

Scroll down to see answers to each of these questions.....

Frequently Asked Questions:

- 1. Why is Medicare denying claims for my newly installed Full Field Digital Mammography unit?**
- 2. What are appropriate assessment categories for the Mammography Report?**
- 3. When do I need to have my medical physicist check my facility and/or equipment?**
- 4. What do I need to do when I install a new mammography unit at my facility?**
- 5. When can I reestablish processor aims?**
- 6. How do I use the personnel attestation form for reaccreditation applications?**
- 7. What are the requirements for transferring Full Field Digital Mammography images to the patient or another facility?**
- 8. How do I check to see if my Radiologist or Mammography Technologist is qualified in mammography?**
- 9. Why did I get 2 bills for my annual inspection?**
- 10. Are the Mammography Quality Standards Act regulations and the State of Iowa Bureau of Radiological Health Mammography Rules (641-Chapter 41.6) the same?**
- 11. Does my facility have to accept self referred patients? If we choose to accept self referred patients, what are the rules that apply?**
- 12. What are the record retention requirements for mammography images?**
- 13. What is the difference between the accreditation, certification and authorization?**

1. Why is Medicare denying claims for my newly installed Full Field Digital Mammography unit?

A number of practices are experiencing payment problems with the CMS for FFDM services. The FDA does not provide MQSA certificates that specifically state that a facility is certified to perform FFDM. Instead, they send CMS a weekly file containing the most recent approval information. Your payer must look at the current MQSA file to see whether your facility is certified to perform digital mammography.

[CMS Transmittal 828](#) explains the handling of these files. You may wish to provide a copy to your local payer.

You may contact the appropriate CMS headquarter representatives:

- Medicare Carrier for non-payment of the professional component
- Medicare Fiscal Intermediary (FI) for non-payment of the technical component

Please provide them with your facility's 6-digit FDA ID number from your MQSA certificate and your MQSA expiration date.

Note: these contact names may be different for your facility, and may have changed since the most recent post.

	Contact Person	Phone	Email
Medicare	Eric Coulson	410-786-3352	Eric.Coulson@cms.hhs.gov
Carrier	Wendy Knarr	TDY Operator: Dial 711. When relay operator asks for phone number, provide (410) 786-0843	wendy.knarr@cms.hhs.gov
Medicare Fiscal Int.	Bill Ruiz	(410) 786-9283	william.ruiz@cms.hhs.gov

2. What are appropriate assessment categories for the Mammography Report?

MQSA Citation:

900.12(c)(1)(i),(ii),(iii)(iv)(A)(B)(C)(D)(E),(v),(vi): Medical records and mammography reports — (1) Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

- The name of the patient and an additional patient identifier;
- Date of examination;
- The name of the interpreting physician who interpreted the mammogram;
- Overall final assessment of findings, classified in one of the following categories:
 - "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);
 - "Benign:" Also a negative assessment;

- (C) *“Probably Benign:” Finding(s) has a high probability of being benign;*
- (D) *“Suspicious:” Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;*
- (E) *“Highly suggestive of malignancy:” Finding(s) has a high probability of being malignant;*
- (v) *In cases where no final assessment category can be assigned due to incomplete work-up, “Incomplete: Need additional imaging evaluation” shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and*
- (vi) *Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.*

In order to promote consistency and clarity in the interpretation of mammograms, the final regulations require that each mammographic report include an overall final assessment of the mammography examination, classified into one of the following six categories: Negative, Benign, Probably Benign, Suspicious, Highly Suggestive of Malignancy, and Incomplete: Need additional imaging evaluation. While the final assessment findings must not vary from these categories and must be stated as written above, limited flexibility is allowed for further description as long as it doesn't change the meaning of the category. The following are considered equivalent to the wording listed in the final regulations and are acceptable final overall assessments.

Negative

Negative Mammogram

Benign

Benign Finding, Benign Findings, Benign Abnormality, Benign Abnormalities, Benign Mammogram

Probably Benign

Probably Benign Finding, Probably Benign Findings, Probably Benign Abnormality, Probably Benign Abnormalities, Probably Benign- Short Interval Follow-up Suggested, Probably Benign Finding - Short Interval Follow-up Suggested, Probably Benign Mammogram

Suspicious

Suspicious Finding, Suspicious Findings, Suspicious Abnormality, Suspicious Abnormalities, Suspicious for Malignancy, Suspicious of Malignancy, Suspicious Abnormality - Biopsy Should Be Considered, Suspicious Finding - Biopsy Should Be Considered, Suspicious Mammogram

Highly Suggestive of Malignancy

Highly Suggestive for Malignancy, Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

Incomplete: Need Additional Imaging Evaluation

Incomplete: Needs Additional Imaging Evaluation, Incomplete: Additional Imaging Evaluation Needed, Incomplete: Need Additional Imaging Evaluation- Comparison with Prior Studies, Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison, Incomplete: Need prior mammograms for comparison, Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete BIRADS assessment category), Incomplete Mammogram: Need Additional Imaging Evaluation

Known Biopsy Proven Malignancy

Known Biopsy Proven Cancer, Known Malignancy, Known Cancer

Post Procedure Mammograms for Marker Placement

There is no requirement that any specific assessment code be assigned to these assessments. Also, there is no specific reporting format required for the report, apart from the requirement that an overall assessment category be included within

NOTE: The State of Iowa rules require a separate and distinct section entitled “Assessment” followed by the appropriate assessment term as explained above.

3. When do I need to have my medical physicist check my facility and/or equipment?

MQSA Requirements for the Mammography Equipment Evaluations (MEE)

When a mammography facility installs new radiographic equipment (x-ray units or processors), the new equipment must be evaluated by a qualified medical physicist **and the accreditation requirements of the facility's accreditation body must be met before the unit is placed into service** (21 CFR 900.12(e)(10)). In this context, "new" means "new to the facility" and, therefore, includes used equipment. Mammography equipment evaluations must also be performed whenever equipment is disassembled and then reassembled at the same or a new location or whenever a major component is changed or repaired. The MEE is required even if a full survey has recently been completed to verify that all functions, which may have been affected by the change or repair, have been successfully restored.

Scope of the MEE

With respect to testing of the equipment, the MEE is more extensive than the survey. It may be regarded as an "acceptance" test for the equipment and an annual survey alone is not sufficient to meet this requirement. The MEE must address all applicable requirements under the equipment section of the regulations (21 CFR 900.12(b)) as well as all applicable QC requirements and testing under 21 CFR 900.12(e), including applicable daily, weekly, quarterly, semiannual, and annual QC tests. Such testing is only applicable to the specific equipment that is repaired, replaced, re-assembled, or added and it is not applicable to other equipment in the facility that has not been affected.

- A. For a **newly installed or re-assembled x-ray unit**, the medical physicist must:
 - 1. Perform all the annual tests listed in section (e)(5) [except (e)(5)(viii), which need not be included if the new unit is not the first one to be accredited in the facility unless new cassettes are being added], the "other modality" tests listed in section (e)(6) (if applicable), the phantom image test listed in section (e)(2), the compression force test listed in section (e)(4)(iii); and
 - 2. Verify that the new x-ray unit meets the equipment standards listed in sections (b)(1-10). Furthermore, if the new unit is the first and/or the only one at the facility, then Sections (b)(11), (b)(12), (b)(14), and (b)(15), which relate to the screen-film combination and the lighting and viewing conditions used at the facility, respectively, must also be verified.
- B. For a **newly installed or reassembled processor**, the medical physicist must perform the following tests/tasks:
 - 1. Sensitometric strip as described in 21 CFR 900.12(e)(1)
 - 2. Phantom image quality as described in 21 CFR 900.12(e)(2)
 - 3. System artifact evaluation as described in 21 CFR 900.12(e)(5)(ix)
 - 4. Dose determination as described in 21 CFR 900.12(e)(5)(vi) – if clinical techniques increase significantly
 - 5. Verification of the appropriate processing solutions as described in 21 CFR 900.12(b)(13).

We also recommend that the medical physicist conduct the "Darkroom Fog" test if the integrity of the darkroom is compromised, and to conduct the fixer retention analysis test, if deemed necessary.

Each processor used clinically must have an MEE, even those at remote sites (if any).

- C. For a **newly installed or reassembled laser printer**, the medical physicist needs to follow the applicable FFDM QC manual.

Examples of major changes or repairs that would call for an MEE include, but are not limited to:

- Replacement of an x-ray tube, collimator, filter, AEC, or AEC sensor.
- A total overhaul of the processor.

Routine processor preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not considered to be major changes or repairs and, consequently, would not require evaluation by a medical physicist.

These evaluations are used by the facility, its accreditation body, and the MQSA inspector to determine whether the new or changed equipment meet the requirements of applicable standards in 21 CFR 900.12(b) and (e). Consequently, the physicist should provide the facility with sufficient documentation that clarifies both the testing performed and the test results. The medical physicist (after consultation with the FDA, if necessary) should decide which tests need to be performed following a particular repair, and should be prepared to explain the rationale behind his or her decision. Before the new or changed equipment is put into service for patient examinations or processing mammograms, the facility must correct all problems relating to the regulations (21 CFR 900.12(e)(10)). There is no provision for a 30-day correction period such as with some QC and physics survey test results.

To get a more detailed list of items/tests that are defined as major repairs and or other tests that require the physicist to conduct in person, consult the PGHS (insert the link), which also provides guidance on many related topics.

Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs

For any adjustment, change, or repair not listed in the table below, or if the facility is unsure as to the full extent of the adjustment, change, or repair, the facility should consult their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

Item	Major Repair	Medical Physicist Involvement
Automatic Exposure Control		
AEC replacement	Y	MP conducts evaluation in person
Thickness compensation internal* adjustment	N	MP oversight
AEC sensor replacement	Y	MP conducts evaluation in person
AEC circuit board replacement	Y	MP conducts evaluation in person
Density control – internal* adjustment	N	MP oversight
Bucky (New to Facility) Replacement		
AEC sensor also replaced	Y	MP conducts evaluation in person
AEC sensor not replaced	N	MP oversight
FFDM detector also replaced	Y	MP conducts evaluation in person
FFDM detector not replaced	N	MP oversight

Cassette Replacement		
Same screen speed	N	MP involvement optional
Faster screen speed	N	MP oversight
Slower screen speed where the dose increase may exceed 3.0 mGy for the standard breast	Y	MP conducts evaluation in person
Collimator		
Replacement	Y	MP conducts evaluation in person
Reassembly with blade replacement	Y	MP conducts evaluation in person
Adjustment	N	MP oversight
Compression Device		
Pressure adjustment	N	MP involvement optional
Thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight
Repair of auto decompression	N	MP involvement optional
Compression Paddle		
Paddle (new to facility) replacement	N	MP oversight
Deflection adjustment	N	MP oversight
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversight
Darkroom		
Repair of light leaks	N	MP involvement optional
Safe light change	N	MP involvement optional
Film Type/Speed Change	N	MP oversight
Processor		
Chemistry type change	N	MP involvement optional
Fixer/Developer replacement	N	MP involvement optional
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Replenishment rate adjustment	N	MP involvement optional
Roller replacement	N	MP involvement optional
X-ray Unit		
kVp, mA or time internal* adjustments	N	MP oversight
High voltage generator replacement	Y	MP conducts evaluation in person
X-ray tube replacement	Y	MP conducts evaluation in person

Filter replacement	Y	MP conducts evaluation in person
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Manufacturer's software modifications (see approved alternative standard)	Y	MP conducts evaluation in person
FFDM detector replacement or repair	Y	MP conducts evaluation in person
FFDM Display (monitor)/Printer Replacement	Check FFDM manufacturer's QC manual	Follow FFDM manufacturer's QC manual

* Internal adjustments refer to equipment adjustments that typically cannot be made by the operator.

4. What do I need to do when I install a new mammography unit at my facility?

You will need to contact (insert link) the Iowa Department of Public Health Mammography Program in order to receive an application for your new unit. In order to begin using the new unit on patients, you will need to submit a completed application, a Mammography Equipment Evaluation performed by your Medical Physicist, and a radiation shielding plan for the room. Your application must be approved by the IDPH Mammography Program before you begin to use the new unit.

Please [click here](#) for a helpful checklist.

5. When can I reestablish processor aims?

In which situations should facilities establish new processor operating levels?

The most warranted and common situations for a facility to establish new processor operating levels are when processor QC testing is initiated for a new processor or when a significant change is made in the processing system. Some significant changes that may necessitate the establishment of new operating levels include: change in film brand/type, change in chemical brand/type, change in replenishment rates, change in specific gravity automixer settings, change of sensitometer or densitometer, or a change in processing conditions (standard vs. extended). Replacement of chemistry (same brand/type) as part of routine preventative maintenance should not necessitate establishment of new operating levels.

Facilities should not use the establishment of new operating levels to correct problems in the processing system, but should troubleshoot and solve the problem with appropriate corrective action. FDA recommends that the facility consult with their medical physicist prior to establishing new operating levels.

During the time a facility is establishing new operating levels for a processor (typically done by performing a five-day data plot average): A) Must the facility continue to plot the data on the processor chart? B) Is the facility exempt from having to stay within the old processor action limits during the averaging period?

While establishing new operating levels for a processor (during which time the facility can continue to process mammograms), the facility must continue to perform the daily processor QC tests (21 C.F.R. 900.12(e)(1)) and should plot the data in the same manner it usually does. This may be done on the same graph as the previous data or on a different graph. In either event, this new data should be clearly identified as being derived during the establishment of the new operating levels, so that both the facility and the inspector are aware of the origins of this data. Because no operating level has yet been established, the facility is exempt from having to stay within any processor action limits during this averaging period. During the averaging period, the facility should daily perform and evaluate a phantom image as a means of monitoring image quality. Because phantom optical densities may also vary during this time period, the facility may limit its evaluation of the phantom image to the fiber/speck/mass scores. The facility is reminded that if the phantom image scores fall below the minimum requirement, the facility must cease performing mammography until the problem has been corrected. (21 CFR 900.12(e)(8)(ii)(A))

6. How do I use the personnel attestation form for reaccreditation, reauthorization?

The personnel attestation is a document that may be submitted in place of the personnel documents required for reaccreditation, reauthorization, and new unit applications except for new digital or CR units.

The personnel attestation must be signed by the lead interpreting physician. Their signature is assuring the State of Iowa that he/she has reviewed the required documents for each of the personnel listed on the attestation and that each person meets the MQSA and State of Iowa requirements to perform mammography services.

If you choose to send in the personnel attestation, you will not need to submit all of the supporting documents to prove that each person meets the MQSA and State of Iowa qualifications. Those documents will be verified at your facility's next annual inspection.

7. What are the requirements for transferring Full Field Digital Mammography images to the patient or another facility?

Citation:

900.12(c)(4)(ii),(iii): Each facility that performs mammograms:

- (ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;*
- (iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.*

Discussion:

What should a facility do if a patient (or someone acting on her behalf) requests permanent or temporary transfer of mammograms and/or reports? Who should pay for it? What recourse does the patient have if the facility overcharges for the transfer or refuses to cooperate?

The facility must transfer the original mammograms and copies of the patient's reports to the patient's designated recipient upon such written request by the patient (or someone acting on her behalf). Facilities should be aware that the Federal Law pertaining to transfer of original mammograms supersedes any conflicting State or Local requirements. The mammograms and reports may be sent to a medical institution, a health care provider, or to the patient. If the designated recipient is not available, the facility should work with the patient (or someone acting on her behalf) to designate an alternate destination. The facility may charge the patient a fee for this service but it must not derive a financial profit from it. If the facility overcharges for the transfer or refuses to transfer the records, the patient should complain to the facility. If that doesn't resolve the issue, the patient should notify the facility's AB. If that still doesn't resolve the issue the patient may inform the FDA via the Facility Hotline at 1-800-838-7715 or by writing to the following address: MQSA Hotline, P.O. Box 6057, Columbia MD 21045-6057. Patients in Certifying States should contact their State Certifying Agency directly.

What documentation should I get when a patient, or an individual acting on the behalf of the patient, or the patient's physician requests the release of the patient's records? How long should I keep the documentation?

Facilities should request that patients, physicians, or individuals acting on behalf of patients sign a release form, or submit a written release request; however, if the facility chooses to accept oral transfer requests, a notation should be made in a log. Other documentation may also be possible. Facilities must keep this documentation for the same 5/10 years as they are required to keep the original records. Facilities should check to see if State or local laws related to release of records require additional documentation.

What are appropriate charges for the transfer of mammographic records? Can I include the cost of making copies of the films?

Appropriate charges for transfer of mammographic records could include items such as administrative time costs incurred in logging-in the request, retrieving the mammography films and reports, having the patient sign a release, packaging and mailing charges for the materials, and photocopying costs incurred in making copies of reports.

Facilities may, but are not required by MQSA to, make copies of the mammographic films. If these copies are requested by the patient or are mandated by State regulations, then the cost of making the copies can be charged to the patient. If the facility wishes to keep copies for its own benefit, the cost cannot be charged to the patient.

If requested by the patient, facilities must produce documentation (e.g., itemized bill) that shows the charges do not exceed the costs associated with this service.

With the introduction of Full Field Digital Mammography, what constitutes a mammogram for retention and transfer purposes, the digital data or the hardcopy film?

There are two sections of the recordkeeping requirement that are affected by the introduction of full field digital mammography (FFDM). The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the original or lossless compressed full field digital data or hardcopy films of final interpretation quality for the time periods

specified in the above regulation. The second section affected by FFDM deals with transferring films. For purposes of transferring films, the facility must be able to provide the medical institution, physician, healthcare provider, patient or patient's representative, with hardcopy films of final interpretation quality or, when it is acceptable to the recipient (e.g., a transfer between two FFDM facilities), with original or lossless compressed full field digital images electronically.

We have an FFDM unit and do not keep hardcopy of our exams (i.e., we retain the images electronically). When patients request the release of their exam, we create a hardcopy for them. May we charge the patient for the cost of creating the hardcopy?

The facility may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests one or more additional hard copies of the mammogram, the facility may pass the costs of the additional hardcopies on to the patient.

Can a facility use lossless compression to transmit images to the patient or other medical institutions for final interpretation?

Yes, provided that such transmission is acceptable to the receiving party. Lossless compression accurately preserves all of the data from the original mammogram and therefore FDA permits images regenerated from lossless compressed data to be used in the same manner as the original mammogram.

Can a facility use lossy compression to transmit images to the patient or other medical institutions for final interpretation?

No. Currently FDA does not permit images regenerated from lossy compressed data to be used in the same manner as the original mammogram.

While not allowed for final interpretation, lossy compressed images of previously obtained mammograms may be transferred to the patient or another medical institution to be used for comparison purposes if the interpreting physician deems that acceptable.

However, we recommend that if lossy compressed images are used for comparison purposes that only algorithms approved or cleared by FDA's Office of Device Evaluation for such purposes be used. In addition, we recommend that phantom and clinical images produced by lossy compression pass all applicable quality control tests and be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.

8. How do I check to see if my Radiologist or Mammography Technologist is qualified in mammography?

The qualification forms that are found under the [Qualification Forms](#) are designed to help you determine whether or not you have all of the documentation needed to prove that all of the qualifications are met for the personnel at your facility. All personnel must meet MQSA and State of Iowa requirements in order to provide mammography services.

9. Why did I get 2 bills for my annual inspection?

Facilities' mammography programs are inspected annually by both the Food and Drug Administration and the State of Iowa:

- The Food and Drug Administration inspection allows your facility to keep the required FDA certification.
- The State of Iowa inspection allows your facility to maintain the required State of Iowa Authorization.

The State of Iowa is the certifier (FDA representative) for all facilities located permanently in Iowa, so a State of Iowa representative acts as both a State of Iowa inspector and an FDA inspector during your facility's annual mammography inspection. By performing both inspections at one visit, it is possible to reduce the amount of the fees the FDA and the State of Iowa charge for your annual inspections.

Because there are two inspections being performed at one time for two different entities, you will receive two separate bills – one from the State of Iowa and one from the Food and Drug Administration.

Remember ~ if your facility qualifies as a governmental entity, your facility may be exempt from the FDA fees. However, the State of Iowa fees will still apply.

10. Are the Mammography Quality Standards Act regulations and the State of Iowa Bureau of Radiological Health Mammography Rules (641-Chapter 41.6) the same?

Most of the rules in the Iowa Administrative Code 641 – Chapter 41.6 are exactly the same as the Mammography Quality Standards Act regulations. However, there are a few rules that are more stringent than MQSA. The actual rule references can be found throughout Chapter 41.6, but they are summarized as follows:

1. All mammography machines must be registered according to IAC 641 – Chapter 39.3(2).
2. Facilities must be authorized by the State of Iowa to perform mammography services in Iowa. This is in addition to the accreditation and certification required by MQSA.
3. Soft copy review workstations used to interpret mammography must be a configuration of two five mega pixel monitors. The workstation must follow a quality control program that the facility's medical physicist has determined to be substantially the same as the facility's image receptor quality control manual requires.
4. Interpreting Physicians must have a valid Iowa Medical License.
5. Interpreting Physicians 8 hours of initial digital mammography education must be Category 1 CME. Applications specialist training is typically not Category 1 CME.
6. Continuing qualifications (15 CME and 960 mammography interpretation counts) must be met at all times when the interpreting physician is interpreting mammography.
7. Back to back requalification is allowed once for interpreting physicians. Subsequent requalification is not allowed without State of Iowa approval.

8. Radiologic Technologists performing mammography must hold a valid Iowa Permit to Practice.
 9. Continuing qualifications (15 CEU and 200 mammogram exams) must be met at all times when the radiologic technologist is performing mammography exams.
 10. Radiologic technologists may use CEU obtained through presenting or training for only 50% (7.5) of the required continuing education requirement.
 11. Back to back requalification is allowed once for radiologic technologists. Subsequent requalification is not allowed without State of Iowa approval.
 12. Medical Physicists must be approved by the State of Iowa to provide services in Iowa.
 13. Mammography reports must include the following information (in addition to the MQSA requirements):
 - The date of the interpretation.
 - A description of the procedure performed.
 - Name of the referring physician or other physician identified by the patient to receive the written report.
 - A separate and distinct section entitled “Assessment”
 14. Repeat analysis must be performed every 250 patients. If a facility performs more than 250 patient per week, weekly repeat analysis is acceptable.
 15. The reviewing physician must sign the medical audit.
 16. Safety standards must be in place and maintained for the mammography unit.
 17. Equipment operators must be monitored for radiation exposure in accordance with IAC 641 – 40.37.
 18. Records of all inspections, reports, and consultations (MP surveys) shall be maintained for 7 years.
-
-

11. Does my facility have to accept self referred patients? If we choose to accept self referred patients, what are the rules that apply?

Guidance for Facilities
choosing to accept self-referred patients

Information provided from Federal Regulations – Policy Guidance Help System:

Does a facility have to accept self-referred patients?

Neither MQSA nor the final regulations require a facility to accept self-referred patients (facilities should check their obligations under their State requirements). However, if a facility does accept self-referred patients, it must send both the mammography report and a lay summary to the patient. It must also have a system to refer such patients to a health care provider when clinically indicated.

What is the difference between self-referred and self-requesting patients and how does this affect what types of reports these patients receive?

Self-referred patients are those who come for mammography, but have no health care provider, or who decline a health care provider, or for whom the provider declines responsibility. Such patients shall receive the written mammography report, in addition to a summary of the report written in lay terms. This would enable self-referred patients to give their new physician their latest mammogram results, when they acquire a primary care doctor. Self-referred patients with abnormal results need to be able to show their new primary care physician exactly what is wrong with their mammogram, along with recommendations made by the physician who interpreted it.

Please note that patients who come to a facility without a health care provider, but are willing to accept a health care provider recommended by the facility and understand that their mammogram reports will be sent to that provider, are no longer to be considered self-referred. Instead, they should be treated like referred patients with respect to communication of results. In some cases, the radiologist can also act as the referring physician, as long as he/she accepts responsibility for the patient's medical care, and this arrangement is acceptable to the patient.

Self-requesting patients are those who come for mammography on their own initiative, but are able to name a health care provider (or accept a health care provider offered by the facility) who accepts responsibility for that patient's clinical breast care. Such patients should receive the same communication of results as referred patients. Please note that in the event that the health care provider declines to accept the mammography report from the facility, the latter should treat the patient as if she were self-referred.

State of Iowa Rules regarding self referred patients

41.6(4) *Obtaining and preserving records.*

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)"e"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

12. What are the record retention requirements for mammography images?

Iowa Administrative Code 641- 41.6(4)c. *Preservation of records.*

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service or not less than ten years, if no additional mammograms of the patient are performed.

(3) If the facility should cease to exist before the end of the 60-month period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

13. What is the difference between the accreditation, certification and authorization?

Basically, your facility must be accredited and certified in order to perform mammography.

In Iowa, you must also be authorized by the State of Iowa. The authorization process is very similar to the accreditation process.

Iowa authorization is included in the accreditation process for those facilities who choose Iowa as their Accrediting Body. All other facilities must complete the authorization process in addition to any requirements of their accreditation body.

To become accredited, your facility will submit a completed application, a Medical Physicist Evaluation of the unit, and a shielding plan. In order to complete this process your facility will need to submit clinical images and a phantom image for review. Once these clinical and phantom images pass the review, your unit will be fully accredited. This accreditation lasts for 3 years. Your unit and facility in about will complete the reaccreditation process every 3 years and anytime you add a new unit. Random clinical images will be pulled once during this 3 year period during your annual certification inspection.

During the initial accreditation process, your facility is operating under a 6 month provisional certificate – which was issued by the State of Iowa as your certifier. Once your unit has received full accreditation, we will issue a full certificate which also lasts 3 years. In order to maintain this certification, you must have annual inspections.

The ultimate goal of accreditation and certification is to ensure that your facility is meeting all of the regulations of the Mammography Quality Standards Act.

In addition to these federal regulations, your facility is also required to meet all of the State of Iowa rules. Links to these rules can be found under the [Rule and Information Links](#) tab.
(Create link)

If your facility has a FFDM unit, most of the rules you will need to follow will be found in your acquisition unit QC manual, but you may also have QC tests for the radiologist review workstation and your DICOM printer. In addition you will still need to meet some regulations that are not found in the QC manuals. These include meeting all of the medical record requirements for the report contents and the image labeling, continuing with the medical audit tracking, and ensuring that all personnel are qualified for FFDM. You will also need to keep policies and procedures about what your mammography processes are - which include infection control and a consumer complaint process – as well as who will be responsible for these tests and the overall mammography program.