

## DR in Clinical Mammography

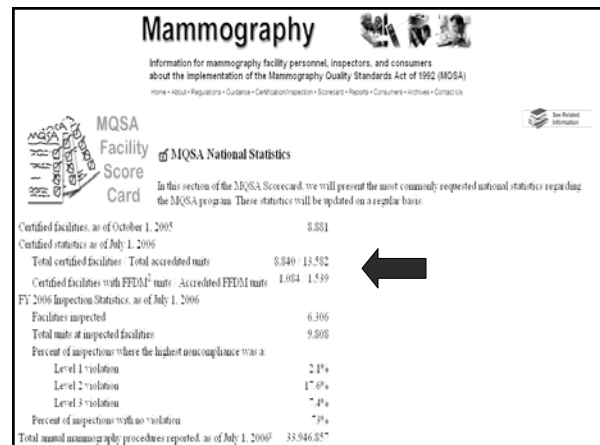
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### Purpose:

- To explore the impact of DR mammography on the practice of clinical medical physics.
- Historical and new methods for providing scheduled and unscheduled mammography physics services for facilities using DR mammography will be presented.

• Medical physics services may be provided in a professional and valuable manner, using combinations of the minimum standard of practice and the “best practices” model.

• The professional medical physicist should consider multiple parameters when determining the appropriate model under which to deliver services.



## Medical Physics Services

- Scheduled
  - Annual Surveys
  - Assist with ACR accreditation
- Unscheduled
  - Equipment Evaluations (FFDM > SFM)
  - Clinical image technical problem solving
- Sort-of scheduled
  - Acceptance Tests and Equipment Evaluations

## Basis for MP service

- Knowledge of DR Mammography Systems
  - GE
  - Hologic/Lorad
  - Siemens
  - Fisher
- Knowledge of ACR requirements and process
- Knowledge of FDA requirements
- Willingness to help
- Availability when help is needed

## Acquisition and Review Workstations

- In the beginning...
- Review workstations were an integral (in most cases) part of an FFDM system.
- GE issued one comprehensive QC manual that covered both acquisition and review.

## Clinical Problem

- Facility had 2 GE 2000D (w/ GE RWS)
- Added 1 GE Seno DS w/Advantage RWS
- MD's used both workstations
- Facility recently added Hologic Selenia and Hologic WS
- Do they need to review all phantom images on all workstations? This seems like a lot of unnecessary work.

## Bob's initial idea and e-mail

- For weekly QC, is it sufficient to acquire 1 image on each machine and evaluate it on any workstation, so long as all workstations are tested each week.
- Once we are convinced that the workstation has not degraded by tracking the score of a single image, wouldn't that be sufficient?
- I searched the GE manuals but could not locate any reference to this type of situation.
- I also checked the AWS QC manual for the 2000DS, but did not locate any reference to this situation. If there is a QC manual for the 2000DS Advantage workstation, I could not locate one anywhere.

## Response from GE

- Client should have received QC manuals for each piece of equipment.
- If they are really not being delivered (as opposed to "lost"), first check with the Field Service Engineer to determine if he/she knows where they are or if he/she can get a copy in case it was not shipped.
- Let me know if manuals do not exist

GE



- Seno DS (AWS) and Seno Advantage (RWS) have separate QC Manuals
- Revision of the 2000 D and RWS QC manuals are in process now
- No date on when new documents will be available.

GE

## Simplify phantom image review

- The current GE QC plans do not mention this, but it is something that evolved from work with NEMA to develop "generic" QC templates for hardcopy devices and for displays/workstations.
- When adding a new display/workstation to a network, send a phantom image to the station and score the image to ensure that it meets the requirements of the image receptor manufacturer (it also is evidence that the acquisition and display stations are communicating).

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- Similarly, if you had a "major repair" to a workstation, then I would advise again sending the phantom image to the station for an evaluation.
- Conversely, if you add an acquisition station, we would advocate sending a phantom image (during MEE) to every workstation that will read images from that acquisition station to ensure that the score agrees with the requirements of the image receptor manufacturer.
- But in neither the NEMA templates nor current GE manuals are we advocating weekly phantom image review between every combination of acquisition and review station.

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- GE website posts the updated QC manuals and other related documents.
- As yet, the product managers have been reluctant to make the initial release of a QC manual for a new product publicly available.
- GE expects that the customer will receive that initial manual.
- The website serves as a means to provide subsequent updates.

GE

## recipe to download QC documents from a GE website

- Go to [http://www.gehealthcare.com/services/repl\\_parts/documentation.html](http://www.gehealthcare.com/services/repl_parts/documentation.html)
- -- From the links to the right and below of the stack of books, select "Xray."
- -- In the list at the left labeled "XR Products," scroll down to "Senographe 2000D and RWS" for the 2000 D MTF procedure, to "Senographe DS" for the DS QC manual, or to "Seno Advantage" for the SA QC manual.

GE

[http://www.gehealthcare.com/services/repl\\_parts/documentation.html](http://www.gehealthcare.com/services/repl_parts/documentation.html)

The screenshot shows the GE Healthcare Common Documentation Library website. At the top, there are navigation tabs for different product lines: CT, MR, NM, PET, US, XR, Radiotherapy, Cardiology, CS, Clinical Systems, DS, and DR. Below these, there are sub-tabs for 'Sub-Acquisition', 'Pre-Clinical', 'Common', and 'AW / TACT'. A search bar is located in the center. On the left, there is a list of 'XR Products' including Senographe 2000D and RWS, Senographe DS, and Seno Advantage. On the right, there are filters for 'Manual Types', 'Classifications', and 'Status'. A search button is at the bottom.

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- The other lists may be left at their default settings, i.e., Manual Types = All, Classifications = General (Class A).
- Click the "Search" button at the bottom of the page. This will open a new window with the search results. The revised procedure for the MTF test is No. 6 in the 2000 D list, "Seno 2000D QC Addendum: Subsystem MTF Measurement"
- You can read a file on line by clicking on the link under "Filename."

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### Common Documentation Library

Search Criteria (Document Type)  
Modality = XR  
Classification = General (Class A)  
Products = Seno Advantage, Senographe 2000D and RWS, Senographe DS, Senovision  
Manual Types = All  
Status = New, Updated, CD, Obsolete

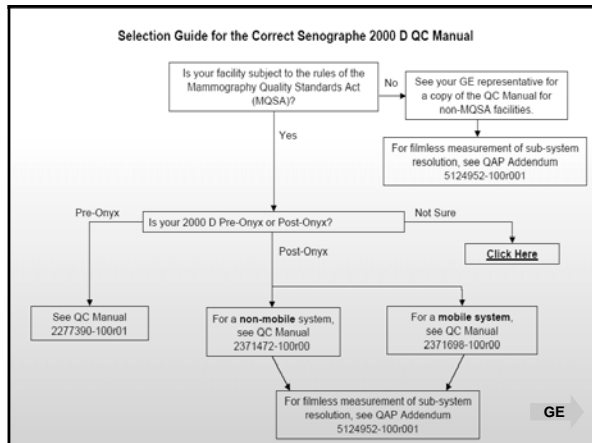
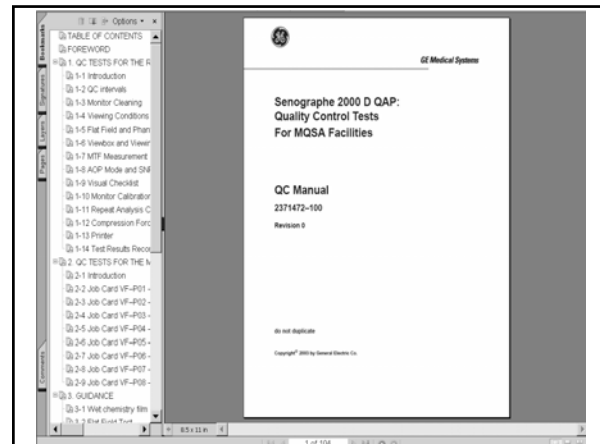
To view the manual, click on the **Filename** hyperlink. After viewing the file you may save the file locally using the "Save as" selection in the File menu. To view the manual's CD information, click on the **CD** hyperlink. To view the manual's description, click on the **Comments** hyperlink. To view the document's download time, click on the **File Size** thumbnail.  
To sort the results by Document Name, click on the **Document Name** header hyperlink. To sort the results by Direction Number, click on the **Direction Number** header hyperlink.

Page 1

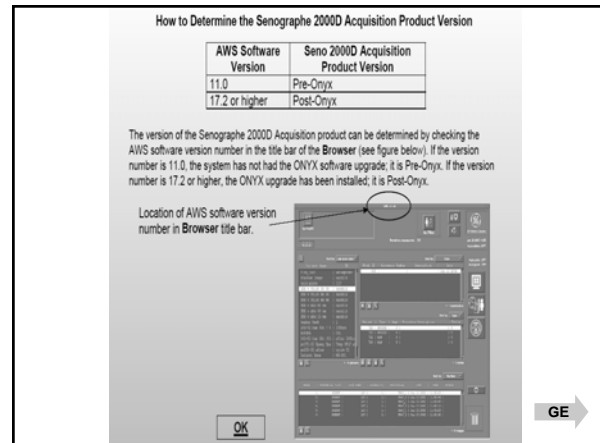
No.	Document Name	Direction	Class/Version	Download/Revision	Date	Status	Size	Comments
1	Selection Guide for Seno 2000D QC Procedures	Guide QC 2000D #02	A	<a href="#">sel_guide2000D_QC02_040927.pdf</a>	0	2004-09-27	New	114K
2	What's New in Post-Op vs. Pre-Op?	Info QC 2000D #01	A	<a href="#">info_letter_2000D_QC_01.pdf</a>	0	2004-04-14	New	156K
3	What's New in Senographe DS QAP	Info QC DS #01	A	<a href="#">whats_new_DS_QAP_01.pdf</a>	0	2004-07-21	New	136K
4	Seno 2000D QC Procedures Pre-Op	2277990-100	A	<a href="#">2277990_100r01.pdf</a>	1	2004-04-08	New	763K
5	Seno 2000D QC Procedures Post-Op	2271472-100	A	<a href="#">2271472_100r01.pdf</a>	1	2004-04-08	New	1240K
6	Mobile Seno 2000D QC Procedures Post-Op	2371698-100	A	<a href="#">2371698_100r01.pdf</a>	0	2004-04-08	New	1182K
7	Seno Advantage QC Manual	2391082-100	A	<a href="#">2391082_100r01.pdf</a>	1	2004-04-13	New	333K
8	Seno 2000D QC Addendum: Subsystem MTF Measurement	5124952-100	A	<a href="#">5124952_100_r2.pdf</a>	2	2005-07-07	Updated	249K
9	Senographe DS Acquisition System QC Manual	5133453-2-100	A	<a href="#">5133453-2-100_r1.pdf</a>	1	2005-09-21	New	1988K

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- You will be asked if you agree to GE's copyright terms and restrictions. If you do, click "Accept."
- The file will be downloaded as a .ZIP file. When extracted, it will be located in sub-folder "Senographe" in folder "XR."

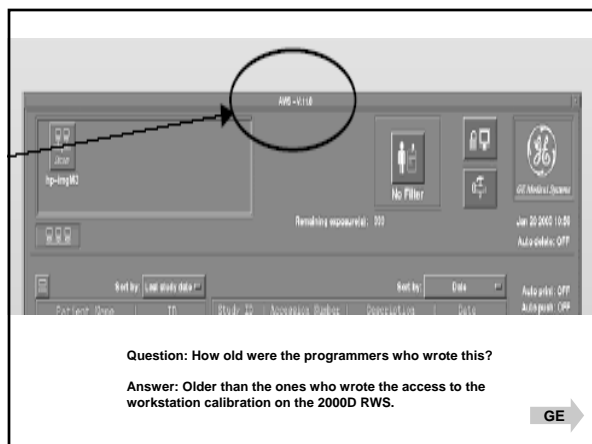
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22 March 2006

To the Radiologic Technologist and the Medical Physicist:

The latest revision of the quality control manual for Senographe DS full-field digital mammography (FFDM) systems is **Senographe DS Acquisition System QC Manual, Revision 1, document no. 5133453-2-100**. If this revision has been received as part of a system upgrade, the QC Technologist and the Medical Physicist should immediately begin to follow the procedures specified in this latest revision. If this revision has been accessed by other means, for example, having been down loaded from GE's Common Documentation Library, the manual will be found to be generally applicable, but in some instances might not apply if dependent on features that have not yet been incorporated on a specific system. Details regarding what is new in this revision of the QC manual and limits on applicability are detailed in the following.

**What's New in 5133453-2-100, Rev. 1?**

QC Manual 5133453-2-100, Rev. 1, was prepared as an update to documents 2404641-100, Rev. 2 and 5133453-100, Rev. 1. Please note the "2-" in the number of the new document as this is what

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- The new manual contains only one new test, Sub-System MTF Measurement, which has been added to the (physicist's chapter).
- The physicist may choose to perform this test as a replacement for two other tests—CNR and MTF Measurement and Evaluation of Focal Spot Performance.
- The latter is a film-based test which is problematic at facilities that have eliminated the use of film.
- The Sub-System MTF Measurement does not require the use of film.
- Otherwise, no tests have been removed and no action limits have been changed in development of the new QC manual.

GE

## Chapter 1, Section 3, Monitor Cleaning

- New information has been provided regarding the appropriate materials to use for cleaning monitor screens. This is intended to apply to both CRT and LCD monitors.
- Cautionary notes to the operator have been separated from the procedure steps to make the notes more readily apparent and improve the clarity of the procedure.
- The procedure steps have been modified to clarify that the operator should first check to see if it is necessary to clean the monitor screen before initiating the actual cleaning. If there is no evidence that the monitor screen needs cleaning, it is not necessary to clean it.

GE

## Chapter 1, Section 5, CNR and MTF Measurement

- The procedure steps were modified slightly to clarify that the compression paddle is to be removed for the measurement.
- The formula used to calculate "Change of CNR" has been added for clarification.
- Additional details regarding the action limits have been added so that they can be more readily compared with the presentation of results by the QAP Tool accessed from the Browser.

GE

## Chapter 1, Section 9, Repeat Analysis Check

- An upgrade being implemented on Senographe DS Systems provides the availability of an automated method of repeat and reject analysis. Additional details regarding this feature are included in the Operator Manual.
- To determine whether or not the automated analysis feature is available on your system, select the QAP button in the Browser and look for the RRA button. If the RRA button is present, the automated analysis feature is available.

GE

- The automated analysis provides three versions of repeat and reject rate calculations. The operator needs to decide on the most appropriate rate for use at the operator's facility. ...
- The operator should be aware that changing from the existing means of calculating the repeat or reject rate to one based on the automated method may lead to a change in the rate that is not associated with any change in clinical procedures. ...
- A procedure is added in Sec. 9-3 for backing up the data base used for the repeat and reject analysis.

GE

## Collimation Assessment

- The Required Test Equipment section has been modified with regard to the "auxiliary image receptor" used to record the deviation between the x-ray field and the light field.
  - Previously this had been limited to a 24 cm x 30 cm mammographic cassette.
  - The requirement has been generalized to allow the use of a detector large enough to record the extent of the x-ray field and the light field, e.g., a general radiography cassette or a computed radiography (CR) Cassette.
  - The operator may also use multiple distributed detectors positioned around the borders of the fields.

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- Previously a radiographic technique is no longer specified, but instead guidelines on technique selection are provided.
- Previous revisions quoted the MQSA rules
  - extension of the CW edge of the x-ray field to the CW edge of the image receptor
  - the absence of visibility of the vertical edge of the compression paddle,
  - but no procedure steps were included to check for compliance with these rules. Those steps have been added ( p.58).
- Space has also been added in data record tables (pp. 61 and 62) to record the results of checking for compliance with those rules.

GE

## Evaluation of Focal Spot Performance

- In accord with Guidance published by FDA, the requirement to test the small focal spot is based on its clinical use.

If the facility does not perform magnification imaging, there is no requirement to do the performance test on the small focal spot.

- For the case where evaluation of the small focal spot is required, additional procedure steps for that measurement have been explicitly added. This material has already appeared in document 5133453-1000, Rev. 1.

GE

## Sub-System MTF Measurement

- This is a new procedure that provides a measurement of the sub-system modulation transfer function (MTF) of the FFDM image acquisition system without the need for film.
- When performing a QC survey or MEE of a Senographe DS, the physicist may use this procedure instead of the following two tests:
  - ✓ CNR and MTF Measurement, Chap. 1, Sec. 5
  - ✓ Evaluation of Focal Spot Performance, Chap. 2, Job Card VF-P02
- Note that to perform this measurement it is necessary that the image processing algorithm FineView be disabled. If the Fine View algorithm is normally enabled during clinical use, you must re-enable FineView at the completion of this measurement.**
- New Sub-sections have been added to Chapter 3, Guidance, to support this new procedures.

GE

## Summary of MEE

Several modifications have been made to the table "Summary of MEE for Senographe DS Mammographic System," These are:

- Collimation Assessment: Checks have been added for the extension of the chest wall edge of the x-ray field to the chest wall edge of the image receptor and the absence of visibility of the compression paddle in the image.
- Sub-system MTF: This section has been added to record the results of the sub-system MTF test.
- kVp Accuracy and Reproducibility: To be in accord with the MQSA rules, specification of the test points as "clinical" kVp's was added for clarification.

Address: <http://www.fda.gov/cdrh/mammography/altstandards.html>

U.S. Food and Drug Administration  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

**Mammography**

Information for mammography facility personnel, inspectors, and consumers about the implementation of the Mammography Quality Standards Act of 1992 (MQSA)

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Approved Alternative Requirements 6 PM Friday 7/28/06

Since the subject alternative standard was approved in 2002, General Electric (GE) has applied to the FDA and, to date ("25/06), has obtained approval to conduct the MEE under Medical Physicist Oversight for the software upgrades and to the GE units shown in the Table below:

Date	Application Name/Description	GE FMI #	Comments
April 2003	Field Modification Instruction (FMI) No. 11497, "ADS & RWS software upgrade."	11497 - ADS & RWS software upgrade	Upgrade applied to facilities with RWS V9.1 software on their review workstation.
May 2003	Service Note (SN) "BDC DIONE 3 INTRODUCTION" combining FMI No. 11496 and FMI No. 11497	11496 and 11497	Combined software upgrade V 10.2 (#11497) with hardware (#11496)
December 2004	Field Modification Instruction (FMI) "ADS software upgrade to V31.3" for the Senographe DS, full-field digital mammography system	12027	Operation of the system to perform stereotactic procedures, (outside MQSA), and to address an issue relating to image labeling (MQSA)
November 2005	Field Modification Instruction (FMI) No. 12026, "Seno Advantage Upgrade to Version 1.2"	12026	Applied to the Seno-Advantage Workstations-final interpretation of clinical mammograms
March 2006	Two software upgrades for the Seno Advantage (SA) diagnostic workstation: 1. The "SA1 to SA2" upgrade 2. The "M3 to M4" upgrade	1. No FMI. Only a "Read Me First" note. 2. FMI # 12061	1. Ensures that the view and laterality labeling is always displayed near the axilla, allows the use of Premium View for final interpretation, and enables a display at full resolution by means of a single button push. 2. Fixes software "bugs" and enables the "full resolution" button.
July 2006	Senographe 2000 D-AWS v17.4.5 Upgrade	1. FMI # 12063 2. No FMI is needed	1. Distributes new documentation and asks the facility to verify it. It also installs "Premium View" (PV) software without enabling it. 2. If facility buys and enables the PV software upgrade, testing under the approved alternative standard applies.

## Bob's FAQ with FDA

- When will inspectors begin to cite facilities for FFDM QC problems?
- As I understand it, MQSA inspectors have begun to "look at" FFDM QC, but no citations are yet issued.
  - Inspectors started citing facilities regarding FFDM observations on 2/15/03.

FDA

Is there an inspection procedure (in place or in the works) for FFDM equipment or QC?

*We have always had guidance for the inspectors regarding how and what to evaluate in an FFDM system during the inspection. This guidance was always sent as a separate document that we updated on a regular basis until recently, when we made it as part of the general inspection procedures document (May 2006).*

FDA

I know that inspection procedures no longer include x-ray measurements for SFM units. Is this true for FFDM units as well?

- Effective May 2006, we deleted x-ray measurements during the inspection regarding collimation, HVL, and dose-related measurements in SF systems.
- We never did those measurements in FFDM systems and have no plans to do that. We retained measurements for the STEP test, Darkroom Fog, and the phantom as always.
- However, the inspectors now use the facility's phantom for the phantom test.

FDA

- We have also extended the scope of the two MEE-related questions (one for the x-ray unit and one for the processors) to include FFDM units and laser printers, respectively.
- We also added a phantom scoring test (during the inspection) using the facility phantom in FFDM systems but have not yet implemented any citations for failing scores. This probably the most noticeable change to date regarding FFDM inspections.

FDA

What is the FDA's position on QC for mammography physician's workstations? As far as I know, facilities are simply supposed to follow the manufacturer's QC programs. Is there anything else to add?

- The physician's RWS is an integral part of the evaluation of the facility's QC records during the inspection.
- The QC records for the RWS are supposed to be those provided with the system by the FFDM image receptor manufacturer (which has been part of the PMA application).
- If the facility changes the RWS later, the new RWS should have a QC program substantially equivalent to the original and should pass the same QC tests or equivalent ones.
- You may find further details about this issue in the following section, which is paraphrased from our policy guidance help system on our website.

FDA

- When GE introduced the Senographe DS (note that's DS without the 2000), they split both the product offerings and the QC manuals into separate acquisition and review segments.
- Notably, there is no weekly review of a phantom image on the RWS in the QC manual for the more recent review station product, the Seno Advantage (SA).

FDA



- Similarly, there is no QC for the review station included in the QC for the acquisition system.
- Considering that there could now be multiple review stations receiving images from multiple acquisition stations and that some of those acquisition stations might be on mobile platforms far removed from central reading facilities,
- the logistics of phantom image evaluation between acquisition and review presented more trouble than it was expected to be worth.

FDA

## July 2006 Update from GE

- The Senographe 2000 D and the "RWS" still share a common QC manual.
- The Senographe DS and Essential each have acquisition system QC manuals.
- The Seno Advantage has a display system QC manual.

## Upgrades and Mammography Equipment Evaluations (MEEs)

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2004

## Major Repairs

- Replace x-ray tube, filter, collimator, generator, detector
  - Major repairs
  - MP conducts evaluation in person
  - MP determines tests to do
- Replace display monitors, change viewing environment of diagnostic workstation
  - See Guidance in Seno Advantage QAP

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## MEEs for Display Repairs

Item	Major Repair	Medical Physicist Involvement*
Graphics display driver replacement	N	MP Oversight
Luminance photometer replacement	N	MP Oversight
Monitor replacement	N	MP Oversight

*\*FDA Guidance defines "MP oversight" as meaning "that the medical physicist should be consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met, with direction by telephone or printed material from the medical physicist if needed."*

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2004

## MEEs for Display Repairs

Item	Major Repair	Medical Physicist Involvement
Substantial changes of illumination in viewing area	Y	MP conducts evaluation in person
Moving the workstation to a new viewing area	Y	MP conducts evaluation in person
Software modifications	Y	MP conducts evaluation in person (see Comments)

**Specific "Tests to Perform" and "Comments" included in QC Plan.**

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## Hardware, Software Upgrades

- Graphics Display Driver
  - Medical Physicist Oversight
- Software upgrades are “major repairs.”
  - Alternative Standard allows MEE under MP Oversight under certain conditions.
- Field Service Engineer has document stating RT’s and MP’s responsibilities.

**It is highly unlikely that you will need to perform a total MEE following an upgrade. Ask first!**

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2004

## FDA Guidance Doc #9 5/06

Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs

Item	Major Repair	Medical Physicist Involvement
Bucky (New to Facility) Replacement		
FFDM detector also replaced	Y	MP Conducts evaluation in person
FFDM detector not replaced	N	MP Oversight
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

Question 3: Can a manufacturer hook up a printer or monitor to its FFDM unit if the printer or monitor were not part of its original Pre-Market Approval (PMA)?

- Manufacturers will need to check the exact wording of their PMA to see if this is allowed.
- However, the facility is not restricted by the PMA and may hook up and use printers and monitors other than those approved by FDA for use with the manufacturer's FFDM unit
- as long as they meet the requirements specified in question #2.

FDA

Question 8: How long must we maintain our quality assurance records for our FFDM unit?

- While the test result records (documentation logs) must be maintained as described above, FDA realizes that maintaining a large number of QC test images may be overly burdensome.
- Therefore, similar to what is already allowed for film-screen, FDA will allow FFDM QC test images to be retained according to the following schedule:

FDA

- Images from daily QC tests
  - previous 30 days
- Images from weekly QC tests
  - previous 12 weeks
- Images from monthly QC tests
  - until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the QA requirements
- Images from quarterly QC tests
  - until the next annual inspection has been completed and FDA has determined that the facility is in compliance
- Images from semi-annual QC tests
  - until the next annual inspection has been completed and FDA has determined that the facility is in compliance, or until the test has been performed 2 additional times at the required frequency, whichever is longer.

FDA

## Q&A From the ACR FAQ (pdf)

- The manufacturer of our FFDM unit has a number of different revisions of their QC manual available. Which one should we follow for the medical physicist and technologist QC tests?
- You should use the most current version of the QC manual for the unit installed at the facility.
  - Note that the correct manual version may depend not only on the FDM unit but also the software version of the unit.
  - If there are any questions, check with the manufacturer of your FDM unit.

ACR

- Section (e) of the FDA regulations requires the MP to follow a QA program that is “substantially the same as the quality assurance program recommended by the IR manufacturer.”
- This complicates the testing since the tests, frequencies and pass/fail criteria vary across manufacturers, models and QC manual versions.
- The ACR has tried to simplify the final pass/fail documentation for these tests by developing a simple form entitled “Medical Physicist’s Mammography QC Test Summary” for each image receptor manufacturer of FFDM equipment.
- All of these forms are routinely updated as the manufacturers update their QC manuals and are available on the ACR website at [www.acr.org](http://www.acr.org).

ACR

## Laser Film Printers FAQs

- Q. Does the ACR or the FDA require an FFDM facility to have a laser film printer at the facility? May the facility use the laser printer of a third party to print hardcopies?
- No and yes. Neither the ACR nor the FDA requires and FFDM facility to have an on-site laser film printer.
  - However, for purposes of transferring films, the FDA does require a facility to be able to “provide the medical institution, physician, health provider, patient or patient’s representative, with hardcopy films of final interpretation quality.”

ACR

## Laser Film Printers FAQs

- Q. Consequently, the ACR and FDA require FDM facilities to have access to a compatible laser film printer (either on-site or at a third party).
- The printer must exist and be tested by a qualified MP according to the FFDM unit manufacturer’s recommendations before the facility performs mammography on patients.
  - The facility must also include information and QC data for the laser film printer in its accreditation application as it does for film processors.
  - Furthermore, MQSA inspectors will review the laser film printer QC when he/she inspects each FFDM unit.

ACR

## FDA-Required Laser Printer QC (Updated October 2005)

FFDM Mfr	Model	Laser Printer QC
General Electric	Senographe 2000D, DS and Essential	Follow the laser printer manufacturer’s QC manual
Fischer	SenoScan	Follow the laser printer manufacturer’s QC manual
Lorad	Selenia	Follow the Lorad Selenia QC Manual
Siemens	Mammomat Novation DR	Follow the laser printer manufacturer’s QC manual (but conduct QC every day that images are printed)

ACR

- Q. Does a facility with an FFDM unit need to submit QC data for their laser film printer even if the physicians interpret only from the soft copy?
- A. Yes. Because the FDA requires that each facility be able to print hardcopy films of final interpretation quality for purposes of transferring images, we require facilities to submit hardcopy images.
- The ACR reviews a copy of the laser camera QC as part of accreditation. You must submit at least one calendar month of laser film printer QC data for each printer used for digital mammography even if it is performed by a third party.
  - We recommend you use the QC chart provided in the laser film printer’s QC manual.
  - Your printers’ QC program must be substantially the same as the quality assurance program recommended by the FFDM manufacturer.

ACR

- Q. Can a facility with an FDM unit use their MRI laser printer to print their digital mammography images?

- A. Possibly.
- FDA recommends that only printers specifically approved or cleared for FFDM use by FDA’s Office of Device Evaluation be used.
  - However, a facility may use other printers.
  - Facilities need to ensure that all printers used by the facility with its FFDM unit comply with a quality assurance program that is substantially the same as that recommended by the FFDM manufacturer and pass the facility’s accreditation body’s phantom and clinical image review process.
  - See the FDA’s Modifications and Additions to Policy Guidance Help System #9.
  - You should consult with your MP to assist you in making this decision.

ACR

Q. My facility can print hardcopy images for our FFDM unit from three separate workstations. Which one should I use to print images to submit for accreditation?

A. The ACR suggests that you print from the workstation you typically use to print hardcopy images to give to patients.

Per FDA guidance, hardcopy images should be of "final interpretation quality", therefore it is important for your radiologist to review and approve these hardcopy images before you submit them for accreditation.

ACR

## Monitors & Workstations FAQs

Q. Do I have to use an FDA-approved review workstation to interpret digital mammograms?

A. No. However, the FDA recommends that only monitors specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. (See [FDA's Modifications and Additions to Policy Guidance Help System #9](#).)

Q. We have just installed our first FFDM unit. Does our medical physicist also have to test the review workstation along with the new FFDM unit as part of the Mammography Equipment Evaluation? Do we have to submit the review workstation test results for accreditation?

A. Yes and yes.

ACR

Q. We have just added a second FFDM unit. Images from this unit are interpreted on our current RWS. This RWS was evaluated during the medical physicist's Annual Survey of our old FFDM unit. Does our medical physicist have to retest that RWS along with the new FFDM unit as part of the MEE? Do we have to submit the RWS test results for accreditation?

A. No and yes. If the RWS was tested previously with another FFDM unit at that site during its MEE or Annual Survey, the MP does not have to retest the WS.

However, the MP should indicate on the MEE summary forms sent with the accreditation application when the WS was tested and the results.

ACR

Q. We just installed a new RWS. (We have had our FFDM unit for several years.) Does our MP have to conduct a MEE of this workstation? Do we have to submit the results of this test to the ACR?

A. Yes and no. It is important that your MP conduct a MEE of your new workstation (and document his results in a report) to ensure that it is operating properly for image interpretation.

- However, you do not need to send this to the ACR at this time.
- We will request the results of the entire system's Annual Survey (which must include the RWS tests) during accreditation renewal.

ACR

## Alternative Standard

- ACR subcommittee has been working on...
- Unified QC program (RT and MP) for all FFDM systems
- ACR committees do not include manufacturers
- ACR is working with NEMA
- Currently in process

## Our experience...

- More unscheduled MP services for FFDM
  - IR replacements – (8 in 3 yrs – 12 units)
  - X-ray tube replacements (5 in 3 yrs)
  - Software upgrades (7 in 3 yrs)
  - RWS changes, AWS unchanged (4 in 3 yrs)
- Schedule these w/facility and QSE to minimize downtime
- Collaborate with the QSE
  - RWS monitor calibration
  - MP requirements for MEE, per manufacturer

### **“Best Practice”**

- The MP provides unique and valuable expertise and contributes to the quality and efficiency of a mammography program.
- Although some larger institutions will have their own in-house MP, most mammography facilities in the US use consulting MP's.
- A MP should be available to consult on problems whenever mammograms are being performed.
- Telephone consultation is often sufficient for an immediate response,
- but when necessary the MP should be available to make an unscheduled visit to the mammography facility within a reasonable time frame, depending on the need.