Compression** Yes \_\_\_\_\_ No \_\_\_\_\_
- IP Fog Test** Yes \_\_\_\_\_ No \_\_\_\_\_

**2) Viewing and Viewing Conditions** Yes \_\_\_\_\_ No \_\_\_\_\_

Room illuminance (monitor surface) is:  $\leq 20$  lux or the limit set by the monitor manufacturer (if less than 20 lux, for soft copy reading)

**3) Printer Quality Control: Follows Manufacturer Specification, if available.** Yes \_\_\_\_\_ No \_\_\_\_\_  
If Manufacturer does not provide QC procedures, use specifications provided in Fuji FCRm QC Manual 3rd addition, page 69

**4) Monitor Quality Control: Follows Manufacturer Specification, if available.** Yes \_\_\_\_\_ No \_\_\_\_\_  
If Manufacturer does not provide QC procedures, use specifications provided in Fuji FCRm QC Manual 3rd addition, page 71

**5) S Value Confirmation** Yes \_\_\_\_\_ No \_\_\_\_\_  
Corrected S Value should not exceed the range of  $120 \pm 20\%$

**6) Evaluation of System Resolution** Yes \_\_\_\_\_ No \_\_\_\_\_  
Measured performance  $8 \pm 1$  lp/mm, both scan directions

**7) CR Reader Scanner Performance** Yes \_\_\_\_\_ No \_\_\_\_\_  
"T" test image smooth and sharp

**8) Mammographic Unit Assembly Evaluation** Yes \_\_\_\_\_ No \_\_\_\_\_

Follows Mammographic Unit Assembly Evaluation Form shown below:

- 1. Free-standing unit is mechanically stable Y---- N----
- 2. All moving parts move smoothly, without obstructions to motion Y---- N----
- 3. All locks and detents work properly Y---- N----
- 4. Image receptor holder assembly is free from vibrations Y---- N----
- 5. Image receptor slides smoothly into holder assembly Y---- N----
- 6. Image receptor is held securely by assembly in any orientation Y---- N----
- 7. Compressed breast thickness scale is accurate to 0.5 cm & reproducible to 2 mm Y---- N----
- 8. Patient or operator is not exposed to sharp or rough edges, or other hazards Y---- N----
- 9. Operator technique control charts are posted Y---- N----
- 10. Operator protected during exposure by adequate radiation shielding Y---- N----
- 11. All indicator lights working properly Y---- N----
- 12. Auto decompression can be overridden to maintain compression with continuous display of override status Y---- N----
- 13. Manual emergency compression release can be activated during power failure Y---- N----

**9) Collimation Assessment**

Yes \_\_\_\_ No \_\_\_\_

Deviation between X-ray field and light field is  $\leq 2\%$  of SID  
 X-ray field does not extend beyond any side of the IR by more than 2% of SID and must cover all the IR on the chest wall side  
 Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% SID or appear on image

**10) AEC System Performance Assessment**

Yes \_\_\_\_ No \_\_\_\_

Measured performance within acceptable limits as stated in the applicable QC Manual.  $\Delta$  mAs/density step; within 5-15%, COV reprod.  $\leq 0.05$ , use baseline CNR level for 4 cm as 100%, then relative CNR level for 2 cm  $\geq 100\%$ , and relative CNR level for 6 cm  $\geq 75\%$

**11) System Artifact Evaluation**

Yes \_\_\_\_ No \_\_\_\_

Examine images for artifacts. No objectionable artifacts on image

**12) Phantom Image Quality Evaluation**

Yes \_\_\_\_ No \_\_\_\_

4 largest fibers, 3 largest speck groups and 3 largest masses are visible

**Phantom Image Quality scores:**

Fibers \_\_\_\_\_  
 Specks \_\_\_\_\_  
 Masses \_\_\_\_\_

**Hard Copy**

Background OD ( $>1.20$ ) \_\_\_\_\_  
 OD  $\pm 0.20$  \_\_\_\_\_  
 DD  $\pm 0.05$  \_\_\_\_\_

**Soft Copy**

S value: baseline  $\pm 20\%$   
 mAs (optional): baseline  $\pm 15\%$

**13) Dynamic Range**

Yes \_\_\_\_ No \_\_\_\_

Measured performance within acceptable limits. Exposures with acrylic thicknesses of 0 cm, 2 cm, & 6 cm are discernible

**14) Primary Erasure**

Yes \_\_\_\_ No \_\_\_\_

Measured performance within acceptable limits. No significant artifacts observed

**15) Inter-Plate Consistency**

Yes \_\_\_\_ No \_\_\_\_

Variation of mAs must be within  $\pm 10\%$   
 Variation of SNR must be within  $\pm 15\%$

**16) kVp Accuracy and Reproducibility**

Yes \_\_\_\_ No \_\_\_\_

Measured average kVp within  $\pm 5\%$  of indicated kVp  
 kVp reproducibility coefficient of variation  $\leq 0.02$

**17) Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**

Yes \_\_\_\_ No \_\_\_\_

Average Glandular Dose for average breast is  $\leq 3$  mGy (300 mrad) \_\_\_\_\_ mrad  
 Coefficient of Variation for either R or mAs shall not exceed 0.05

**18) Beam Quality Assessment (HVL) Measurement**

Yes \_\_\_\_ No \_\_\_\_

HVL meets minimum specifications in the applicable QC manual.  
 HVL (mmAl)  $\geq$  kVp/100 for Mo/Mo & Std. Breast

**19) Radiation Output Rate**

Yes \_\_\_\_ No \_\_\_\_

Radiation Output Rate is  $\geq 800$  mR per second @28 kVp (Mo/Mo) for 3 seconds

## **X. FFDM Data Entry**

### **Personnel Responsibilities**

The person with the primary responsibility for maintaining the SAR's Data system is Melinda Davis. Melinda will act as the data system administrator. She is responsible for data entry, maintenance of the system, and quality assurance of the system.

### **Data Handling and Transmission Systems**

The primary data handling system for the SAR is the Mammography Database. This is where tracking data for SAR is located. In addition, the data transmission system used by the SAR is a direct link to the FDA's Mammography Program Reporting and Information System (MPRIS Web).

### **Periodic Audits of Data Handling and Transmission**

#### **DATA HANDLING**

Annually, the System Administrator will audit all tables within the Mammography Database. All errors and updates will be recorded and a report will be generated to document the findings of the audit. The Section Chief of Radiation Control will review the report. Following any revisions, the System Administrator and the Section Chief of Radiation Control will sign the final audit. The final audit will be kept on file for future review.

#### **DATA TRANSMISSION**

All data entries into the MPRIS will be tracked. This tracking system is located within the Mammography Database. Any errors that occur while entering data in MPRIS Web will be documented in the tracking system and an audit of the system will be performed annually. The final audit will be kept on file for future review.

### **Procedure for Electronically Notifying the FDA of the Reasons a Facility is Denied Accreditation**

When a facility is denied accreditation the Denied Accreditation form is filled out on the Mammography Database and the information is used to generate the SAR Facilities that were Denied Accreditation Report, which is sent by email to the following individuals at the FDA:

- |                             |                             |
|-----------------------------|-----------------------------|
| 1. Henry Chan, FDA Liaison: | henry.chan@fda.hhs.gov      |
| 2. Dan Trammel:             | Dennis.trammel@fda.hhs.gov  |
| 3. Vickie Jernigan:         | vickie.jernigan@fda.hhs.gov |

Also, when a facility's unit (s) are denied accreditation the reason(s) for this denial are entered into the MPRIS System, by changing the units status and then editing the units failure record.

## **Backup for Data System**

Following each Audit of data handling system a copy of the mammography database will be stored on a CD-ROM as a back up. In addition, all information that is entered in the data handling system is retained in the Accreditation Program Files (Hard Copy).

The primary back up to the System Administrator is Sherry Davidson.

## ***XI. FFDM Consumer Complaints***

### **Purpose:**

The purpose of this mechanism is to provide a written and documented system to collect and resolve serious consumer complaints that could not be resolved at a facility. This mechanism will also be used in cases where the complaint comes directly to the State of Arkansas Mammography Accreditation Body.

### **Definitions:**

1. **Serious Complaint:** this is a report of a serious adverse event, which means an event that significantly compromises clinical outcomes or one for which a facility fails to take appropriate corrective action in a timely manner. Examples of serious adverse events include: poor image quality, missed cancers, the use of personnel that do not meet the applicable requirements of 900.12 (a), and failure to send the appropriate person(s) mammography reports or lay summaries within 30 days.
2. **Unresolved complaint:** a report of a serious adverse event to a mammography facility in which the actions of the facility to address the event did not satisfactorily resolve the complaint.
3. **Direct complaint:** a report of a serious adverse event to the State of Arkansas Mammography Accreditation Body regarding a facility accredited by the SAR.

### **Mechanism:**

All complaints should be submitted in writing to the Arkansas Department of Health, Radiation Control, 4815 P.O. Box 1437, Slot H-30, Little Rock, AR 72203. However, if a serious complaint is submitted verbally to the SAR, it will be reviewed by the mammography team and forwarded to the facility for resolution through the use of the facility's consumer complaint mechanism.

All Arkansas accredited facilities are required to post the address and telephone number to which complaints may be submitted.

The accreditation staff will follow-up on all serious complaints within thirty (30) days of receipt of the unresolved and/or direct complaint to the SAR. The initial complaint and follow-up report will remain in the facility's accreditation file for future reference. In addition to the information in the facility's accreditation file, a table in the mammography database will track the status of the complaint (**Database information:** accreditation number, date of the complaint, type of the complaint, description of the complaint, date that follow-up by

accreditation staff began, follow-up actions by SAR, and the date that the complaint was resolved).

Consumer Complaints are part of the facility's permanent record. This record will be maintained for at least 3 years after the resolution of the complaint.

## ***XII. FFDM Procedures for Assessing Personnel Qualifications***

All personnel involved in the production, processing, and interpretation of mammograms and related quality assurance activities must meet the quality standards of 21 CFR 900.12(a). Using the guidance documents provided in the FDA's Policy Guidance Help System (PGHS), the accreditation staff reviews the interpreting physician, medical physicist, and radiologic technologist documentation submitted with the accreditation application. The results of the review are documented on the personnel qualification review forms.

The personnel qualification review forms are shown on the next three pages.

**FFDM INTERPRETING PHYSICIAN** Total Number \_\_\_\_\_ MAS \_\_\_\_\_

Physician Name \_\_\_\_\_

**Initial Requirements**

1. Current Arkansas Medical License Yes \_\_\_\_\_ No \_\_\_\_\_

***Initial Training and Experience before 4/28/99***

2.A.1. Certificate from FDA Approved body (ACR, AOBR, RCSPC) in Radiology or Diagnostic Radiology Yes \_\_\_\_\_ No \_\_\_\_\_

**OR**

2.A.2. 2 months documented training in mammography Yes \_\_\_\_\_ No \_\_\_\_\_

**AND**

3. 40 hrs. of training in mammography Yes \_\_\_\_\_ No \_\_\_\_\_

**AND**

4. Have read 240 pt. Exams in any 6 month period (directly supervised if done after 10/01/1994) Yes \_\_\_\_\_ No \_\_\_\_\_

5. 8 hours of FFDM specific education Yes \_\_\_\_\_ No \_\_\_\_\_

***Initial Training and Experience on or after 4/28/99***

2.B.1. Certificate from FDA Approved body (ACR, AOBR, RCSPC) in Radiology or Diagnostic Radiology Yes \_\_\_\_\_ No \_\_\_\_\_

**OR**

2.B.2. 3 months documented training in mammography Yes \_\_\_\_\_ No \_\_\_\_\_

**AND**

3. 60 hrs. of Cat. I training in mammography with at least 15 hrs in the 3 years immediately preceding initial qualifying date Yes \_\_\_\_\_ No \_\_\_\_\_

**AND**

4. Have read 240 pt. 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 Yes \_\_\_\_\_ No \_\_\_\_\_

5. 8 hours of FFDM specific education Yes \_\_\_\_\_ No \_\_\_\_\_

**Continuing Education and Experience**

1. 15 hrs. Category 1 CME documented in past 36 months Yes \_\_\_\_\_ No \_\_\_\_\_

2. Has interpreted or multi-read at least 960 exams over a 2 year period Yes \_\_\_\_\_ No \_\_\_\_\_

**FFDM RADIOLOGIC TECHNOLOGIST**

Total Number \_\_\_\_\_ MAS \_\_\_\_\_

Technologist Name \_\_\_\_\_

**Initial Requirements**

1. Current ARRT "R" card Yes \_\_\_\_\_ No \_\_\_\_\_

***Initial Training before 4/28/99***

2.A. 40 hours of documented mammography training or equivalent Yes \_\_\_\_\_ No \_\_\_\_\_

**OR**

Current ARRT "M" Yes \_\_\_\_\_ No \_\_\_\_\_

***Initial Training on or after 4/28/99***

2.B.1. 40 hours of documented mammography training which includes:  
 Breast Anatomy                      QA/QC Techniques  
 Physiology                              Imaging of patients with Breast Implants  
 Positioning and compression

Yes \_\_\_\_\_ No \_\_\_\_\_

**AND**

2.B.2. Performed at least 25 mammography exams under direct supervision  
 of a MQSA qualified individual

Yes \_\_\_\_\_ No \_\_\_\_\_

3. 8 hours of FFDM specific education Yes \_\_\_\_\_ No \_\_\_\_\_

**Continuing Education and Experience**

1. 15 hrs. CEU documented in past 36 months Yes \_\_\_\_\_ No \_\_\_\_\_

2. 200 pt. Exams/24 months  
(Applicable after 6/30/01) Yes \_\_\_\_\_ No \_\_\_\_\_

**FFDM MEDICAL PHYSICIST**

MAS \_\_\_\_\_

Physicist Name \_\_\_\_\_

**Initial Requirements**

- 1.A. Current Arkansas Vendor Service Card (State Approval) **STATE REQUIREMENT**  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- OR**
- 1.B. Board Certification (ABR or ABMP)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- OR**
- 1.C. State License  
 Yes \_\_\_\_\_ No \_\_\_\_\_

**AND****Option 1 - Master's Degree or Higher**

2. M.S. or Ph.D in a Physical Science (w/20 semester hr. in physics)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- AND**
3. 20 Contact Hours Training in Surveys  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- AND**
4. Experience in Conducting Surveys (1 facility & 10 units - supervised)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
5. 8 hours of FFDM specific education  
 Yes \_\_\_\_\_ No \_\_\_\_\_

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

- \* Qualified under Interim Regulations prior to 4/28/99  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- AND**
2. B.S in a Physical Science (w/10 semester hr. in physics)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- AND**
3. 40 Contact Hours Training in Surveys (after B.S. degree)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
- AND**
4. Experience in Conducting Surveys (1 facilities & 20 units - supervised)  
 (after B.S. degree)  
 Yes \_\_\_\_\_ No \_\_\_\_\_
5. 8 hours of FFDM specific education  
 Yes \_\_\_\_\_ No \_\_\_\_\_

**Continuing Education and Experience**

1. 15 hrs. CME documented in past 36 months  
 Yes \_\_\_\_\_ No \_\_\_\_\_
2. Performed 2 facility surveys on at least 6 units in past 24 months  
 (Applicable after 6/30/01)  
 Yes \_\_\_\_\_ No \_\_\_\_\_

Prior to the issuance of a 6-month Provisional Certificate for a new facility, the facility must submit complete documentation for its interpreting physician, its radiologic technologist(s), and the medical physicist who performed the initial evaluation on the mammography equipment. For reaccreditation or reinstatement applications, personnel qualifications are reviewed within two (2) weeks of receipt.

If documentation is incomplete or unacceptable, the facility is notified by telephone and in writing. The documentation required is specified, a detail description of requirements is included, and acceptable forms of documentation are noted.

### ***XIII. FFDM Materials Sent to Facilities During the Accreditation Process***

Throughout the previous sections, materials sent to facilities during the accreditation process have been noted. Other than the previously listed materials other materials sent include the application form, application guide, six-month reminder letter, three-month reminder letter, provisional certification letter, provisional certification of a new unit letter, full certification letter (new facility and reaccreditation), full certification (adding a new unit), and full certification (reinstatement).

#### **A. Documents and Images**

##### **Application Forms**

The FFDM application form and application guide are shown on the next seven pages.

**FDA APPROVED ACCREDITING BODY  
ARKANSAS DEPARTMENT OF HEALTH  
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 Contact: \_\_\_\_\_

Fax Number: \_\_\_\_\_ **Contact's E-mail:** \_\_\_\_\_

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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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 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. 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 and \$500. 00 reinstatement fee.**

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 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 proceeding 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  
**AND**
5. 8 hours of FFDM specific education

### **Continuing Education**

6. 15 hrs. Category 1 CME documented in past 36 months

### **Continuing Experience**

7. 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

**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 training specific to FFDM

### **Continuing Education**

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

### **Continuing Experience**

7. 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

**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 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 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 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 ninety (90) 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, 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).

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Date

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Facility Administrator

**B. Notification Letters (No deficiencies)**

The following notification letters are sent out during the accreditation process: six month reminder letter, three month reminder letter, provisional certification letter, provisional certification of a new unit letter, full certification letter (new facility and reaccreditation), full certification (adding a new unit), and results of a passing random clinical image review.

*1) Reminder letters of accreditation expiration*

The six-month reminder letter is listed on the next page (Printed on ADH Letterhead).

**CERTIFIED MAIL**

DATE OF THE LETTER

FACILITY CONTACT

FACILITY NAME

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

**Accreditation No: MAS0XXX**

Dear CONTACT GREETING:

Your facility's FDA mammography certification will expire on EXPIRATION DATE. The State of Arkansas Department of Health is currently the Accrediting Body for your facility. For your convenience, an Accreditation Form and Guide are enclosed. **To ensure a timely re-accreditation, the Department requires a minimum of three (3) months to process your application.**

If the application is not received at least three (3) months prior to the current certificate expiration date and problems arise during your facility's reaccreditation process, the possibility exists that your FDA Certificate to Perform Mammography will expire before your facility is re-accredited. If the certificate expires, you will not be allowed to perform mammography until a new certificate is issued.

If you are planning to re-accredit with the State of Arkansas, please submit the Application Form, all documents listed in Section 6 of the application guide, and the application fee to us at least three (3) months prior to your FDA mammography certificate expiration date. **ONLY SUBMIT ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF FATTY BREASTS - IDENTIFY THE IMAGES AS FATTY AND DENSE.** If you have more than one mammography unit, please include one set fatty and one set dense for each unit subject to reaccreditation and clearly mark the images as to which unit they represent. If additional films are required, we will contact you and request that they be submitted. **All images submitted must be hard copy originals.**

If you have any questions concerning this application or if we can be of any assistance to you, please call this office at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosure

An example of the three-month reminder letter (Provisional or New unit) is shown on the next page (Printed on ADH Letterhead).

DATE OF THE LETTER

**CERTIFIED MAIL**

FACILITY CONTACT  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL

**Accreditation No.:MAS0XXX**

Dear CONTACT GREETING:

The Department has completed the review of your accreditation application. The Department's DATE OF PROVISIONAL ACCREDITATION LETTER, letter notified you of the expiration date (EXPIRATION DATE) and requested submission of Clinical Images for review. As noted in Item 6F of the Application Guide, you are required to submit two (2) sets of clinical images that have been interpreted as normal, one set demonstrating imaging of fatty breasts and one set demonstrating imaging of dense breasts. Clinical Image Review requires approximately one month to complete, and a failure of a set of films will result in an increased review period. Therefore, it is recommended that the required two (2) sets of patient films be submitted as soon as possible. **ONLY SUBMIT ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES DEMONSTRATING IMAGING OF FATTY BREASTS -IDENTIFY THE IMAGES AS FATTY AND DENSE.** If you have more than one mammography unit, please include one set fatty and one set dense for each unit subject to reaccreditation and clearly mark the images as to which unit they represent. If additional films are required, the Department will request that they be submitted. **All images submitted must be hard copy originals.**

**Please be aware that if problems arise during your facility's Clinical Image Review process, the possibility exists that your FDA certificate to perform mammography will expire before the accreditation process is completed. If the certificate expires, you will not be allowed to perform mammography under MQSA until your facility has successfully completed the accreditation process.**

If you have any questions concerning this application or if we can be of assistance with your mammography program, please call this office at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

An example of the three-month reminder letter (Reaccreditation) is shown on the next page (Printed on ADH Letterhead).

DATE OF THE LETTER

**CERTIFIED MAIL**

FACILITY CONTACT  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL

**Accreditation No.:MAS0XXX**

Dear CONTACT GREETING:

The Department's DATE OF SIX-MONTH REMINDER LETTER, letter notified you of the expiration date (EXPIRATION DATE) and requested submission of Clinical Images for review. As noted in Item 6F of the Application Guide, you are required to submit two (2) sets of clinical images that have been interpreted as normal, one set demonstrating imaging of fatty breasts and one (1) set demonstrating imaging of dense breasts. Clinical Image Review requires approximately one month to complete, and a failure of a set of films will result in an increased review period. Therefore, it is recommended that the required two sets of patient films be submitted as soon as possible. **ONLY SUBMIT ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES DEMONSTRATING IMAGING OF FATTY BREASTS - IDENTIFY THE IMAGES AS FATTY AND DENSE.** If additional films are required, the Department will request that they be submitted. **All images submitted must be hard copy originals.**

**Please be aware that if problems arise during your facility's Clinical Image Review process, the possibility exists that your FDA certificate to perform mammography will expire before the accreditation process is completed. If the certificate expires, you will not be allowed to perform mammography under MQSA until your facility has successfully completed the accreditation process.**

If you have any questions concerning this application or if we can be of assistance with your mammography program, please call this office at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

*2) Provisional certification letters*

An example of the letter sent to facilities that successfully meet the requirements to become provisionally certified is shown on the next page.

DATE OF THE LETTER

CONTACT, CONTACT TITLE

FACILITY NAME

RE: Accreditation – MAS0XXX

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Department has received the application and information for FACILITY NAME. The following have been reviewed and were found to be acceptable:

1. Mammography Equipment Evaluation for FFDM UNIT MANUFACTURER model number: MODEL NUMBER, dated DATE OF MAMMOGRAPHY EQUIPMENT EVALUATION, signed by PHYSICIST'S NAME.
2. Phantom Image for FFDM UNIT MANUFACTURER model number: MODEL NUMBER, dated DATE OF PHANTOM IMAGE
3. Interpreting Physician(s), Technologist(s) and Medical Physicist personnel documentation.

This completes the initial review for accreditation. Your facility's information has been submitted to the Food and Drug Administration (FDA). **While your facility is certified by the FDA, this certification is only approved for a six-month provisional usage period, which will expire on DATE OF CERTIFICATION EXPIRATION.**

Prior to the provisional usage expiration date, you must submit Clinical Images for review. As noted in Item 6F of the Application Guide, you are required to submit two sets of clinical images which have been interpreted as normal, one set demonstrating imaging of dense breasts and one set demonstrating imaging of fatty breasts. Clinical Image Review requires approximately two (2) months to complete, and failure of a set of films will result in an increased review period. Therefore, it is recommended that the required two sets of patient films be submitted at least two (2) months prior to the DATE OF CERTIFICATION EXPIRATION, expiration date.

**ONLY SUBMIT ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF FATTY BREASTS - IDENTIFY THE IMAGES AS FATTY AND DENSE.** If additional films are required, a colleague from Radiation Control will request that they be submitted. **All images submitted must be hard copy originals.**

If you have any questions regarding the accreditation process, please contact this office at (501) 661-2301. Please address correspondence to ***Mail Slot #H-30.***

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

An example of the letter sent to facilities that successfully meet the requirements to have an added unit provisionally certified is shown on the next page.

DATE OF THE LETTER

CONTACT NAME, CONTACT TITLE  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL CODE

RE: Accreditation – MASXXX New Unit

Dear CONTACT GREETING:

The Department has received the application and information for FACILITY NAME's new mammography unit. The following have been reviewed and were found to be acceptable:

1. Mammography Equipment Evaluation for UNIT MANUFACTURER AND MODEL NUMBER, dated DATE OF MEE, signed by PHYSICIST'S NAME.
2. Phantom Image for UNIT MANUFACTURER AND MODEL NUMBER, dated DATE OF PHANTOM IMAGE.

This completes the initial review for accreditation of your new mammography unit. Your facility's change of information has been submitted to the Food and Drug Administration (FDA). **While your facility is certified by the FDA, the new unit is only approved for a six-month provisional usage period, which will expire on PROVISIONAL EXPIRATION DATE.**

Prior to the provisional usage expiration date, you must submit Clinical Images for review. As noted in Item 6F of the Application Guide, you are required to submit two sets of clinical images which have been interpreted as normal, one set demonstrating imaging of dense breasts and one set demonstrating imaging of fatty breasts. Clinical Image review requires approximately one month to complete, and failure of a set of films will result in an increased review period. Therefore, it is recommended that the required two sets of patient films be submitted at least two (2) months prior to the PROVISIONAL EXPIRATION DATE, expiration date.

**ONLY SUBMIT ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF FATTY BREASTS - IDENTIFY THE IMAGES AS FATTY AND DENSE.** If additional films are required, we will request that they be submitted. **All images submitted must be hard copy originals.**

If you have any questions regarding the accreditation process, please contact me at (501) 661-2301. Please address correspondence to ***Mail Slot #30.***

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

An example of the letter sent to facilities that successfully meet the requirements to become reinstated and provisionally certified is shown on the next page.

DATE OF THE LETTER

FACILITY CONTACT, CONTACT TITLE

FACILITY NAME

ADDRESS 1

CITY, AR POSTAL CODE

RE: Accreditation – MAS0XXX –

Dear CONTACT GREETING:

The Department has received the application and information for FACILITY NAME. The following have been reviewed and were found to be acceptable:

1. Corrective Action Plan dated DATE OF CORRECTIVE ACTION PLAN.
2. Phantom Image for FFDM UNIT MANUFACTURER model number: UNIT MODEL NUMBER, dated DATE OF PHANTOM IMAGE.
3. Interpreting Physician(s), Technologist(s) and Medical Physicist personnel documentation.

This completes the initial review for accreditation. Your facility's updated information has been submitted to the Food and Drug Administration (FDA). **While your facility is certified by the FDA, the re-instatement is only approved for a 6-month provisional usage period, which will expire on PROVISIONAL EXPIRATION DATE.**

Prior to the provisional usage expiration date, you must submit Clinical Images for review and verification of the completion of your facility's corrective action plan.

As noted in Item 6F of the Application Guide, you are required to submit two sets of clinical images, which have been interpreted as normal, one (1) set demonstrating imaging of dense breasts and one (1) set demonstrating imaging of fatty breasts. Clinical Image Review requires approximately one (1) month to complete, and failure of a set of films will result in an increased review period. Therefore, it is recommended that the required two sets of patient films be submitted at least two (2) months prior to the PROVISIONAL EXPIRATION DATE, expiration date.

**ONLY SUBMIT ONE SET IMAGES THAT DEMONSTRATE IMAGING OF DENSE BREASTS AND ONE SET OF IMAGES THAT DEMONSTRATE IMAGING OF FATTY BREASTS. PLEASE IDENTIFY THE IMAGES AS FATTY AND DENSE.** If additional films are required, the Department will request that they be submitted. **All images submitted must be hard copy originals.**

If you have any questions regarding the accreditation process, please contact this office at (501) 661-2301. Please address correspondence to **Mail Slot #30**.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Radiation Control Section

MD:md

*3) Full Certification Letter*

An example of the letter sent to facilities that complete accreditation or the reaccreditation process and become fully certified is shown on the next two pages. Along with the notification, the films are sent back to the facility (first page printed on ADH letterhead).

DATE OF THE LETTER

**Certified Mail**

FACILITY CONTACT, CONTACT TITLE  
 FACILITY NAME  
 ADDRESS 1  
 ADDRESS 2  
 CITY, AR POSTAL CODE

Accreditation Number: MAS0XXX  
 FDA ID Number: FDA ID NUMBER

Dear CONTACT GREETING:

The Department has completed the review of FACILITY NAME's Application for Accreditation to perform Mammography under MQSA. The following items were reviewed and found to be acceptable:

1. PHYSICIST SURVEY OR MEDICAL EQUIPMENT EVALUATION for FFDM UNIT MANUFACTURER AND MODEL NUMBER, dated DATE OF PHYSICIST SURVEY OR MEDICAL EQUIPMENT EVALUATION, signed by PHYSICIST'S NAME.
2. Phantom image dated DATE OF PHANTOM IMAGE.
3. Personnel documentation for physician, physicist, and technologist.
4. Adipose images, patient number: FATTY FILM ID NUMBER, dated DATE OF FATTY IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS
5. Dense images, patient number: DENSE FILM ID NUMBER, dated DATE OF DENSE IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS

Your facility's information has been submitted to the Food and Drug Administration (FDA) to become Fully Certified under MQSA. This accreditation will expire on NEW EXPIRATION DATE . If you have not received your Certificate from the FDA within two weeks, please notify the Department.

The aforementioned patient films are enclosed.

If you have any questions regarding the accreditation process or if we can be of any assistance with your mammography program, please contact this office at (501) 661-2301. Please address correspondence to me at Mail Slot #30.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

An example of the letter that is sent to facilities that have successfully completed the accreditation process for adding a new unit is shown on the next two pages (first page printed on ADH letterhead).

DATE OF THE LETTER

**Certified Mail**

FACILITY CONTACT, CONTACT TITLE  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL CODE

Accreditation Number: MAS0XXX  
FDA ID Number: FDA ID NUMBER

Dear CONTACT GREETING:

The Department has completed the review of FACILITY NAME's Application for the accreditation of a new unit to perform Mammography under MQSA. The following items were reviewed and found to be acceptable:

1. Mammography Equipment evaluation for UNIT MANUFACTURER AND MODEL NUMBER, dated DATE OF PHYSICIST SURVEY OR MEE, signed by PHYSICIST'S NAME.
2. Phantom image dated DATE OF PHANTOM IMAGE.
3. Adipose images, patient number: FATTY FILM ID NUMBER, dated DATE OF FATTY IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS
4. Dense images, patient number: DENSE FILM ID NUMBER, dated DATE OF DENSE IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS

Your facility's information has been submitted to the Food and Drug Administration (FDA) to become Fully Certified under MQSA. This certification will expire on CERTIFICATION EXPIRATION DATE.

The aforementioned patient films are enclosed.

If you have any questions regarding the accreditation process or if we can be of any assistance with your mammography program, please contact this office at (501) 661-2301. Please address correspondence to me at Mail Slot #30.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

An example of the letter that is sent to facilities that have successfully completed the accreditation process for full certification following reinstatement is shown on the next two pages (first page printed on ADH letterhead).

DATE OF THE LETTER

**Certified Mail**

FACILITY CONTACT, CONTACT TITLE  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL CODE

Accreditation Number: MAS0XXX  
FDA ID Number: FDA ID NUMBER

Dear CONTACT GREETING:

The Department has completed the review of FACILITY NAME's Application for the accreditation of a new unit to perform Mammography under MQSA. The following items were reviewed and found to be acceptable:

1. Mammography Equipment evaluation for UNIT MANUFACTURER AND MODEL NUMBER, dated DATE OF PHYSICIST SURVEY OR MEE, signed by PHYSICIST'S NAME.
2. Phantom image dated DATE OF PHANTOM IMAGE.
3. Adipose images, patient number: FATTY FILM ID NUMBER, dated DATE OF FATTY IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS
4. Dense images, patient number: DENSE FILM ID NUMBER, dated DATE OF DENSE IMAGES.
  - Comments:
    - a. MLO: COMMENTS ON THE MLO VIEWS
    - b. CC: COMMENTS ON THE CC VIEWS
    - c. Other: ALL OTHER COMMENTS

Your facility's information has been submitted to the Food and Drug Administration (FDA) to become Fully Certified under MQSA. This certification will expire on CERTIFICATION EXPIRATION DATE.

The aforementioned patient films are enclosed.

If you have any questions regarding the accreditation process or if we can be of any assistance with your mammography program, please contact this office at (501) 661-2301. Please address correspondence to me at Mail Slot #30.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

#### *4) Denial of Accreditation*

If a facility is denied accreditation, the Food and Drug Administration will be notified of the denial and the reason for denial. This will be done by e-mail and through the MPRIS.

#### *XIV. FFDM Procedures for Notifying Facilities of Deficiencies*

Notification procedures for specific deficiencies that were not previously shown in the previous sections of these procedures are shown in this section. These include the following letters: notification of failure first submission of clinical images (new accreditation), notification of failure first submission of clinical images (reaccreditation), failure of first submission of clinical images (adding a new unit), failure of first submission of clinical images (reinstatement), failure of second submission of clinical images (accreditation and reaccreditation), failure of second submission of clinical images (adding a new unit), denied certification letter (accreditation and reaccreditation), and denied certification (adding a new unit). In addition to the letter informing the facility of a deficiency, a copy of the Right to Appeal Form will be sent.

An example of the letter notifying a facility (new accreditation) of the failure of its first submission of clinical images is shown on the next page.

**Certified mail**

DATE OF THE LETTER

FACILITY CONTACT

CONTACT TITLE

FACILITY NAME

RE: Clinical Image Review: ACCREDITATION NUMBER

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Department has completed the initial clinical image review associated with the accreditation application for ACCREDITATION NUMBER, dated DATE OF APPLICATION. The Department's DATE OF PROVISIONAL LETTER, letter detailed items, which had been reviewed and were found to be adequate.

As discussed in the DATE CONTACTED BY PHONE , telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your first submission of adipose (fatty) and dense images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers regarding your first submission of dense and adipose (fatty) images are detailed below.

**Clinical Image # DENSE IMAGE ID-Dense**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)*****Clinical Image #FATTY FILM ID-Fatty**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)***

**Since your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that accreditation applications are allowed three (3) film submittals for clinical images. Since your first submission of TYPE OF FILMS THAT FAILED images has failed review, you have two submissions remaining. If both additional submissions fail, your accreditation will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2301.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a second clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#DENSE IMAGE ID, #FATTY IMAGE ID)

An example of the letter notifying a facility (reaccreditation) of the failure of its first submission of clinical images is shown on the next page.

**Certified mail**

DATE OF THE LETTER

FACILITY CONTACT

CONTACT TITLE

FACILITY NAME

RE: Clinical Image Review: ACCREDITATION NUMBER

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

The Department has completed the initial clinical image review associated with the accreditation application for ACCREDITATION NUMBER, dated DATE OF APPLICATION.

As discussed in the DATE CONTACTED BY PHONE, telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your first submission of adipose (fatty) and dense images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers about your first submission of adipose (fatty) and dense images are below.

**Clinical Image # DENSE IMAGE ID-Dense**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)***

**Clinical Image # FATTY IMAGE ID-Fatty**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)***

**Since your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that accreditation applications are allowed three (3) film submittals for clinical images. Since your first submission of TYPE OF FILMS THAT FAILED images has failed review, you have two submissions remaining. If both additional submissions fail, your accreditation will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2301.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a second clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#DENSE IMAGE ID, #FATTY IMAGE ID)

An example of the letter notifying a facility (adding a new unit accreditation) of the failure of its first submission of clinical images is shown on the next page

**certified mail**

DATE OF THE LETTER

FACILITY CONTACT  
 CONTACT TITLE  
 FACILITY NAME  
 ADDRESS 1  
 ADDRESS 2  
 CITY, AR POSTAL CODE

RE: Clinical Image Review: ACCREDITATION NUMBER-New unit

Dear CONTACT GREETING:

The Department has completed the initial clinical image review associated with the accreditation application for the MANUFACTURER OF NEW UNIT, MODEL NUMBER, dated DATE OF APPLICATION. The Department's DATE OF PROVISIONAL LETTER, letter detailed items, which had been reviewed and were found to be adequate.

As discussed in the DATE CONTACTED BY PHONE, telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your first submission of adipose (fatty) and dense images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers regarding your first submission of dense and adipose (fatty) images are detailed below.

**Clinical Image # DENSE IMAGE ID-Dense**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)*****Clinical Image #FATTY FILM ID-Fatty**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)***

**Since your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that accreditation applications are allowed three (3) film submittals for clinical images. Since your first submission of TYPE OF FILMS THAT FAILED images has failed review, you have two submissions remaining. If both additional submissions fail, the accreditation for your new mammography unit will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2301.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a second clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#DENSE IMAGE ID, #FATTY IMAGE ID)

An example of the letter notifying a facility (reinstatement) of the failure of its first submission of clinical images is shown on the next page.

**Certified mail**

DATE OF THE LETTER

FACILITY CONTACT  
 CONTACT TITLE  
 FACILITY NAME  
 ADDRESS 1  
 ADDRESS 2  
 CITY, AR POSTAL CODE

RE: Clinical Image Review: ACCREDITATION NUMBER-Reinstatement

Dear CONTACT GREETING:

The Department has completed the initial clinical image review associated with the reinstatement accreditation application for ACCREDITATION NUMBER, dated DATE OF APPLICATION. The Department's DATE OF PROVISIONAL REINSTATEMENT LETTER, letter detailed items, which had been reviewed and were found to be adequate.

As discussed in the DATE CONTACTED BY PHONE , telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your first submission of adipose (fatty) and dense images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers regarding your first submission of dense and adipose (fatty) images are detailed below.

**Clinical Image # DENSE IMAGE ID-Dense**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)*****Clinical Image #FATTY FILM ID-Fatty**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: (PASS or FAIL)***

**Since your first submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your reinstatement accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that reinstatement accreditation applications are allowed two (2) film submittals for clinical images. Since your first submission of TYPE OF FILMS THAT FAILED images has failed review, you have one submission remaining. If the additional submission fails, your reinstatement will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2173.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a second clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#DENSE IMAGE ID, #FATTY IMAGE ID)

An example of the letter notifying a facility (new accreditation and reaccreditation) of the failure of its second submission of clinical images is shown on the next page.

**Certified mail**

DATE OF THE LETTER

FACILITY CONTACT

CONTACT TITLE

FACILITY NAME

RE: Clinical Image Review: ACCREDITATION NUMBER

ADDRESS 1

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

As discussed in the DATE CONTACTED BY PHONE, telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your second submission of TYPE OF IMAGES THAT FAILED clinical images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your second submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers regarding your second submission of TYPE OF IMAGES THAT FAILED images are detailed below.

**Clinical Image # ID OF FILM THAT FAILED- TYPE OF FILM THAT FAILED**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: FAIL***

**Since your second submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that accreditation applications are allowed three (3) film submittals for clinical images. Since your second submission of TYPE OF FILMS THAT FAILED images has failed review, you have one submission remaining. If the additional submission fails, your accreditation will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2301.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a third clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#CLINICAL IMAGE ID)

An example of the letter notifying a facility (adding a new unit accreditation) of the failure of its second submission of clinical images is shown on the next page

**Certified mail**

DATE OF THE LETTER

FACILITY CONTACT

CONTACT TITLE

FACILITY NAME

RE: Clinical Image Review: ACCREDITATION NUMBER

ADDRESS 1

New Unit ID: MANUFACTURER, MODEL NUMBER

ADDRESS 2

CITY, AR POSTAL CODE

Dear CONTACT GREETING:

As discussed in the DATE CONTACTED BY PHONE, telephone conversation, the Clinical Image Review Committee (CIRC) has completed the evaluation of your second submission of TYPE OF IMAGES THAT FAILED clinical images. These films were reviewed by at least two different interpreting physicians on the Department's CIRC. **Your second submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review.**

The results and detailed comments from the Clinical Image Reviewers regarding your second submission of TYPE OF IMAGES THAT FAILED images are detailed below.

**Clinical Image # ID OF FILM THAT FAILED- TYPE OF FILM THAT FAILED**

Comments:

1. MLO Views: COMMENTS ON MLO VIEWS
2. CC Views: COMMENTS ON CC VIEWS
3. Other Comments: OTHER COMMENTS

***OVERALL IMAGE QUALITY: FAIL***

**Since your second submission of TYPE OF IMAGES THAT FAILED images has failed clinical image review**, in order to proceed with your accreditation application, one additional set of normal TYPE OF IMAGES THAT FAILED films needs to be submitted for review. As noted under Item 6G of the Application Guide, each additional review of clinical images requires an additional fee of \$100.

The Department suggests that you discuss the results of the clinical image review with your lead interpreting physician and your consultant physicist. It should be noted that accreditation applications are allowed three (3) film submittals for clinical images. Since your second submission of TYPE OF FILMS THAT FAILED images has failed review, you have one submission remaining. If the additional submission fails, your accreditation will be denied.

**Please submit one set of TYPE OF IMAGES THAT FAILED images, which have been read as normal, and the \$100 additional review fee as soon as possible. All images submitted must be hard copy originals.** Please note that your current FDA certificate to perform mammography expires on EXPIRATION DATE. If you have any questions regarding current status of your accreditation review or if we can be of further assistance, please contact me at (501) 661-2301.

The failure of a set of clinical images, like any other adverse accreditation decision, can be appealed. If after further review you feel that the deficiencies noted are inaccurate and/or did not warrant failure, and wish to appeal, please follow the steps outlined in the attached appeal procedure. It should be noted that an appeal will count as a third clinical image submission.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Enclosures - Clinical Images (#CLINICAL IMAGE ID)

An example of the letter notifying a facility (accreditation reaccreditation) of the failure of its third submission of clinical images is shown on the next two pages.

**CERTIFIED MAIL**

DATE OF LETTER

FACILITY ADMINISTRATOR  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL CODE

Dear ADMINISTRATOR GREETING:

The Arkansas Department of Health and Human Service's Mammography Accreditation Body has completed the review of your facility's accreditation application. Unfortunately, this application has been denied. This denial is based on the failure of the TYPE OF IMAGES THAT FAILED clinical images reviewed by the Clinical Image Review Committee (CIRC).

As stated during the telephone conversation of DATE OF TELEPHONE CONVERSATION with PERSON CONTACTED, your facility's final submission of TYPE OF IMAGES THAT FAILED images failed clinical image review on DATE THAT SUBMISSION FAILED. Three sets of TYPE OF CLINICAL IMAGES THAT FAILED clinical images were submitted to the CIRC for review and all have failed the review process. The results and comments regarding the first and second sets of TYPE OF IMAGES images were noted on a previous letters sent on DATE OF FIRST FAIL LETTER and DATE OF SECOND FAIL LETTER. The results and comments regarding the final set of TYPE OF IMAGES THAT FAILED images are detailed below:

- **Third Submission of TYPE OF FAILING IMAGES Images:** ID# FILM ID, Date of Images: DATE OF IMAGES
- **Overall Evaluation:** Fail
- **COMMENTS:** ALL COMMENTS
- **Reason(s) for Failure:** REASONS FOR FAILURE

During the accreditation process you are allowed three submissions of clinical images (Application Guide Item 6F). Since all three submissions of TYPE OF IMAGES THAT FAILED images have failed, your accreditation application dated DATE OF APPLICATION is denied.

In order to resume performing mammography your facility should be reinstated. The reinstatement process involves several steps, which are detailed below.

- C. First, a Corrective Action Plan (CAP) should be submitted. This plan should detail the actions that will be taken to address the clinical image deficiencies noted by the CIRC. This CAP should also document the estimated completion date for each of the corrective actions. This corrective action plan should include the following:
  - 4. ACTION ONE THAT SHOULD BE TAKEN
  - 5. ACTION TWO THAT SHOULD BE TAKEN
  - 6. ACTION THREE THAT SHOULD BE TAKEN
  
- D. Along with the Corrective Action Plan, your facility should submit an accreditation application. This application must include a current physicist survey (within 6 months), one phantom image, and \$500 application fee and any updates to the personnel documentation for the Interpreting Physicians, Radiologic Technologist, and Medical Physicist. Once this information is received and reviewed a colleague from the Arkansas Department of Health Mammography Accreditation Program will inform you that you have been approved for reinstatement and the information will be forwarded to the Food and Drug Administration and your facility will be given a 6-month Provisional Reinstatement of the unit.

For your convenience, I am including a blank application form.

### **RIGHT TO APPEAL**

If you feel that the decisions regarding your facility were inaccurate or did not warrant failure, you may appeal the decision. This process is outlined on the Appeal Procedure, which is included.

If you have any questions regarding this letter or the reinstatement process please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Encl: Clinical Images (#CLINICAL IMAGE ID), Appeal Procedure

An example of the letter notifying a facility (accreditation adding a new unit) of the failure of its third submission of clinical images is shown on the next two pages.

## CERTIFIED MAIL

DATE OF LETTER

FACILITY ADMINISTRATOR  
FACILITY NAME  
ADDRESS 1  
ADDRESS 2  
CITY, AR POSTAL CODE

Dear ADMINISTRATOR GREETING:

The Arkansas Department of Health Mammography Accreditation Body has completed the review of your facility's accreditation application to add the UNIT MANUFACTURER, MODEL NUMBER. Unfortunately, this application to add the new unit to your facility's certificate has been denied. This denial is based on the failure of the TYPE OF IMAGES THAT FAILED clinical images reviewed by the Clinical Image Review Committee (CIRC).

As stated during the telephone conversation of DATE OF TELEPHONE CONVERSATION with PERSON CONTACTED, your facility's third submission of TYPE OF IMAGES THAT FAILED images failed clinical image review on DATE THAT SUBMISSION FAILED. Three sets of TYPE OF CLINICAL IMAGES THAT FAILED clinical images were submitted to the CIRC for review and all have failed the review process. The results and comments regarding the first and second sets of TYPE OF IMAGES images were noted on a previous letters sent on DATE OF FIRST FAIL LETTER and DATE OF SECOND FAIL LETTER. The results and comments regarding the final set of TYPE OF IMAGES THAT FAILED images are detailed below:

- **Third Submission of TYPE OF FAILING IMAGES Images:** ID# FILM ID, Date of Images: DATE OF IMAGES
- **Overall Evaluation:** Fail
- **COMMENTS:** ALL COMMENTS
- **Reason(s) for Failure:** REASONS FOR FAILURE

During the accreditation process you are allowed three submissions of clinical images (Application Guide Item 6F). Since all three submissions of TYPE OF IMAGES THAT FAILED images have failed, your accreditation application dated DATE OF APPLICATION is denied.

In order to resume performing mammography with the UNIT MANUFACTURER, MODEL NUMBER unit, the unit should be reinstated. The reinstatement process involves several steps, which are detailed below.

- A. First, a Corrective Action Plan (CAP) should be submitted. This plan should detail the actions that will be taken to address the clinical image deficiencies noted by the CIRC. This CAP should also document the estimated completion date for each of the corrective actions. This corrective action plan should include the following:
  1. ACTION ONE THAT SHOULD BE TAKEN
  2. ACTION TWO THAT SHOULD BE TAKEN
  3. ACTION THREE THAT SHOULD BE TAKEN
  
- B. Along with the Corrective Action Plan, your facility should submit an accreditation application. This application must include a current physicist survey for the unit (within 6 months), one phantom image, and \$500 application fee and any updates to the personnel documentation for the Interpreting Physicians, Radiologic Technologist, and Medical Physicist. Once this information is received and reviewed, a colleague from the Arkansas Department of Health Mammography Accreditation Program will inform you that you have been approved for reinstatement and the information will be forwarded to the Food and Drug Administration and your facility will be given a 6-month Provisional Reinstatement Certificate.

For your convenience, I am including a blank application form.

### **RIGHT TO APPEAL**

If you feel that the decisions regarding your facility were inaccurate or did not warrant failure, you may appeal the decision. This process is outlined on the Appeal Procedure, which is included.

If you have any questions regarding this letter or the reinstatement process please contact me at (501) 661-2301.

Sincerely,

Melinda Davis, R.T. (R)  
Mammography Program Leader  
Mammography Program  
Radiation Control Section

MD:md

Encl: Clinical Images (#CLINICAL IMAGE ID), Appeal Procedure

### ***XV. FFDM Procedures for Monitoring Corrections of Deficiencies***

As previously noted throughout these procedures, facilities may be required to submit written documentation of equipment repairs, follow-up equipment evaluations, additional clinical images for review, and/or other documentation as required based on the deficiency noted. In addition, the Department may elect to conduct an onsite visit of a facility to verify deficiency corrections or compliance with a plan of corrective action.

### ***XVI. FFDM Suspension and Revocation of Accreditation***

#### **Definitions**

Suspension of accreditation means that the facility's accreditation has been temporarily placed on hold. Once the suspension has been lifted, its original accreditation is restored and the expiration date is unchanged. Because the facility's certification status has not changed it can still perform mammography while its accreditation is under suspension (unless other action is taken by the State or FDA).

Revocation of accreditation means that the facility's accreditation has been rescinded. The facility must reinstate and apply for a new accreditation with a new expiration date. Because the facility's certification status has not changed, it can still perform mammography after the revocation (unless other action is taken by the State or FDA).

#### **Suspension and Revocation Process**

The DEPARTMENT may decide to suspend or revoke a facility's mammography accreditation based on a number of things, such as, the "degree of risk" or on the SAR's evaluation of how long it will take the facility to correct its problem(s). Ultimately, the decision of whether or not to suspend or revoke a facility's accreditation will be made by the Section Chief of Radiation Control with input from the FDA and the Leadership of the Arkansas Department of Health Statewide Services Business Unit (SSBU). During the decision making process the Section Chief will maintain contact with the FDA and Leadership of the SSBU via email and/or telephone.

The terms and conditions of a facility's mammography accreditation will be subject to revisions or modifications of the Mammography Quality Standards Act (MQSA). A facility's accreditation may be suspended or revoked because of changes to the Act. In addition a facility's accreditation may be suspended or revoked because of rule, regulations, or orders issued by the Food and Drug Administration and/or the Arkansas Department of Health. If the action taken is under State law, the SAR will inform the facility that the action is not under the MQSA.

Mammography accreditation may be revoked or suspended, for any material false statement in the application or any statement of fact required under provision of the MQSA or of the Arkansas Regulations. Violation of, or failure to observe any of the terms and conditions of the MQSA, or of any rule, regulation or order of the Food and Drug Administration and/or the Arkansas Department of Health may result in revocation or suspension of the accreditation. If the action is taken under State law, the SAR will inform the facility that the action is not under the MQSA.

Whether the accreditation is suspended or revoked, there should be a corresponding FDA action that coincides with the SAR action. During the decision making process there will be a great deal of coordination between the SAR and FDA. This will be done to avoid situations where the SAR and FDA are giving mixed signals to the facility. In addition, this will limit situations, in which, the accreditation and certification expiration dates no longer match. The DEPARTMENT will make a concerted effort to ensure that the accreditation and certification expiration dates remain synchronized.

### **Mammography Program Reporting and Information System (MPRIS) Input and FDA Notification**

Once the decision has been made to revoke or suspend a facility's accreditation, the facility's accreditation status will be changed to Status Code 6 "accreditation revoked/suspended" in MPRIS. Regardless of whether the SAR suspends or revokes the facility's accreditation, it will transmit the same code. In addition, the SAR will transmit the reason for the suspension or revocation to its FDA-AB liaison via email.

### **Facility Notification of Suspension or Revocation**

Once the determination has been made that a facility's accreditation will be suspended or revoked, a letter informing them of the revocation will be sent to the facility's administrator. In addition the letter will inform the facility's administrator of his or her right to appeal the decision, the appeal process, and the possible actions that could be taken by the FDA following the suspension or revocation. A copy of this letter will be sent to the facility's accreditation contact, the lead interpreting physician, the mammography QC technologist, and the Department's liaison at the FDA.

### **FDA Actions Following Suspension of a Facility's Accreditation**

If the facility's accreditation is suspended, FDA can take the following actions:

1. Take no action and leave the facility's certification status unchanged
2. Suspend the certificate under 21 CFR 900.14 (Facility stops mammography until the suspension is lifted; there is no change in certificate expiration date.)
3. Revoke the certificate under 21 CFR 900.14 (Facility stops mammography until the facility is reinstated and a new provisional certificate is issued. (The facility owner/operator cannot own/operate a facility for 2 years.)

### **FDA Actions Following Revocation of a Facility's Accreditation**

If the facility's accreditation is revoked, FDA can take the following actions:

1. Take no action and leave the facility's certification status unchanged
2. Declare the certification "no longer in effect" under 21 CFR 900.13 (Facility stops mammography until the facility is reinstated and a new provisional certificate is issued.) (This action can be taken much quicker than 21 CFR 900.14 actions.)
3. Suspend the certificate under 21CFR 900.14 (Facility stops mammography until the suspension is lifted, and there is no change in certificate expiration date.)

4. Revoke the certificate under 21 CFR 900.14 (Facility stops mammography until the facility is reinstated and a new provisional certificate is issued.) (The facility owner/operator cannot own/operate a facility for 2 years.)

### ***XVII. FFDM Policies and Procedures for Processing Accreditation Applications***

#### **A. Documents and Images**

Accreditation applications and renewals must have the following information submitted:

1. Supportive documentation of training and experience in mammography for technical and professional staff in accordance with 21 CFR 900.12. Credentials must be current and complete, including all continuing education training.
2. Mammography equipment information and the number of units to be accredited.
3. A set of operating and emergency procedures for the mammography equipment.
4. A signed copy of the Attestation of Mammography Quality Assurance Program as outlined in 21 CFR 900.12.
5. A copy of the current physicist report must be submitted. This report of the equipment calibration tests must be performed within six months of the application date.
6. A hard-copy phantom image demonstrating appropriate techniques for a 4.5 cm compressed breast.
7. For renewals, two sets of patients' FFDM images must be submitted. These patients' films must have been taken within 90 days prior to the application date. Images older than 90 days will be returned to the facility and the application will not be reviewed pending receipt of correct patient images. All FFDM images submitted must be hard copy originals.
8. For new units and new facilities, two sets of patients' images must also be submitted. These patients' images must have been taken during the provisional certification period. All FFDM images submitted must be hard copy originals.
9. The proper accreditation fee must be submitted at the time of application. If the fee is not submitted, the application will not be processed until the fee is received.

#### **B. Timeliness of Application**

It is the policy of the Department to regard reaccreditation application received within three (3) months of the current FDA certificate expiration date as timely.

#### **C. Interim Accreditation**

A 45-day Interim Accreditation is used to extend the accreditation period of a facility, allowing the facility to perform mammography while completing the reaccreditation process. If a facility submits their reaccreditation application at least three (3) months prior to their certificate expiration date and has shown a good faith effort in completing the process but has had problems arise during the accreditation process, the Department reserves the right to grant interim accreditation and request an Interim Notice from the FDA, for the facility. The facility must meet the following criteria in order for the SAR to grant interim accreditation and request an Interim Notice.

- The facility has an expired or expiring three (3) year FDA Mammography Facility Certificate.
- The reaccrediting facility has applied for reaccreditation in a timely manner, i.e., all accreditation materials including the first sets of clinical images were received three (3) months prior to the expiration date of its certificate;
- The delay should not otherwise be due to inappropriate facility activities.

The Department considers three (3) months prior to the certificate expiration to be an adequate time frame for completion of the reaccreditation process under our current system. If the delay in completion of the reaccreditation process is due to inappropriate facility activities during the process or submission of the reaccreditation application less than three months prior to the certificate expiration, a 45-Day Interim Accreditation will not be granted to the facility. If the delay in the completion of the reaccreditation process is through no fault of the facility, a 45-Day Interim Accreditation may be granted.

#### **D. Application Processing**

The Accrediting Body (AB) staff reviews all material documentation and procedures within 14 days of receipt. Verification of corrective actions for deficiencies or additional information is requested as needed. The staff reviews the phantom image within 14 days of receipt. This phantom evaluation is based on scoring methods and criteria listed in Section I of these procedures. Clinical images are processed as soon as possible. Typically, the clinical images are reviewed and returned by the Clinical Image Review Committee within 30 days of initial review. The average total time for review of a complete and accurate application is approximately six (6) weeks. Accreditation activities are tracked in the mammography database.

#### **E. Notification of Facility**

##### **Results Notification**

Facilities are notified as soon as possible of deficiencies in phantom images and clinical images. The notification includes the reasons or causes of the failure. Additional images are requested as required.

##### **Notification of Pending Certificate Expiration**

Within six (6) months of the expiration of their current accreditation, facilities are notified of the impending expiration date. A renewal application and guide are furnished with the six-month notification letter. Examples of these letters were noted in section XIII of this manual.

If no response is received, another notification is made within three months of the expiration of their accreditation. In this letter, the facilities are cautioned that should there be problems with accreditation information or clinical images, it is possible that the facility certification will expire and that they will be required to cease providing mammography services.

#### ***XVIII. FFDM Appeal Process***

##### **A. Appeal Process for Suspension or Revocation**

If a facility's accreditation is revoked or suspended this decision may be appealed through the administrative hearing process. In these cases the administrative hearing procedures will be followed as outlined in Section 5 — Rules of Practice in the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation.

## B. Appeal Process for Accreditation Findings

- **APPEAL BASED ON PHANTOM IMAGE REVIEW RESULTS.**  
If a facility believes that the phantom image deficiencies noted during the accreditation process were inaccurate and/or did not warrant failure, they should have their Medical Physicist contact (in writing) the DEPARTMENT and request an appeal.

In addition, the Medical Physicist should explain in detail, why it is believed that the noted deficiencies were inaccurate and return the request along with the phantom image. Once received, the request, along with the phantom image evaluation sheet, the phantom image, and the notification of deficiency letter will be reviewed by the Accreditation Staff. In addition, the phantom image will be re-evaluated by all phantom image reviewers and all the other Certified MQSA inspectors employed by the Arkansas Department of Health. Once the results from these phantom image evaluations are completed the total number of passing evaluations will be calculated. If the total number of passing evaluations is greater than or equal to the total number of failing evaluations, the failing review will be overturned. If after the evaluations the total number of passing reviews is less than the total number of failing reviews, the failing review will stand. It should be noted this process will take approximately one week to complete. If the facility's certification expires while the appeal process is on-going, they must cease performing mammography.

- **APPEAL BASED ON CLINICAL IMAGE REVIEW RESULTS.**  
If a facility believes that the clinical image deficiencies noted during the accreditation process were inaccurate and/or did not warrant failure, they should have their Lead Interpreting Physician contact (in writing) the SAR and request an appeal. This request should explain, in detail, why he or she believes that the noted deficiencies were inaccurate and/or did not warrant failure. Also the films should be returned with the request. Once the appeal request is received, the films will be sent to two additional clinical image reviewers. Once the results from these clinical image evaluations are received the total number of passing evaluations will be calculated. If the total number of passing evaluations is greater than or equal to the total number of failing evaluations the failing review will be overturned. If after the evaluations the total number of passing reviews is less than the total number of failing reviews, the failing review will stand. It should be noted this process takes approximately six weeks to complete. If the facility's certification expires while the appeal process is on-going, they must cease performing mammography.
- Applicants may appeal all other adverse accreditation status decisions through the administrative hearing procedures in Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation, Section 5 - Rules of Practice. These regulations address the informal and formal hearing procedures for adverse accreditation findings. The process allows any aggrieved person to appeal to the Arkansas State Board of Health.

In addition, if after the State of Arkansas' appeal process is completed, a facility still disagrees with an adverse accreditation decision, they can request a review of the decision by the Food and Drug Administration. Once the SAR receives a request, the request along with all accreditation materials (letters, review forms, clinical images, phantom images, etc.) will be forwarded to the Food and Drug Administration via the accreditation liaison.

### **C. Notification of Right to Appeal**

On all correspondence notifying a facility of an adverse accreditation decision, a paragraph will inform the facility of its Right to Appeal the decision. In addition, a document explaining appeal procedure will be included with the correspondence. This document is shown on the following page.

### **D. Procedure for Appeal**

#### ACCREDITATION APPEAL PROCEDURE

##### **Appeal Based on Phantom Image Review Results**

If a facility believes that the phantom image deficiencies noted during the accreditation process were inaccurate and/or did not warrant failure, they should have their Medical Physicist contact (in writing) the SAR and request an appeal. In addition, the Medical Physicist should explain in detail, why he or she believes the noted deficiencies were inaccurate and/or did not warrant failure. Also the phantom image should be returned for further review. Once this request is received, along with the phantom image evaluation sheet, the phantom image, and the notification of deficiency letter will be reviewed by the Accreditation Staff. In addition, the phantom image will be re-evaluated by all phantom image reviewers and all the other Certified MQSA inspectors employed by the Arkansas Department of Health. Once the results from these phantom image evaluations are completed, the total number of passing evaluations will be calculated. If the total number of passing evaluations is greater than or equal to the total number of failing evaluations, the failing review will be overturned. If after the evaluations the total number of passing reviews is less than the total number of failing reviews, the failing review will stand. It should be noted this process takes approximately one week to complete. If the facility's certification expires while the appeal process is ongoing, the facility must cease performing mammography.

##### **Appeal Based on Clinical Image Review Results**

If a facility believes that the clinical image deficiencies noted during the accreditation process were inaccurate and/or did not warrant failure, they should have their Lead Interpreting Physician contact (in writing) the DEPARTMENT and request an appeal. This request should explain, in detail, why he or she believes that the noted deficiencies were inaccurate and/or did not warrant failure. Also the films should be returned for further review. Once the appeal request is received, the films will be sent to two additional clinical image reviewers. Once the results from these clinical image evaluations are received the total number of passing evaluations will be calculated. If the total number of passing evaluations is greater than or equal to the total number of failing evaluations the failing review will be overturned. If after the evaluations the total number of passing reviews is less than the total number of failing reviews the failing review will stand. It should be noted this process takes approximately six weeks to complete. If the facility's certification expires while the appeal process is on-going, they must cease performing mammography.

##### **All other Appeals**

Applicants may appeal all other adverse accreditation status decisions through the administrative hearing procedures in Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation, Section 5 - Rules of Practice. These regulations address the informal and formal hearing procedures for adverse accreditation findings. The process allows any aggrieved person to appeal to the Arkansas State Board of Health.

In addition, if after the State of Arkansas' appeal process is completed, a facility still disagrees with an adverse accreditation decision, they can request a review of the decision by the Food and Drug Administration.

#### ***XIX. FFDM Facility Update Audit***

In correlation with any change noted during the annual MQSA inspection or reported to the DEPARTMENT between facility inspections, the facility will be asked by the DEPARTMENT to complete a Facility Update Questionnaire for the purpose of tracking any notable changes which might affect accreditation thru the DEPARTMENT. An example of the Facility Update Questionnaire is shown on the next page.

**FACILITY UPDATE QUESTIONNAIRE**

MAS \_\_\_\_\_

FDA ID# \_\_\_\_\_

*Please report any changes to pertinent information in the spaces provided below:*

Facility Name \_\_\_\_\_ Facility Ownership/Management \_\_\_\_\_

Facility Physical Address \_\_\_\_\_

Facility Mailing Address \_\_\_\_\_

Facility Accreditation Contact \_\_\_\_\_

Phone Number \_\_\_\_\_

Fax Number \_\_\_\_\_

New Mammography Unit (Manuf/Model#/Date of Certification) \_\_\_\_\_

Change to Major Component of Existing System/Date \_\_\_\_\_

Change in Active Status of Equipment or Facility/Effective Date \_\_\_\_\_

Change in Status of Personnel assigned (to include QA/QC Technologist, Lead Interpreting Physician or Medical Physicist) \_\_\_\_\_

\_\_\_\_\_

For agency use only:

Info update on    /    /    (m/d/y)

Entries \_\_\_\_\_

Errors \_\_\_\_\_

***XX. FFDM HIPAA Statement*****HIPAA and release of information for MQSA purposes**

Implementation of the Health Insurance Portability and Accountability Act (HIPAA) has raised a number of issues with respect to mammography facilities that operate under the Mammography Quality Standards Act (MQSA). Two issues are arising with increasing frequency. The first concerns the protection of patient information during MQSA inspections. The second deals with whether other medical entities (e.g., referring physicians, pathology departments, surgeons) can release patient biopsy information to mammography facilities for purposes of the MQSA medical outcomes audit without obtaining patient authorization. The HIPAA regulations address these matters as follows:

Regarding the first issue, sections 164.512(b) and (d) of the HIPAA regulations allow a mammography facility to release patient information to an MQSA inspector without patient authorization because MQSA inspectors are performing health oversight activities required by law.

As to the second issue, section 164.512(b) of the HIPAA regulations allows a covered entity (e.g., referring physician, pathology department, surgeon) to release patient biopsy information to a mammography facility for purposes of the MQSA medical outcomes audit without patient authorization because the disclosure: (1) is to "a person subject to FDA jurisdiction;" (2) concerns an FDA-regulated product or activity for which the mammography facility has responsibility; and (3) relates to the quality, safety or effectiveness of the product or activity.

***XXI. FFDM Accrediting Body Switching Procedure*****Background:**

In those states that have approved accreditation bodies, facilities may choose to be accredited either by the American College of Radiology or by the state accreditation body (accreditation body). In some instances, facilities accredited by one accreditation body have chosen to change to the other (i.e., new) accreditation body. This occurs most commonly at the time of renewal of accreditation, but may occur prior to that time, and may in some cases occur subsequent to a denial or expiration of accreditation. The latter two cases are in some ways the simplest, but also create their own set of special requirements. These will be dealt with separately later in this document.

To facilitate notification of intent to change accreditation bodies under the FDA database system, i.e., the MPRIS Web, FDA has requested that new accreditation bodies notify FDA and the prior accreditation body by e-mail whenever they learn that a facility intends to change accreditation bodies. When the new accreditation body notifies FDA that a facility intends to change accreditation bodies, FDA can manually change the facility's accreditation body affiliation in MPRIS, which will allow the new body to update the facility record and prevent the old body from doing so. There have been problems when a prior accreditation body receives such notice from a facility, and then changes the status of the facility to withdrawn.

This does not create a problem as long as FDA changes the facility affiliation before the accreditation body changes the status to withdrawn. The new accreditation body will process an accreditation application from the facility, and if it passes, FDA will receive a record to that effect, and issue a new certificate. If the facility fails and is denied accreditation, FDA will receive a record to that effect, recall the facilities certificate, if not expired, and the facility will have to go through reinstatement to again apply for accreditation. However, if the prior accreditation body changes the facility status to withdrawn before the facility affiliation is changed, the MPRIS record will show the facility as withdrawn, and the facility's certificate will be inadvertently recalled. The notification procedure below is intended to preclude such problems.

#### Database issues:

The availability of two accreditation bodies creates special database needs that are exacerbated when facilities change accreditation bodies. It is necessary that our database be affiliated with only one of the two accreditation bodies, permitting only it to enter data for any given facility, and that the affiliated accreditation body be the accreditation body that accredits the facility. However, when a facility decides to change accreditation bodies, and applies to the new accreditation body for reaccreditation it is necessary for the database affiliation to be changed to accept data for the facility from the new accreditation body and preclude acceptance of data from the prior accreditation body.

The number of facilities that change accreditation bodies is small compared with the total of mammography facilities in the United States. Consequently it was determined that notification of the intent of facilities to change accreditation bodies would not be automated in MPRIS since it would be an exceptional case rather than a routine procedure.

#### Notification procedure for accreditation bodies when informed of a facility's intent to change accreditation bodies:

FDA has determined, in consultation with the accreditation bodies, that the following procedures should be followed to process a facility's request to change accreditation bodies.

1. When an accreditation body receives notice of a facility's intent to change its accreditation from it to another body, it should make no change in the facility status until it has been notified that the new body has received and accepted an application for accreditation from the facility.
2. When an accreditation body receives notice of a facility's intent to change its accreditation to it, but does not receive an acceptable application for accreditation, the accreditation body should make no notification and make no changes to its database.
3. Upon receipt and acceptance of an application for accreditation from a facility intending to change accreditation bodies, the new accreditation body should notify both FDA<sup>1</sup> and the prior accreditation body by e-mail.

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<sup>1</sup> At present, such e-mail messages should be addressed to Dan Trammel, [Dennis.trammel@fda.hhs.gov](mailto:Dennis.trammel@fda.hhs.gov) and Stella Wei, [stella.wei@fda.hhs.gov](mailto:stella.wei@fda.hhs.gov)

4. Upon receipt of this notification, FDA should switch the facility's affiliation in MPRIS so that MPRIS will accept data for the facility from the new body, and not accept data from the prior body.
5. To preclude FDA from receiving a status change report before the facility affiliation is manually changed, both accreditation bodies should wait two business days after the notification of acceptance of an application before transmitting updated records for the facility to FDA. The prior body need not transmit any further record for the facility. The new body should only transmit a record when there is a change in the facility's status.

Change of accreditation body subsequent to denial or expiration of accreditation:

A facility that has been denied accreditation, or has allowed its accreditation to lapse, should be reinstated before it can resume performing mammography. Reinstatement involves submission and completion of a corrective action plan to the satisfaction of the accreditation body, and in some cases the FDA. The requirements should be no less stringent for a facility that decides to change accreditation bodies to seek reinstatement. Facilities should be requested to provide a complete accreditation and certification history when applying for accreditation and this becomes particularly cogent when a facility seeks reinstatement with a new accreditation body. It is essential that the new body be fully aware of the issues that made reinstatement necessary.

In such cases, in addition to the accreditation history provided by the facility, the new accreditation body should contact the prior accreditation body by e-mail, with a copy to the FDA accreditation liaison officer, and request a complete history of the facility's prior accreditation or attempts at accreditation. The prior accreditation body should provide such history, including pertinent information about any failure or revocation of accreditation.

The new accreditation body, in consultation with FDA through the accreditation body liaison officer, when appropriate, should then request a corrective action plan from the facility in accordance with the accreditation body's policies.

Accreditation body of record:

When switching accreditation bodies, which accreditation body is the facility's accreditation body of record may be ambiguous if the change is not subsequent to a denial or expiration of accreditation. The facility's certificate will usually remain in effect until it expires, is replaced by a new certificate, or accreditation is denied. That certificate is predicated upon accreditation by the prior accreditation body. Unless such accreditation were revoked for cause, FDA would not usually make a determination that a facility's certificate were no longer in effect.

However, once the MPRIS affiliation has been changed, only the new accreditation body is able to change facility status information in MPRIS. It is therefore incumbent on the new accreditation body to ensure that the facility is able to operate as long as it should be able to do so under FDA and accreditation body policy. When a facility has not completed renewal of accreditation before its certificate has expired, the DEPARTMENT will make a determination concerning reinstatement of the facility in accordance with SAR policies.

***XXII. FFDM Procedure for Recommending 90-day Extension of a Provisional Certificate***

To apply for a 90-day extension to a provisional certificate, a facility must submit a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

Some examples of significant adverse impacts to access to mammography in a geographic area include but are not limited to the following:

1. The facility provides mammography services at cost reductions (e.g., participation in the CDC National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Program).
2. The facility provides services to an ethnic population who would not otherwise obtain a mammogram (confirmed by client surveys).
3. The facility provides services to Medicare or Medicaid patients.
4. The facility is a “directed facility” for an insurance company/health maintenance organization (facility must provide the insurance company/health maintenance organization directing patients to the facility).

Once the request is received, a member of the accreditation staff will evaluate the validity of the statement by performing follow-up interview with the facility’s administrator. The purpose of the interview is to obtain documentation of the facility’s actions; and to get information regarding the projected number of mammograms that will be performed by the facility and other relevant information about the adverse impact associated with the facility not receiving an extension.

Based on the statement of the facility and the information obtained from the follow-up interview the accreditation staff will meet and form a consensus on whether the request should be recommended. At this point the recommendation, along with the facility’s request, and a summary of the additional information obtained from the interview will be forwarded to the SAR AB Liaison for review. This information will be documented using the Provisional Certification 90-Day Extension Request Form. This form is shown on the next page.

**Provisional Certification 90-Day Extension Request Form****Facility Name:** *Facility Name***FDA ID:** 000000**SAR ID:** MAS000**Facility's Accreditation Body:** State of Arkansas (Arkansas Department of Health)**Request:***Verbatim transcription of the request from the facility***Circumstances:***Description of the circumstances that prevented accreditation during initial 6-month provisional usage period***Will the Population of the Geographic Area be Underserved, if the Extension is not Granted:**  
*(Yes/No/Unable to determine)***Number of Mammography Facilities within a 15-mile radius of the requesting facility:** *(# if known)***Does the State of Arkansas recommend the 90-Day Extension:** *(Yes/No)***Facility Contact:** Contact Name, Contact Title  
Phone: (xxx) xxx-xxxx  
Fax: (xxx) xxx-xxxx**Request Generated by:** Melinda Davis, Program Leader  
Accrediting Body  
Phone: (501) 661-2301  
Fax: (501) 280-4993

Once this form is completed it should e-mailed to the following people:

- Joanne Choy: [joanne.choy@fda.hhs.gov](mailto:joanne.choy@fda.hhs.gov)
- Marisa Baima: [marisa.baima@fda.hhs.gov](mailto:marisa.baima@fda.hhs.gov)
- Henry Chan: [henry.chan@fda.hhs.gov](mailto:henry.chan@fda.hhs.gov)

All the information will be forwarded to the FDA within 2 business days after receipt of the original statement. This information will be sent via e-mail to the attention of Joanne Choy, Marisa Baima, and Henry Chan. Their contact information is as follows:

- Joanne Choy: [joanne.choy@fda.hhs.gov](mailto:joanne.choy@fda.hhs.gov)
- Marisa Baima: [marisa.baima@fda.hhs.gov](mailto:marisa.baima@fda.hhs.gov)
- Henry Chan: [henry.chan@fda.hhs.gov](mailto:henry.chan@fda.hhs.gov)

Once the results of the FDA's decision regarding the request are known, the facility will be notified by telephone. In addition, a follow-up letter will be generated to confirm the content of the telephone conversation. The results of the request will be noted in the correspondence with the facility, along with notification that there can be no renewal of a provisional certificate beyond the 90-day extension.

In addition, if the facility's expiration date is imminent and the 90-day extension has been denied the facility will be instructed how to apply for provisional reinstatement.

### ***XXIII. FFDM Conflict of Interest***

In compliance with 21 CFR 900.3(b)(3)(viii) and The Arkansas Department of Health and Human Services Policy No. 1081 (VI)(A)(H)(see attachment), no ADH employee, DEPARTMENT board member, commissioner, professional personnel, reviewers, consultants, administrative personnel, nor other representatives of DEPARTMENT may use his/her position to secure special privilege or exemption for personal gain or for the benefit of any family member or acquaintance. Said personnel shall not engage in any activity which would constitute a conflict of interest as outlined in the above referenced policies.

Further, the failure of any person or entity to disclose as required under any term of Policy Directive GPD-1, or the violation of any rule, regulation or policy promulgated by the Arkansas State Department of Finance and Administration pursuant to this Directive, shall be considered a material breach of the terms of the contract, lease, purchase agreement, or grant and shall subject the party failing to disclose or in violation to all legal remedies available to the Department under the provisions of existing law.