

North Carolina Radiation Protection



Mammography News - Spring 2004

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Stereotactic

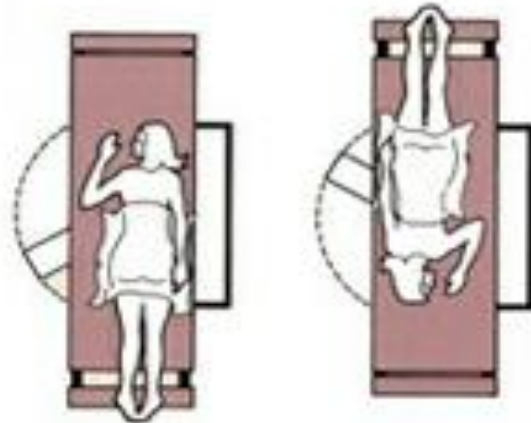
The information contained in this newsletter is a result of data obtained from the 2002-2003 inspection of all stereotactic facilities.

The word “*stereotactic*” means precise location in space.

Stereotactic breast biopsies represent a new way to precisely and accurately sample tissue from a suspected abnormality found on a mammogram without surgery.

The breast is compressed and a local anesthetic is injected. A sample of tissue is removed from the breast.

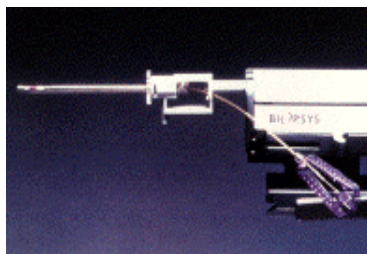
FULL RANGE OF MOTION



TRUE 360 ACCESS



Breast Biopsy System



STEREOTACTIC UNITS

44% of Facilities have Fischer Units

44% of Facilities have Lorad Units

9% of Facilities have USSC/ABBI Units

2% of Facilities have Siemens

These are the four major manufactures of stereotactic units used in the North Carolina facilities. Of the four major manufactures Fisher and Lorad are the major contributors.

Image Resolution of Monitors

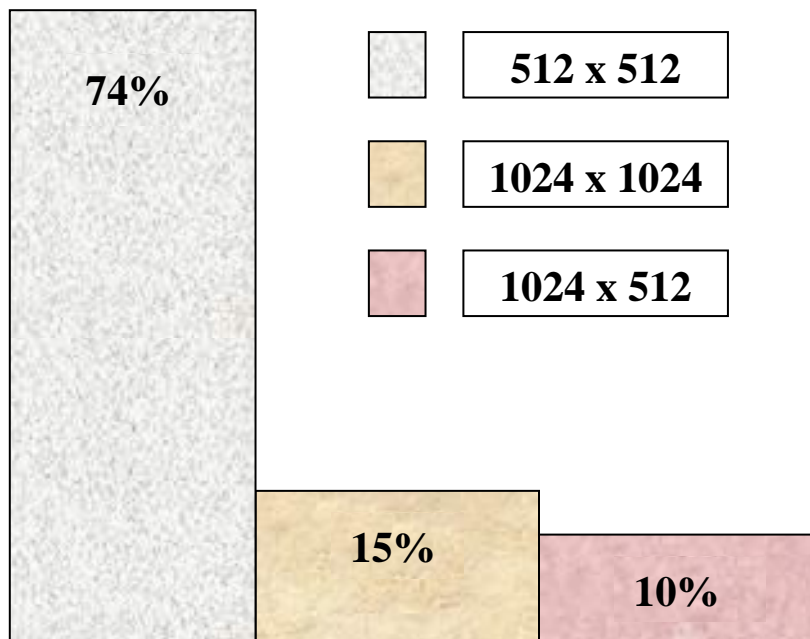
512 Mode: High contrast resolution for differentiation of soft tissue masses at reduced dose.

1024 Mode: High spatial resolution for enhanced imaging of subtle calcifications.

74% use 512 x 512 pixel resolution

15% use 1024 x 1024 pixel resolution

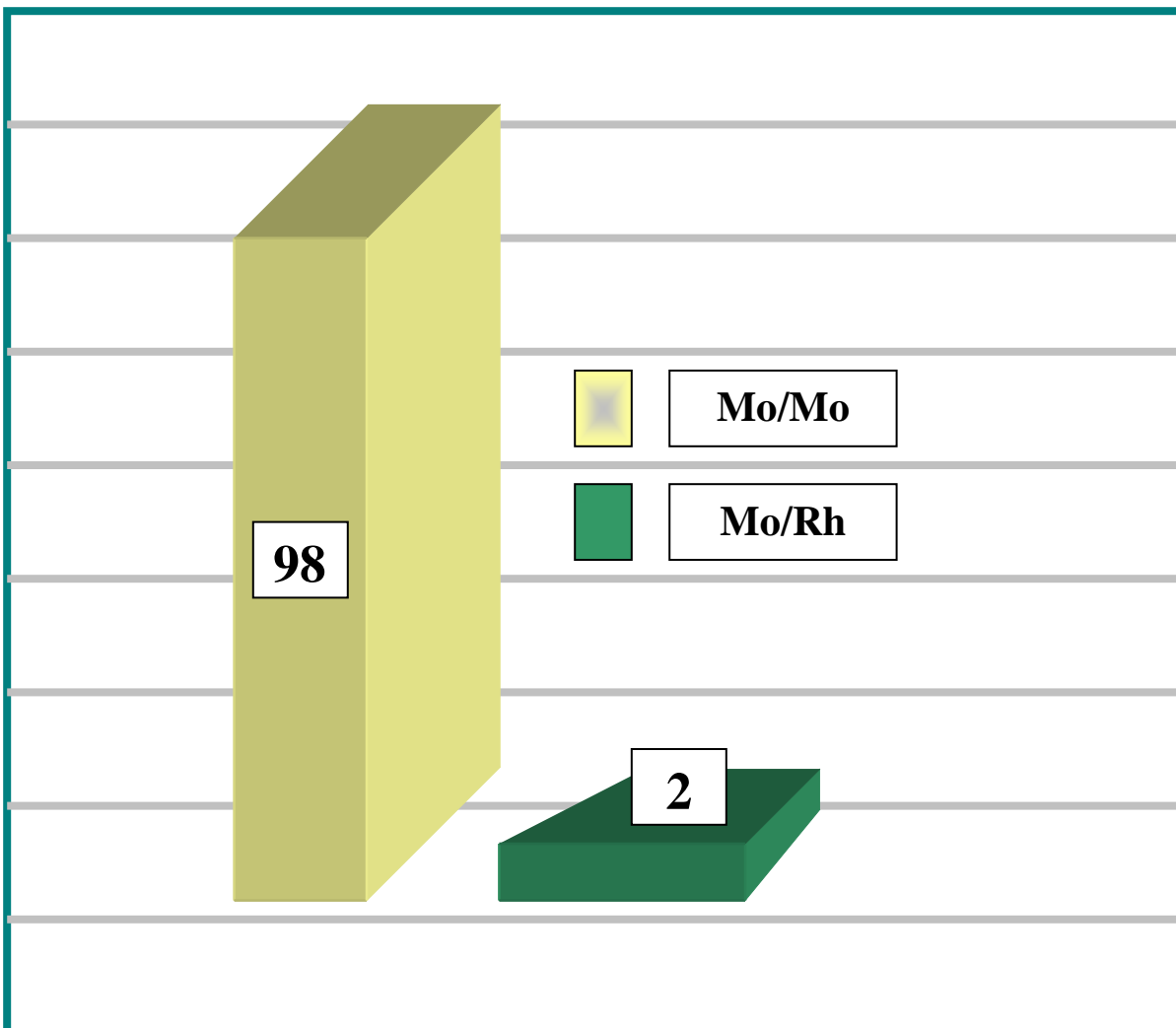
10% use 1024 x 512 pixel resolution



Target Filter Combination

98% of facilities use Mo/Mo target filter combination

2% of facilities use Mo/Rh target filter combination

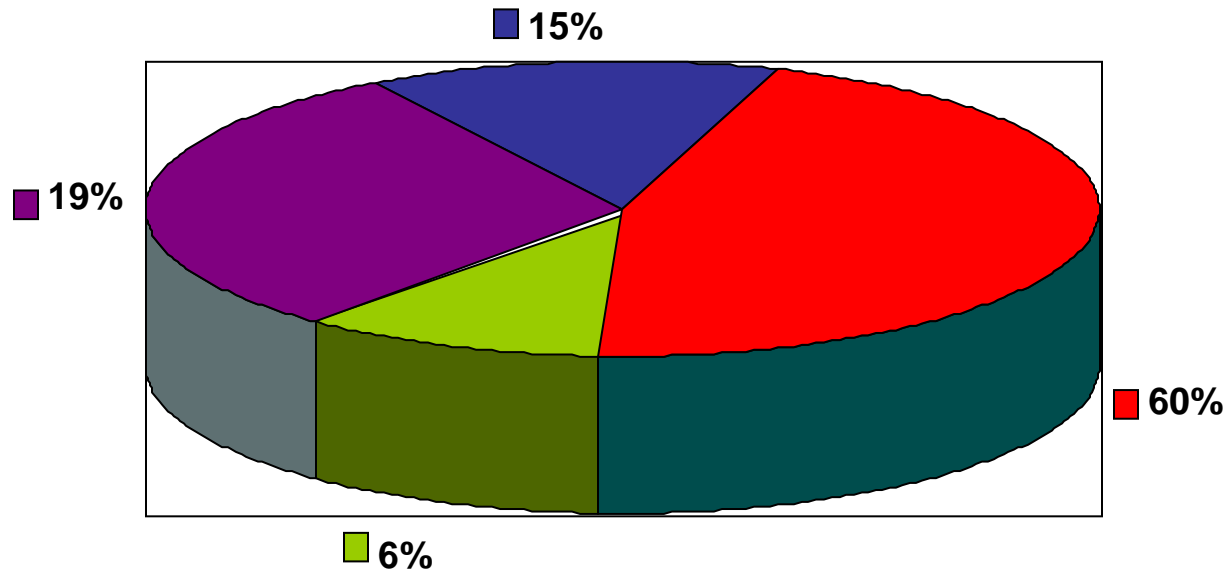


Dose Limits

- The recommended *dose* limit is 300mRad. Depending upon technique, age of unit, and other unknown factors the dose ranged from 26mRad and 519mRad.
- The *average* dose is 245mRad for all units. The *average dose is 200mRad for units under 300mRad. The mAs for all facilities ranged between 43.2 and 260. Facilities that had dose less than 275mRad used an average mAs of 106.*
- *Facilities who use 168 mAs and higher, regardless of kVp, resulted in doses above 300mRad.*
- *There were four facilities that used techniques below 168 mAs that also resulted in high dose. The dose measurements ranged from 278mRad and 339mRad.*



Kilo-Voltage Peak KVP



■ 26kVp ■ 27kVp ■ 25kVp ■ 28kVp

6% used 26kVp with an average mAs of 120. 1 out of 3 had doses above 275 mRad.

15% used 27kVp with an average mAs of 99. 1 out of 7 had doses above 300 mRad.

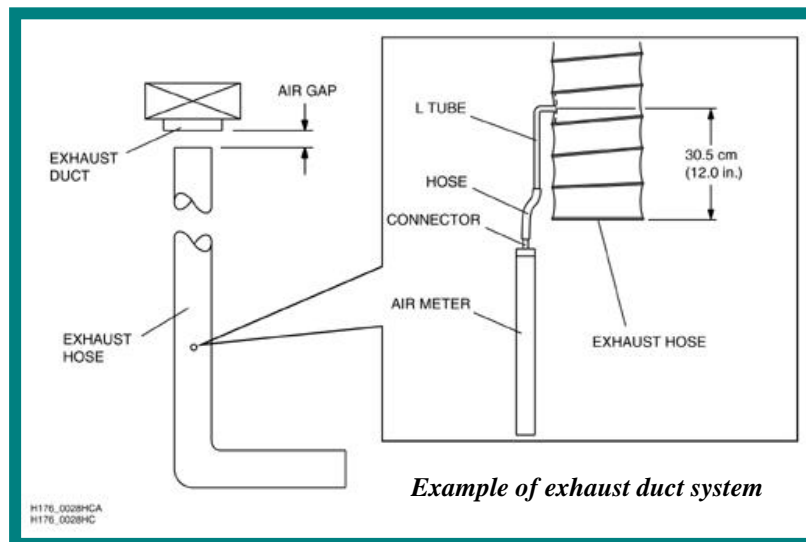
19% used 25kVp with an average mAs of 175. 4 out of 9 had doses above 300 mRad. The higher mAs is used to compensate for low kVp and low contrast, resulting in higher dose.

60% used 28kVp with an average mAs of 114. 7 out of 28 had doses above 275 mRad. 5 out of 7 had doses above 300mRad.

Darkroom Ventilation and the State Code

- A minimum of 10 complete changes of air per hour inside the darkroom and two per hour outside the darkroom are recommended.
- Air exchanges are necessary for high-quality processing and safe handling and storage of film and chemicals.
- A service person from a heating and air-conditioning firm should be able to measure this.

Arthur G. Haus Susan M. Jaskulski
The Basics of Film Processing in Medical Imaging



Dryer Venting Requirements

"To protect the processor and such equipment as might be directly interfaced with the processor, the dryer must be vented according to the following specifications. Failure to properly vent the dryer exhaust can cause corrosion within the processor and interfaced equipment. In addition, the probability of processor-related film artifacts is increased."

- The processor exhaust duct must be connected to the building ducting system. Disposal of effluent air must comply with prevailing environmental codes. *
- The following table should be used to determine the proper amount of negative air within the duct at the end to be connected to the processor. To prevent venturi effect at the duct opening, all measurements should be made at a point 30.5 cm (12 in.) from the open end of the duct to be attached to the processor.

Kodak X-Omat Processors

Duct Size	Negative Static Pressure	Water Head
	Minimum	Maximum
76 mm (3 in.) diameter	0.76 mm (0.03 in.)	1.02 mm (0.04 in.)
102 mm (4 in.) “	0.25 mm (0.01 in.)	0.51 mm (0.02 in.)

- Measurement can be made using a Dwyer Air Meter, Model No. 460 or equivalent..."

Service Bulletin
KODAK X-OMAT Processors
Service Bulletin No. 101

The Manufactures Installation Manuel is the Code for North Carolina

North Carolina Educational/Assistance Centers – 2003-2004

A listing of these facilities is provided for your convenience. These Centers are scattered throughout the state to provide an easy way for mammography facilities to get questions answered and mammography concerns addressed. These facilities were selected based on past performance on MQSA inspections, information provided by the inspectors, and strategic geographic locations. These facilities are an excellent resource for information on QC and other MQSA matters.

County	Facility	Contact	Phone
Buncombe	Asheville Breast Center Asheville, NC	Patricia Wilson	(828) 213-0837
Cabarrus	Northeast Medical Center Concord, NC	Nora Helms	(704) 783-2054
Cabarrus	Northeast Medical Center – Outreach Services Concord, NC	Betty Rhyne	(704) 783-1729
Craven	Craven Diagnostic Center New Bern, NC	Rick Fisher	(252) 634-6400
Cumberland	Cape Fear Valley Medical Center Fayetteville, NC	Teresa Thompkins	(910) 609-6616
Cumberland	Cape Fear Valley Medical Center – Mobile, Fayetteville, NC	Teresa Thompkins	(910) 609-6608
Duplin	Duplin General Hospital Kenansville, NC	Katrina Grady	(910) 296-2665
Durham	Duke University Medical Center - South, Durham, NC	Marie Stone	(919) 684-7642
Forsyth	Breast Screening Center @ Ardmore Plaza, Winston-Salem, NC	Linda Meeks	(336) 716-5453
Mecklenburg	Presbyterian Breast Center Diagnostic Screening, Charlotte, NC	Elizabeth Currie	(704) 834-4177
Moore	Pinehurst Radiology Associates Pinehurst, NC	Pam Smith	(910) 295-4400
New Hanover	Delaney Radiologists Imaging Center Wilmington, NC	Lois Watkins	(910) 762-3882
Orange	UNC Hospitals –NC Clinical Cancer Center, Chapel Hill, NC	Janet Fouschee	(919) 966-2959
Pitt	Eastern Radiologists Breast Imaging Center, Greenville, NC	Jana Gurganus	(252) 754-5233
Wake	Rex Healthcare, Raleigh, NC	Joyce Watson	(919) 784-3024
Wake	Rex Healthcare - Mobile, Raleigh, NC	Joyce Watson	(919) 784-3024
Wake	Wake Radiology – Merton Drive, Raleigh, NC	Billie Pennington	(919) 787-7411
Washington	Washington County Hospital, Plymouth, NC	Yvonne Cooper	(252) 793-4135
Watauga	Watauga Medical Center, Boone, NC	Gloria Payne	(828) 262-4100

***Please contact Jerry Britt at (919) 571-4141 or Gerald.Britt@ncmail.net
To arrange a visit to a Mammography Education/Assistance Center.***

PLEASE DO NOT CALL THE FACILITY DIRECTLY.

Topics in the World of MQSA

Infection Control Policy

The Infection Control Policy is addressed in MQSA as the following:

21 CFR 900.12(e)(13) Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

- Comply with all applicable Federal, State, and local regulations pertaining to infection control; and
- Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or
- If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

Comments:

The Infection control policy should include the following information:

- Name of the disinfectant used
- Copy of disinfectant reference material, for example: instructions for use
- Step-by-step instructions on how to disinfect the mammography unit when contaminated with blood or other potentially infectious materials, for example: where to spray the disinfectant (on the cloth), and how long to leave the disinfectant on the unit, etc.
- How to disinfect when there is blood or body fluid contamination (usually indicated on the disinfectant)
- How disinfection will be documented and where (verification of disinfection is an MQSA requirement)

Documentation of in-between patient cleaning is not a requirement of MQSA but the written procedure for performing this task is required.

It is advisable for ease during the inspection and for the facility employees, that these items be clearly stated and that a copy of the manufacturer's recommendations is kept with the disinfection policy.

Your infection control policy needs to include *HIGH LEVEL DISINFECTION*.

In the event of blood or body fluids, the policy should specify how the equipment will be cleaned. Additionally, there must be a log or some mechanism in place to document the equipment had High Level Disinfection on these occasions. The routine log for daily cleaning would not be sufficient for this purpose.

Question: We clean the mammography unit between each patient. Do we still have to document (through the use of logs or charts) cleaning after the equipment comes in contact with blood or other potentially infectious materials?

The regulations require that equipment be cleaned and disinfected after contact with blood or other potentially infectious materials. Many facilities perform routine cleaning between all patients. However, in most cases, this routine cleaning is not sufficient to disinfect the equipment, either because different materials are required or the materials used are not left in contact with the equipment for a sufficient amount of time to achieve disinfection. Because of this, and the importance FDA places on this aspect of quality assurance, the facility is required to maintain a record of those instances when disinfection procedures were performed.

Uniformity of Screen Speed

The uniformity of screen speed requirement is addressed in MQSA as the following:

21 CFR 900.12(e)(5)(viii): Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

Comments:

Please be aware that if the physicist does not document for screen artifacts during this test, the facility will be in violation and cited.

Alternative Standards for Processor QC

Conducting the daily processor QC when the sensitometer is not available. On 10-18-1999, FDA approved a request for an alternative to sensitometric-densitometric testing of processor performance that can be used for a period of up to 2 weeks when the facility's sensitometer is unavailable.

When using the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions.
2. The optical density of the film at the center of the phantom image changes no more than +/-0.20 from the established operating level.
3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than +/-0.05 from the established operating level.

In addition

4. To evaluate base plus fog an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within +0.03 of the established operating level.

As with the original test, this alternative test must be conducted "each day clinical films are processed, but before processing of clinical films." All results must be recorded. Again, as with the original test, if processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

Continuing Education/Mammographic Modality

The continuing education requirement for specific mammography modality is address in MQSA as the following:

21 CFR 900.12 (a)(2)(iii)(A) and (C): Continuing Education Requirements:

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

Comments:

All personnel will have to document training in each modality used even if the only modality is screen film. If a facility has screen film and digital imaging, they will have to document continuing education in both. For interpreting physicians and technologists the number of hours for each modality is six. As for medical physicists there is not a specific number of hour requirement. If the documentation does not break down the amount of credit issued by specific mammographic modality, the facilities can use the limited attestation policy to document specific mammographic modality along with the course agenda. The inspectors will begin citing facilities on April 28, 2006. However: you will be asked to show new modality training at the time of inspection.

Policy for Medical Audit

The medical audit general requirements is addressed in MQSA as the following: 21 CFR 900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

Comments:

The inspectors will be looking for a medical audit policy documenting how the medical audit will be performed. We will be specifically looking for the mechanism of tracking patients assessed with a "Suspicious", "Highly Suggested of Malignancy", or recommend for biopsy report. The documentation should follow the patient from mammogram to biopsy, concluding with how the biopsy results will be documented. In the event that a patient does not have a biopsy or biopsy results are not obtainable, the facility should document what is done in those instances.

Policy for Self Requesting Mammogram

Comments:

Facilities in North Carolina that offer screening mammography may not accept self-referred patients because a doctor is not involved. However under the NC

State Regulations 15A NCAC 11.0603 (a)(1)(G) they may accept self requesting patients, if certain conditions are met.

The inspectors will be reviewing the self requesting policies at facilities that accept self-requesting patients. This policy shall document the actions of the facility for a self requested patient, following the patient from point of contact to the end of the mammography procedure. In the event that a self-requesting patient's doctor declines the report or care of the patient. The facility must have a documented procedure to verify that the report goes to a physician who is willing to provide follow-up care with the patient. **EXAMPLE:** listing of the doctors that will accept self requested patients should be available. There should be a mechanism in place for updating that list and this should be explained to the inspector.

As for facilities that do not accept self requesting mammograms, they will have to have a policy in place stating that fact.

Definitions:

Self-referred: No Doctor's order, patient receives both the lay report and the physician's report. (Not allowed in NC)

Self requesting: No Doctors order, but patient has a physician responsible for her care. (Patient receives lay report and the attending physician receives physician's report). See conditions listed above MD referral: Patient has written order. (Patient receives lay letter and Dr. receives physician report)

If you have any questions, please contact the North Carolina Radiation Protection Mammography Branch (919) 571-4141

Technique Charts

Must be working charts (what is used clinically) and correlates to the phantom.

Must be visibly displayed

Must have a manual back-up technique including kVp and mAs.

Should include appropriate target filter combinations, kVp and density for phototimed exposures.

Radiation Safety Guide

We have developed a Radiation Safety Guide specifically for mammography and stereotactic facilities. Included is a template for technique charts. The inspectors will bring a copy when they perform your annual inspections.

Policy Guidance System provided by FDA

We highly recommend that you download the guidance system or access it frequently to answer your MQSA questions.

Our Staff

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We would like to encourage you to visit our website regularly. We attempt to keep you current on changes and issues of interest in mammography.

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