AbstractID: 9717 Title: MQSA Inspections: How to prepare your facility

Mammography

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

Inspection News Updates

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Communication of Mammography Results to Referring Healthcare Providers and Patients

The Division of Mammography Quality and Radiation Programs has been made aware that sometimes there are issues with the methods some facilities use to track that mammography results are provided to referring healthcare providers and patients. Some MQSA facilities may not be consistently tracking or monitoring that medical reports and/or lay summaries are being provided on time or at all. As a result, some referring healthcare providers and patients are not receiving their exam results or are not receiving them in a timely manner. In most instances, facilities have established written procedures in place to issue the reports, however, in practice, the tracking of reports is sometimes not adequate to ensure timely issuance of the mammography results.

MQSA allows facilities to develop or use a procedure and tracking system that works best for them. Facilities need to monitor their systems to ensure that their policy and procedures are actually and correctly being followed. FDA supports the use of computer

tracking and paper or patient log systems to assist in tracking timely issuance of medical reports and lay summaries. Some radiology computer reporting systems can track individual reports and generate summary reports indicating when a mammography report or lay summary has been issued. By routinely checking these summary reports, facilities can ensure that all mammography results have been issued in a timely manner. Facilities are encouraged to check with their computer support vendors to see if their software can generate such summary reports. FDA encourages all facilities to reassess their current systems, whether they are computerized or paper logs to ensure that they communicate mammography results to all patients and their referring healthcare providers.

Another sometimes overlooked problem deals with facilities that fax or email medical reports and/or lay summaries. Policies and procedures to deal with faxes and emails that are reported as "failed" are important to ensure that reports and lay summaries are resent in a timely manner.

Facilities may obtain additional information about medical records and mammography reports from the MQSA Policy Guidance Help System located on this website (Search on keywords: Medical Records, Mammography Reports, Mammographic Assessments, Written Report, Recordkeeping, and Communication of Mammography Results.)

Quality Control Testing for Printers and Monitors

1. Printer and/or Monitors without QC Manuals

Under the Mammography Quality Standards Act (MQSA) final regulation 900.12(e)(6), facilities using a mammographic modality other than screen-film must follow a quality control program that is "substantially the same as the quality assurance program recommended by the image receptor manufacturer…". While all full field digital mammography (FFDM) manufacturers have quality control (QC) manuals, in some cases, the QC manual instructs the facility to test monitors and printers according to the component's QC manual. In these cases, it is the responsibility of each facility to ensure that it obtains and follows the component's QC manual for its monitors and printers.

2. Facilities Using the Same Printer or Monitor with FFDM Units from Different Manufacturers

For facilities that are using FFDM units from different manufacturers, each with its own QC requirements for printers and monitors, there may be uncertainty regarding the QC tests to perform on these components. The following three examples should help facilities decide.

a. Each FFDM manufacturer QC manual requires that the same or equivalent test be done, but at different time frequencies. In this case facilities need to perform the test at the more stringent frequency.

b. Each FFDM manufacturer QC manual requires that different but equivalent tests be done. In this case facilities may perform only one of the tests at the more stringent frequency. The medical physicist should provide a written statement for the facility's

quality control records, indicating that in his or her opinion, the two tests are equivalent.
c. Each FFDM manufacturer QC manual requires that different tests (not equivalent) be done. In this case facilities need to perform each test at the frequency required in the respective FFDM manufacturer QC manual.

Medical Physicist Responsibilities Regarding Laser Printer Mammography Equipment Evaluation (MEE)

We recently learned that some medical physicists are not including appropriate testing of the laser printer in their survey /MEE report to the facility. There seems to be confusion between the required MEE testing of a laser printer: (1) before it is first put into clinical use; (2) following reassembly; or (3) after major repairs vs. the routine Quality Control (QC) testing of the laser printer after it is placed into clinical use. In some cases, the medical physicists did not test the laser printer at all. In other cases, they did inappropriate testing and, in a few cases, they did appropriate testing but did not include documentation of the tests in the facility survey / MEE report. Therefore, we want to clarify the MQSA requirements regarding this issue.

The final regulations require that all test procedures be conducted as specified in the QC manual of the FFDM system manufacturer. Some of these QC manuals specify both periodic QC (daily, weekly, or annual) and MEE testing for the laser printer. Other manuals do not address the subject and refer the user to the laser printer manufacturer's QC manual. For easy reference, the following table summarizes laser printer test procedures in current QC manuals:

FFDM System	QC Manual	Weekly/Daily	Annual	MEE	QC Procedures - Comments
GE- All systems	All	Yes*	No	No	*Per printer mfr. QC manual
Fischer	Rev.10-10/07	Daily check	No	No	Follow printer mfr. QC manual
Selenia	Rev. 7–8/07, **Sec. 2.1	Yes	No	Yes**	Follow the Selenia QC manual
Siemens	Rev. 5–4/07	Before clinical use	No	Yes	Follow printer mfr. QC manual
Fuji	3rd Edit.–4/07	Yes	Yes	Yes	Follow applicable printer QC manual

As the above table shows, some of the FFDM QC manuals do not specifically address the laser printer MEE testing requirements when first installed, reassembled, or after having undergone a major repair. Hence, the facility or medical physicist has to obtain this information from the laser printer manufacturer. In some cases, the QC manuals only address the interface between the FFDM unit and the laser printer. They do not address the basic requirement that the laser printer, before it is used clinically for mammography, has to be operating as designed by the laser printer manufacturer. Since the MEE requires

that both these areas be checked, the medical physicist may have to consult both the FFDM manufacturer's QC manual and the laser printer QC or operator's manual to determine which tests are required to assure that the laser printer is functioning properly.

Some medical physicists incorrectly assume that simply scoring a laser printed phantom image satisfies all the requirements of the laser printer MEE. However, in most cases, this practice would not be acceptable. To avoid unnecessary follow-ups by MQSA inspectors, we urge all medical physicists to review the FFDM manufacturer's QC manual and, where necessary, the laser printer QC or operator's manual to determine the appropriate testing. They then need to clearly document the testing of the laser printer in their reports.

Attention Mammography Community - Pending Inspection Software Citations will be Activated on January 1, 2008

On January 1, 2008, FDA will modify the current inspection software (FISS Version 6.03) to allow citations for failures in the following areas:

- Failing phantom score(s) in full field digital mammography (FFDM) systems – As you know, MQSA inspectors have been scoring phantom images in FFDM systems since 2006, but we have withheld issuing citations for failing these image scores to give the inspectors adequate time to become comfortable with the FFDM scoring procedure and to give the facilities a "heads-up" view of our intent in this area. Effective January 1, 2008, failing phantom image scores in FFDM systems will have the same observation levels as screen-film (S-F) systems.

- Failing to take corrective action before resuming clinical use if the dose reported by the medical physicist exceeds 3 mGy (300 mrad). Specifically, we added the following data entries in early 2006:

    - Dose value (mrad) reported -------, and if the inspector entered a value over 300 mrad, the software prompts the inspector to answer the following question:
    - C/A taken before resuming clinical use? (yes/no)

Thus, effective January 1, 2008, if the inspector answers "no" to the above question, the software program will issue a level 2 observation, which will be applicable to both S-F and FFDM systems.

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See Related Information

Updated Trends in Mammography Dose and Image Quality

(Related Article: Dose and Image Quality in Mammography: Trends during the First Decade of MQSA)

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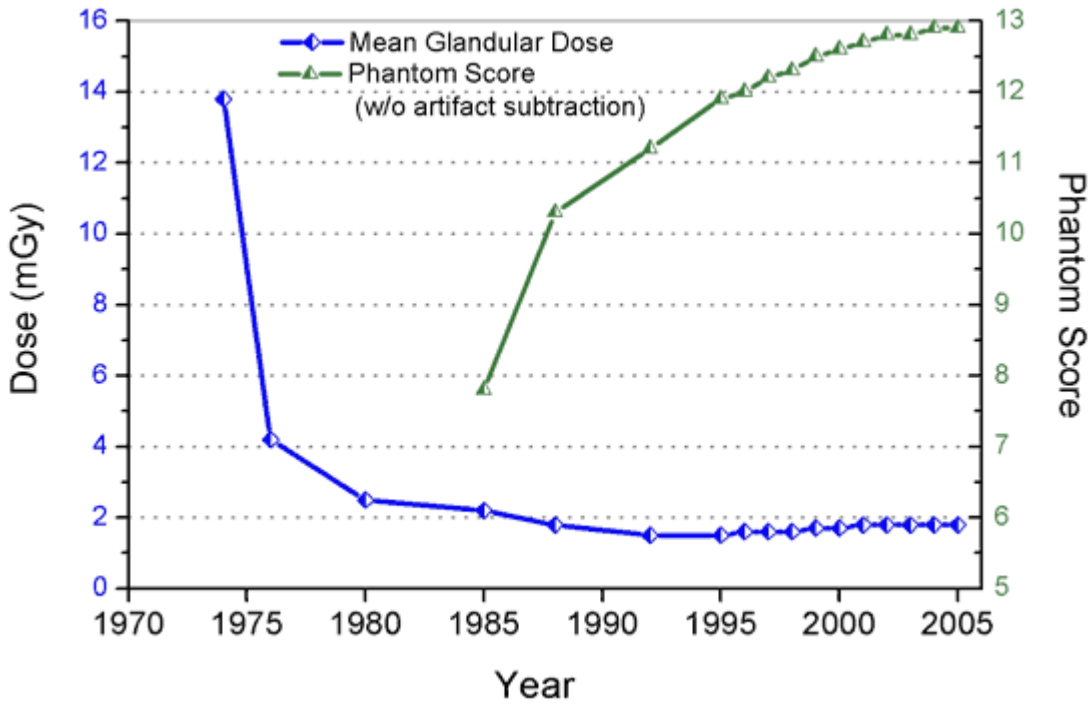

This graphic displays average values for mean glandular dose and estimates of image quality in mammography for the period from the early 1970's to 2005. Doses in mammography have consistently decreased with time, with the most substantial reductions in dose occurring from the early 1970's to the early 1980's. Image quality data is presented from the mid-1980's to present, and shows consistent improvement with time.

The early studies of 1974 and 1976 reported substantial contributions from xeromammography and direct-film procedures. Even during the first year of MQSA inspections in 1995, there were a number of facilities still using xeromammography. Technological improvements such as efficient screen-film technologies, molybdenum target-based x-ray units for mammography, and improvement in film processing quality contributed to further reduction in dose during the eighties and into the nineties. Dose and image quality trends have leveled off in recent years as the technical aspects of mammography became optimized. For further discussion on trends in dose and image quality in mammography refer to the article posted on the FDA's website.

Average values for mean glandular dose are either reported by, or derived from data reported by the following sources:

1974	Bicehouse HJ. Survey of Mammographic Exposure Levels and Techniques Used in Eastern Pennsylvania. 7th Annual National Conference on Radiation Control, 1975. DHEW Publication (FDA) 76-8026.
1976	Butler PF, Jensen JE. Breast Exposure: Nationwide Trends; A Mammographic Quality Assurance Program- Results to Date. Radiologic Technology 50(3),

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	1978; pp 251-257.
1980	Breast Exposure: Nationwide Trends. In: Internal project progress report. Rockville MD: Bureau of Radiological Health, US Department of Health and Human Services, Food and Drug Administration, 1981.
1985, 1988, 1992	Conway BJ, Suleiman OH, Rueter FG, Antonsen RG, Slayton RJ. National Survey of Mammographic Facilities in 1985, 1988, and 1992. Radiology 1994; 191: 323-330.
1995 to present	Mammography Quality Standards Act (MQSA) inspection findings.

Image Quality scores are reported from the following sources:

NOTE: All image quality scores are reported without artifact subtraction.

1985	RMI 152 phantom with 'C' insert; 1985 Nationwide Evaluation of X-ray Trends (NEXT) survey data.
1988	RMI 156 phantom with 'C' insert; 1988 NEXT survey data.
1992	RMI 156 phantom with 'D' insert; 1992 NEXT survey data.
1995 to present	Mammography Quality Standards Act (MQSA) inspection findings

Updated June 16, 2006

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See Related Information

MQSA National Statistics

In this section of the MQSA Scorecard, we present the most commonly requested national statistics regarding the MQSA program. These statistics are updated on the first of each month.

Certified facilities, as of October 1, 2007	8,837
Certification statistics, as of March 1, 2008	
Total certified facilities / Total accredited units	8,871 / 13,547
Certified facilities with FFDM[2] units / Accredited FFDM units	2,847 / 4,310
FY 2008 inspection statistics, as of March 1, 2008	
Facilities inspected	3,284
Total units at inspected facilities	4,917
Percent of inspections where the highest noncompliance was a:	
Level 1 violation	1.3%
Level 2 violation	16.1%
Level 3 violation	6.1%
Percent of inspections with no violation	76.5%
Total annual mammography procedures reported, as of March 1, 2008[1]	35,787,362

[1] This number is an aggregate of the total number of procedures performed annually as reported by facilities to their accreditation bodies. Facilities are asked to disclose this information at their initial accreditation, and then at the time of their re-accreditation, which takes place once every three years. FDA began collecting these data in 1998. The aggregate does not reflect the current number of procedures performed at these facilities, but only the numbers reported by them during the three-year period prior to the current date. We have aggregated only the numbers reported by certified, non-Veterans Administration facilities.

[2] FFDM - Full Field Digital Mammography unit.

Updated March 3, 2008