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1999 Mammography

QUALITY CONTROL MANUAL

Radiologist's Section

Clinical Image Quality

Radiologic Technologist's Section

Medical Physicist's Section

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Radiologist's Section
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Medical Physicist's Section

American College of Radiology
Committee on Quality Assurance in Mammography

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PREFACE

In 1987, Dr. Gerald Dodd, former Chairman of the American College of Radiology (ACR) Breast Task Force, recognized the need for a "cookbook" style manual on mammography quality control. Dr. Dodd asked that we convene a committee of experts on mammography quality control to tackle the job under the auspices of the ACR. In 1990, the hard work of the original ACR Committee on Mammography Quality Assurance, (Dr. Gerald Dodd, Dr. Joel Gray, Ms. Mary Ann Harvey, Mr. Arthur Haus Dr. R. Edward Hendrick, Dr. Russell Holland, Dr. Robert McClelland, Mr. John McCrohan, Mr. Raymond Rossi, and Dr. Daniel Sullivan), resulted in the publication of three separate manuals: one for the radiologic technologist, one for the medical physicist, and one for the radiologist. Through financial support from the ACR and a grant from the American Cancer Society (ACS), these manuals were provided free of charge to each site accredited by, or applying to, the ACR Mammography Accreditation Program. Second and third editions of the *ACR Mammography Quality Control Manual* were printed and distributed to all ACR-accredited and applicant sites in 1992 and in 1994 (with the addition of Dr. Lawrence Bassett, Dr. Stephen Feig, Ms. Margaret Botsco, R.T. (R)(M), Ms. Priscilla Butler, M.S., Ms. Rita Heinlein, R.T.(R)(M) and Dr. E. Lee Kitts, Jr. to the Committee). A significant addition to the 1992 and 1994 manuals was the Positioning and Compression Guide developed by Dr. Bassett, Dr. Feig, and Ms. Heinlein.

The *ACR Mammography Quality Control Manual* has received widespread acceptance since its introduction in 1990. The ACR Standards for the Performance of Screening Mammography, adopted by the ACR Board of Chancellors in September 1990, explicitly recognized the importance of quality control in mammography, recommending the performance of tests detailed in the ACR manual. Since January 1992, the ACR Mammography Accreditation Program has required accredited sites to perform and maintain records of the quality control tests in the *The ACR Mammography Quality Control Manual*.

The 1992 Mammography Quality Standards Act (MQSA) significantly elevated the impact of the ACR manual. The 1992 and 1994 *ACR Mammography Quality Control Manuals* were adopted by reference under the Food and Drug Administrations Interim Rules for Mammography Facilities. All mammography programs in the United States had to employ QC measures that were substantially the same as those outlined in the *ACR Mammography Quality Control Manual*. While the FDA's Final Rules for Quality Mammography Standards no longer require that the manual be used as the guideline for conducting QC tests, they have maintained most previous quality control requirements and have added several new ones.

This 1999 Edition of the *ACR Mammography Quality Control Manual* has been modified to be consistent with MQSA Final Rule requirements. The revised manual outlines MQSA requirements and provides guidance on conducting and evaluating QC tests in a manner consistent

with MQSA Final Rules. The manual goes beyond minimum MQSA requirements by recommending tighter performance criteria in some areas to encourage improved image quality, but we have made every effort to delineate the difference between MQSA requirements and further ACR recommendations. Another new addition to this manual is the "Clinical Image Quality" section that has been developed through the efforts of Dr. Steven Feig, Dr. Lawrence Bassett, and Ms. Rita Heinlein.

All of the members of the ACR Committee on Quality Assurance have donated generously of their time and expertise to produce the ACR Mammography Quality Control Manual. Others outside the committee have also volunteered their time and expertise in reviewing drafts of the manual and have provided valuable comments and suggestions; they have our heartfelt thanks. They include Mr. Robert Pizzutiello, Dr. Martin Yaffe, Mr. Eric Berns and especially Dr. Libby Brateman for her thorough and timely critique of the 1999 edition.

As with the first three editions of the *ACR Mammography Quality Control Manual*, special thanks go to Ms. Pamela Wilcox-Buchalla, Senior Director of ACR Accreditation Programs, for serving as the managing editor of these manuals, and to Ms. Susan Flesher, Ms. Victoria Lamb, Mr. Keith Stanger and Mr. Paul Wiegmann for typing, editing and publishing these manuals with such careful attention to detail and quality. Special thanks go also to Ms. Marie Zinninger, Associate Executive Director of the ACR, who has enabled and encouraged this project from its inception, along with the Mammography Accreditation Program, mammography standards, and a number of other significant ACR mammography projects. A final special thanks goes to Ms. Priscilla (Penny) Butler, who has been a member of the ACR Committee on Quality Assurance since 1994 and has played an integral part in improving mammography QC nationally over the last decade. In 1998, she joined the staff of the ACR as Director of Special Projects and has already focused her energy, organization, and dedication to the substantial task of this revised *1999 ACR Mammography Quality Control Manual*.

R. Edward Hendrick, Ph.D.
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1999 Mammography

QUALITY CONTROL MANUAL

Radiologist's Section

Contents

INTRODUCTION

Widespread mammographic screening has the potential to significantly reduce mortality from breast cancer. However, the effectiveness and success of such screening and of all mammography depends on the consistent production of high-resolution, high-contrast mammographic images. Poor quality mammography can lead to missed breast cancers. Poor quality mammography also can generate equivocal examinations prompting additional tests and increasing patient anxiety, and undermining the publics confidence in the value of mammography. Achieving high image quality requires vigilant attention to every step of quality control. High standards must be maintained.

The American College of Radiology (ACR) established a voluntary mammography accreditation program in 1987, in part to direct attention to the need for reproducibly high-quality mammography. Calls for quality assurance in mammography have come from breast imaging radiologists, medical physicists and other professional organizations and regulatory groups. The ACR Committee on Quality Assurance in Mammography established practices and standards for quality control in screen-film mammography. Since the original publication of this manual in 1990, it has been updated and revised several times to reflect improvements in mammographic technology and quality control (QC) procedures. This edition of the manual reflects changes mandated as a result of the implementation of the Food and Drug Administrations Final Rules for the Mammography Quality Standards Act (MQSA). For each quality control test there is a box that cites the MQSA Requirements for that test.

In some cases the ACR believes that criteria more stringent than MQSA will lead to greater improvements in image quality. A section titled "Recommended Performance Criteria and Corrective Action" is incorporated into each test to describe these ACR-recommended performance levels.

The "Radiologist's Section" details the radiologist's responsibilities in an ongoing mammography quality control program. The lead mammography radiologist (interpreting physician) has the responsibility for ensuring that all quality assurance requirements are met. This is mandated by MQSA and is good practice. The medical physicist is responsible for overseeing all equipment-related quality assurance practices. A designated quality control technologist must be identified by the mammography facility to conduct all quality assurance activities not assigned to the lead mammography radiologist or the medical physicist.

In "Clinical Image Quality," the "Patient Positioning and Compression" section has been revised, and updated illustrations have been incorporated. A new section on "Clinical Image Evaluation" has been added in this edition. Based on the assessment procedure used in the ACR Mammography Accreditation Program (MAP), this section provides guidance to the radiologist and the technologist on how to recognize specific deficiencies in mammographic images and their probable causes, and methods of correcting those deficiencies.

Details of the technologist's and physicist's tests are given in the following two sections. The stated frequency for each quality control test is a minimum frequency. A test should be done more frequently when it is being introduced and whenever inconsistent results are found. In addition, it is important to adopt the attitude that quality assurance is a continuous, not episodic, process. An effective quality control program will not eliminate problems, but it will allow identification of problems before they seriously affect clinical results. Quality control in xeromammography, and in the emerging technologies of digital and stereotactic mammography, has not been addressed in this document.

The radiologist and technologist must look at every film with quality control in mind. Deviations from high-quality performance may occur quickly or gradually. Abrupt changes in quality may be detected during routine clinical work. More gradual or subtle changes require regular quality assurance testing for detection. The quality control program provides a frame of reference within which even gradual or subtle problems can be identified, isolated and resolved.

DEFINITIONS OF QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

Quality assurance (QA) is a comprehensive concept that comprises all management practices instituted by the lead mammography radiologist to ensure that:

1. every imaging procedure is necessary and appropriate to the clinical problem at hand,
2. the images generated contain information critical to the solution of that problem,
3. the recorded information is correctly interpreted and made available in a timely fashion to the patient s physician, and
4. the examination results in the lowest possible radiation exposure, cost and inconvenience to the patient consistent with objective 2 (above).

The QA program comprises many facets, including efficacy studies, continuing education, quality control, and preventive maintenance and calibration of equipment. A useful part of the QA program is the Quality Assurance Committee (QAC). This group is responsible for oversight of the program, setting the goals and direction, determining policies and assessing the effectiveness of QA activities. The QAC should consist of one or more radiologists, a medical physicist, a supervisory mammography radiologic technologist, the quality control technologist and other radiology department personnel involved in caring for mammography patients. This may include a nurse, desk attendant, medical secretary, and others. It may also include medical and paramedical staff from outside the radiology department, such as a surgeon, referring physician, nurse educator, nurse from a comprehensive breast clinic, etc. Anyone who helps provide care to the patient seeking breast cancer screening or diagnosis should be considered as a member of the QAC since their efforts affect the quality of care and the satisfaction of the patient.

Routine evaluation and communication via the QAC is particularly effective in larger mammography facilities. Very small mammography services with a small number of radiologists and technologists may not need a formal QAC as long as communication among the staff is routine and effective.

Quality control (QC) is an integral part of QA and consists of a series of distinct technical procedures that ensure the production of a satisfactory product, i.e., a high-quality screening or diagnostic image. Four steps are involved:

1. acceptance testing to detect defects in equipment that is newly installed or has undergone major repair,
2. establishment of baseline performance of the equipment,
3. detection and diagnosis of changes in equipment performance before they become radiologically apparent, and
4. verification that causes of deterioration in equipment performance have been corrected.

Specifics of the QC program for screen-film mammography are provided by the American College of Radiology in this manual.

RADIOLOGIST'S RESPONSIBILITIES

The Mammography Quality Standards Act (MQSA) specifies that a lead interpreting physician be identified by the mammography facility to have the general responsibilities of ensuring that all MQSA-required activities are met. This individual will most likely be the lead mammography radiologist. The lead mammography radiologist's (lead interpreting physician's) specific responsibilities in mammography QC are to:

1. Ensure that technologists have adequate training and continuing education in mammography.
2. Provide an orientation program for technologists based on a carefully established procedures manual (see the Comments section below).
3. Ensure that an effective QC program exists for all mammography performed at the site. The radiologist should provide motivation, oversight, and direction to all aspects of the QC program.
4. Select a single technologist to be the primary QC technologist to perform the prescribed QC tests and to oversee tests that have been delegated to other individuals.
5. Ensure that appropriate test equipment and materials are available to perform the technologist's QC tests.
6. Arrange staffing and scheduling so that adequate time is available to carry out the QC tests and to record and interpret the results.
7. Provide frequent and consistent positive and negative feedback to technologists about clinical film quality and QC procedures.
8. Select a medical physicist who will oversee the equipment-related QC program and perform the physicist's tests.
9. Review the technologist's test results at least every 3 months, or more frequently if consistency has not yet been achieved; review the physicist's test results annually, or more frequently when needed.
10. Oversee or designate a qualified individual to oversee the radiation protection program for employees, patients, and other individuals in the surrounding area.
11. Ensure that records concerning employee qualifications, mammography technique and procedures, infection control procedures, QC, safety, and protection are properly maintained and updated in the mammography QC procedures manual.

MQSA REQUIREMENTS:

Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all MQSA QA requirements. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

Responsibilities of all mammography radiologists (interpreting physicians) in mammography QC are to:

1. Follow the facility procedures for corrective action when asked to interpret images of poor quality.
2. Participate in the facility's medical outcomes audit program.
3. Provide documentation of their current qualifications to each mammography facility where they practice, according to MQSA and local rules.

MQSA REQUIREMENTS:

Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall (A) follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality and (B) participate in the facility's medical outcomes audit program.

In addition, mammography radiologists need to be involved in an ongoing process of QA to assess the quality of mammographic interpretation. However, procedures for interpretive quality assurance are not specifically addressed in this manual.

The QC tests outlined in this ACR program are described in detail in a "cookbook" style and are divided into a "Radiologic Technologist's Section" and a "Medical Physicist's Section." The radiologist should make sure that these sections are available to the appropriate personnel.

COMMENTS

1. Radiologists performing mammography must assume the primary responsibility for the quality of mammography and for the implementation of an effective QA program at their site. The staff's commitment to high quality will often mirror that of the lead mammography radiologist. The individuals performing QC tests need to know that the radiologist understands the program and is interested in the results. The radiologist needs to review the test results and trends periodically and provide direction when problems are detected.

2. The radiologist must make sure that adequate time is available for the QC program. Most tests take little time (see Table 3 on page 123, "Radiologic Technologist's Section"). However, the necessary time must be incorporated into the daily schedule.

3. In order to ensure consistency in QC test performance, a primary QC technologist should be selected. It is not desirable, for example, to rotate this assignment among a group of technologists. Such a practice would introduce into the test results variability extraneous to the items being tested. However, properly trained backup QC technologists are essential to provide continuity when the primary QC technologist is unavailable.

4. An on-site medical physicist (or one who is readily available) should administer each facility's QC program, perform the tests designated as medical physicist QC tests, and oversee the work of the QC technologist. When this is not feasible and during the physicist's absence, the radiologist should oversee the QC program.

5. The radiologist is ultimately responsible for the quality of films produced under his or her direction and bears ultimate responsibility for both proper QC testing and QA procedures in mammography.

Working as a team, the mammography radiologist, QC technologist, and medical physicist should develop and follow a mammography QA procedure manual that is available to all members of the staff. The QC testing described in this *ACR Quality Control Manual* should be a central part of the site's QA procedures manual.

The site's QA procedures manual should contain:

- clearly assigned responsibilities and clearly developed procedures for QA/QC testing;
- records of the QC tests performed by the QC technologist and medical physicist;
- a description of the orientation program for operators of mammography equipment, including its duration and content;
- procedures for proper use and maintenance of equipment;
- mammographic techniques to be used, including pertinent

information on positioning, compression, appropriate image receptors and kVp-target-filter combinations and the image quality and average glandular doses with those techniques;

- precautions to protect the operator of the equipment, the patient, and individuals in surrounding areas from unnecessary radiation exposure;
- policies and employee responsibilities concerning personnel radiation monitoring;
- proper maintenance of records, including records of QC and QA testing, equipment service and maintenance, and QA meetings; and
- procedures for cleaning and disinfection of mammography equipment.

MQSA REQUIREMENTS:

Infection Control. 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 (i) comply with all applicable Federal, State and local regulations pertaining to infection control, and (ii) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility, or (iii) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

MEDICAL PHYSICIST'S RESPONSIBILITIES

The medical physicist's responsibilities relate to equipment performance and should include image quality assessment, patient dose evaluation and operator safety concerns. Specific tests include:

ANNUALLY

- Mammographic unit assembly evaluation
- Collimation assessment
- Evaluation of system resolution
- Automatic exposure control (AEC) system performance assessment
- Uniformity of screen speed
- Artifact evaluation
- Image quality evaluation
- kVp accuracy and reproducibility
- Beam quality assessment (half-value layer measurement)
- Breast entrance exposure, AEC reproducibility, average glandular dose, and radiation output rate
- Measurement of viewbox luminance and room illuminance

The medical physicist must also review the tests performed by the QC technologist and provide recommendations for improvement (if necessary) during the annual survey.

MQSA REQUIREMENTS:

The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements. The survey report shall be sent to the facility within 30 days of the survey.

The medical physicist must conduct appropriate tests after installation of new equipment, reassembling existing equipment, replacement of the X-ray tube, or other major service to the mammography unit.

MQSA REQUIREMENTS:

Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted when a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

COMMENTS

Many manufacturers sell dedicated mammographic units whose quality ranges from poor to excellent. Radiologists should insist on buying high-quality mammography units. The quality of new equipment can be better ensured by the use of purchase specifications. Purchase specifications also describe to vendors the type of equipment that is desired by the purchaser. Purchase specifications usually require vendors to provide detailed technical and performance specifications to the purchaser prior to the selection of equipment. These vendor-provided specifications can then be used to help determine the equipment to be purchased and as a set of quantitative performance specifications to be compared with measurements on the mammography equipment during acceptance testing. The purchase should be made contingent on satisfactory performance during acceptance testing. Acceptance testing is more rigorous than the QC program detailed here and should be conducted by an experienced medical physicist. This QC program is intended to document consistency of performance after the unit has been accepted and put into service.

RADIOLOGIC TECHNOLOGIST'S RESPONSIBILITIES

The radiologic technologist's general responsibilities center on patient care and image quality. More specifically, these include patient positioning, compression, image production, film processing and infection control. The specific QC procedures to be conducted by the QC technologist include:

DAILY	• Darkroom cleanliness • Processor quality control
WEEKLY	• Screen cleanliness • Viewboxes and viewing conditions • Phantom images
MONTHLY	• Visual checklist
QUARTERLY	• Repeat analysis • Analysis of fixer retention in film
SEMI-ANNUALLY	• Darkroom fog • Screen-film contact • Compression

MQSA REQUIREMENTS:

Quality control technologist. Responsibility for all individual tasks within the QA program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way to meet MQSA QA requirements.

COMMENTS

1. Although written primarily for the QC technologist, radiologists should read in detail the "Important Points" in the "Radiologic Technologist's Section."
2. Processor QC is essential for producing fine-detail, high-contrast mammograms. Radiologists should refer to Technologist Test #2, "Processor Quality Control," and be thoroughly familiar with these procedures. Sensitometry should be performed and results plotted daily before patient imaging begins. The radiologist should be comfortable reviewing the results of sensitometric testing and must make sure that appropriate corrective actions are taken before patient films are processed when test results are outside of control limits.

The choice of chemistry used in the processor is as important as the selection of film type, developer temperature, or processor type. MQSA requires that facilities use the chemistry recommended by the film manufacturer or chemistries that result in equivalent performance (See VI. "MQSA Requirements of Mammography Equipment" in the "Medical Physicist's Section"). In most facilities, processor chemicals are mixed and delivered to the processor by a local vendor. Over-dilution of the developer is occasionally a problem. Unfortunately it is difficult or impossible for the radiologist or technologist to test and confirm the existence of the problem. If this problem is suspected, the facility may be able to obtain assistance from a medical physicist, QC specialist, or the film manufacturer in testing the developer.

3. Proper viewing conditions and viewbox luminance are essential in mammography. Radiologists should give particular attention to the information given in Technologist Test #9, "Viewboxes and Viewing Conditions." If a separate viewbox is used by the QC technologist to check the density and quality of the mammography images, this viewbox should be similar to the reading viewbox in luminance and color of the light and should be used with ambient lighting conditions similar to those in the room where the mammograms are interpreted.

4. Radiologists should notice and call the radiologic technologist's attention to image quality problems, including artifacts, whenever they occur.

SPECIMEN RADIOGRAPHY

Specimen radiography should be performed on all resections of nonpalpable breast lesions to confirm that the abnormality in question has been removed. In addition, specimen radiography should be performed on core needle biopsies of microcalcifications to ensure that adequate sampling of the targeted microcalcifications have been obtained. This can be done with dedicated mammography units or with specialized radiographic units designed for specimen work. A kVp setting lower than that used for clinical mammography is generally recommended. Settings of 22 to 26 kVp are typically used for dedicated mammography units with molybdenum (Mo) as the target and filter; lower kVp settings may be used for specimen radiographic units with tungsten/aluminum (W/Al) target filter combinations, depending on the unit. Magnification may be helpful for fine calcifications. Compression is generally necessary, especially for noncalcified lesions. Compression can be performed with standard compression paddles or with a variety of plastic specimen compression devices that are commercially available. Many of these specimen compression devices have coordinate systems to assist the pathologist in locating the lesion. Disposable plastic compression devices are also commercially available. The grid should be removed for specimen radiography, because short exposure times may result in grid lines. The specimens are generally thin after compression, and scatter is minimal, so the use of a grid for scatter rejection is unnecessary.

CONCLUSION

In addition to this technical QC program, the radiologist needs to be involved in an ongoing program to assess the quality of mammographic interpretation. Procedures for interpretive QA are not addressed in this manual but have been published in the radiologic literature (Sickles, 1992; Bassett, Hendrick, Bassford, et al., 1994).

MQSA 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 physicians mammography report. Analysis of these outcome data shall be made individually and collectively for interpreting physicians at the facility.

The public expects our profession to provide accurately interpreted mammograms of the highest quality. Only a strong, consistent commitment to QA by all parties involved in performing mammography will validate that trust.

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Clinical Image Quality

PATIENT POSITIONING AND COMPRESSION

1. INTRODUCTION

Breast positioning is an art that has undergone significant changes recently. Incorrect positioning is the most common problem encountered when evaluating clinical images. When mammography and xeromammography were performed with conventional X-ray equipment, positioning was limited to maneuvers in which the patient was turned while lying on her side or seated directly under the overhead tube. With the evolution of dedicated equipment that allows rotation of the X-ray tube, the possibilities for breast positioning became greater. Rather than relying on methods that were based on traditional radiographic projections (lateral and craniocaudal), the art of positioning has been refined by combining a better understanding of the breast's anatomy and mobility with the greater versatility of modern dedicated equipment. In addition, it is now understood that breast positioning should be tailored to the patient's specific habitus and breast problem. Today, the resourceful radiologist and technologist can rely on a great variety of positioning techniques to improve breast cancer detection and facilitate the evaluation of breast abnormalities.

This section provides a guide to performing: 1) the standard views for screening, 2) views used to localize the exact position of an abnormality in the breast, and 3) views used to better define the nature of an abnormality. Methods for performing mammograms under special circumstances, with challenging patients, for example, are also included. The views are named in accordance with new ACR recommendations for standardized mammographic terminology. Table 1 presents each of the views discussed in this section, along with its new recommended labeling code and its purpose.

Table 1. STANDARDIZED TERMINOLOGY AND ABBREVIATIONS FOR VIEWS

	Labeling Code	Purpose
Laterality		
Right	R*	
Left	L*	
Projection/View		
Mediolateral oblique	MLO	Standard View
Craniocaudal	CC	Standard View
90° Lateral		
Mediolateral	ML	Localize, define
Lateromedial	LM	Localize, define
Spot compression		Define
Magnification	M*	Define
Exaggerated craniocaudal	XCCL	Localize
Cleavage	CV	Localize
Axillary tail	AT	Localize, define
Tangential	TAN	Localize, define
Roll	RL (rolled lateral)†	Localize, define
	RM (rolled medial)†	Localize, define
	RS (rolled superior)†	Localize, define
	RI (rolled inferior)†	Localize, define
Caudocranial	FB (from below)	Define
Lateromedial oblique	LMO	Define
Superolateral-to-inferomedial oblique	SIO	Define
Implant displaced	ID†	Augmented breast

* Used as prefix before projection (RMMLO = Right Magnification Mediolateral Oblique),

† Used as suffix after projection (LCCRL = Left CranioCaudal upper breast tissue Rolled Laterally;

RCCID = Right CranioCaudal Implant Displaced).

2. LABELING OF MAMMOGRAMS

Mammography films are important medical documents. Standardized labeling of mammograms is important to ensure that films are not lost or misinterpreted. Except for view and laterality, all labels should be placed as far from the breast as possible (See Figure 1). The following labeling guidelines are presented in three groups: (1) those that are currently **required** under the **Mammography Quality Standards Act (MQSA) Final Rules,** (2) those that are **strongly recommended** but are not required under the federal rules, and (3) those that are **recommended** but not required under federal rules.

REQUIRED. A permanent identification (ID) label that contains at least the following information: **facility name, facility location** (at a minimum the location shall include the **city, state and ZIP code**), **patient name** (**first and last**), and **additional patient identification number** (e.g., medical record number or social security number; date of birth is less desirable), and **the date of the examination**.

Radiopaque markers indicating laterality (R/L) and projection/view (MLO, CC) placed near the aspect of the breast closest to the axilla. These radiopaque markers should be placed on the cassette holder so that they can be read directly from overhead. They should not be so large as to be distracting, but large enough to be clearly read. Standardized abbreviations for mammography views have been developed, and these should be used to eliminate confusion from one facility to another (Table 1).

The **technologist who performed the examination** must be identified on the image. Technologist identifiers, such as unique initials, should be placed either on a designated place in the patient ID area or with radiopaque letters on the cassette holder. The facility should maintain a log of the technologists and their identifying initials.

Cassette/screen identification (usually designated by an Arabic numeral written or pressed on the screen). This is used to identify screens with artifacts or defects.

Mammography unit number (or other unique identifier) if there is more than one unit in the facility. Usually this is a Roman numeral.

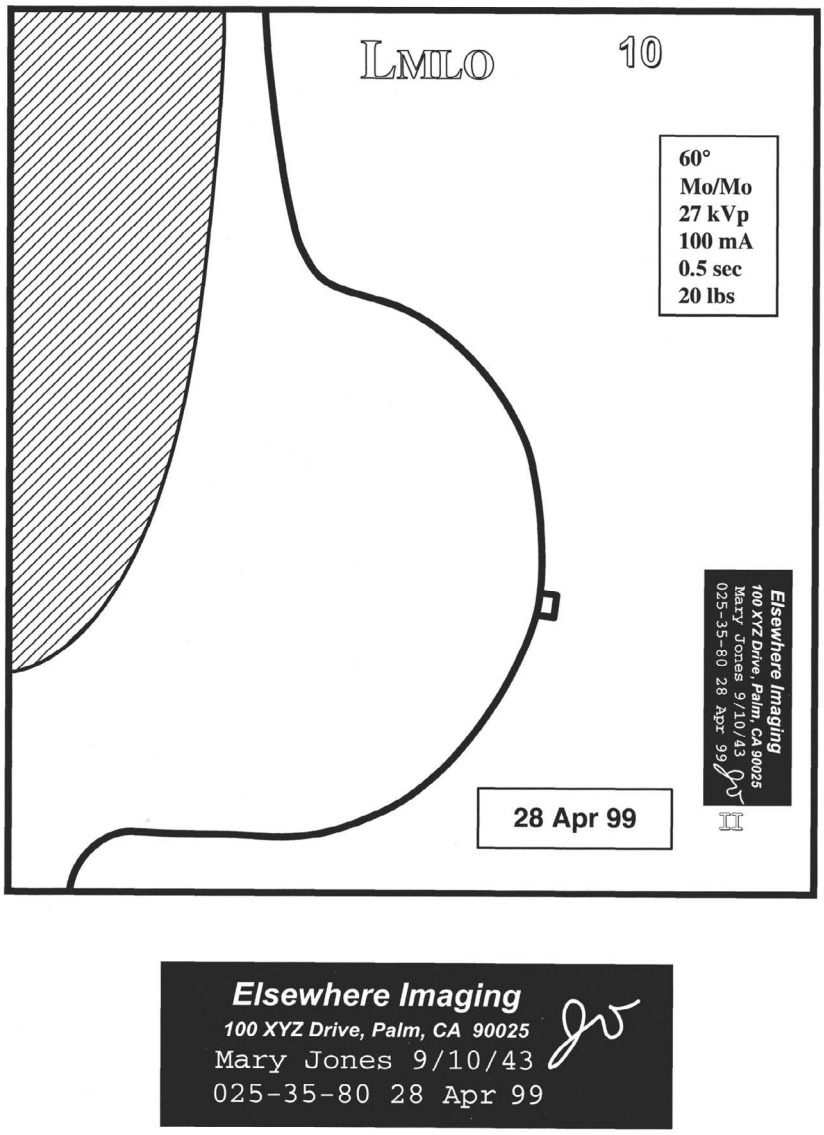


Figure 1. Proper film identification and labeling.

STRONGLY RECOMMENDED. A **flash card** patient ID system is strongly recommended because it is the most **permanent**. An advantage of flash labels over stick-on labels is that flash labels reproduce on copy films. The ID should fit squarely in its designated space, near the edge of the film. A flash system is not acceptable if any information is illegible, does not fit, or is lopsided, causing cut-off of information. If the flash system does not meet these requirements, the radiologist should request the film manufacturer's help in putting together a satisfactory one.

RECOMMENDED. Separate **date stickers** are recommended, as they allow for the date to be easily read with overhead light. They can be color-coded by year to facilitate the sorting of examinations.

It is also recommended that **technical factors** appear on the film: target- filter, kVp, mAs, exposure time, compression force, compressed breast thickness, and degree of obliquity.

MQSA REQUIREMENTS:

Mammographic image identification. Each mammographic image shall have the following information on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

- **(i) Name of patient and additional patient identifier**
- **(ii) Date of examination**
- **(iii) View and laterality. This information should be placed on the image near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.**
- **(iv) Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.**
- **(v) Technologist identification**
- **(vi) Cassette/screen identification**
- **(vii) Mammography unit identification, if there is more than one unit at a facility**

Except for view and laterality, labels should be placed as far as possible from the breast so as not to distract from evaluating the breast image. Collimating close to the surface of the breast is not recommended because light transmitted through clear areas of the film adversely affects film viewing (Figure 2A). Collimating close to the edge of the breast does not significantly improve image contrast since there is virtually no X-ray scatter from air. Therefore, collimation should be to the edge of the film so that as much of the film as possible will be exposed (Figure 2B).

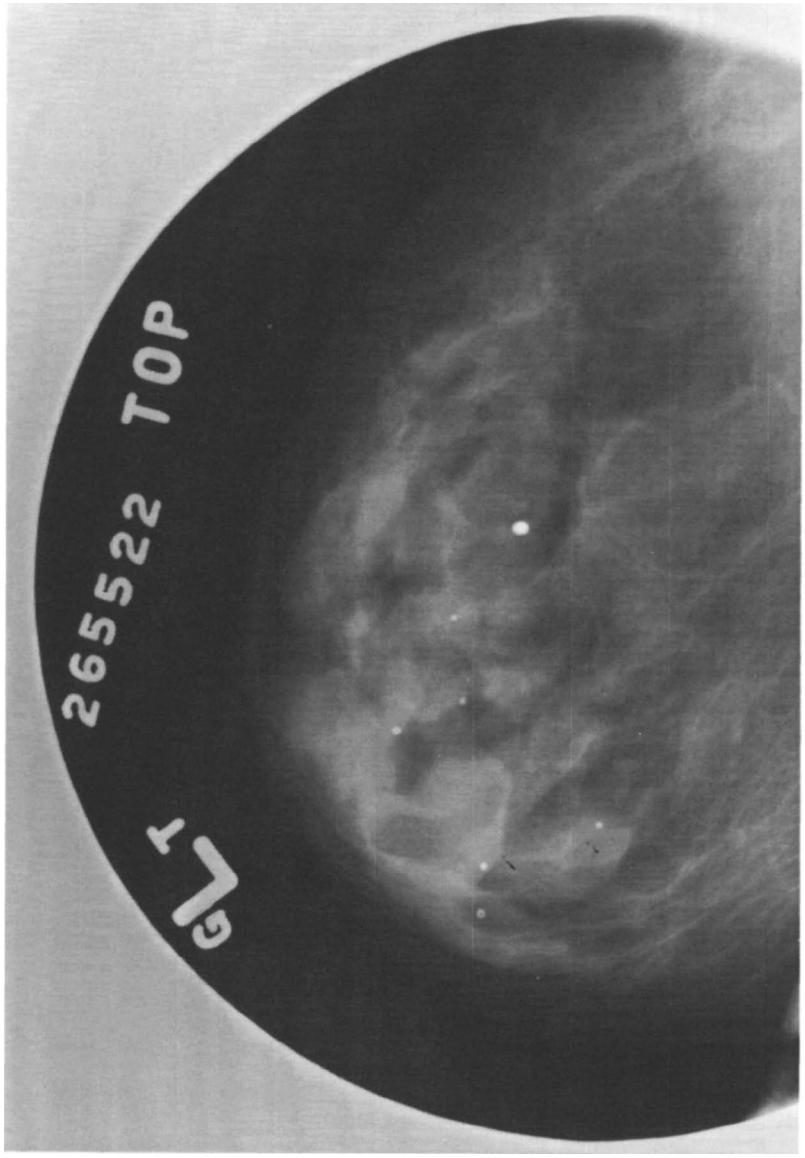


Figure 2A. Incorrect collimation. Image is collimated too close to the breast, leaving a large amount of unexposed film, which results in excessive ambient light from the viewbox reaching the radiologist's eyes. Film labeling is also incorrect.

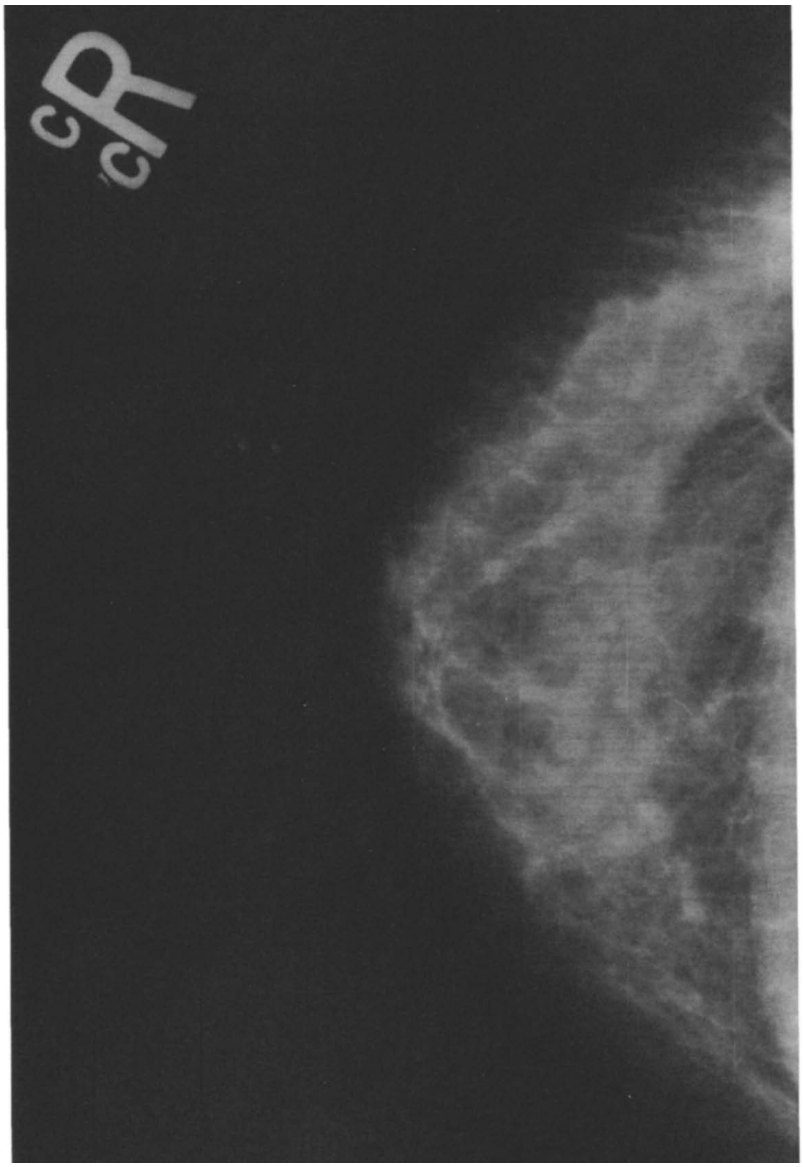


Figure 2B. Correct collimation with proper laterality/view marker.

3. BREAST COMPRESSION

Breast compression and patient positioning are major considerations in obtaining consistently high-quality mammograms. Properly applied compression is one of the most neglected and most important factors affecting image quality in mammography. The primary goal of compression is to uniformly reduce the thickness of the breast so it is more readily and uniformly penetrated by the X-ray beam from subcutaneous region to chest wall (Figures 3A and B). This is best achieved with a rigid compression with a 90° angle between the posterior and inferior surfaces. A compression device with a rounded

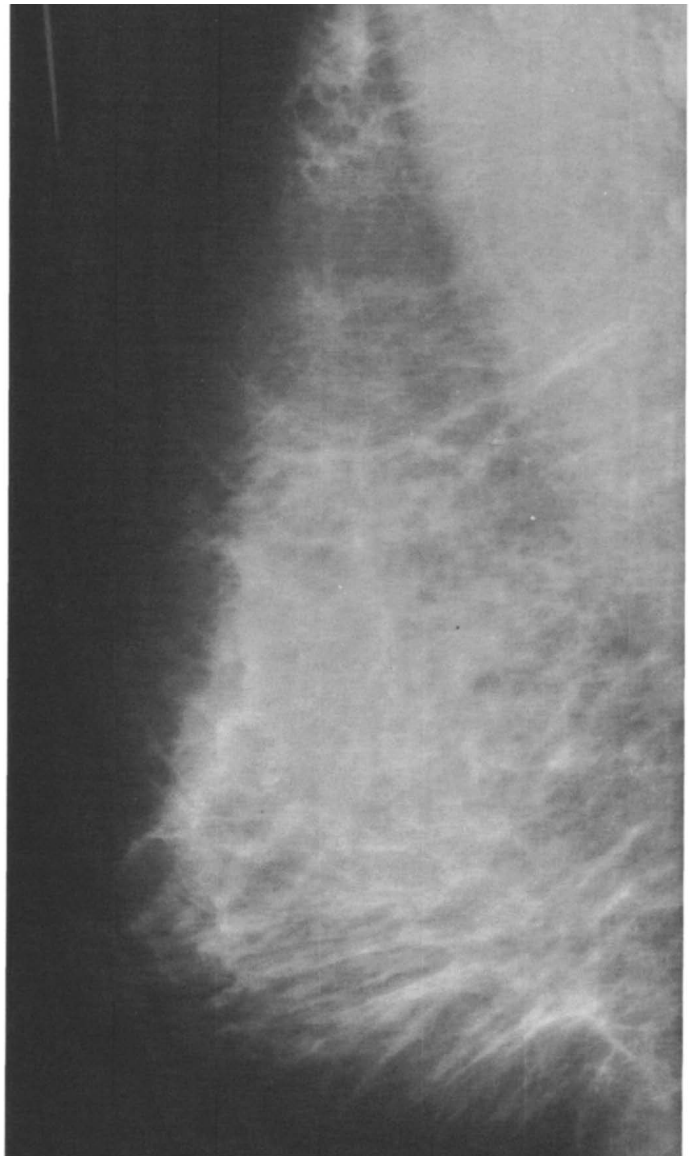


Figure 3A. Inadequate compression. MLO view shows inadequate separation of the fibroglandular tissues, motion blurring of the linear structures, and underexposure. Each of these findings is related to inadequate compression.

or gently sloping posterior edge will not uniformly compress the deep breast tissue or hold it firmly in place during exposures. In addition, a straight rather than rounded contour along the posterior surface of the compression device is required. This is because compression of the breast tissue should be uniform along the posterior aspect of the mammography film, which is straight and not curved. During compression, the compression plate should remain parallel to the plane of the image receptor. Under MQSA, it may not deflect by more than 1 cm, unless designed to do so. This is particularly important with the low-energy (25-30 kVp), less-penetrating X-ray beams that are used in mammography.

There are other important reasons why proper compression is essential for mammography. Compression reduces the object-to-image receptor distance, reducing geometric blurring. Compression separates structures within the breast. Proper compression results in more uniform film optical density by flattening the breast to a more uniform thickness, facilitating the distinction between more compressible, less dense benign structures such as asymmetric normal tissue and cysts, and less compressible, denser malignant lesions. By reducing the breast thickness, proper compression reduces the breast dose needed for a proper exposure and improves contrast by decreasing scattered radiation. Furthermore, proper compression immobilizes the breast, lessening the chance of motion blurring (Figure 3B).

A well-designed and properly applied compression device, combined with a technologist's skill in gently but firmly pulling the breast onto the receptor, will maximize the amount of breast tissue that can be imaged. Mammographic systems that feature some type of foot pedal to control the downward movement of the compression device enable the technologist to use both hands for breast positioning. All mammography units will be required to have power-driven compression by October 28, 2002.

Because the use of proper compression is so crucial, it is important to define the amount of compression desired in mammography today. In some cases, in an attempt to be kind to the patient, the technologist does not apply adequate breast compression, resulting in poor image quality and higher patient dose. The overall result is not beneficial to the patient. On the other hand, if compression is too vigorous, women will find the examination unacceptable—a disincentive to return for periodic screening mammograms. Ideally, the degree of compression should be determined by two factors: the maximum degree to which the individual patient's breast can actually be compressed and the amount of compression that the patient can tolerate at that time. Ideally the breast should be compressed until the tissue is taut: gentle tapping will not indent the skin when breast compression is **taut**. At a maximum, compression should be less than painful.

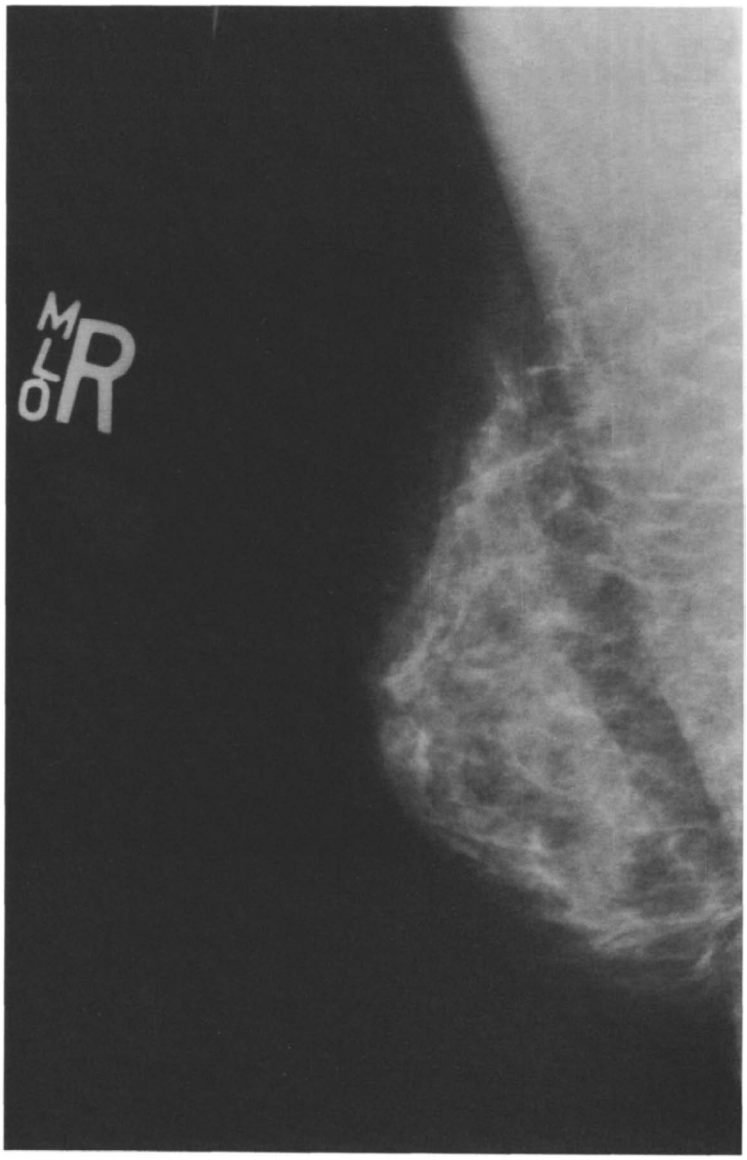


Figure 3B. Adequate compression. MLO view of another patient shows separation and uniform density of fibroglandular tissues and good detail of the linear structures.

Patients can often tolerate more compression if they are prepared for it and if it is applied slowly rather than unexpectedly and all at once. Before beginning the examination, it is critical that the technologist establish a rapport with the patient. The informed patient, educated as to what compression is, how long it will last, and why it is important, will tolerate more compression. It should be explained that compression may be uncomfortable, but should not be painful, and that compression will greatly improve the quality of the examination. For some women, the breasts may become very sensitive just before or during menstruation or occasionally at other times in the menstrual cycle. For these women, mammography should be scheduled at a time when the breasts are least sensitive. For patients whose breasts are particularly

sensitive, medications that relieve breast tenderness, such as those with ibuprofen, may be taken prior to the mammographic examination.

The compression device and top of the cassette holder ("bucky" assembly) should be cleaned after each patient. The manufacturer's specific recommendations should be followed in order to avoid damage to the compression plate. See Section VI of the Radiologic Technologist's Section of this manual.

4. PATIENT POSITIONING

STANDARD VIEWS

The mediolateral oblique and craniocaudal views are routinely performed for all mammographic examinations, and these two views suffice for a screening examination. Since they may be the only views done, it is essential that they be performed optimally. Proper breast positioning is based on an understanding of the normal anatomy and the normal mobility of the breast. **The mobile aspects of the breast are the lateral and inferior margins; the medial and superior margins are fixed.** The principle of mobile versus fixed tissue is used in breast positioning to maximize the amount of tissue that can be visualized. The objectives are to (1) move the mobile tissues rather than the fixed tissues and, (2) avoid moving the compression plate against the fixed tissues.

While it is desirable to have the nipple in profile on the routine views, the primary goal in breast positioning is to show as much tissue as possible. Therefore, breast tissue should not be sacrificed to show the nipple in profile. The nipple should be shown in profile in at least one view. When the nipple is not shown in profile on any view, an extra view for nipple profile can be done.

MEDIOLATERAL OBLIQUE (MLO)

The properly performed mediolateral oblique (MLO) view offers the best opportunity to visualize the maximum amount of breast tissue in a single view. For the MLO, the plane of the cassette holder is angled 30° to 60° from the horizontal, so that the cassette is parallel to the pectoral muscle. The X-ray beam is directed from the superomedial to the inferolateral aspect of the breast. In order to image the maximum amount of tissue, it is imperative that the angle of the image receptor is parallel to the angle of the pectoral muscle of the individual patient (Figure 4A). To determine the angle of the pectoral muscle, the technologist places her fingers in the patient's axilla behind the muscle. The patient's shoulder should be relaxed in neutral rotation. The technologist gently moves the pectoral muscle forward to accentuate the movable lateral border (Figure 4B). Tall, thin patients will require a steeper (50°-60°) angle than short, heavy patients (30°-40°). Patients of average height and weight will require an angle between 40° and 50°. Using an angle that is not parallel to the pectoral muscle will result in less tissue being imaged. Except in rare cases, the positioning angle is the same for both breasts. Some facilities record the angle used for the MLO on the film so that it can be reproduced for the next examination.

Figure 4A. Mediolateral oblique. Aligning the angle of the bucky to the pectoral muscle.

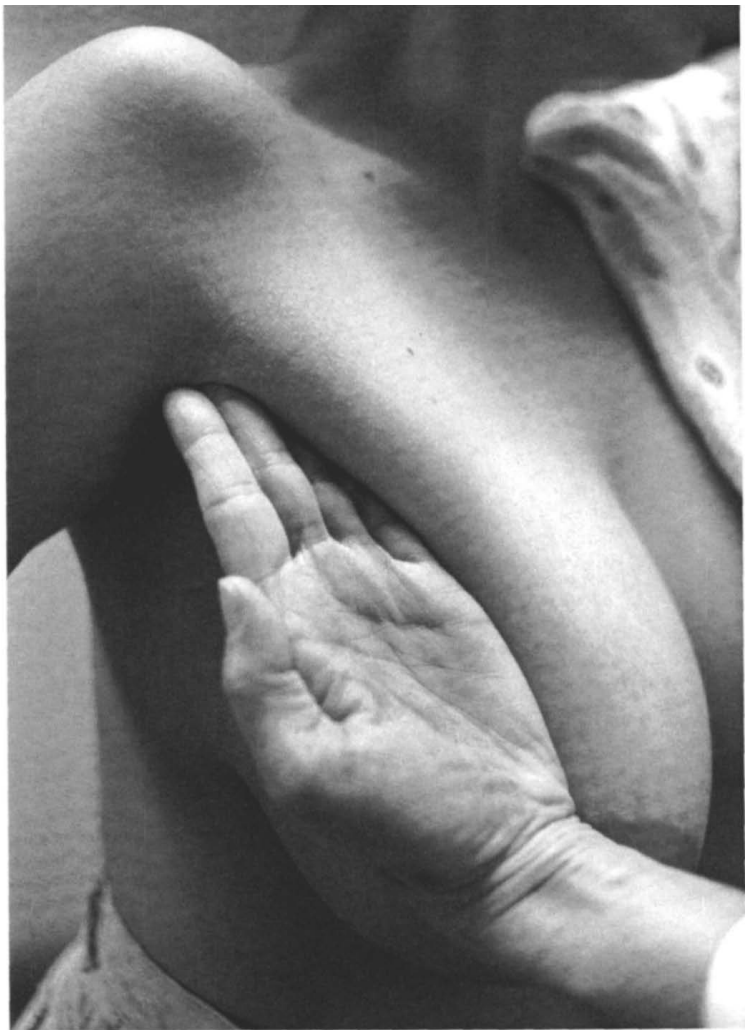


Figure 4B. Mediolateral oblique. Determining the angle of the pectoral muscle.

Applying the principle of moving the mobile tissue toward the fixed tissue, lift the breast, then pull both breast tissue and pectoral muscle anteriorly and medially (Figure 4C). The patient's hand on the side being imaged should be resting on the handlebar. Move the patient's shoulder as close to the center of the bucky as possible. This will place the corner of the cassette holder posterior to the axilla, behind the pectoral muscle, but in front of the latissimus dorsi (Figure 4D). The patient's arm is draped behind the cassette holder with the elbow flexed to relax the pectoral muscle. Rotate the patient toward the cassette holder so that the edge of the cassette holder replaces your hand in maintaining the breast and muscle in its mobilized position (Figure 4E).

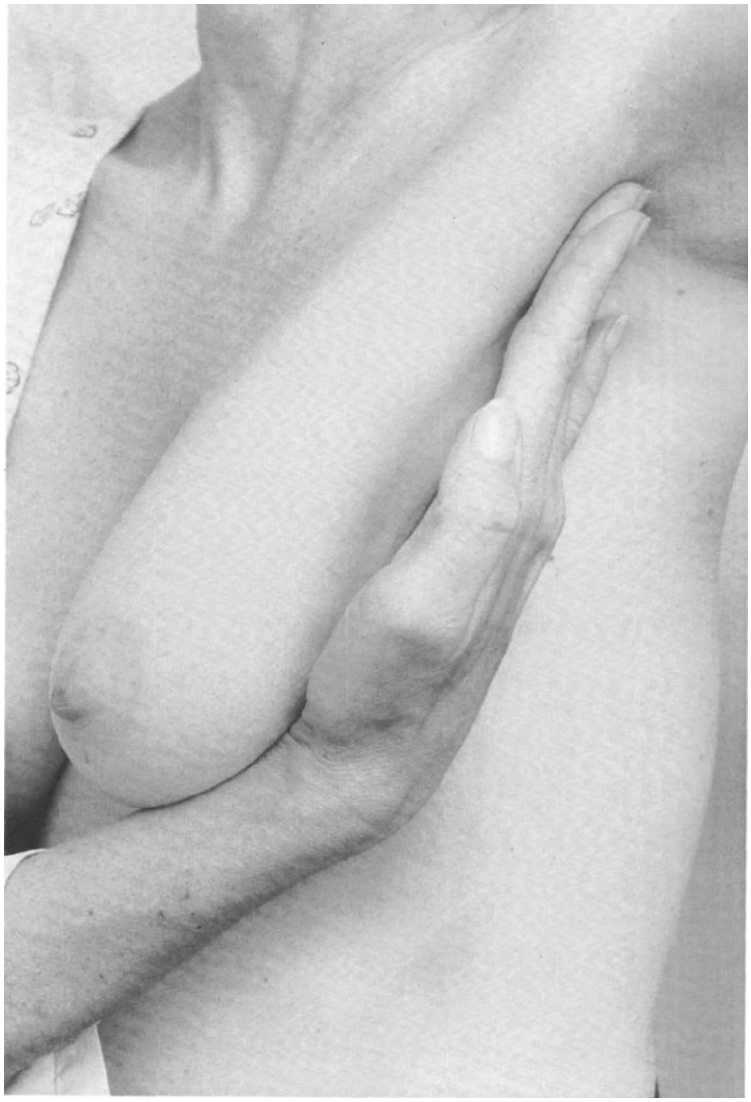


Figure 4C. Mediolateral oblique. Moving the breast and pectoral muscle anteriorly and medially.

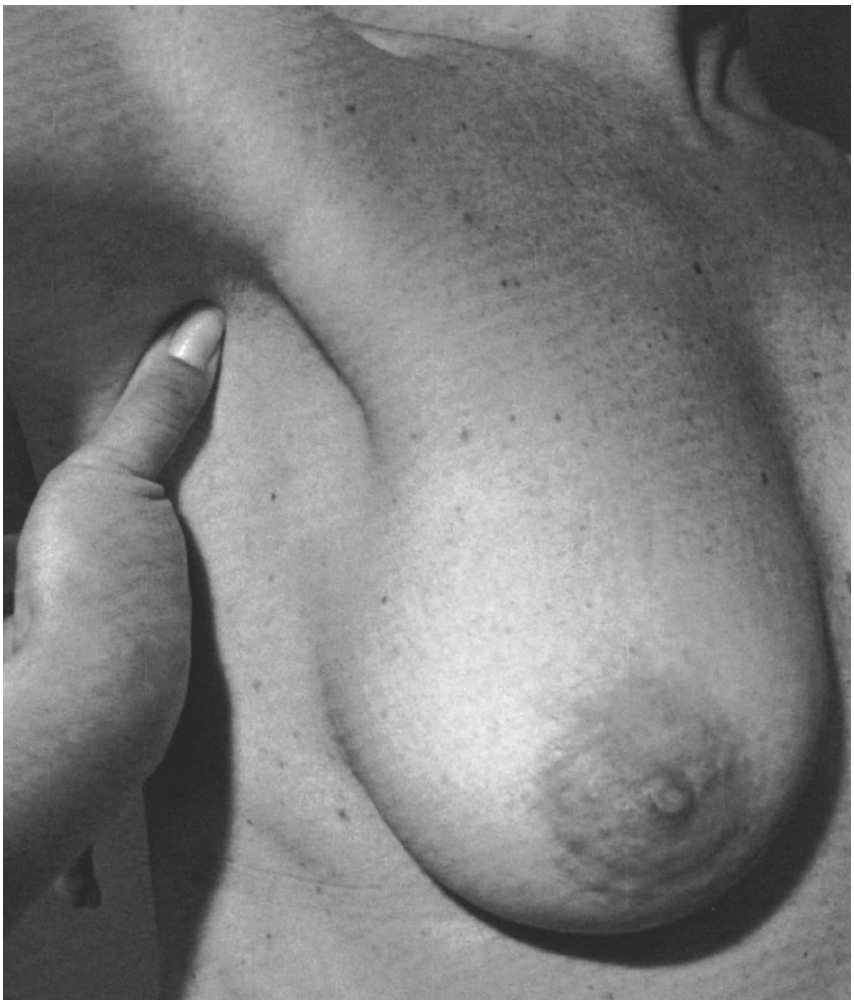


Figure 4D. Mediolateral oblique. The corner of the bucky will be positioned in the posterior aspect of the axilla.

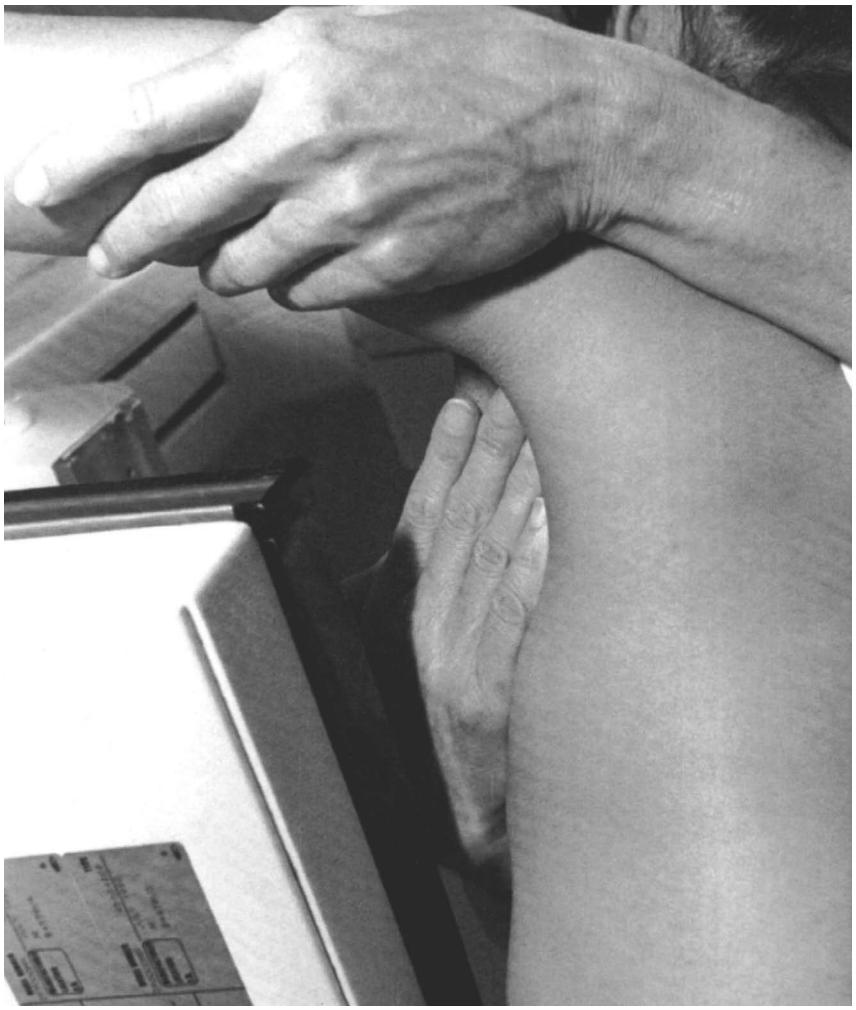
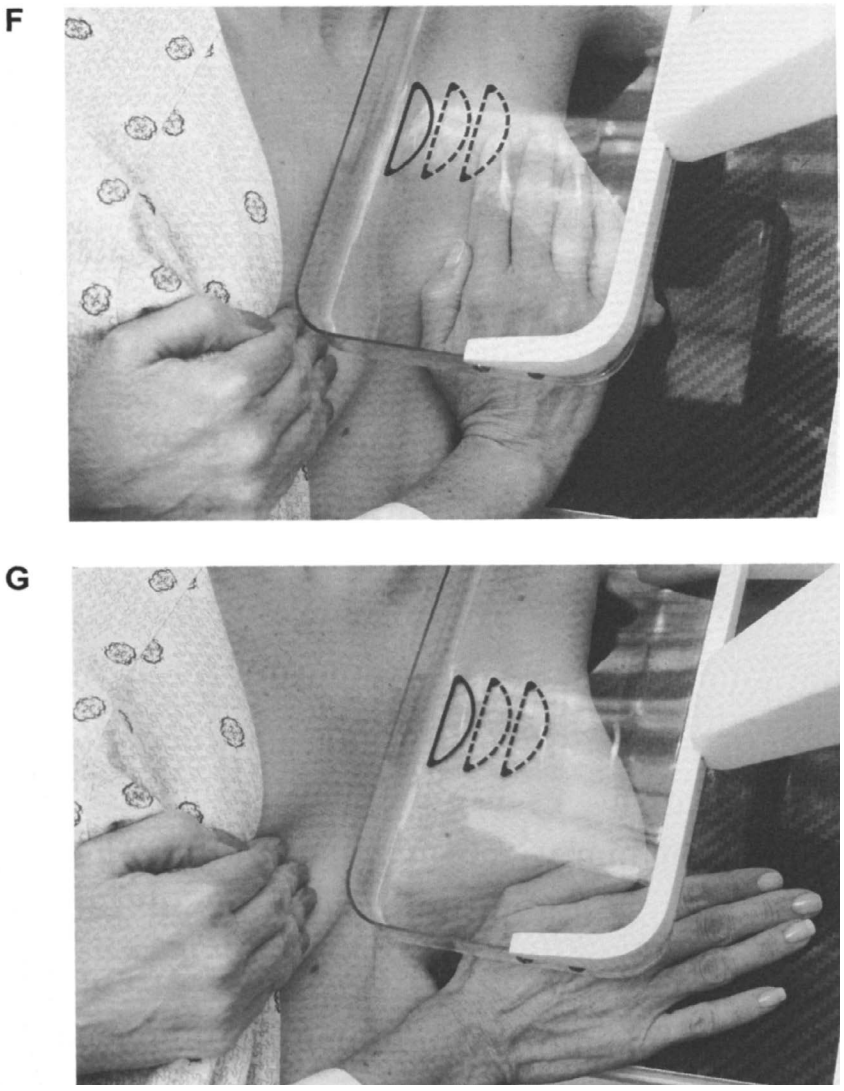
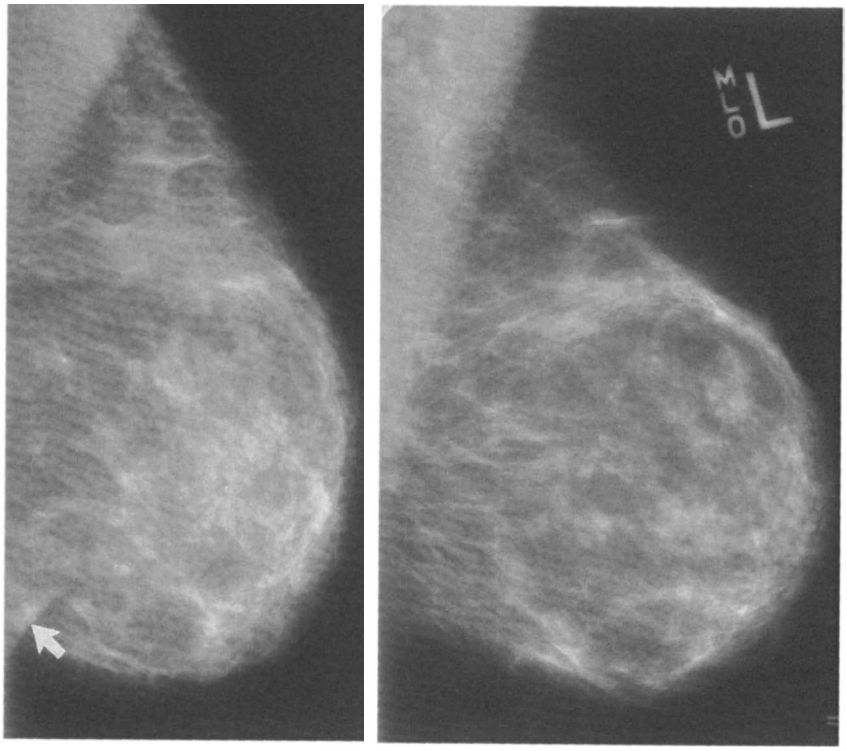


Figure 4E. Mediolateral oblique. The edge of the bucky will replace your hand, maintaining the breast and muscle in their mobilized position.

Hold the breast out and up, away from the chest wall to prevent overlapping of tissue (Figure 4F). Begin to apply compression. After the compression paddle passes the sternum, continue to turn the patient until her hips and feet are facing the mammography unit. The upper corner of the compression paddle should be just below the clavicle. While moving your hand out of the field, continue to support the anterior aspect of the breast with your hand until there is enough compression to maintain the breast in this position (Figure 4G). We call the combined hand movements the "out-and-up" maneuver. The importance of the out-and-up maneuver cannot be overemphasized. If the hand supporting the breast is removed too soon the breast will fall, resulting in inadequate separation of tissues (Figures 4H and I). The final step involves pulling abdominal tissue down in order to open the inframammary fold (s). The entire breast, from inframammary fold to axilla, should be centered on the cassette holder. (Figures 4K and L). There will be cases where the whole breast cannot be adequately compressed on a single MLO view; and in these cases an additional anterior compression view, either at the same obliquity or at a 90° angle, should be performed



Figures 4F & G. Mediolateral oblique. Out-and-up maneuver.



H I

Figures 4H & I. Mediolateral oblique. Two mammograms of the same patient illustrating the importance of the out-and-up maneuver. Improper performance (H), with hand removed before sufficient compression is applied, results in poor separation of tissues and downward sloping of the breast contour, giving the breast the appearance of a "camel's nose." Note inferior skin fold in H (arrow). Properly executed out-and-up maneuver maximizes separation of breast structures (I).

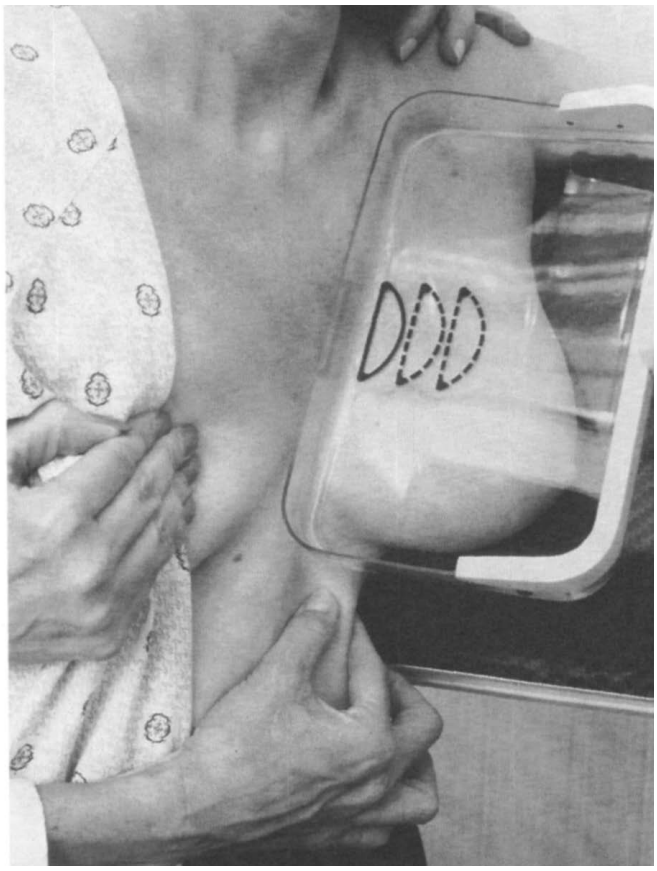


Figure 4J. Mediolateral oblique. Opening the inframammary fold.

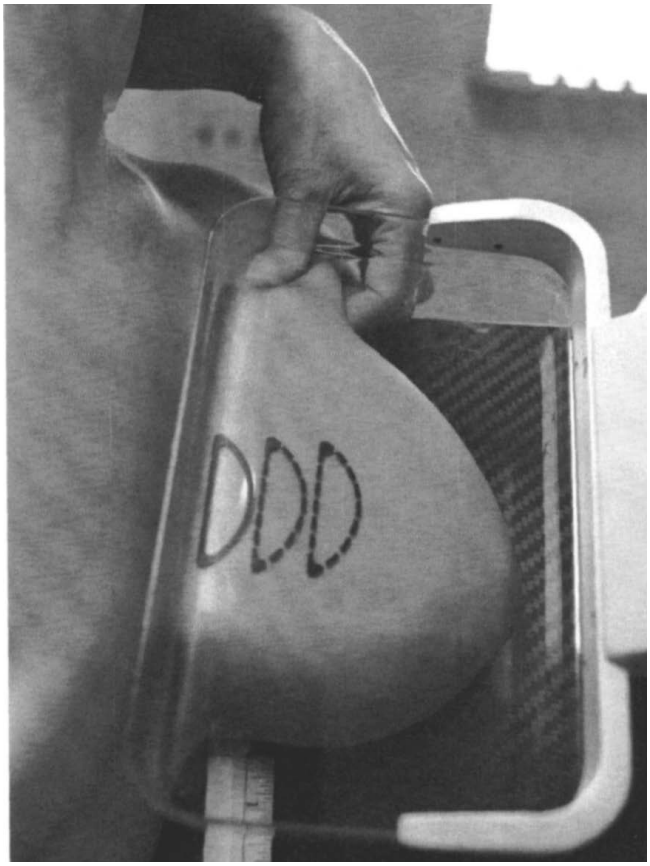


Figure 4K. Mediolateral oblique. Improper centering. The mound of the breast is centered, which results in exclusion of superior tissue.

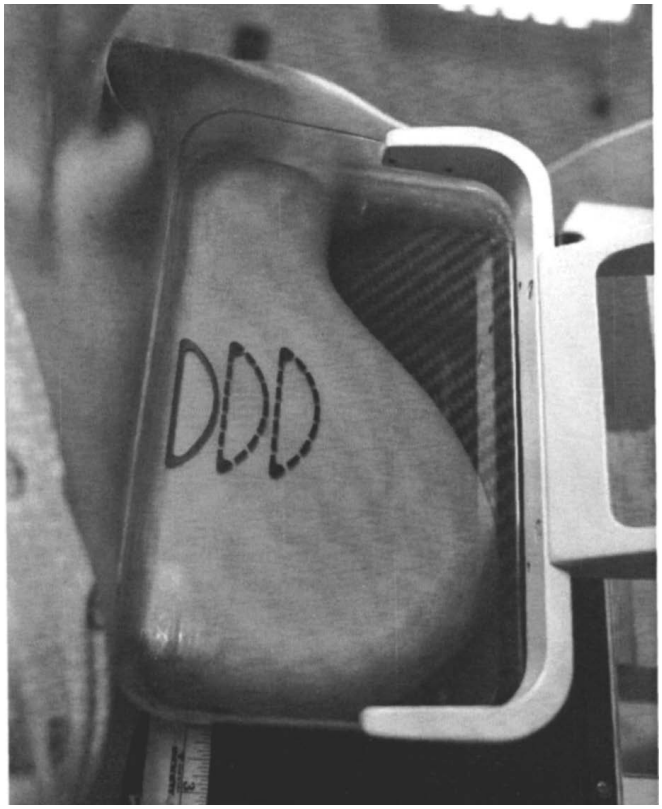


Figure 4L. Mediolateral oblique. Proper centering of the breast.

Criteria on the mammogram indicating that positioning for the MLO is optimal include: (1) pectoral muscle is wide superiorly with a convex anterior border, extending to or below the posterior nipple line; (2) fat is visualized posterior to all of the fibroglandular tissues; (3) deep and superficial breast tissues are well separated; (4) close inspection shows no evidence of motion blur; and (5) the inframammary fold is open (Figure 4M).

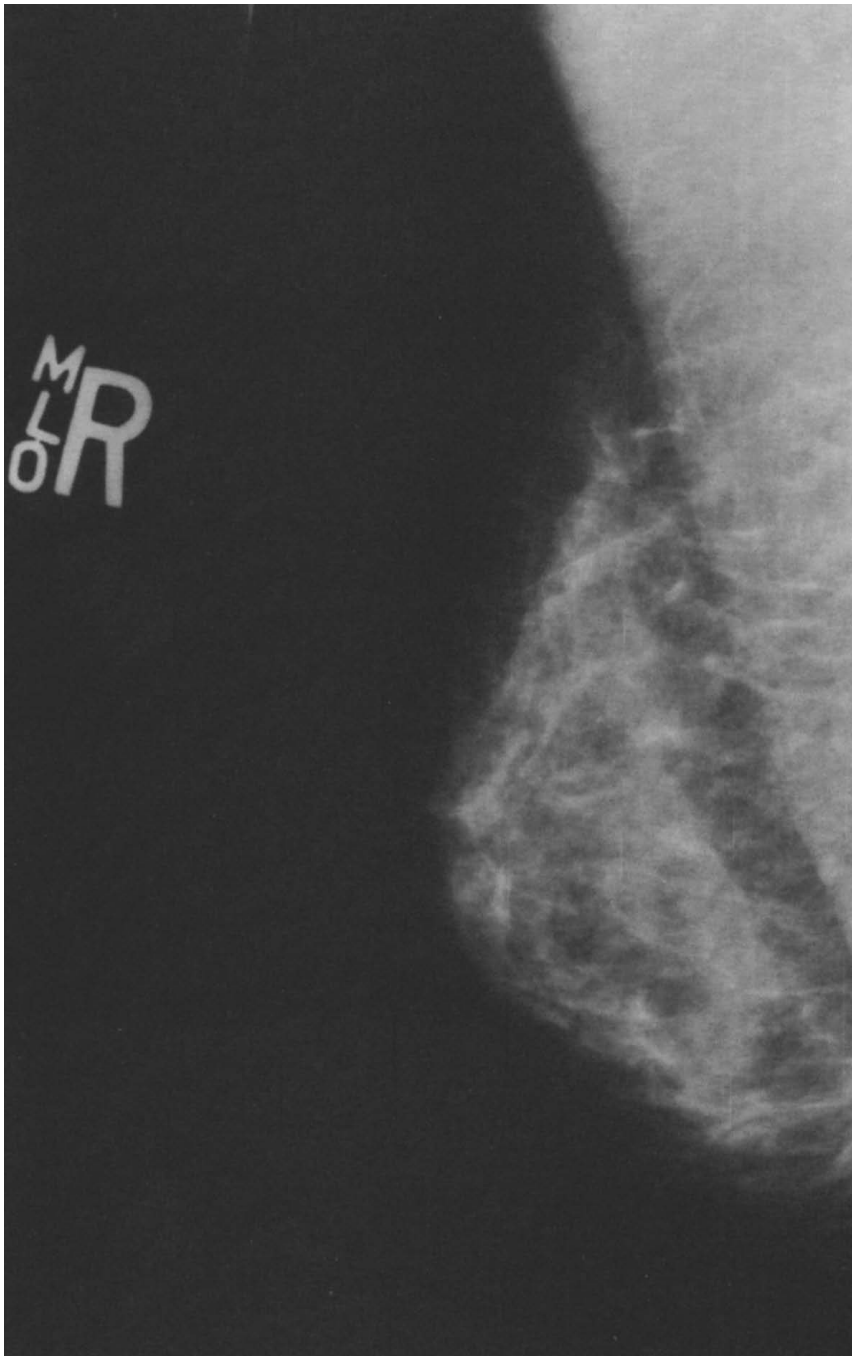


Figure 4M. Mediolateral oblique. Properly positioned MLO.

CRANIOCAUDAL CC

The craniocaudal view should be done in such a manner as to ensure that any tissue that may have been missed on the MLO will be depicted on the CC. If any tissue is missed on the MLO, it is likely to be the medial tissue. Therefore, it is necessary to demonstrate as much of the medial tissue as possible on the CC projection. This should be done along with visualizing as much lateral tissue as possible and can be accomplished without excessive exaggeration to the medial or lateral side by performing the **CC** in the following manner.

The technologist will have more control over patient positioning if she stands on the medial side of the breast being examined. As with the MLO, the principle of mobile versus fixed margins is used. Lift the mobile inframammary fold (IMF) as high as its natural mobility will allow (Figures 5A and B). This distance may range from 1-1/2 to 7 cm from the neutral position. Raise the cassette holder to meet the edge of the elevated IMF. With one hand under the breast and the other on top of the breast, gently pull breast tissue away from the chest wall and position the nipple in the center of the cassette holder (Figure 5C). This two-hand technique gently pulls the breast tissue away from the chest wall to maximize the amount of breast tissue visualized. With one hand placed on top of the breast near the chest wall, hold the breast in this position (Figure 5D).

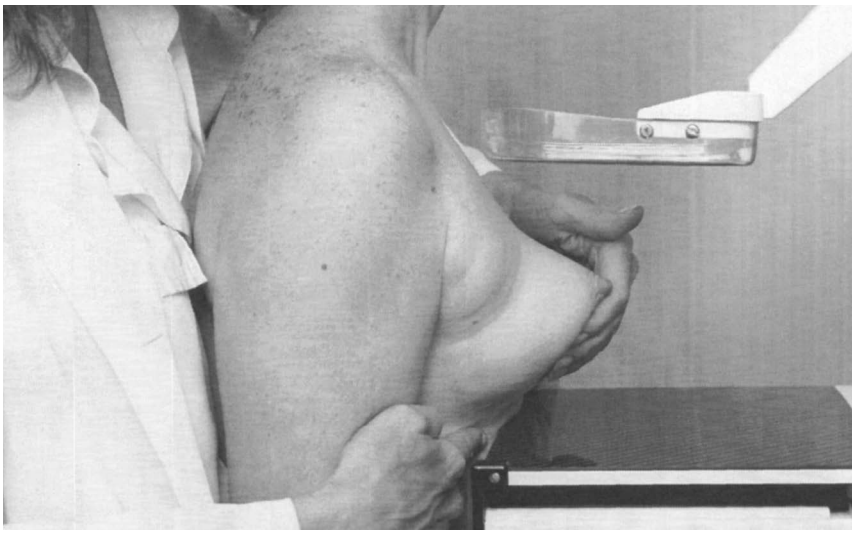


Figure 5A. Craniocaudal. Incorrect position of bucky at the level of the neutral (not elevated) inframammary fold (IMF).

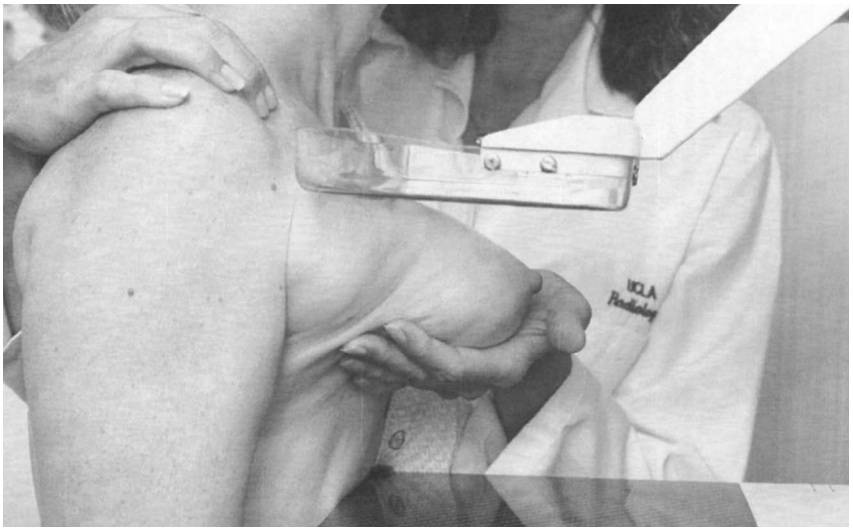


Figure 5B. Craniocaudal. Elevating the IMF.

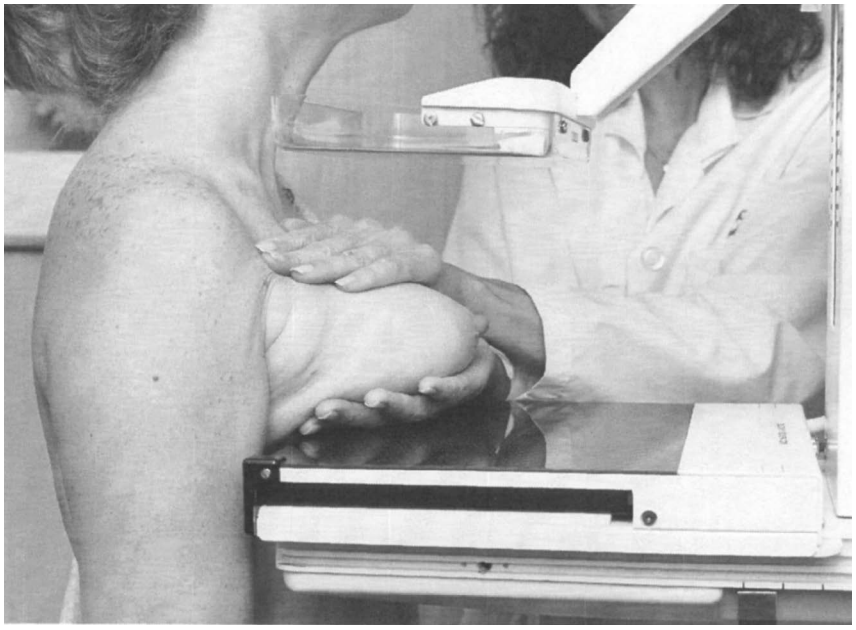


Figure 5C. Craniocaudal. Using both hands for positioning. Both hands pull the breast onto the bucky.

Lift the contralateral breast, rotating the patient until the chest wall edge of the bucky is flush against the sternum (Figure 5E). Drape the contralateral breast over the corner of the cassette holder (rather than placing it behind the cassette holder). Bring the patient's head forward around the tube

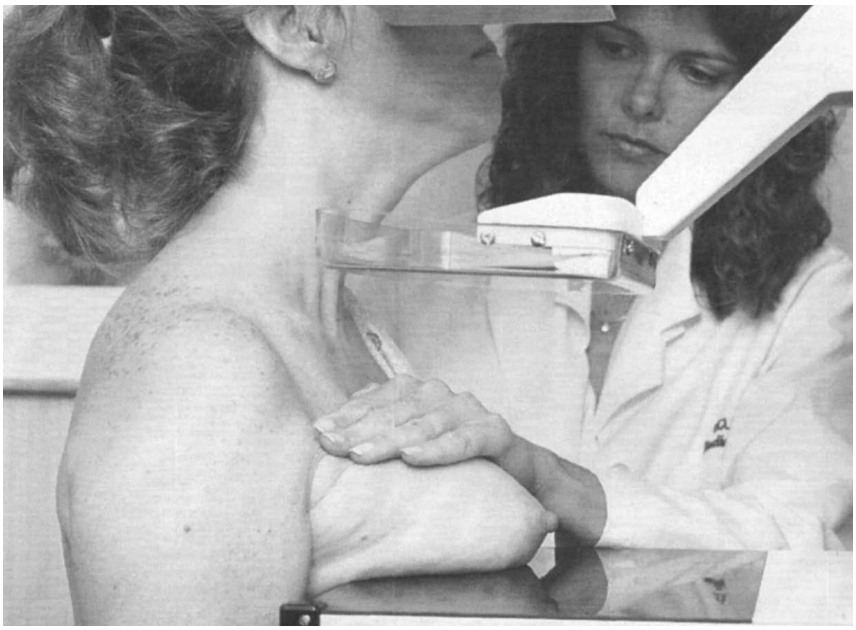


Figure 5D. Craniocaudal. Using both hands for positioning, the technologist uses one hand to hold the breast in place.

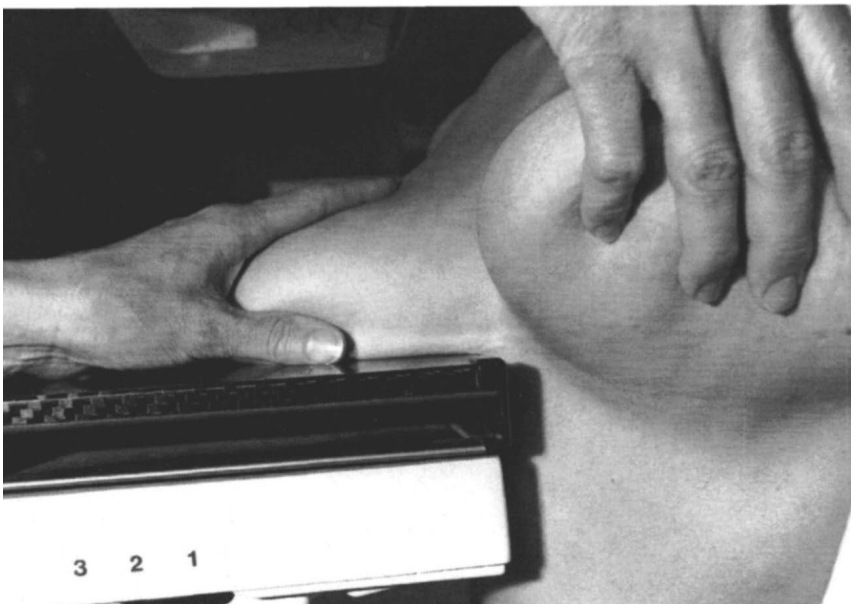


Figure 5E. Craniocaudal. While lifting the contralateral breast to rotate the patient until the sternum is against the bucky.

assembly. This will enable the patient to lean into the machine, in order to position the superior breast tissue over the image receptor. Bring the patient's arm on the side not being imaged forward to hold onto the handlebar. These maneuvers will improve visualization of medial tissue.

The next maneuver will improve visualization of the posterior lateral tissue. Using the hand that is on top of the breast, reach past the chest wall edge of the cassette holder to lift the posterior lateral aspect of the breast onto the cassette holder. This should be done without rotating the patient (Figure 5F). The technologist's arm is placed behind the patient's back with her hand resting on the shoulder near the base of the neck of the side being examined (Figure 5G). This allows the technologist to use her hand to keep the patient's shoulder "relaxed down" while at the same time applying gentle pressure to her back to prevent her from pulling away from the mammography unit. Using the fingers of the hand on the shoulder, slide the skin up over the clavicle to relieve any pulling sensation on the patient's skin during subsequent compression. As compression is applied, move the hand holding the breast toward the nipple while smoothing lateral tissue forward to eliminate folds. On the side being imaged, the patient's arm hangs relaxed by her side with the humerus externally rotated (Figure 5H).

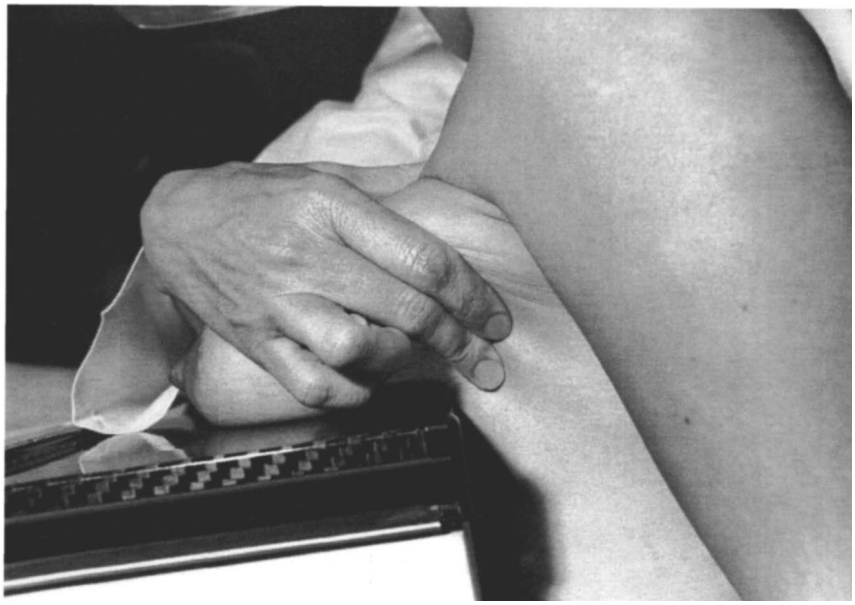


Figure 5F. Craniocaudal. Lift and pull the posterior lateral aspect of the breast onto the bucky.

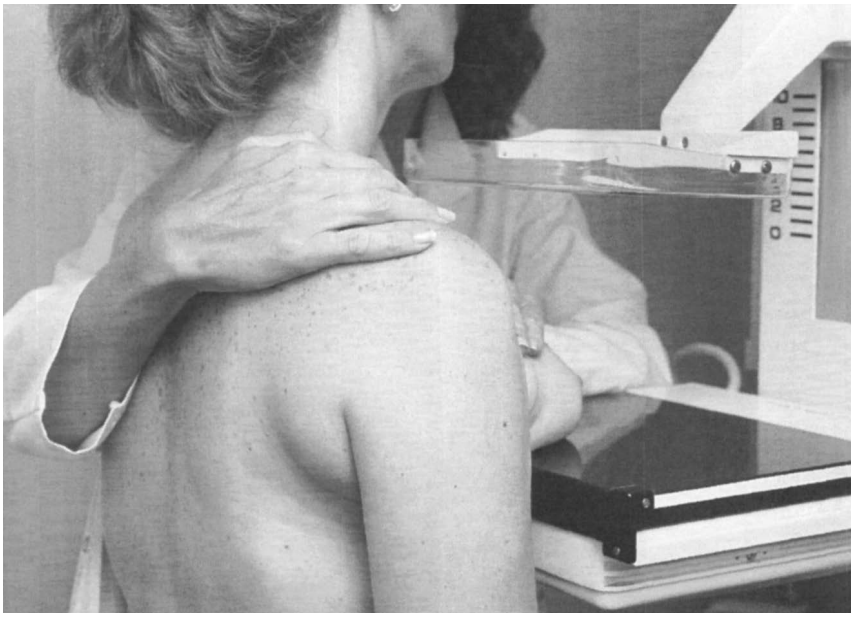


Figure 5G. Craniocaudal. The technologist's arm is placed behind the patient's back with the hand on the patient's shoulder.

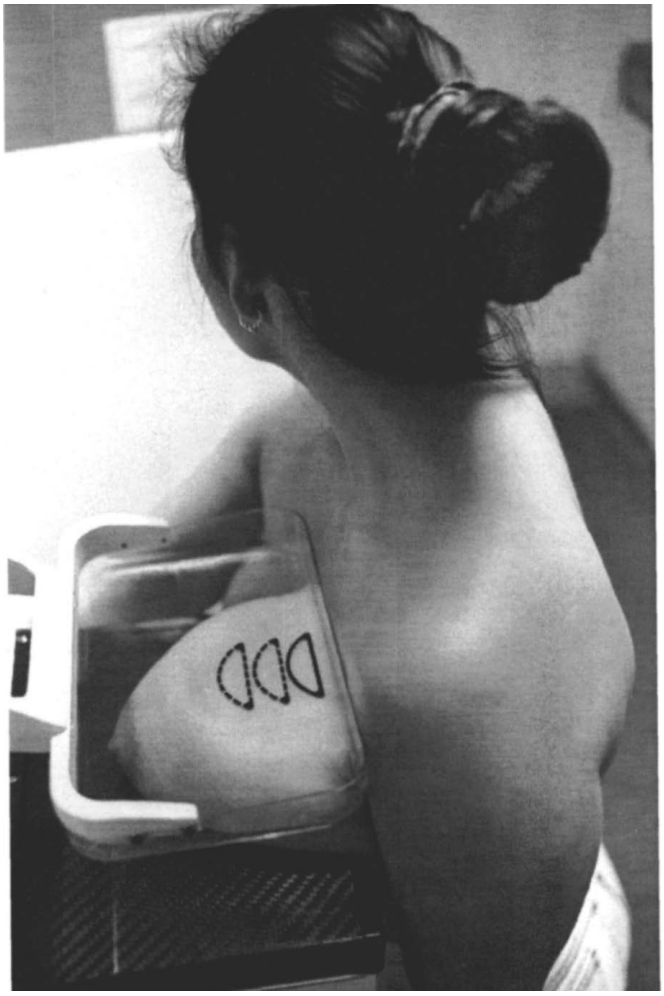


Figure 5H. Craniocaudal. Correct position of breast with compression applied.

This arm position will also remove skin folds. If skin folds are still present, slide your finger under the compression device and use it to roll out the skin fold laterally. (Figure 5I).

Incorrect positioning for the CC will result in a significant loss of tissue in the image (Figure 5J). Criteria on the mammogram indicating optimal positioning for the CC include: (1) all medial tissue visualized, (2) nipple centered on the image, and (3) posterior nipple line (PNL) measures within 1 cm of the MLO, or visualization of pectoral muscle (Figure 5K).

Figure 5I. Craniocaudal. The technologist rolls her finger out laterally to remove skin folds.

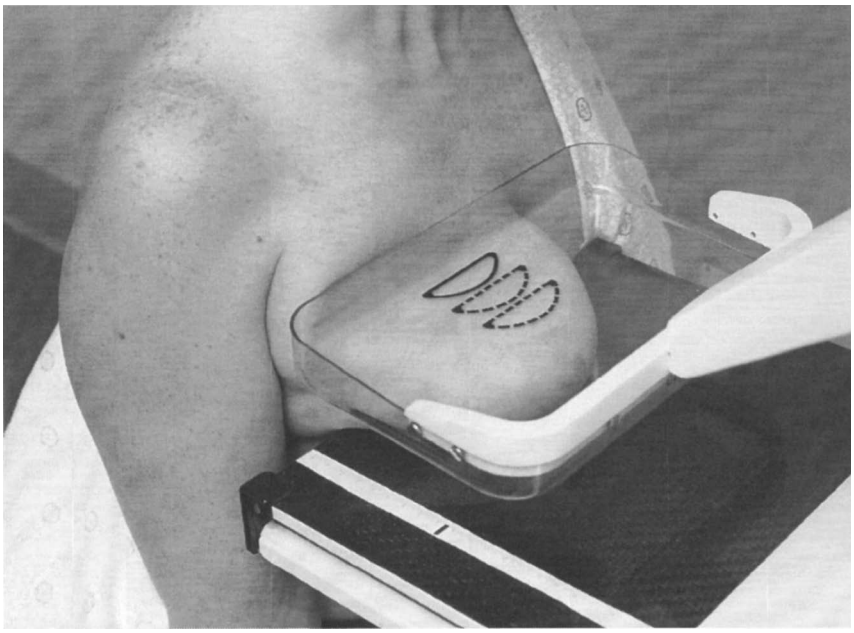


Figure 5J. Craniocaudal. Improper positioning of the CC view. The cassette holder is at the level of the neutral IMF and the breast tissue was placed, not pulled, onto the image receptor. Note the significant amount of superior and posterior breast tissue behind the lip of the compression plate. Measurement line on tape, indicating the position of the nipple, shows that less breast tissue is included than in the properly positioned CC in Figure 5H. Comparing the distance from the shoulder to the lip of the compression plate to that in Figure 5H provides additional evidence of the difference in the amount of breast tissue that will be depicted.

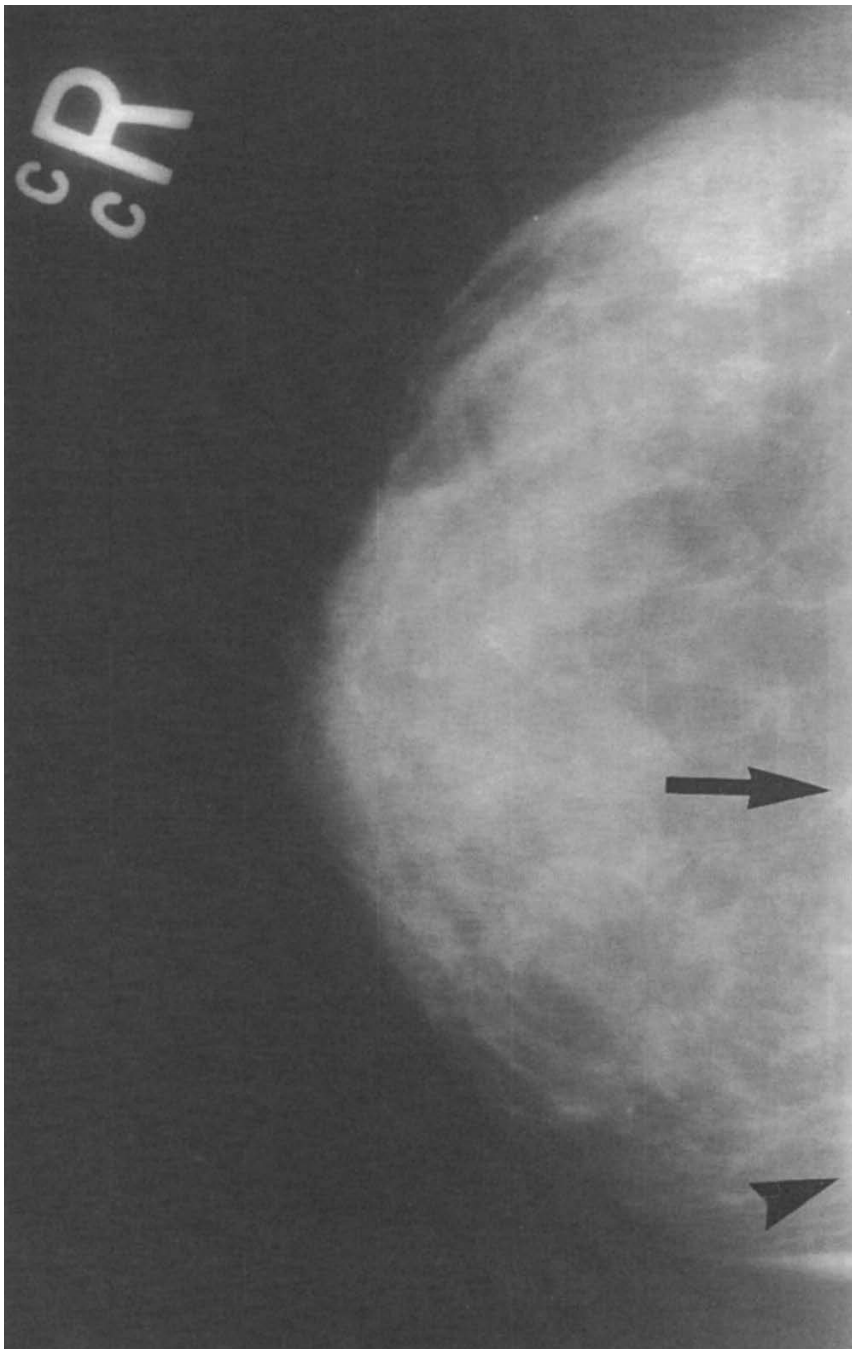


Figure 5K. Craniocaudal. Properly positioned mammogram. Note that all medial tissue is visualized in the image. In this case, pectoral muscle (arrow) and its medial insertion (arrowhead) are visualized.

5. ADDITIONAL VIEWS

90⁰ LATERAL

The 90° lateral (true lateral, straight lateral) view is the most commonly used additional view. This view is used in conjunction with the standard views to triangulate the exact location of lesions in the breast. The 90° lateral view is also used to demonstrate gravity-dependent calcifications (milk of calcium). When an abnormality is seen on the MLO/CC view but not on the standard craniocaudal view, it should first be determined whether it is real, superimposed tissue, artifact on the film, or in the skin. Sometimes, repeating the oblique view with a slightly different angulation or obtaining a 90° lateral view will provide this information.

A change in location of a lesion relative to its distance from the nipple on the 90° lateral view can be used to determine whether the lesion is in the lateral, central, or medial aspect of the breast. For example, if on the 90° lateral view the lesion moves up relative to the nipple or is higher than on the MLO, the lesion is in the medial aspect of the breast. If on the 90° lateral film the lesion moves down relative to the nipple or is lower than in the MLO, the lesion is in the lateral aspect of the breast. If the lesion does not shift significantly in MLO versus 90° lateral films, it is located in the central aspect of the breast.

When an abnormality has been identified, the most appropriate lateral view, medial-to-lateral versus lateral-to-medial, is the one that provides the shortest object-to-image receptor distance, to reduce geometric unsharpness.

MEDIOLATERAL (ML)

For the mediolateral (Figure 6A) view, the tube arm is rotated 90°. The patient's arm on the side being examined is abducted 90° resting across the top of the cassette holder. Again using the principle of mobile versus fixed margins, pull breast tissue and pectoral muscle anteriorly and medially. Lift the breast out and up while gently pulling the breast away from the chest wall. Rotate the patient toward the cassette holder and begin compression. When the compression paddle has passed the sternum, continue rotating the patient until the breast is in a true lateral position centered on the cassette holder. Continue to hold the anterior breast in position while applying compression. Open the inframammary fold by gently pulling abdominal tissue down.

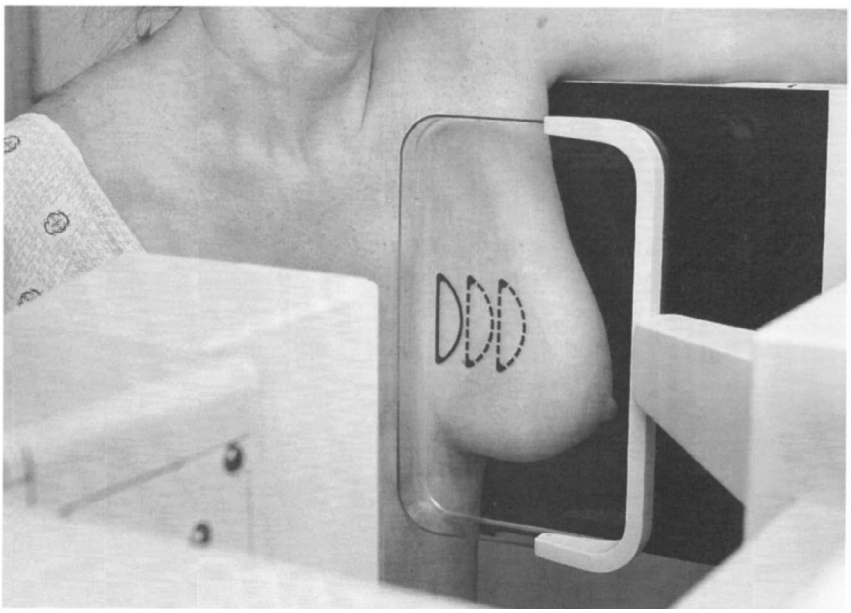


Figure 6A. 90° Lateral. 90° mediolateral.

LATEROMEDIAL (LM)

For the lateromedial (Figure 6B) view, the tube arm is rotated 90° with the top of the cassette holder at the level of the suprasternal notch. The patient is positioned with her sternum against the edge of the cassette holder, her neck extended with her chin resting on the top of the cassette holder. Pull the mobile lateral and inferior tissue up and toward the midline. Begin rotating the patient toward the cassette holder. Bring the compression paddle down past the latissimus dorsi. After the compression paddle has passed the latissimus dorsi, lift the patient's arm on the side being imaged over the cassette holder. The elbow should be flexed to relax the pectoral muscle. Continue rotating the patient until the breast is in a true lateral position centered on the cassette holder. Open the inframammary fold by gently pulling abdominal tissue down.

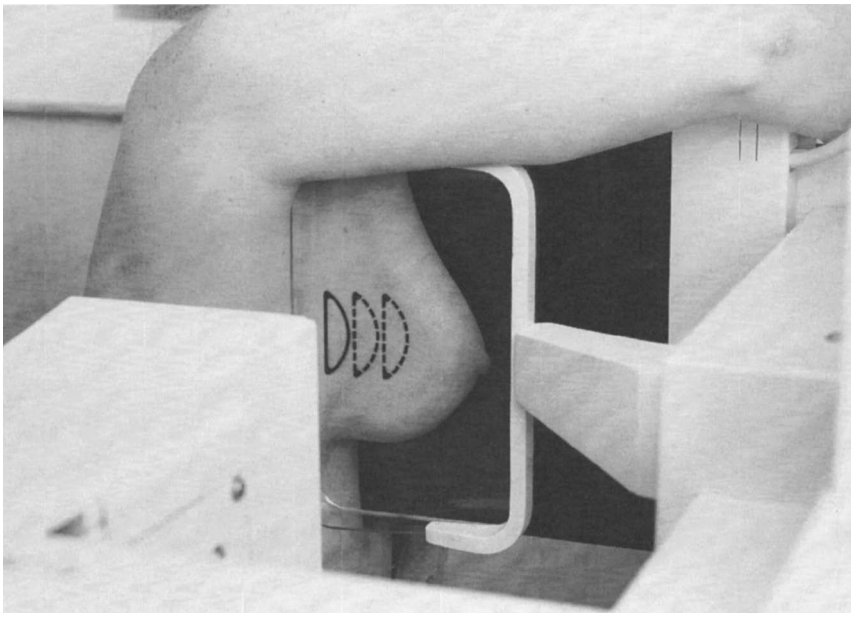


Figure 6B. 90° Lateral. 90° lateromedial.

SPOT COMPRESSION

Spot or coned compression is a simple technique that merits more frequent application. Spot compression views are especially helpful with obscure or equivocal findings in areas of dense tissue. Compared with whole breast compression, spot compression allows for greater reduction in thickness of the localized area of interest, and improves separation of breast tissues (Figure 7A). Spot compression requires collimation to the area of interest. This collimation, combined with the decreased breast thickness, results in higher contrast and more precise evaluation of findings (Figures 7B and C). Variably sized spot compression devices, especially the smaller ones, can facilitate more effective localized compression. Using the original mammogram, the technologist determines the placement of the small compression device by determining the location of the lesion. To determine the location of the lesion, measure (1) the depth relative to a line drawn directly posterior from the nipple, (2) the distance from that line to the lesion in the

Figure 7A. Spot compression. This technique allows for greater localized compression and displaces tissues overlying the area of interest.

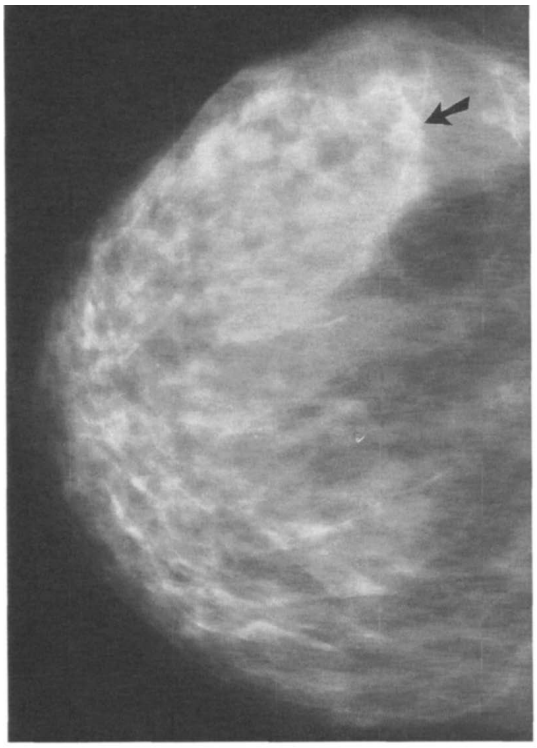


Figure 7B. Spot compression. CC mammogram shows a suspicious density with irregular margins (arrow) that was not present on the MLO.

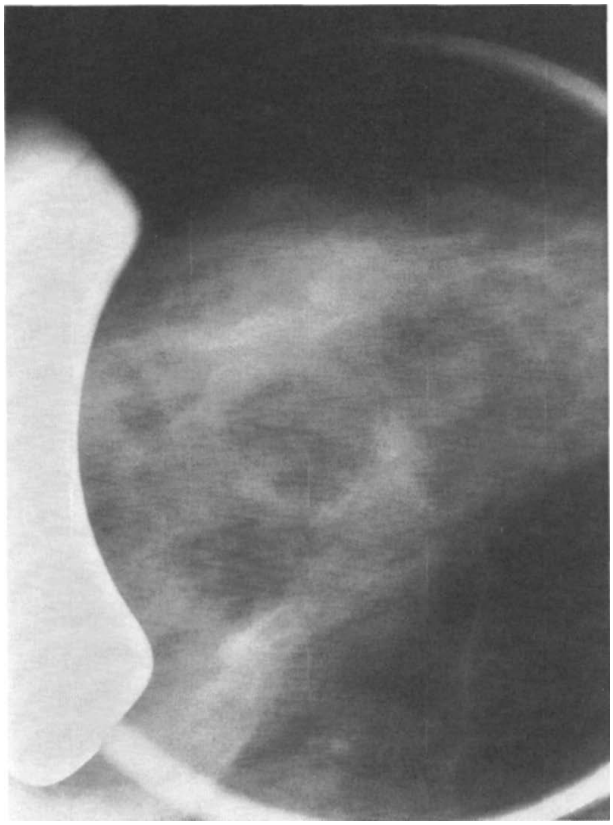
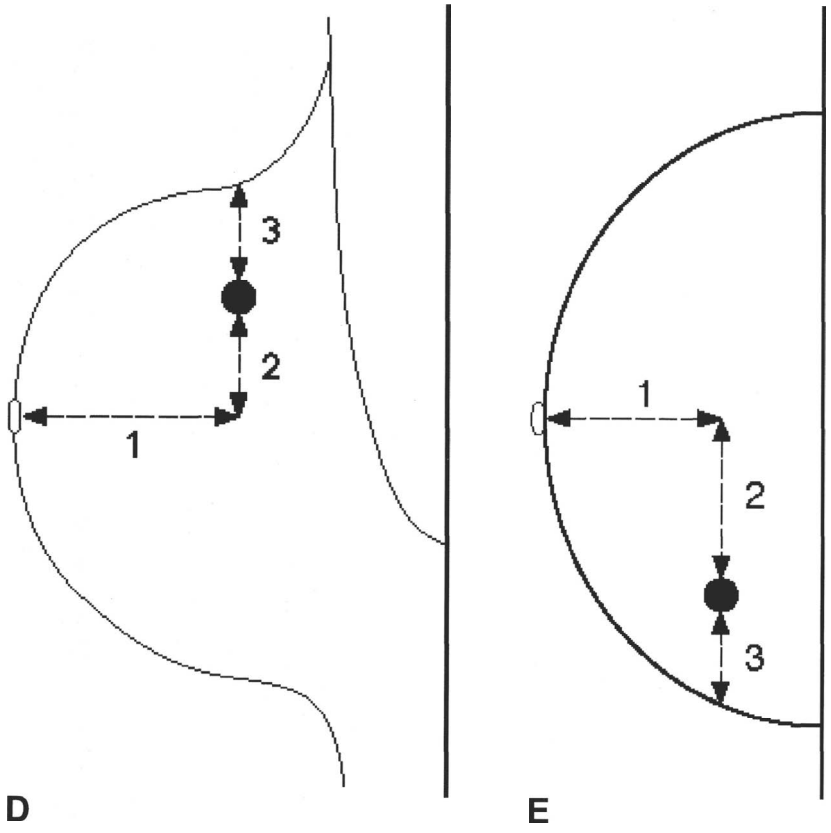


Figure 7C. Spot compression. With spot compression, the density is no longer present, indicating that it represented superimposition of normal tissues.

superior-to-inferior ormedial-to-lateral direction, and (3) the distance from the lesion to the skin surface (Figures 7D and E). Then reposition the patient, using your hand to simulate compression. Transfer the three measurements to the breast and use a marker to identify the location of the lesion (Figures 7F, G and H). Reposition to center the spot compression device over the lesion. Spot compression is often combined with magnification using the small focal spot to improve resolution of detail within the breast.



Figures 7D & E. Spot compression. Applying the three measurements in the MLO (D) and the CC (E) projection. (1) The depth relative to a line drawn directly posterior from the nipple, (2) the distance from that line to the lesion in the superior-to-inferior or medial-to-lateral direction, and (3) the distance from the lesion to the skin surface.

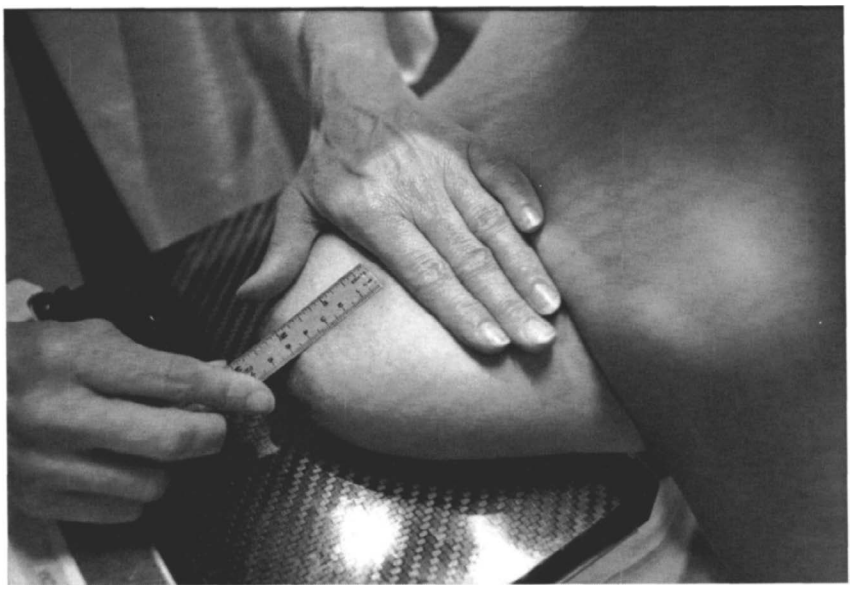


Figure 7F. Spot compression. The location of the lesion is determined from the original films by its distance from the nipple.

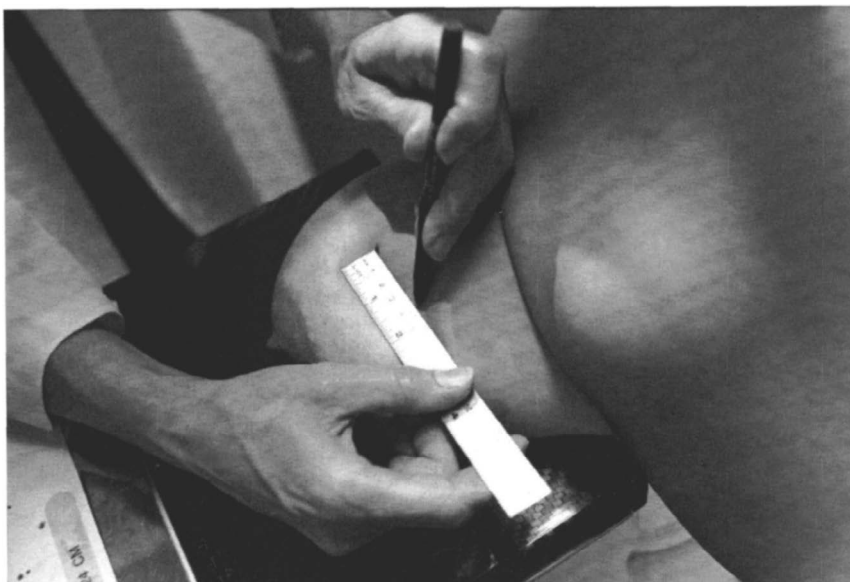


Figure 7G. Spot compression. The distance from that line to the lesion in the lateral direction.

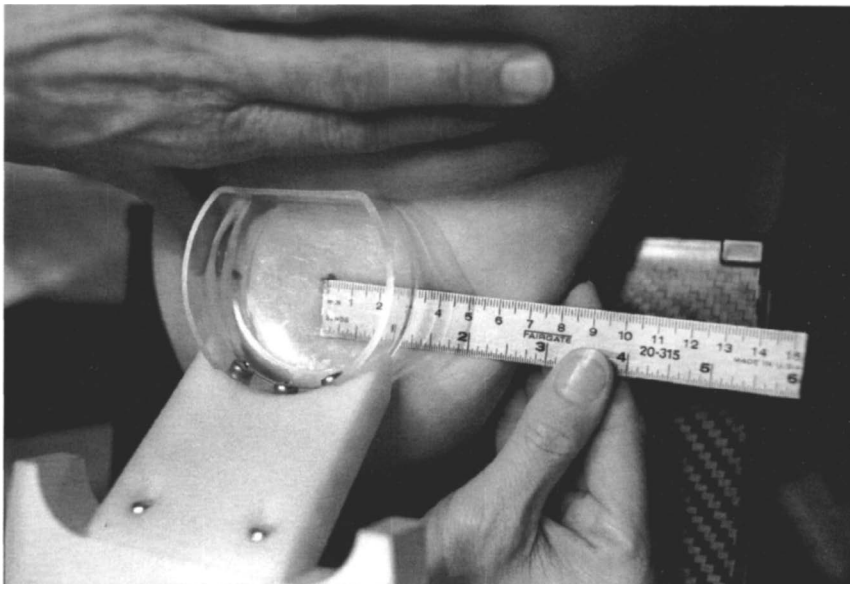


Figure 7H. Spot compression. The distance from the lesion to the skin measured before compression is applied.

MAGNIFICATION (M)

Magnification views with or without spot compression can be helpful in differentiating benign from malignant lesions by permitting a more precise evaluation of margins and other architectural characteristics of a focal density or mass. Magnification views also permit better delineation of the number, distribution, and morphology of calcifications. This technique may also reveal unexpected findings that were not evident on routine views. It requires an X-ray tube with a microfocal spot in order to offset the geometric unsharpness resulting from the increase in the magnification of breast structures. It also requires a magnification platform (Figure 8) to separate the compressed breast from the cassette for a 1.5 to 2 times magnification (the greater the magnification, the smaller the focal spot required). With magnification mammography, it

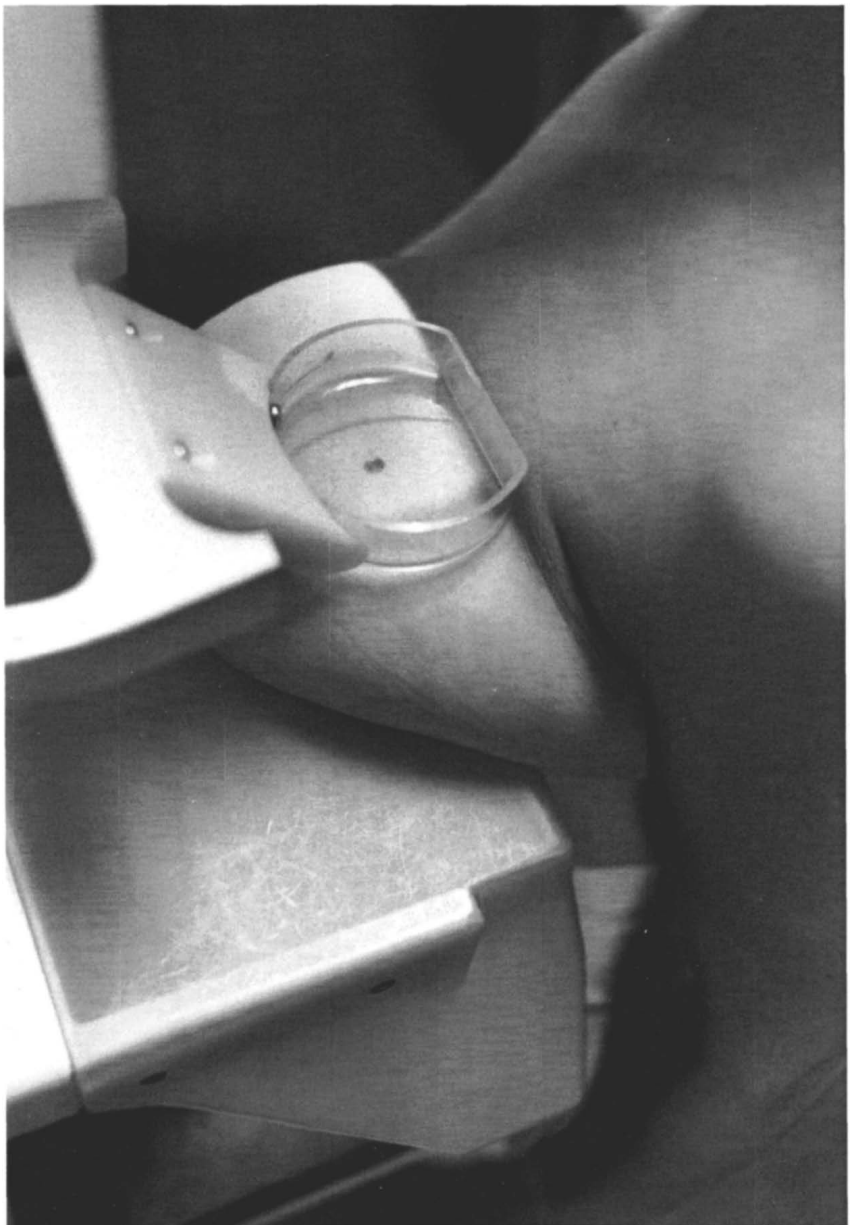


Figure 8. Magnification setup.

is critical that the patient remain still for the relatively longer exposure times resulting from the use of the unit's small focal spot. The air gap resulting from separation of the breast from the image receptor prevents a significant amount of scattered radiation from reaching the film, and a grid is not used.

EXAGGERATED CRANIOCAUDAL (XCCL)

An exaggerated craniocaudal view (Figures 9A through C) will depict deep lesions in the outer aspect of the breast including most of the axillary tail. Begin positioning the patient as for the routine CC. After elevating the inframammary fold, rotate the patient until the lateral aspect of the breast is positioned on the cassette holder. If the shoulder is in the way of the compression paddle, a 5° lateral tube angle can be used to allow the compression paddle to clear the humeral head. Do not push the shoulder down. Both shoulders should be at the same level. (Figures 9B and C).

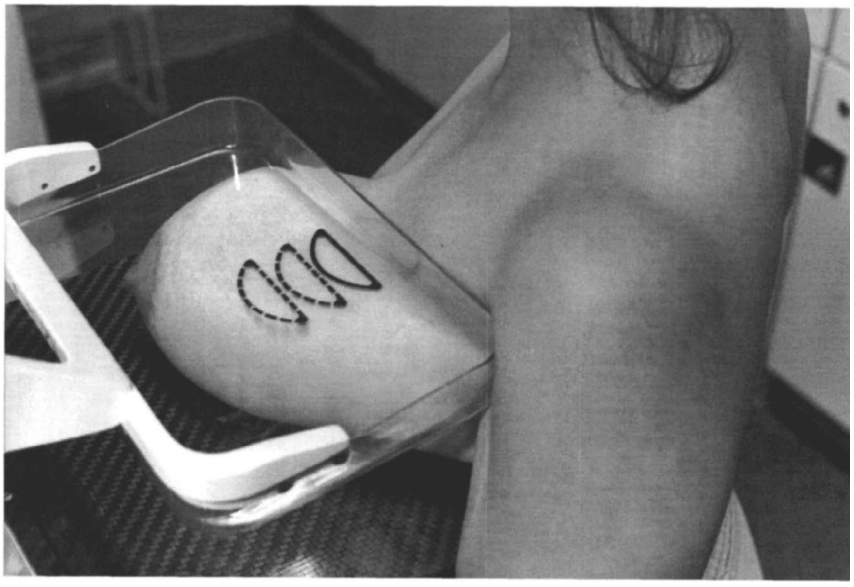


Figure 9A. Exaggerated craniocaudal. Patient is rotated to bring deep lateral tissues onto the bucky.

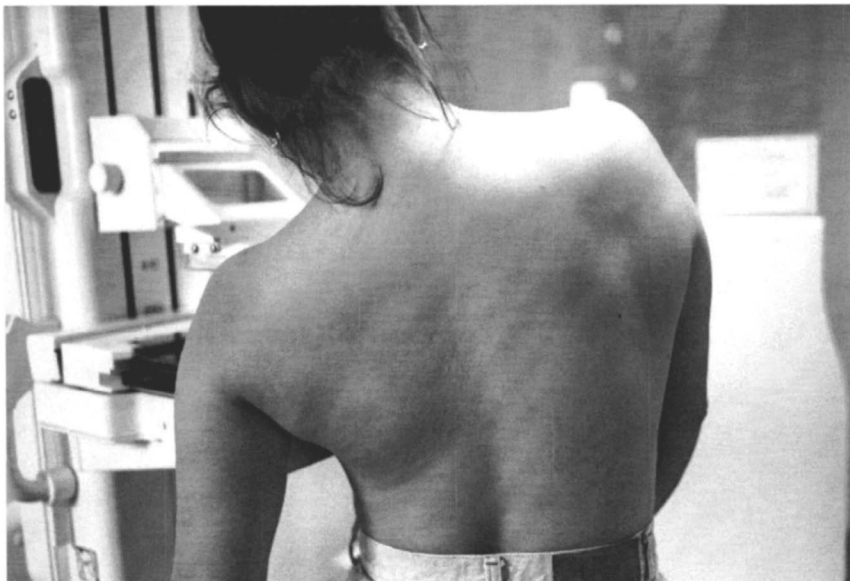


Figure 9B. Exaggerated craniocaudai. Pushing the shoulder down will distort the lateral aspect of the breast.

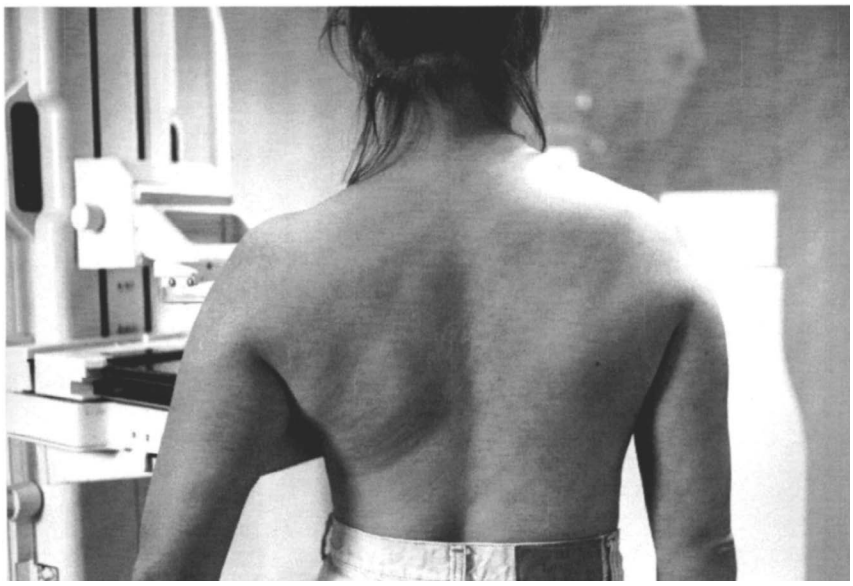


Figure 9C. Exaggerated craniocaudai. Both shoulders should be at the same level.

CLEAVAGE (CV)

The cleavage view (valley view, double breast compression view) is performed to visualize deep lesions in the posteromedial aspect of the breast. The patient's head is turned away from the side of interest. This positioning can be done with the technologist standing behind the patient and wrapping her arms around the patient to reach her breasts (Figure 10A) or with the technologist standing in front of the patient on the medial side of the breast being imaged. Whether standing behind or in front of the patient, be sure to elevate the inframammary folds and position both breasts on the cassette holder. Remember to pull all of the medial tissue of both breasts anteriorly in order to image the cleavage. Automatic exposure can be used by placing the breast of interest over the photocell with the cleavage slightly off center (Figure 10B). Manual technique must be used if the photocell is under an open cleavage.

Figure 10A. Cleavage. Standing behind the patient, the technologist places both breasts onto the cassette holder.

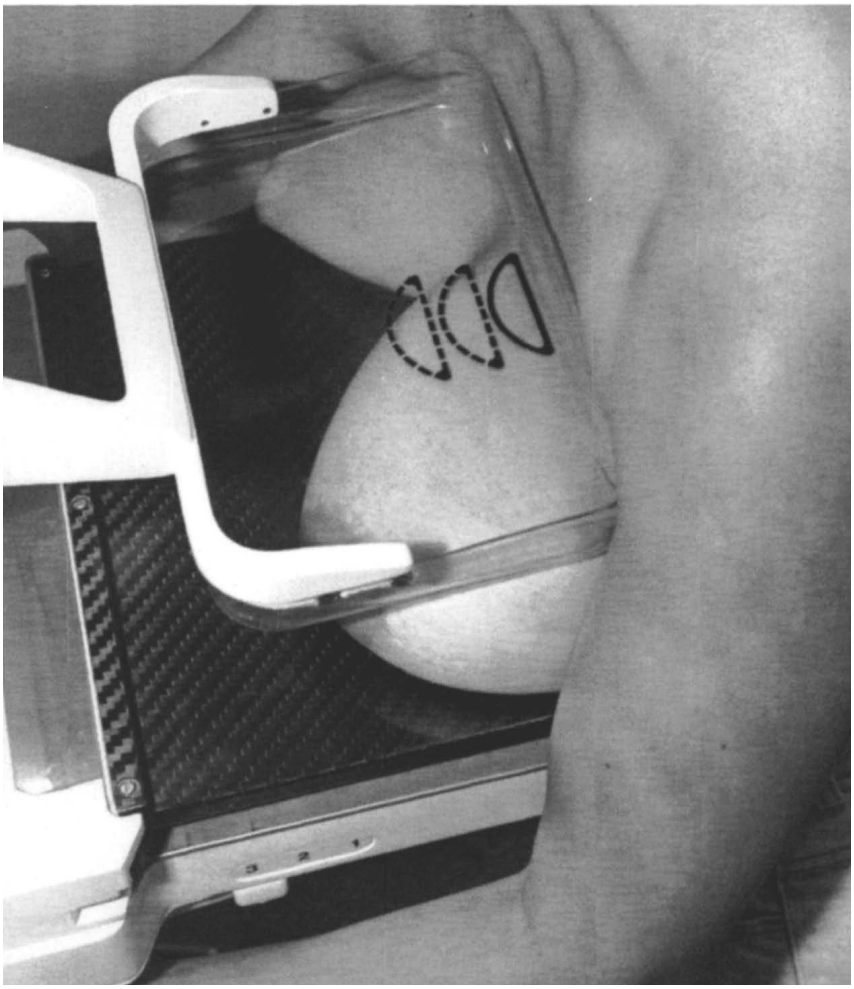
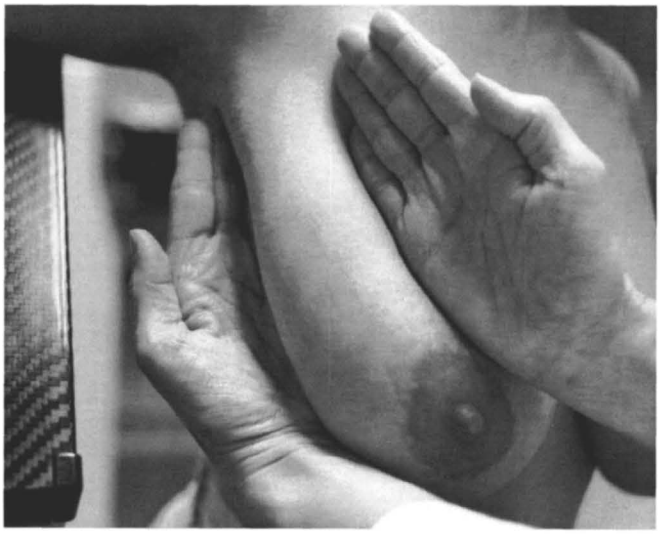


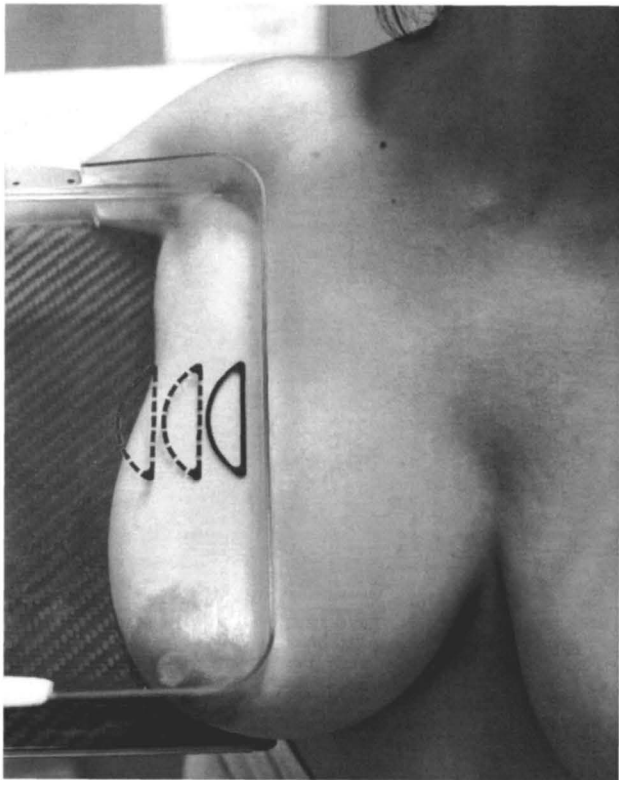
Figure 10B. Cleavage. Breast of interest is placed over the photocell with cleavage slightly off center.

AXILLARY TAIL (AT)

The axillary tail view may be used to demonstrate the entire axillary tail as well as most of the lateral aspect of the breast. The tube arm is rotated to an angle that will place the cassette holder parallel to the axillary tail (Figure 11A). The patient is turned to bring the axillary tail in contact with the cassette holder. The patient's arm on the side being imaged is draped behind the top of the cassette holder with the elbow flexed and the hand resting on the handlebar. Gently pull the axillary aspect of the breast out and away from the chest wall and place it on the cassette holder. Hold the axillary tail in place while slowly applying compression (Figure 11B).



A



B

Figures 11A & B. Axillary tail. The patient remains upright and the C-arm is rotated parallel to the axillary tail of the individual patient.

TANGENTIAL (TAN)

The tangential view is used for palpable lesions that are obscured by surrounding dense glandular tissue on the mammogram. The C-arm is rotated and the patient is turned so that the X-ray beam is tangential to the palpable lump. Performing tangential views can be facilitated by placing a lead marker (BB) directly over the lump and directing the X-ray beam tangential to the lead marker. This maneuver places the palpable lump directly over the subcutaneous fat, which often allows visualization of the abnormality.

Tangential views can also be used to verify that calcifications seen on a mammogram are located within the skin. Using a fenestrated plate with radiopaque alphanumeric indicators or a hole plate for guidance, place a lead marker (BB) on the breast over the calcifications (Figure 12A). It is important to place the marker on the correct side of the breast, e.g., superior versus inferior, medial versus lateral surface. Rotate the C-arm or the breast tissue until the lead marker is tangential to the X-ray beam (Figures 12B and C). Seeing a shadow of the marker on the cassette holder indicates that the area of concern will be tangential to the X-ray beam.

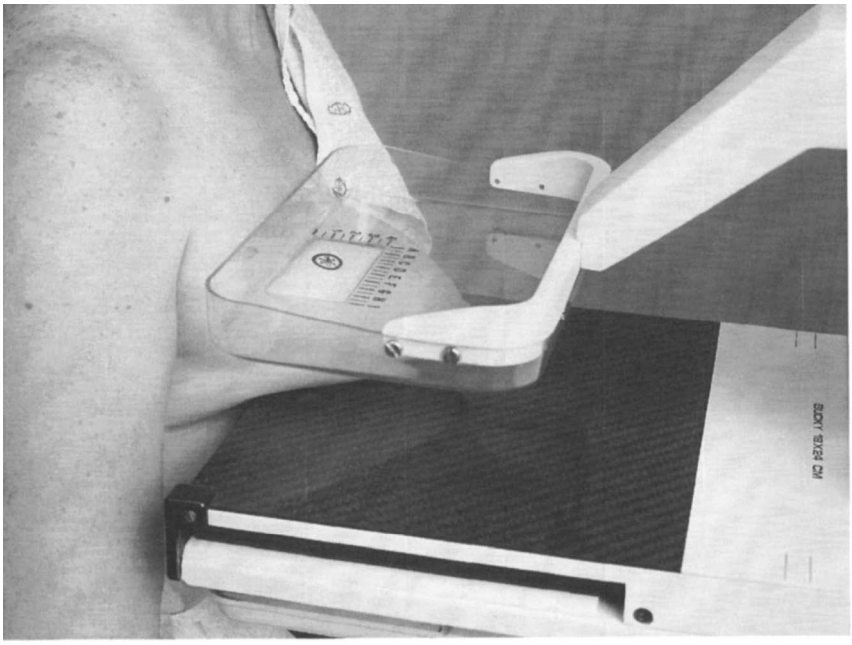


Figure 12A. Tangential view. A BB is placed directly over the suspected skin calcifications.

Figure 12B. Tangential view. Make a mound of the breast with the nipple at one end and the marker at the other end.

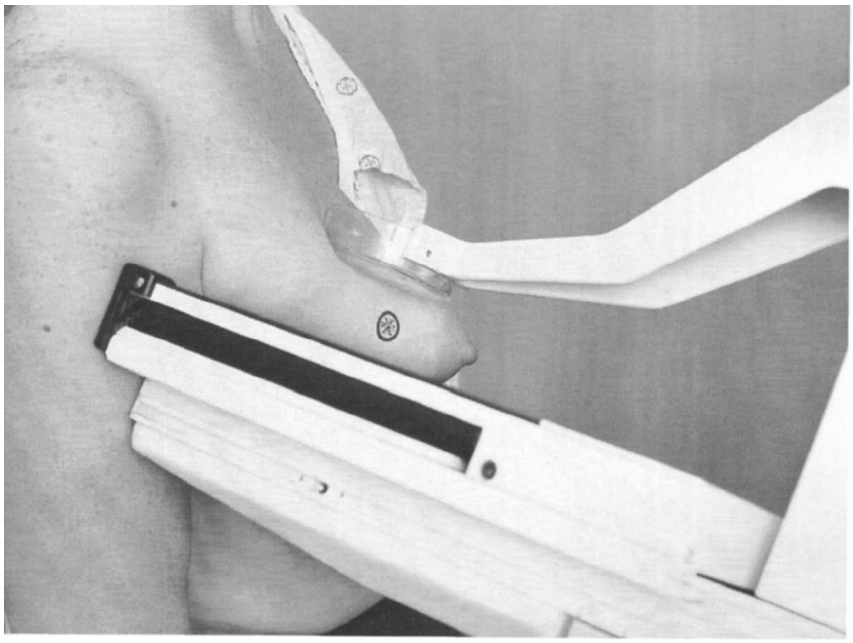
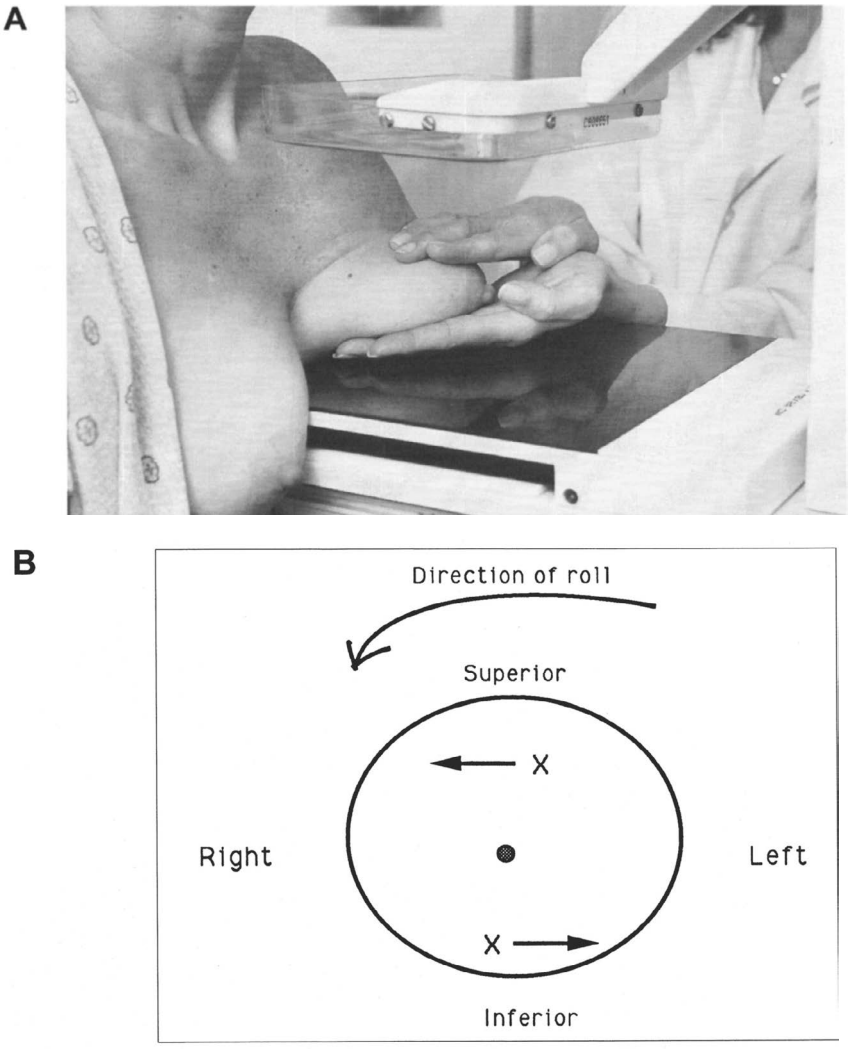


Figure 12C. Tangential view. The breast is correctly positioned for a view tangential to the BB.

ROLL (RL, RM)

The roll view is used to separate superimposed breast tissues. The purpose is to confirm the presence of an abnormality, to better define a lesion, or to determine the location of a finding seen on only one of the standard views. The patient is repositioned using the same projection that demonstrated the abnormality. Placing your hands on either side of the breast, "roll" the tissue in opposite directions (Figures 13A and B). Compression will maintain the breast in the "rolled" position. A radiopaque marker indicating the direction of the roll should be placed on the film.

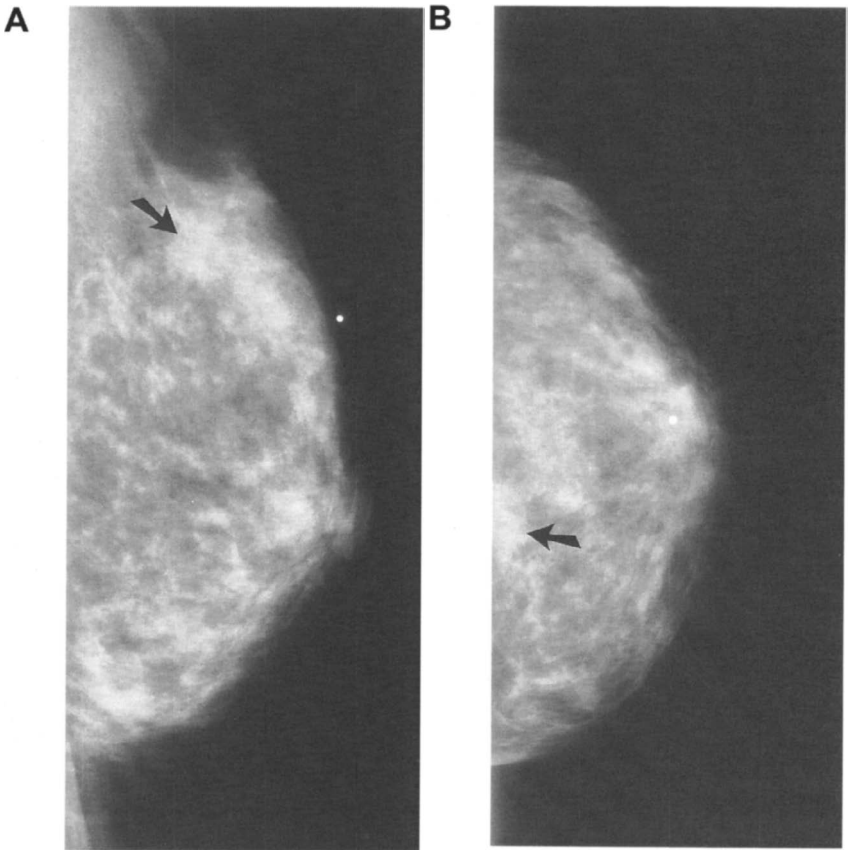


Figures 13A & B. Roll view. (A) The technologist's hands are used to "roll" the breast. (B) The lesion (X) will be seen to move according to its location in the breast.

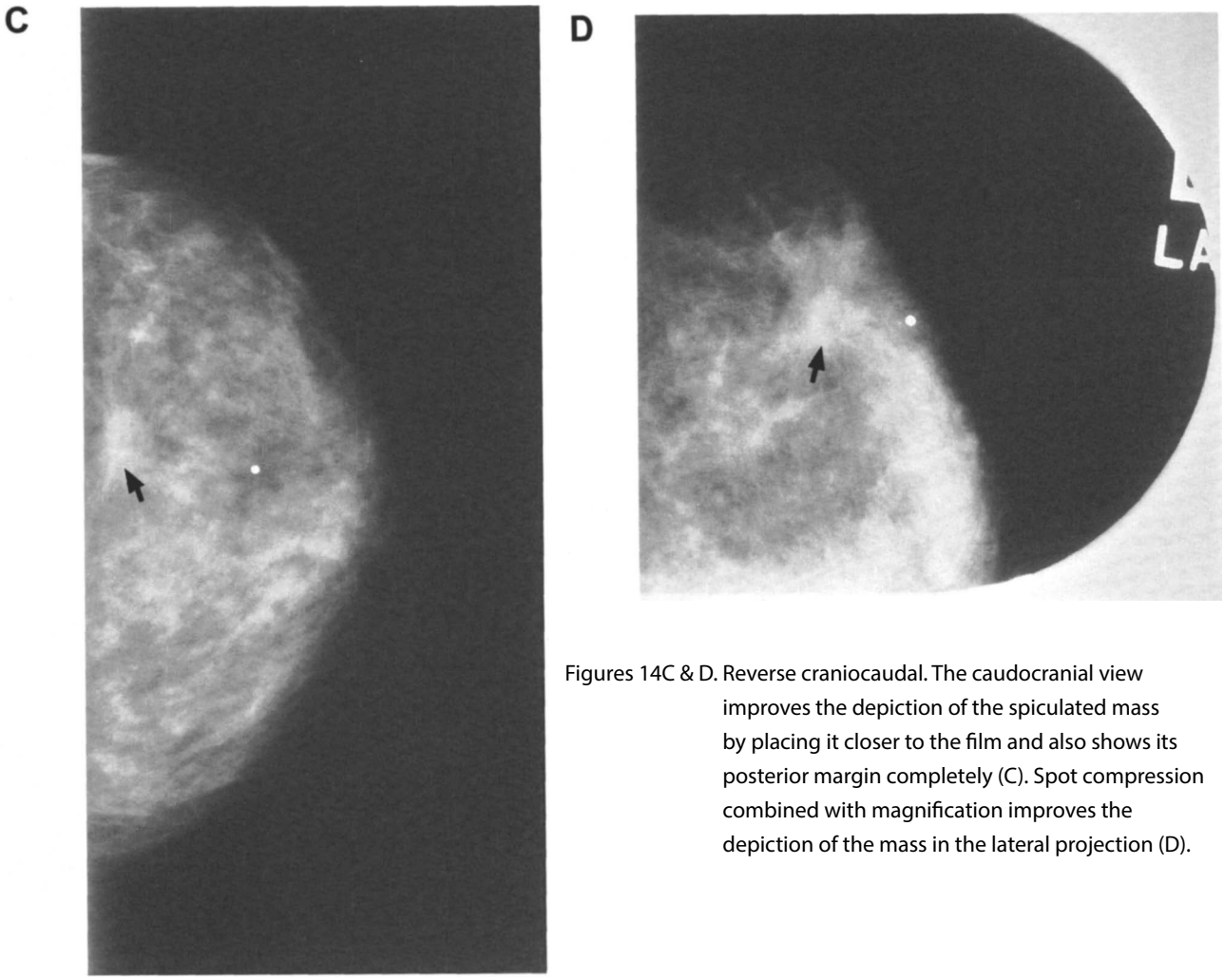
6. SPECIAL CIRCUMSTANCES

CAUDOCRANIAL (FB)

The caudocranial (reverse CC) view will improve visualization of lesions in the uppermost aspect of the breast due to the reduced object-to-film distance (Figures 14A through D). Since the compression device comes from below, this view will not exclude the fixed posterior tissue in the superior aspect of the breast (Figures 14B and C). It can also be used during needle localization to provide a shorter route to an inferior lesion. This view can also be used to maximize the amount of tissue visualized in the male breast or in a woman with kyphosis.



Figures 14A & B. Reverse craniocaudal (caudocranial position). A patient presented with a palpable mass high in the breast. The mass (arrow) was barely visible on lateral (A) and CC (B) views.



Figures 14C & D. Reverse craniocaudal. The caudocranial view improves the depiction of the spiculated mass by placing it closer to the film and also shows its posterior margin completely (C). Spot compression combined with magnification improves the depiction of the mass in the lateral projection (D).

Rotate the tube arm 180°. The patient will face the unit with one leg on either side of the tube head. Elevate the inframammary fold, then adjust the height of the tube arm so that the superior border of the breast will be in contact with the cassette holder. With one hand on top of the breast and the other hand under the breast, gently pull the tissue away from the chest wall and center the breast on the cassette holder (Figure 14E). Slowly apply compression.

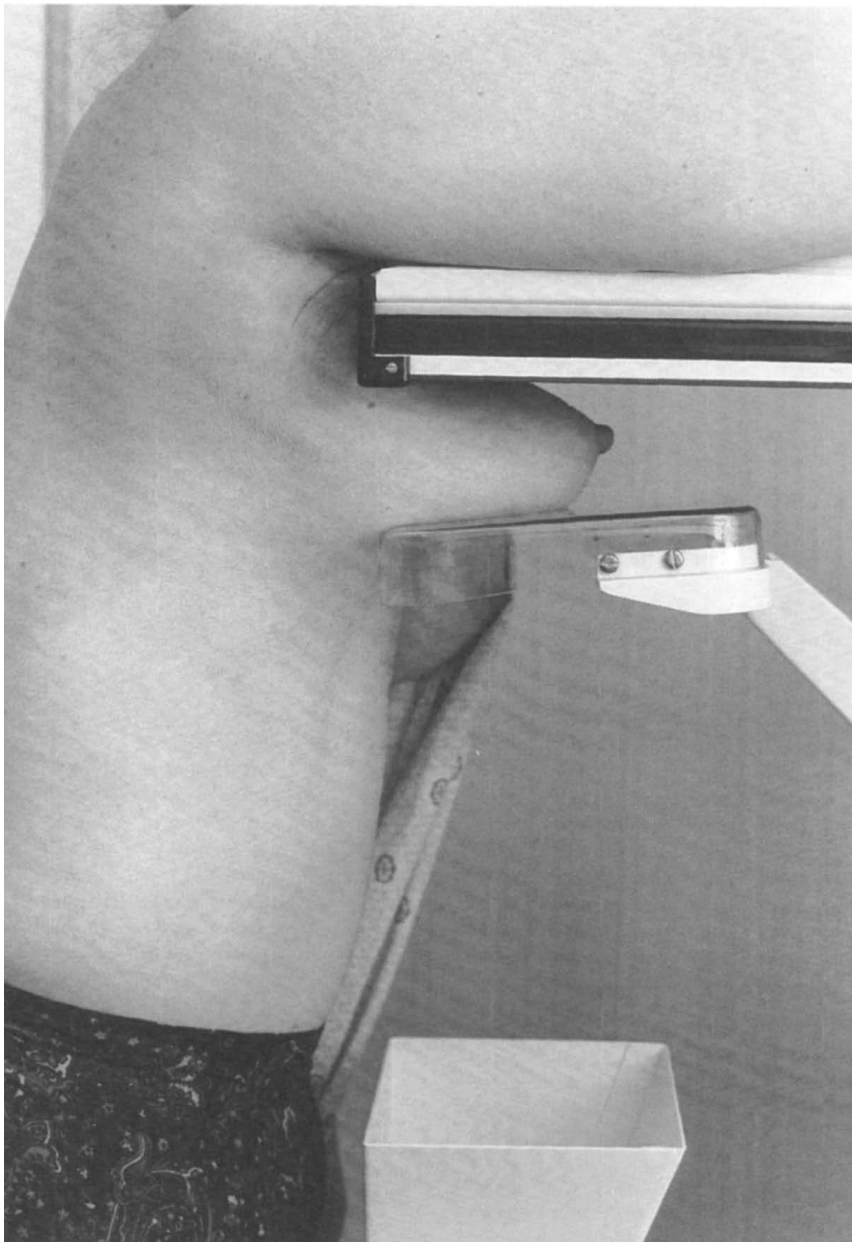


Figure 14E. Reverse craniocaudal. Caudocranial position.

LATEROMEDIAL OBLIQUE (LMO)

The lateromedial oblique (true reverse oblique) view is performed with the X-ray beam directed from the lower-outer to the upper-inner aspect of the breast, the exact reverse of the MLO. This view will improve visualization of the medial breast tissue due to the reduced object-to-film distance. The cassette holder is placed parallel to the plane of the pectoral muscle, optimizing the amount of breast tissue that is depicted. The lateromedial oblique can be used to more comfortably position the breast and therefore visualize more tissue in a patient with pectus excavatum, a patient who has had recent open heart surgery, or a patient with a prominent pacemaker.

The tube arm is rotated to the appropriate angle with the beam at an inferolateral to superomedial direction. Adjust the height of the cassette holder so that the breast is centered. The patient should lean forward to place the edge of the cassette holder against the sternum. The patient's arm will be draped over the top of the cassette holder, with the elbow flexed (Figure 15). Gently pull the breast out and up from the chest wall, making sure all medial tissue is in front of the cassette holder. Begin to rotate the patient toward the film. Bring the compression device down beyond the latissimus dorsi, then finish rotating the patient forward until all the breast tissue is centered on the film. After the breast is fully compressed, open the inframammary fold by gently pulling abdominal tissue down.

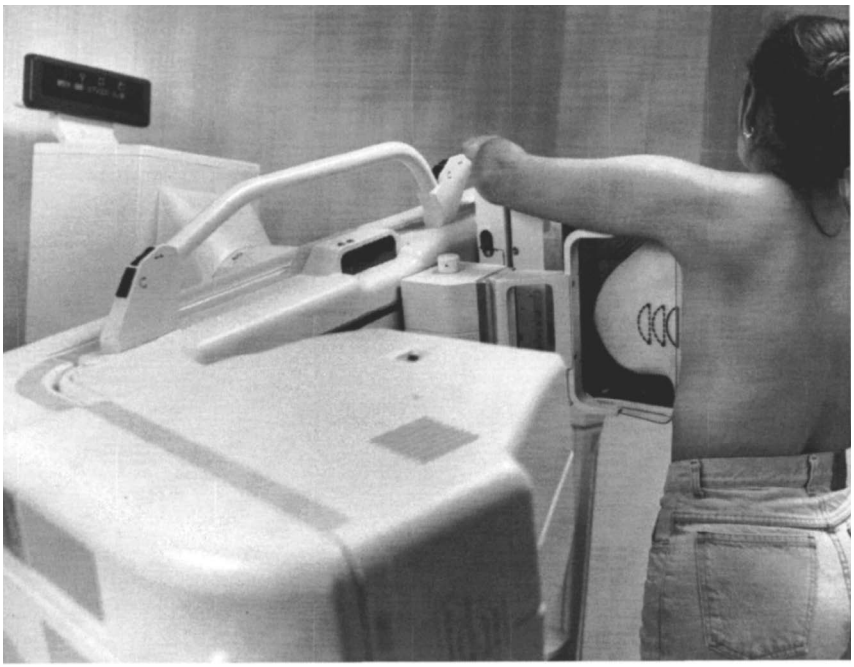


Figure 15. Lateromedial oblique also known as reverse oblique.

SUPEROLATERAL-TO-INFEROMEDIAL OBLIQUE (SIO)

An oblique view can also be performed with the central ray directed upper-outer to lower-inner (see Figure 16). This view has been incorrectly termed a reverse oblique. As a whole-breast projection it has limited usefulness.

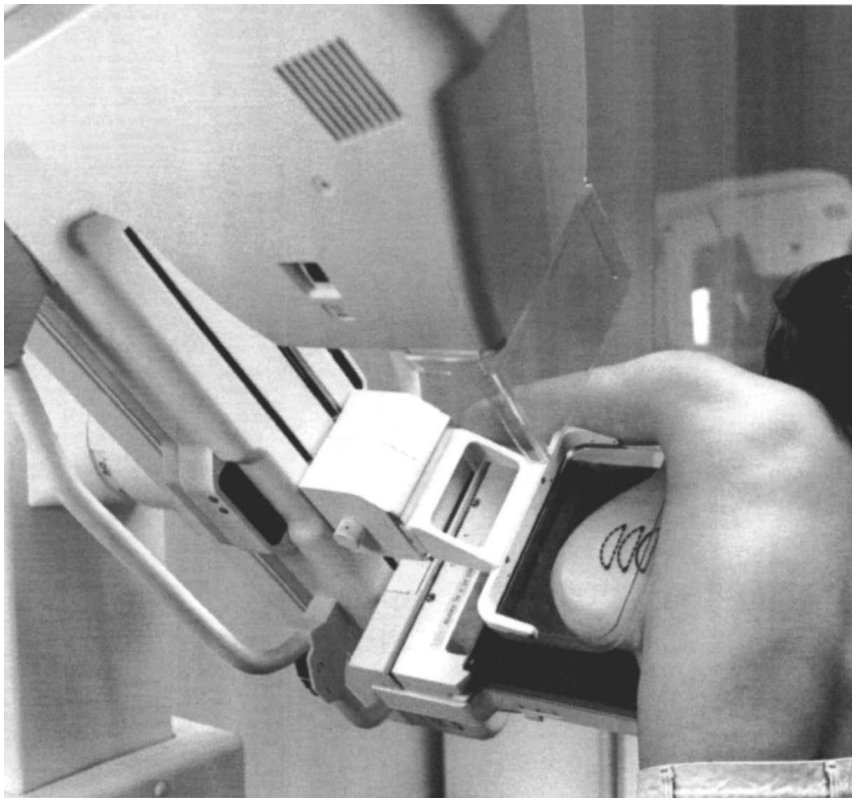
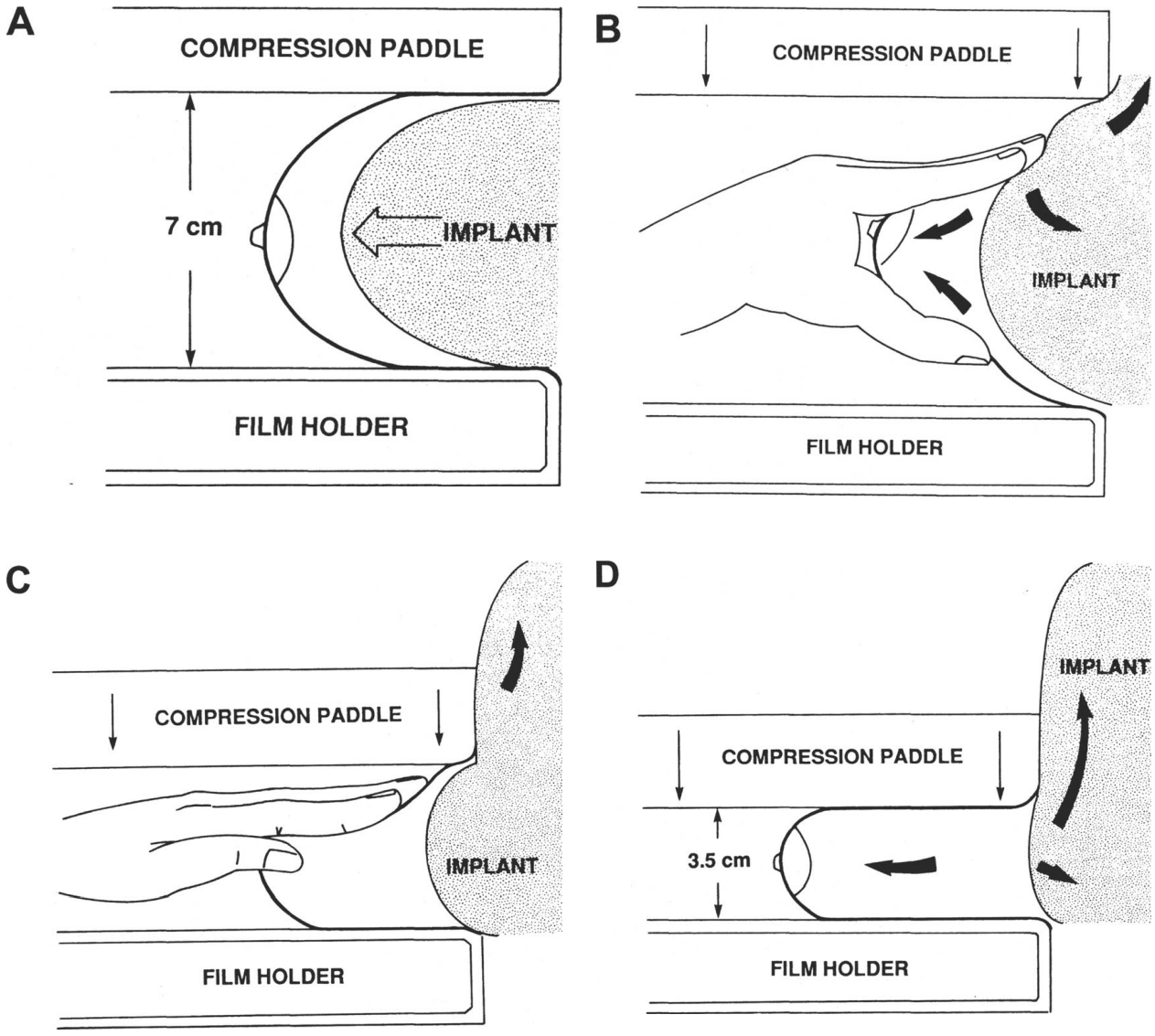


Figure 16. Superolateral-to-inferomedial oblique.

THE AUGMENTED BREAST (ID)

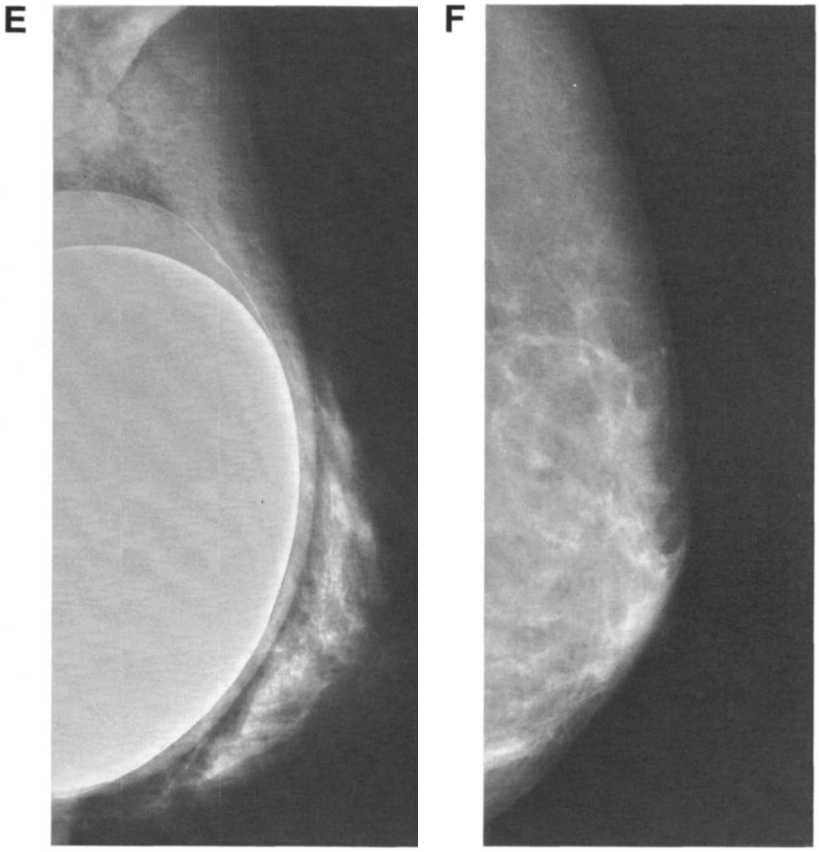
Imaging the augmented breast presents special problems and challenges to the radiologist and technologist and requires special consideration. The routine CC and MLO implant-included views require manually set exposure factors, and the degree of compression is limited by the compressibility of the implant (Figure 17A). In addition to these routine views, patients with augmented breasts should have modified CC implant displaced and modified MLO implant displaced view. In the modified implant displaced views, the prosthesis is displaced posteriorly and superiorly against the chest wall while gently pulling the breast tissue anterior to the prosthesis onto the image receptor and holding it in place with the compression device (Figures 17B through D).



Figures 17A, B, C, & D. Imaging the augmented breast. (A) Compression of the breast and the undisplaced prosthesis. (B-D) Displacement of the prosthesis and compression of only the breast.

(Reprinted from Eklund GW, Busby RC, Milter SH, et at. Improved imaging of the augmented breast. AJR. 1988;151:469-473.)

For a CC implant displaced view, the tissue superior and inferior to the prosthesis will be pulled forward, as will all the anterior tissue. For an MLO implant displaced view, the tissue superomedial and inferolateral will be pulled forward with the anterior tissue. This procedure can greatly improve visibility of breast tissue (Figures 17E and F).



Figures 17E & F. MLO views including the implant (E) and with the implant displaced (F).

There are five essential steps for positioning the CC and MLO implant displaced views. The five steps for the CC view are:

1) Have the patient bend forward from the waist, use your fingers to pull the breast tissue forward while displacing the implant posteriorly, and then have the patient stand again.
2) Have the patient place her contralateral hand under her breast and firmly against the ribs.
3) Gently pull the breast tissue onto the cassette holder and place the edge of your fingers, holding the inferior tissue, against the edge of the bucky.
4) Ask the patient to push her body against her hand (which results in further displacement of the implant).
5) Apply compression (a spatula can be used to hold the tissue forward and will facilitate the compression).

The five steps for the MLO implant displaced view are:

1) Have the patient bend forward from the waist, use your fingers to pull the breast tissue forward while displacing the implant posteriorly, and then have the patient stand again;
2) Ask the patient to place her hand on the handlebar with the corner of the bucky posterior to the axilla.
3) Place the edge of your fingers, holding the lateral tissue, against the edge of the bucky.
4) Ask the patient whether she feels the bucky against her ribs or against her breast. If she replies "breast" then ask her to lean her body against the bucky; if she replies "ribs" you should start over because the implant is not sufficiently displaced.
5) Apply compression.

The steps described above are more easily performed on breasts with subpectoral implants, implants placed behind the pectoral muscle. Implants that are placed in front of the muscle, also called subglandular or retromammary implants, are more susceptible to capsular contraction, which makes it difficult to displace the implant. It may also be difficult to perform implant displacement views on patients who have very little native breast tissue. If the implant cannot be adequately displaced, a 90° lateral with the implant included should be added to the routine CC and MLO implant-included views.

7. POSTMASTECTOMY IMAGING

Imaging the postmastectomy side is controversial. Those who recommend this procedure might include an MLO projection of the skin over the mastectomy site, a spot view of any area of concern, and an anteroposterior view of the axilla.

1. INTRODUCTION

Peer review of clinical images by radiologists with special expertise and training has been an important component of the ACR Mammography Accreditation Program since its inception in 1987. The clinical image evaluation includes an assessment of positioning, compression, artifacts, exposure, contrast, sharpness, noise, and labeling. For accreditation purposes, the standard MLO and CC views of each breast of a woman with primarily fatty breasts and of a woman with primarily dense breasts are evaluated for each mammography unit. The two types of breast tissue compositions represent different imaging challenges. Due to the variations in the body habitus of patients and their ability to cooperate, it is not possible to attain ideal breast positioning and compression in all women. Therefore, facilities are requested to submit what they consider to be their best representative images. Clinical image evaluation is complementary to phantom image evaluation in assessing the overall quality of mammography at a facility applying for accreditation. **Failure to pass clinical image review is the most common reason for failing to obtain accreditation.**

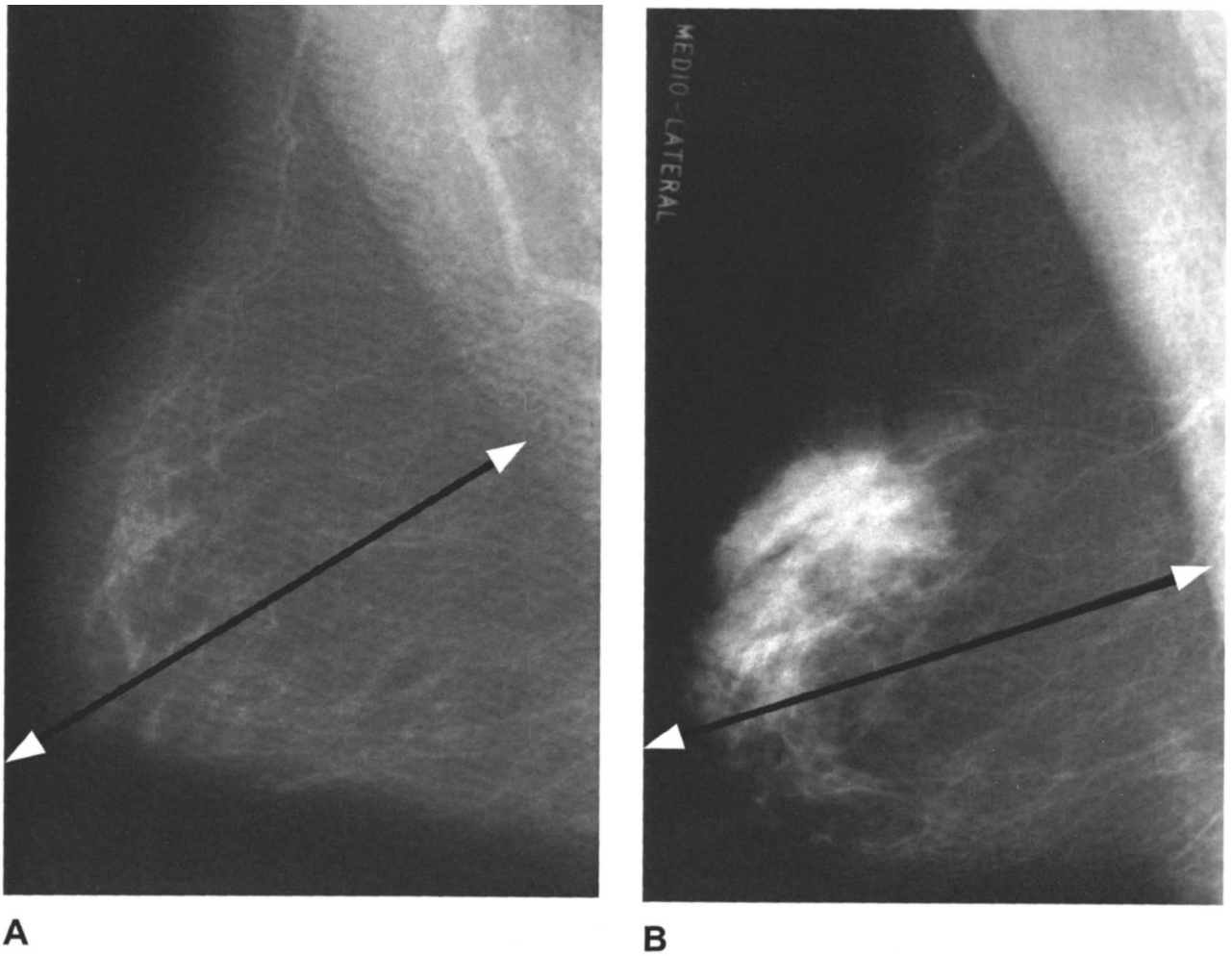
It should be emphasized that clinical image evaluation is not intended to be an activity that takes place only at the time of accreditation. On the contrary, technical assessment of clinical images should be an ongoing, daily quality assurance activity performed by the radiologist interpreting mammograms. It is important that radiologists provide regular feedback to the radiologic technologists who perform mammography, including positive reinforcement and constructive criticism about the technical quality of examinations. Learning to recognize specific deficiencies in images and their possible cause will allow the radiologist and radiologic technologist to address image deficiencies quickly.

MQSA REQUIREMENTS:

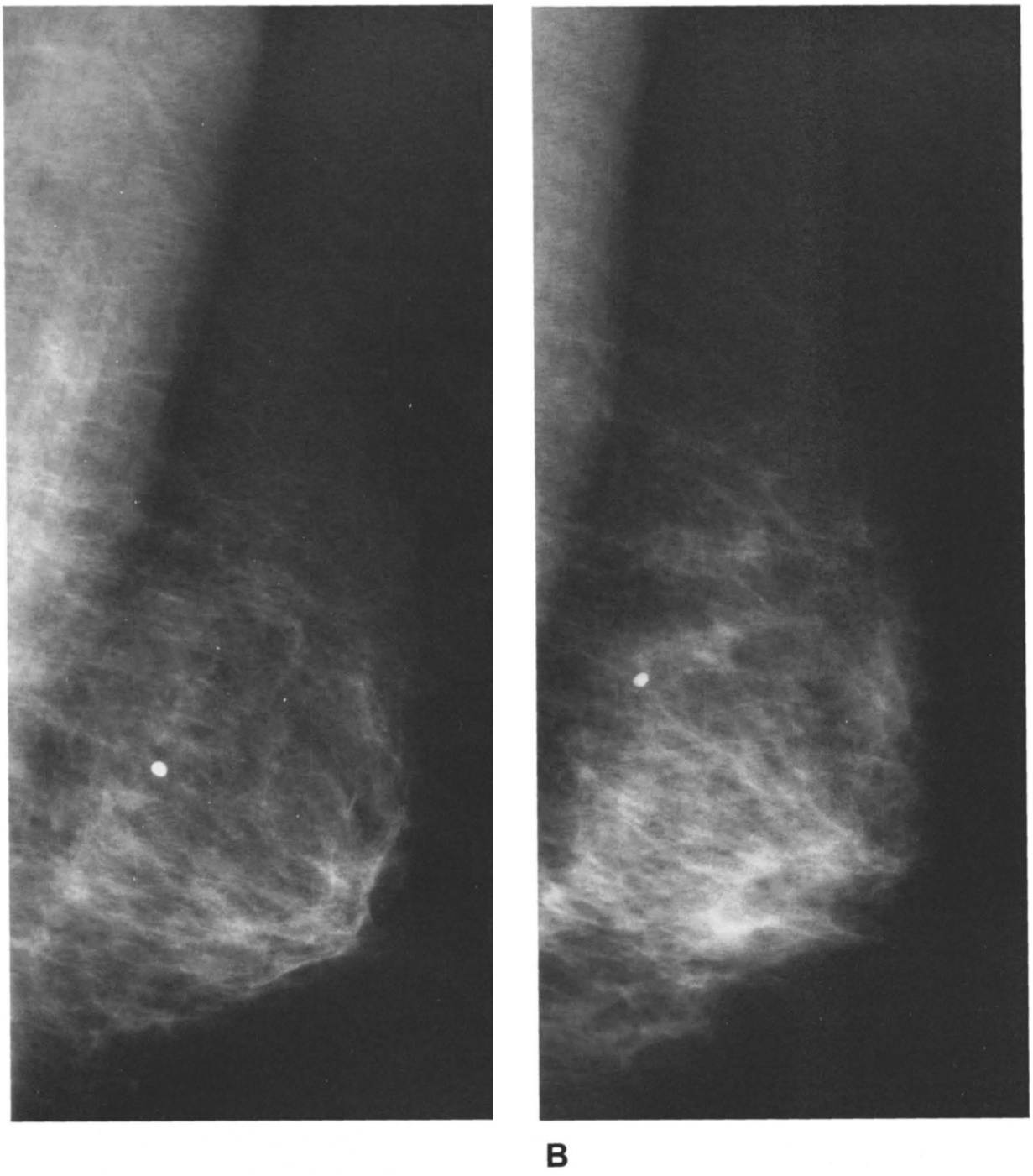
Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall (A) follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and (B) participate in the facility's medical outcomes audit program.

2. MEDIOLATERAL OBLIQUE VIEW POSITIONING

To ensure that the greatest possible amount of tissue has been included in the image, a generous amount of pectoralis muscle should be visualized. It is desirable for the inferior extent of the muscle to be visible down to the posterior nipple line (PNL) (Figures 18A and B). The latter criterion can be achieved in more than 80% of women. The PNL is drawn at an angle approximately perpendicular to the muscle, extending posteriorly from the nipple to the pectoralis muscle or the edge of the film, whichever comes first. Depiction of retroglandular fat posterior to all of the fibroglandular tissue is indirect evidence that all the fibroglandular tissue has been included. The pectoralis muscle should also be sufficiently wide (Figures 19A and B).

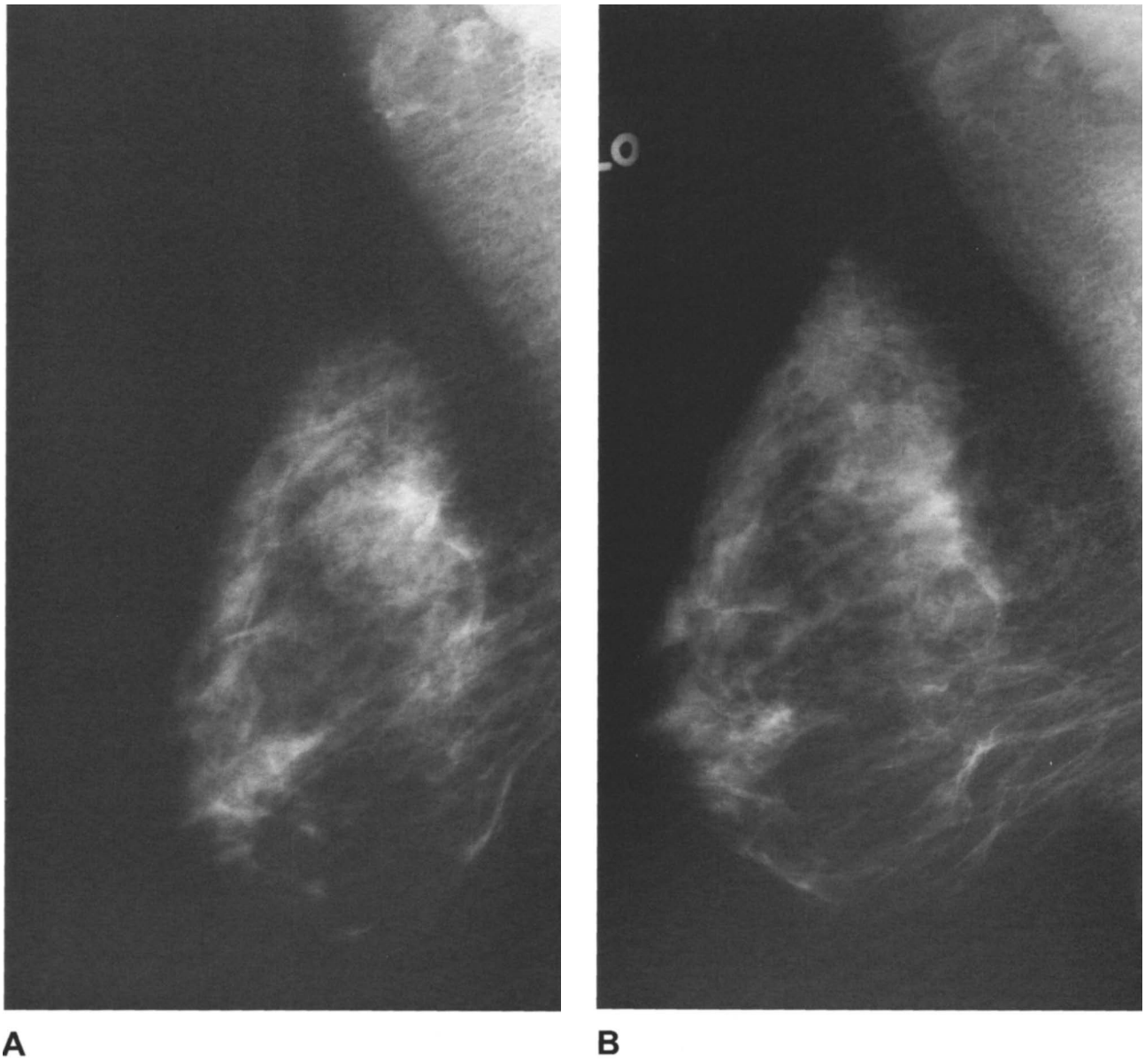


Figures 18A & B. On a properly positioned MLO view, the inferior aspect of the pectoral muscle should come to the posterior nipple line (PNL). A convex anterior margin to the pectoral muscle (A) is preferable to a concave margin (B) because the latter may exclude posterior breast tissue.



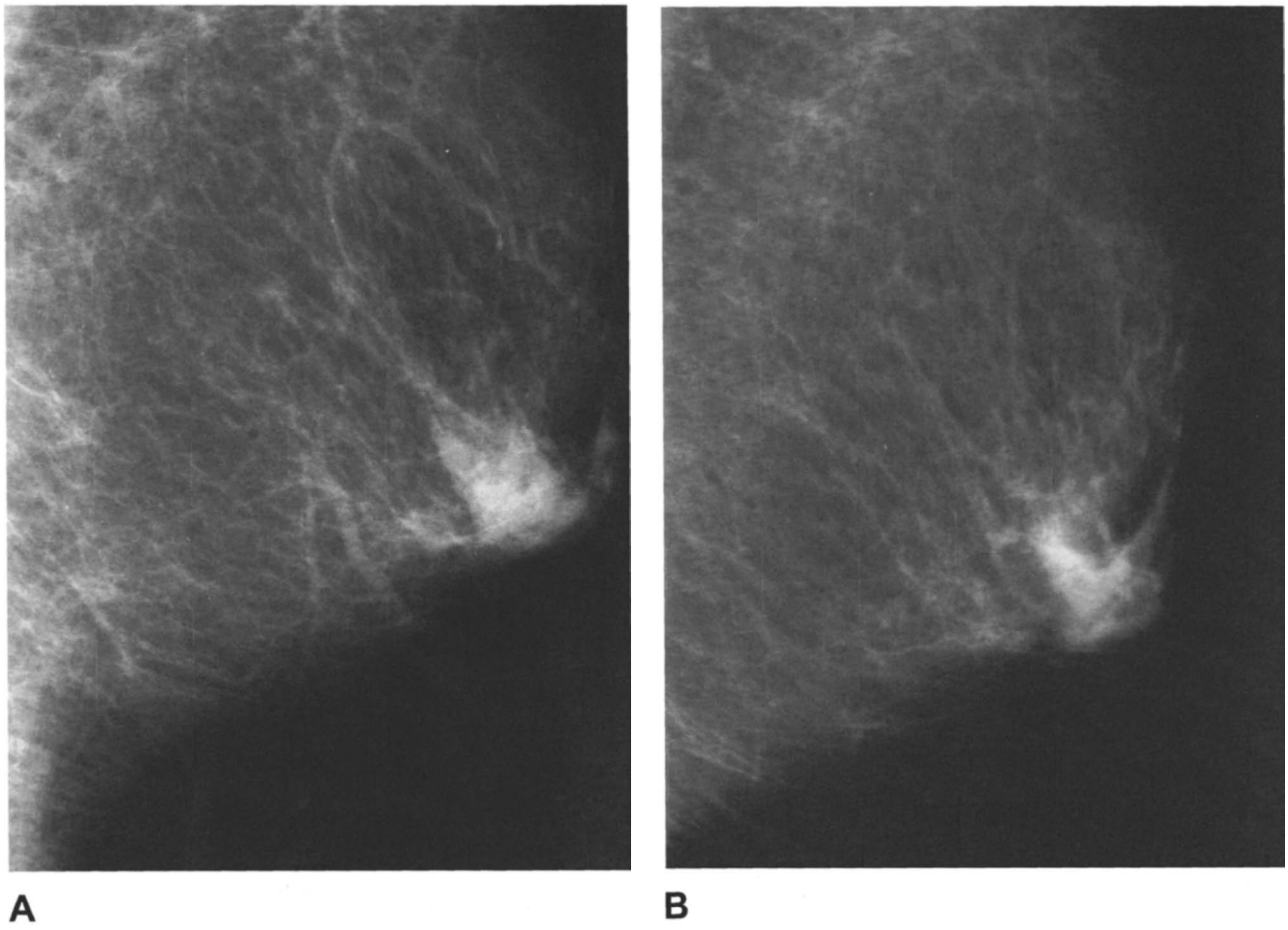
Figures 19A & B. Signs of better positioning in (A) compared with (B) include extension of the pectoralis muscle below the posterior nipple line, greater inclusion of the pectoralis muscle, and inclusion of more posterior breast tissue. Because the breast is better positioned in (A) there is more breast tissue behind the calcification. Film (A) also exhibits improved compression and therefore less superimposition of breast tissue yielding improved visualization of fibroglandular tissues.

If proper maneuvers have been performed prior to and during the application of compression the breast will not be sagging (Figures 20A and B). An open inframammary fold (Figures 21A and B) also indicates proper positioning and compression. Skin folds at the posteroinferior aspect of the breast should be minimal or absent (Figures 22A and B).

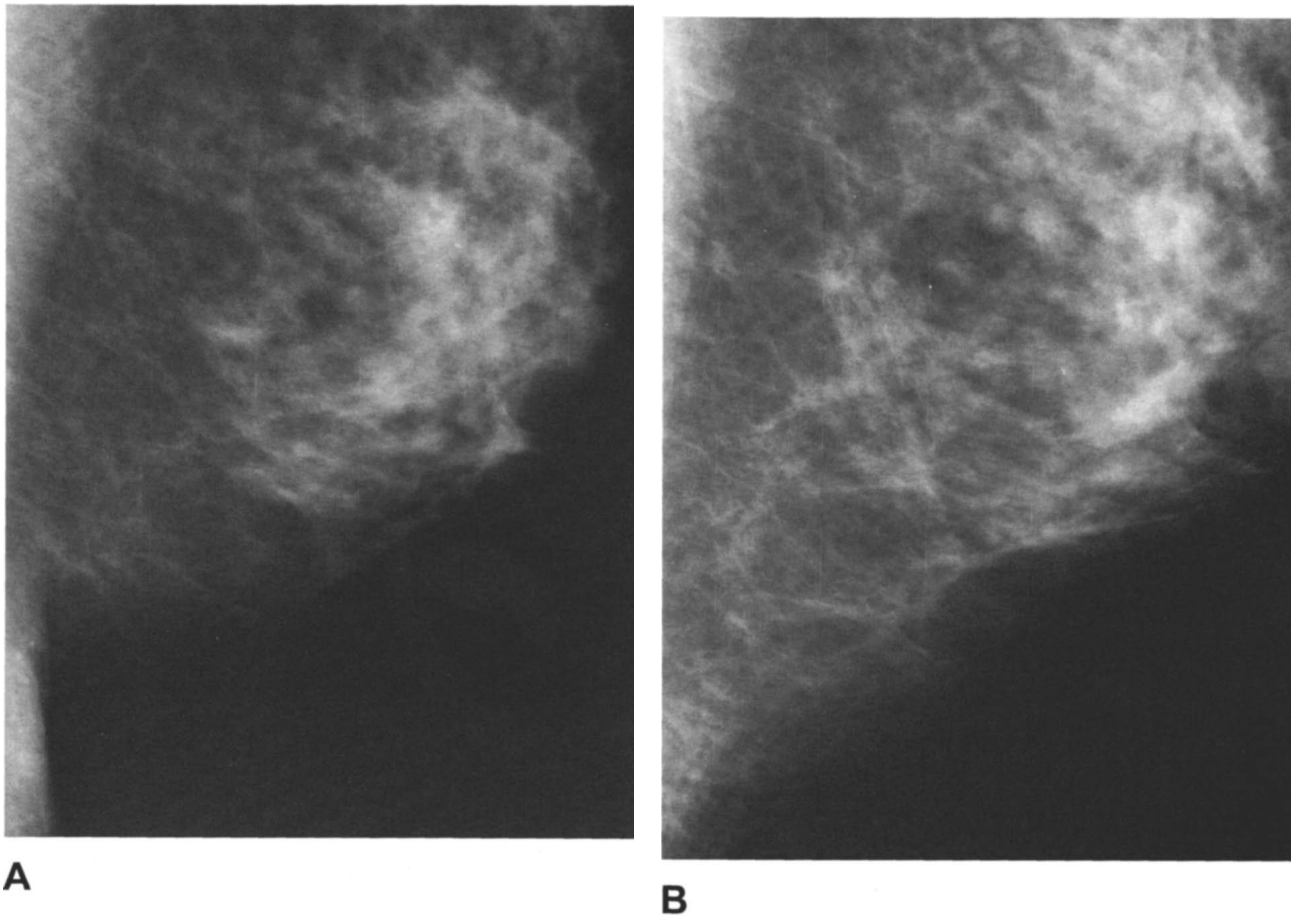


A B

Figures 20A & B. (A) The breast is sagging because it was not pulled out and up prior to compression. Consequently, there is less posterior tissue (including inframammary tissue), and the breast cannot be well compressed. Compare with the better positioning and compression shown in (B).



Figures 21A & B. (A) The open inframammary fold (IMF) indicates adequate inclusion of lower posterior breast tissue. (B) Absence of the IMF in the same patient indicates exclusion of tissue from that region of the breast.

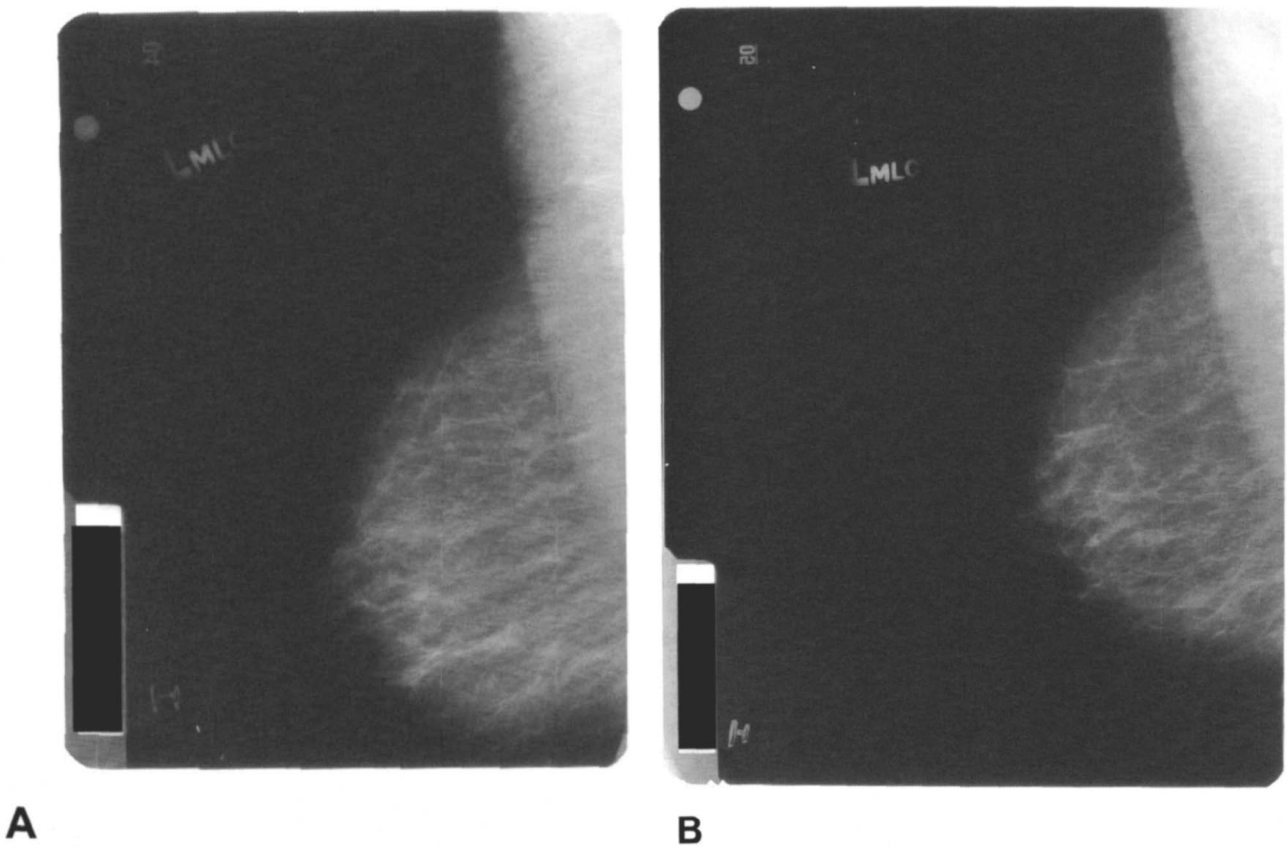


Figures 22A & B. (A) The skin fold in the inframammary area prevents adequate visualization of that region. (B) The same breast with skin fold eliminated.

It is important to have image receptors and compression devices available in both 18 X 24 cm and 24 X 30 cm sizes for each mammography unit and to use the appropriate size for each view. If a large breast is imaged on the smaller image receptor, either the axillary or inferior aspect of the breast is likely to be excluded from the image (Figures 23A and B). Significant problems are also encountered when using the large image receptor for a small breast, including inability to achieve adequate compression and sagging of the breast on the MLO view. These problems occur because the patient's arm, shoulder or abdomen becomes superimposed between the breast and the large image receptor, preventing effective breast compression.

MQSA REQUIREMENTS:

Image receptor sizes. Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 X 24 cm and 24 X 30 cm.



Figures 23A & B. Inappropriate use of a small (18x24 cm) image receptor size (A) for a large breast may include less inferior breast tissue and/or less upper axillary tissue than would be included with (B) a larger 24 x 30 cm image receptor.

3. CRANIOCAUDAL VIEW POSITIONING

Even when the CC is properly performed, the pectoralis muscle is only visualized in about 30% to 40% of patients. When the pectoralis muscle is not seen, the best indicator of the amount of posterior tissue included on the CC is the measurement of the PNL (Figure 24). On the CC view the PNL is drawn directly posterior from the nipple to the edge of the film. The general rule is that the length of the PNL on the CC view should be within 1 cm of its length on the MLO when the MLO is properly positioned. Usually the length of the PNL is greater on the

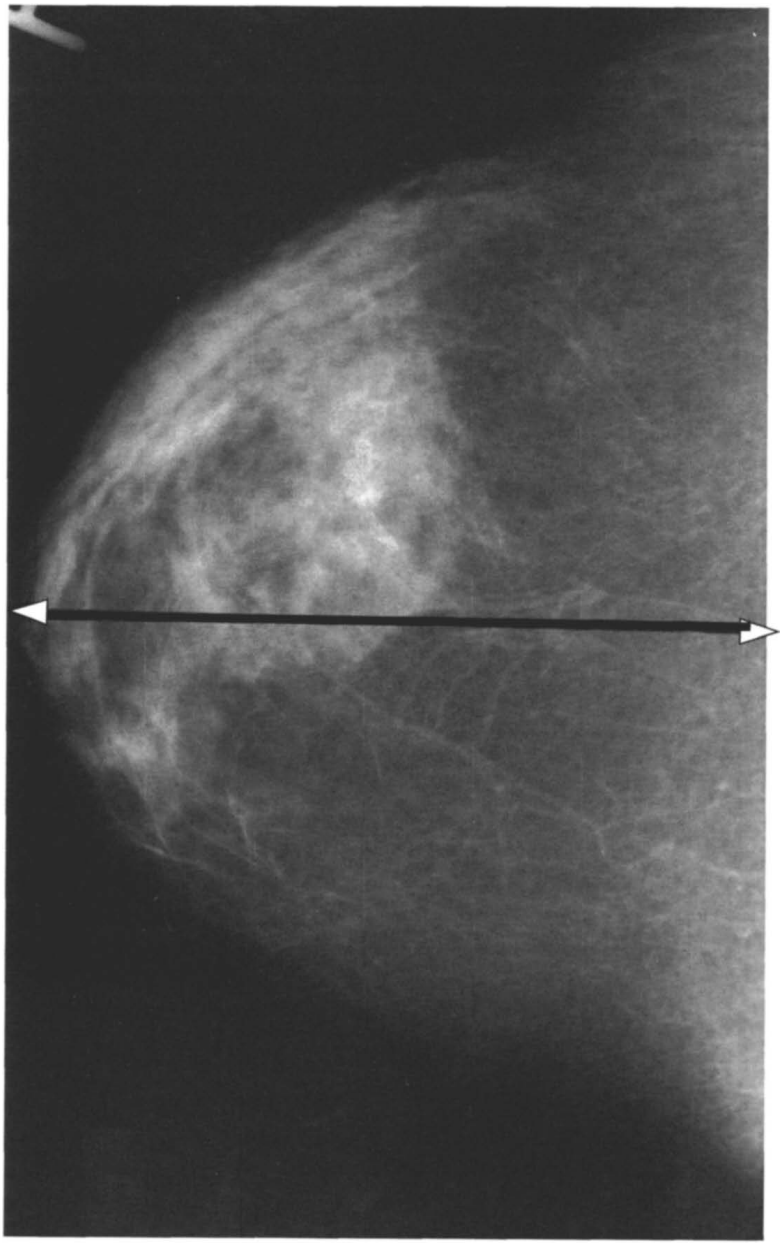


Figure 24. If the posterior nipple line (PNL) measured from the back of the nipple to the edge of the film on the CC view is within 1 cm of its length on the MLO view, sufficient posterior tissue has been included on the CC view (same patient as in Figure 18B).

MLO than on the CC; however, in approximately 10% of patients the length of the PNL will be greater on the CC. Visualization of the pectoralis muscle on the chest wall directly behind the nipple means that sufficient posterior breast tissue has been included on the CC view (Figure 25). Proper positioning techniques will maximize the likelihood that lesions in the far posterior breast are included on the image (Figures 26A and B).

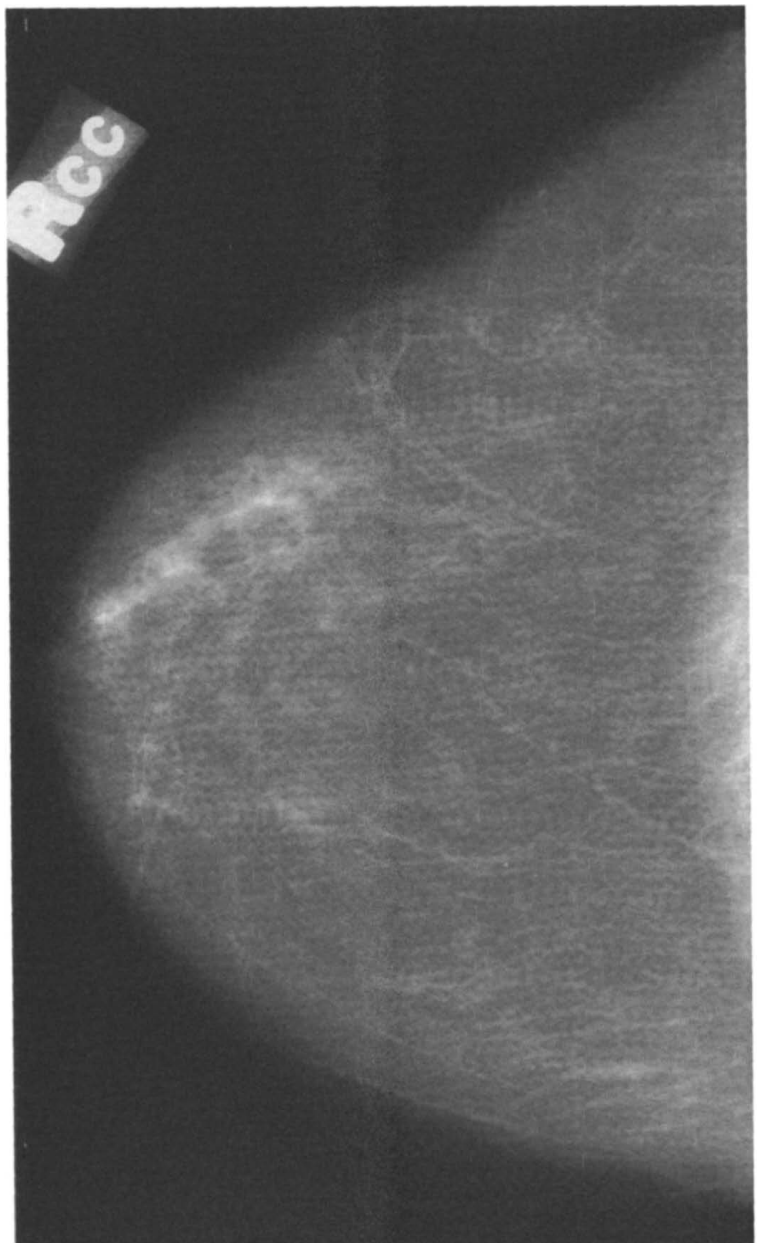
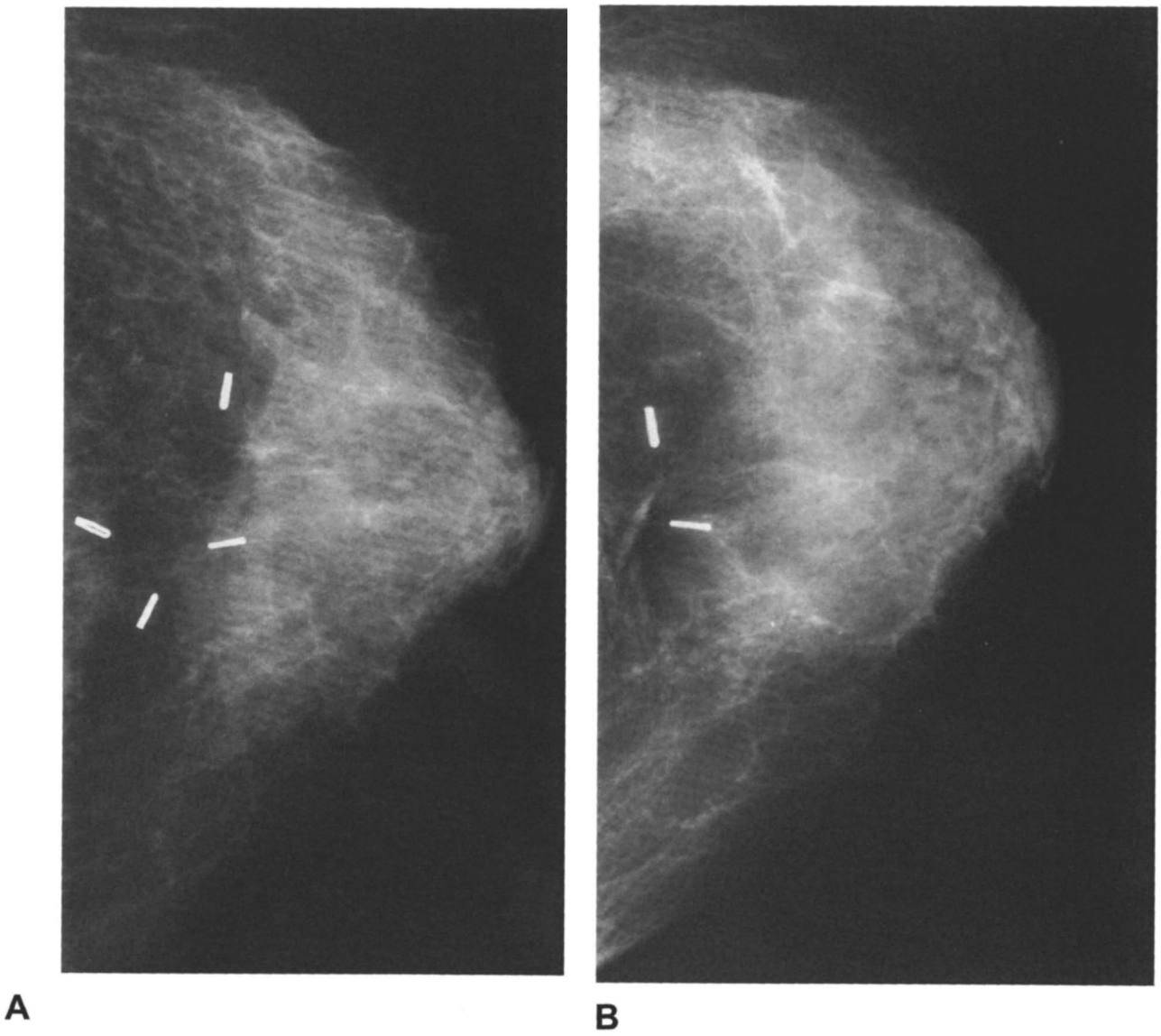


Figure 25. Presence of pectoralis muscle along the posterior nipple line on a CC view indicates adequate inclusion of breast tissue in the AP direction on this projection.

The posteromedial breast tissue is the area most likely to be excluded on an MLO. For this reason it is of paramount importance to include the posteromedial aspect of the breast on the CC. When the positioning is done properly, all of the fibroglandular tissue of the medial aspect of the breast can be included in the image without exaggerating to the medial or lateral side. Although as much lateral tissue as possible should be included on the CC, lateral tissue should never be included at the expense of medial tissue.



Figures 26A & B. (A) Proper positioning of a post-lumpectomy patient allows inclusion of more posterior breast tissue than (B), where CC positioning was suboptimal. Note visibility of additional surgical clips in (A).

Assuming that the right and left breasts are the same size, the extent of tissue in the AP direction should be similar for right and left breasts in both CC images and similar for right and left breasts in both the MLO images. Portions of the breast should not project beyond the margins of the image. Although it is not always possible to position the nipple in profile when including a maximum amount of breast tissue, large variations in nipple location, especially when right and left sides are compared, usually signify inconsistencies in positioning.

4. COMPRESSION

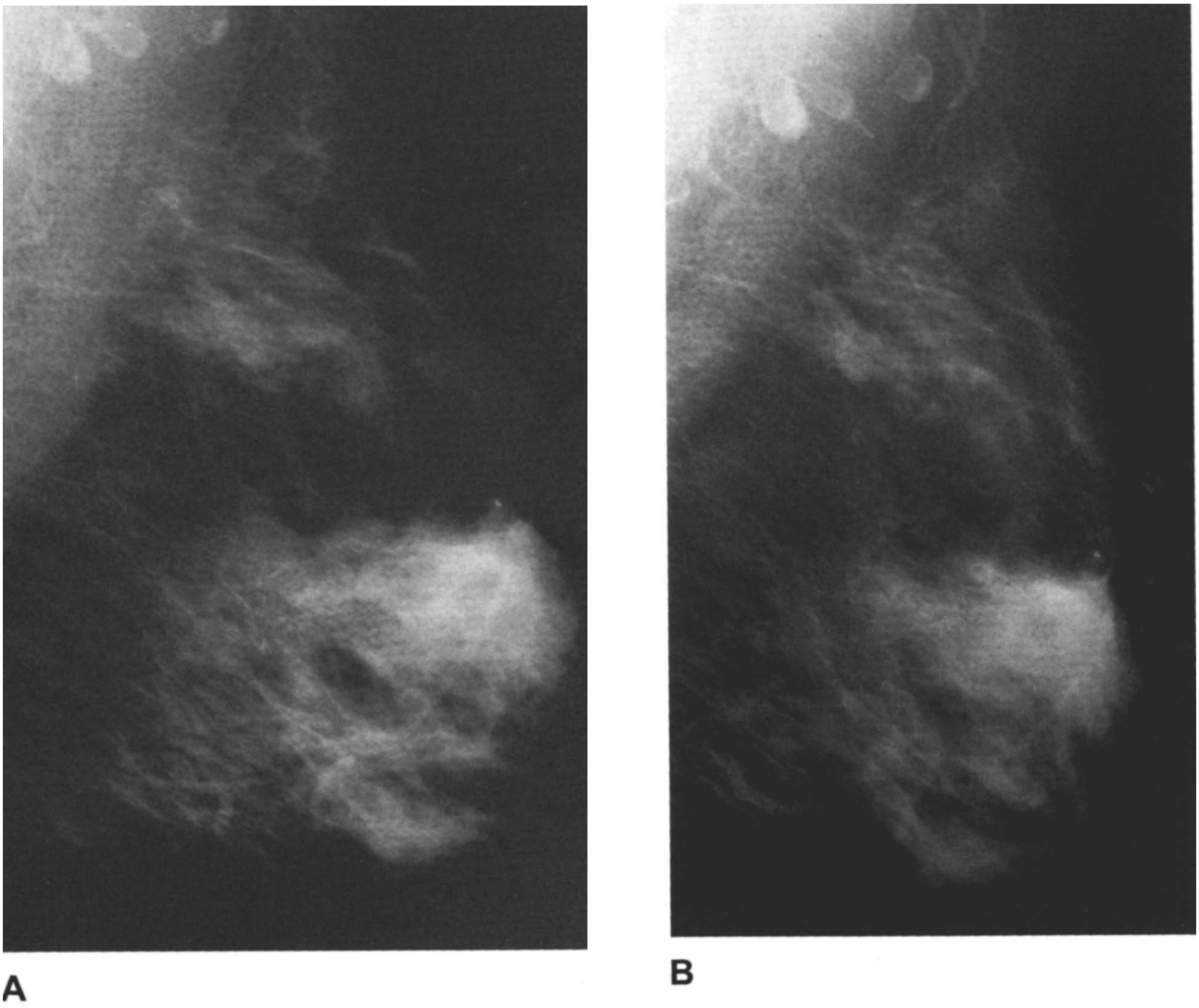
Compression decreases breast thickness, which reduces dose, scattered radiation, and object unsharpness. By making the breast more uniform in thickness, film optical density differences are more likely to correspond to subtle attenuation differences in the breast rather than differences in breast thickness. Compression also eliminates motion by holding the breast still.

Inadequate compression is manifested on clinical images by overlapping breast structures, non-uniform exposure of fibroglandular tissues, poor penetration of thicker portions of the breast, overexposure of thinner areas, and motion unsharpness. It is useful to observe whether structures are less well separated on MLO views than on the CC views, since the former images often will be less satisfactorily compressed. Underexposure of a single image, especially when phototimed, is often a reliable sign that the particular view was not done with optimal compression. Detection of a breast cancer within dense fibroglandular tissues requires separation and exposure of these tissues with compression. Motion blurring resulting from inadequate compression is more commonly seen on the MLO views. Motion may be manifested by blurring of the thin linear structures in the inferior aspect of the breast or blurring of calcifications. Motion blurring may be seen throughout the entire image or may be localized to only a portion of the breast.

After the breast is properly positioned for an MLO, compression is used to maintain the breast upright on the image receptor. If compression is inadequate, the breast may be sagging, the so-called "camel's nose" appearance (Figures 20A and 27A and B).

The most common cause of undercompression is the use of inadequate compressive force by the technologist. Although this may reflect patient discomfort, technologists can usually limit the degree of discomfort by applying compression slowly. Variations in the degree of compression between the right and left sides for the same projection suggest a lack of attention on the part of the technologist.

Poor compression on the MLO may result when the focus of compression is on adjacent body parts rather than the breast. This may be seen on the image if a large quantity of axillary or abdominal tissue is included when compression of the breast itself is poor. If the arm is visualized with corresponding undercompression of the breast, inclusion of the arm is almost certainly the cause of poor results. An unsuitable or faulty compression device will not compress the breast uniformly. Consistently lower exposure levels near the chest wall are suggestive of this defect.



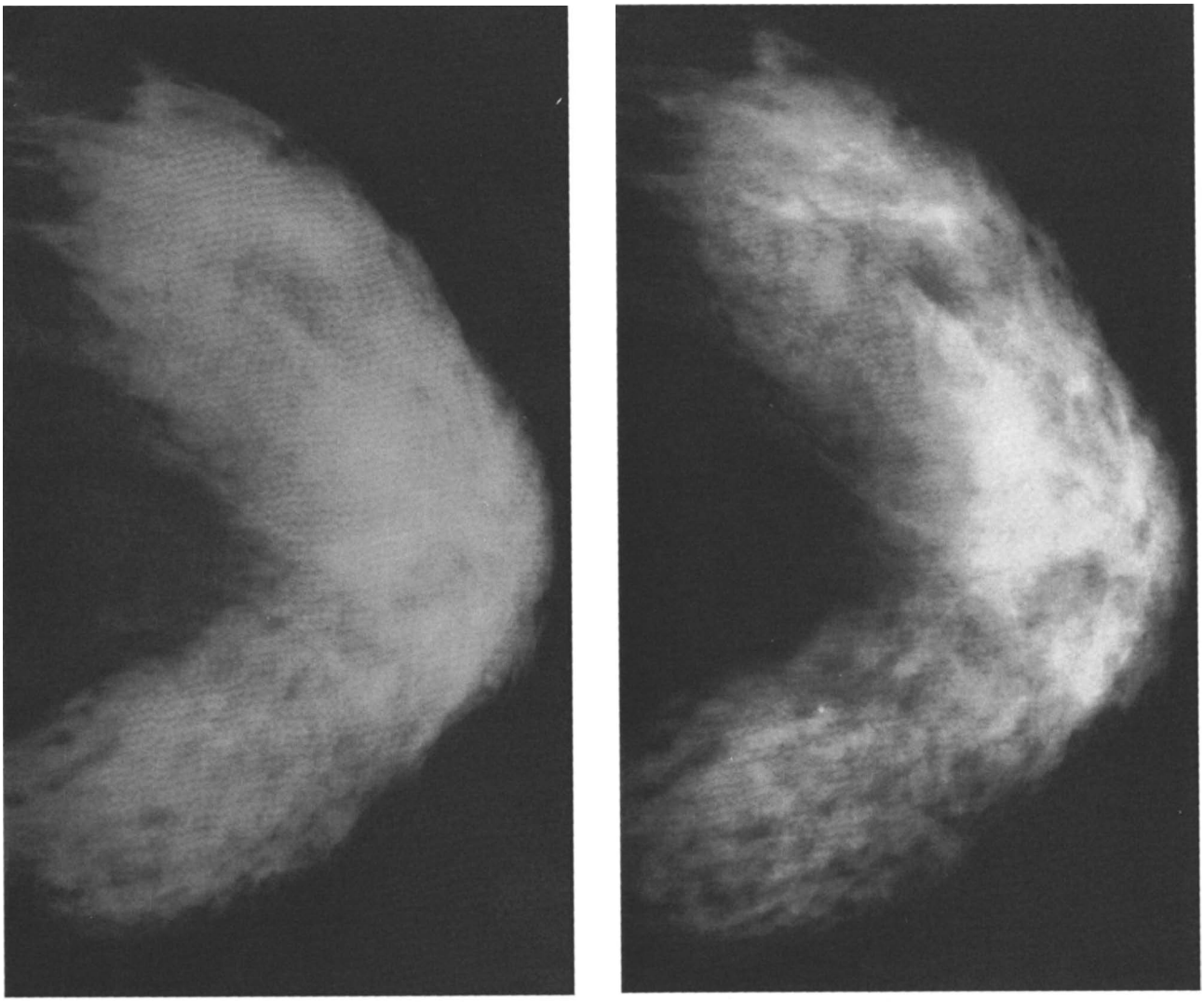
Figures 27A & B. (A) Better compression can be identified by better spreading out of the breast markings. (B) Fewer horizontal breast markings are one indication that the breast is sagging. Also note that the IMF is absent.

5. EXPOSURE

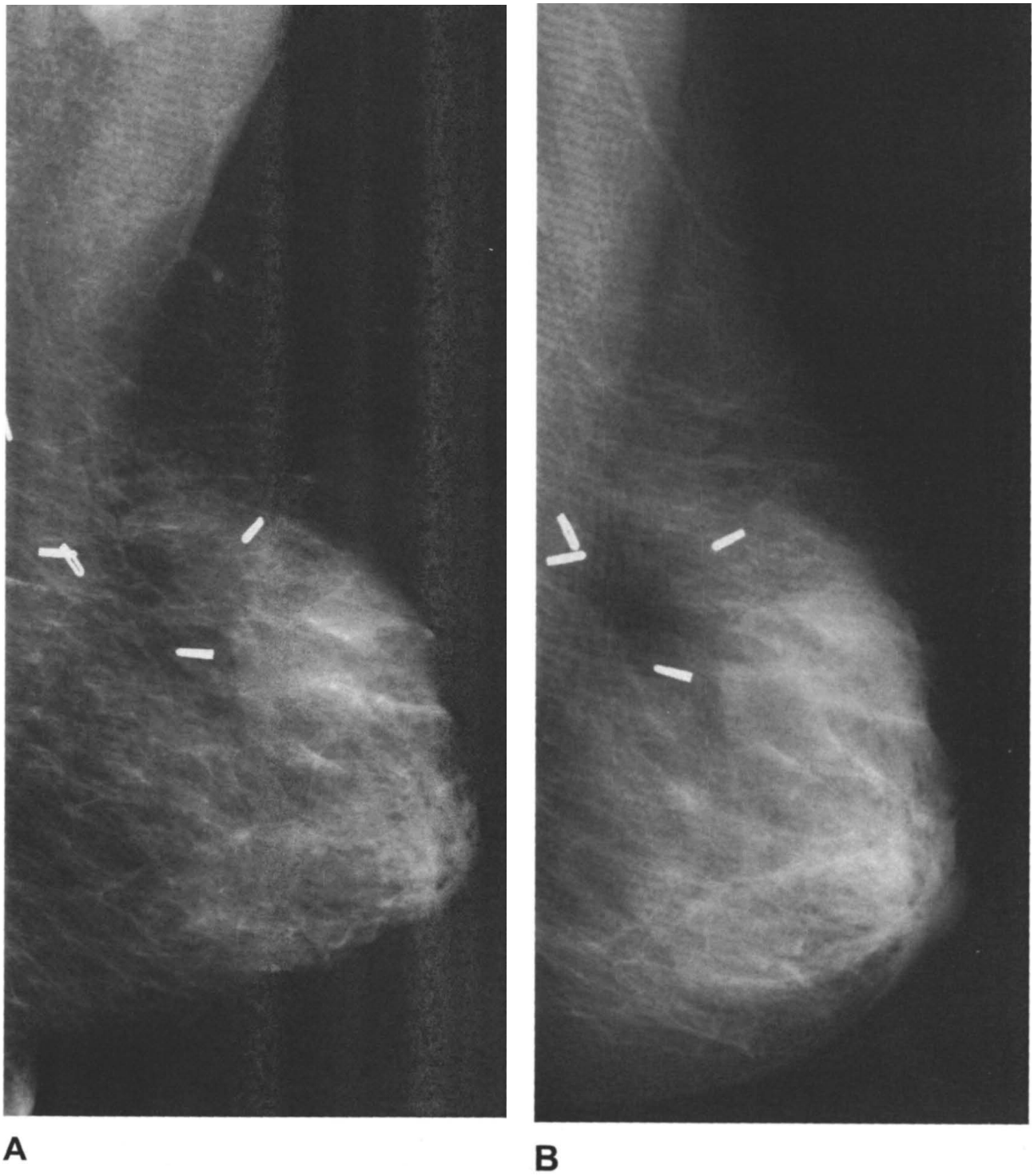
Exposure should be evaluated with good viewing conditions. Appropriate viewing conditions include adequate viewbox luminance, low ambient room light to minimize light reflected off the surface of the film, and masking of films to eliminate viewbox light that has not passed through the exposed area of the film from reaching the eye (see Measurement of Viewbox Luminance and Room Illuminance in the Medical Physicist's Section of this manual). When images are adequately exposed it will be difficult to see the skin and subcutaneous tissues until the images are masked so that extraneous viewbox light is blocked out.

NOTE: Exposure should be monitored in each clinical image by both the radiologic technologist and the radiologist. To accomplish this effectively, the technologists viewing conditions must match the radiologists viewing conditions.

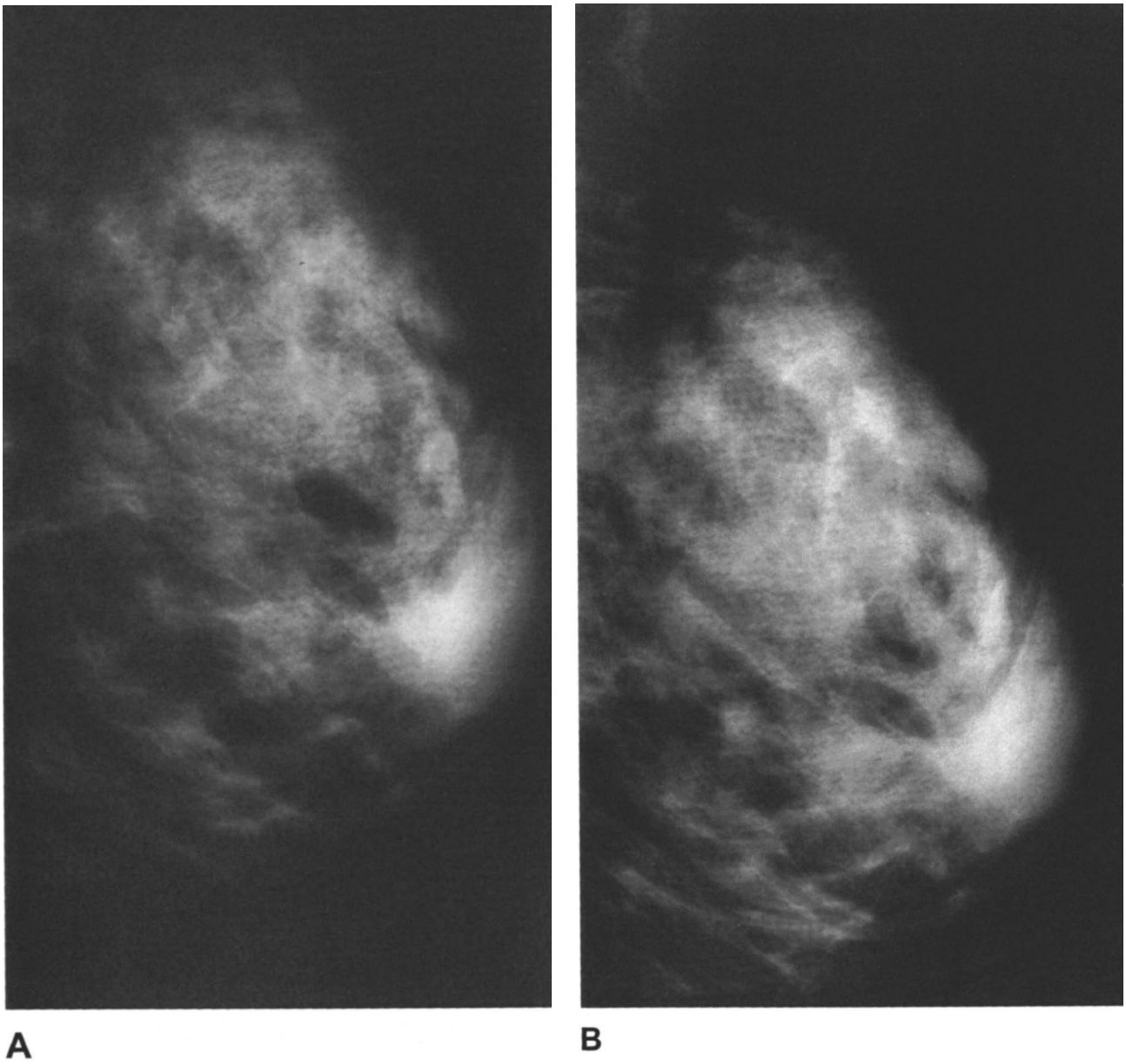
Underexposure is the most common problem in mammography. It is often manifested by underexposure of dense fibroglandular tissue making it impossible to perceive details within the fibroglandular tissue (Figures 28, 29, 30). Underexposure results in decreased radiographic contrast wherever optical densities are low (below 1.0), limiting visualization of certain fine detail, especially microcalcifications, and low-contrast lesions. Underexposure that is present only in the densest portions of the breast will limit the detection of microcalcifications and lesions within those dense, glandular tissues. Areas of the film with optical densities below 1.0 are underexposed. Fibroglandular areas should show variable optical density within the "gray" range of the film. A uniformly washed-out appearance in fibroglandular areas signifies underexposure. The pectoralis muscle is one of the densest structures on the MLO and may have optical densities below 1.0 on a well-exposed mammogram. It is important, however, that the muscle be exposed sufficiently to show underlying breast tissues (Figure 31).



Figures 28A & B. (A) Inadequate exposure of dense tissue occurred because the AEC detector was placed under the posterior fatty tissue rather than under the anterior denser tissue in this breast. (B) Placement of the detector under the dense tissue resulted in better penetration.



Figures 29A & B. Better exposure is evident from better penetration of the denser fibroglanduiar tissue in (A) than in (B). The improved compression in (A) also contributes to the better exposure. This case represents an example of exposure differences that are less striking than those in Figure 28.



Figures 30A & B. Better exposure of the dense fibroglanduiar tissue provides better contrast in (A) compared with (B). This will require high-intensity viewboxes or even bright lighting to visualize the fatty tissue. An image such as (A) should not be considered overexposed.

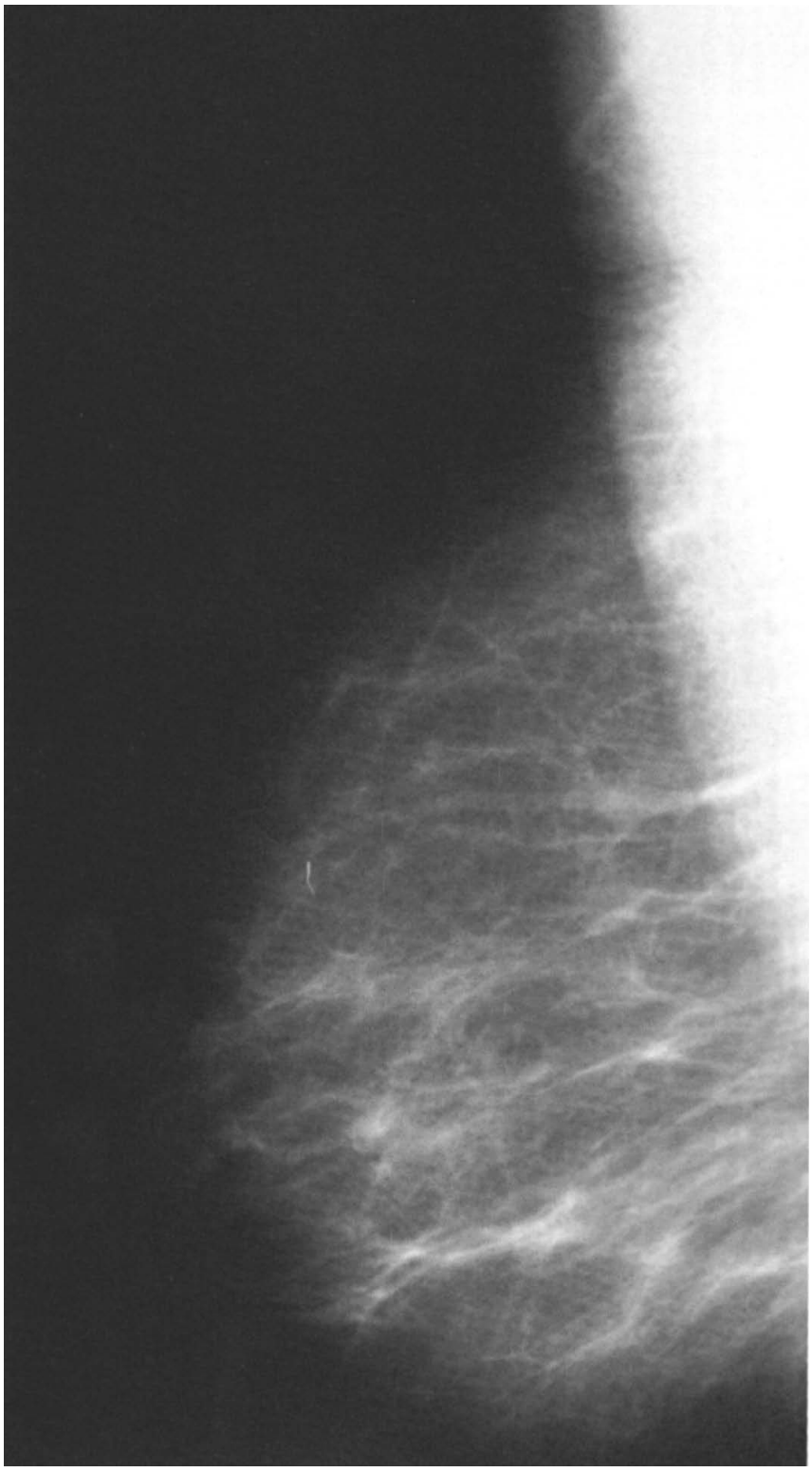
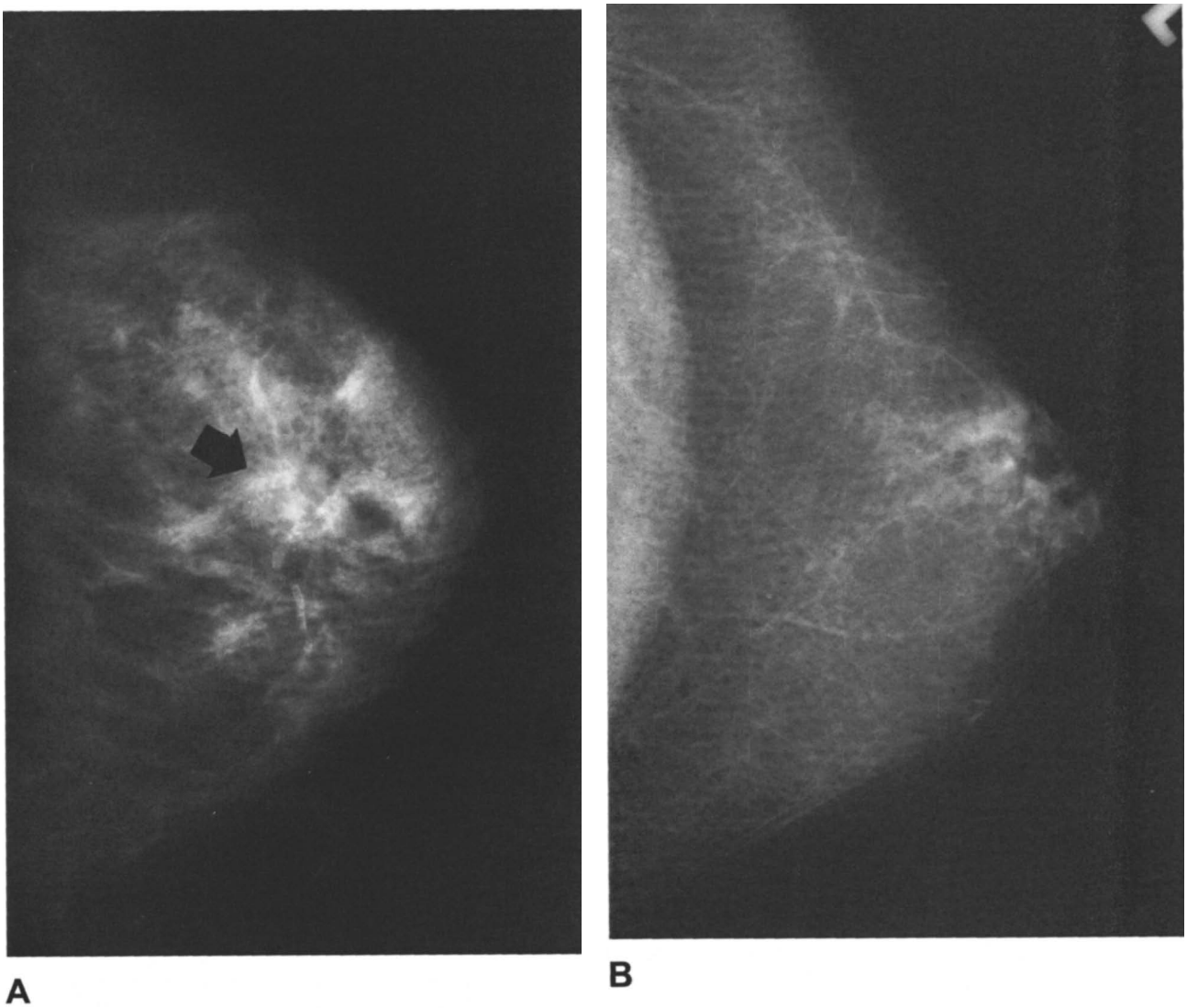


Figure 31. Underexposure of the pectoralis muscle may prevent visualization of underlying structures in the breast. Also note the lint artifact.

Causes of underexposure include processing deficiencies, inadequate compression, poor automatic exposure control (AEC) function, or improper AEC setting. When AEC (phototiming) is used, undercompression may result in underexposure if the phototimer does not compensate adequately for the different breast thicknesses. Poor phototimer compensation or phototimer variability may also account for different exposure levels on the CC and MLO views. Not infrequently, the optical density levels on mammograms reflect the preference of the radiologists who interpret the examinations. Underexposure in order to visualize the skin line without a bright light is an error. Underexposure is probably the leading cause of false-negative mammograms in dense breasts (Figures 32A and B).

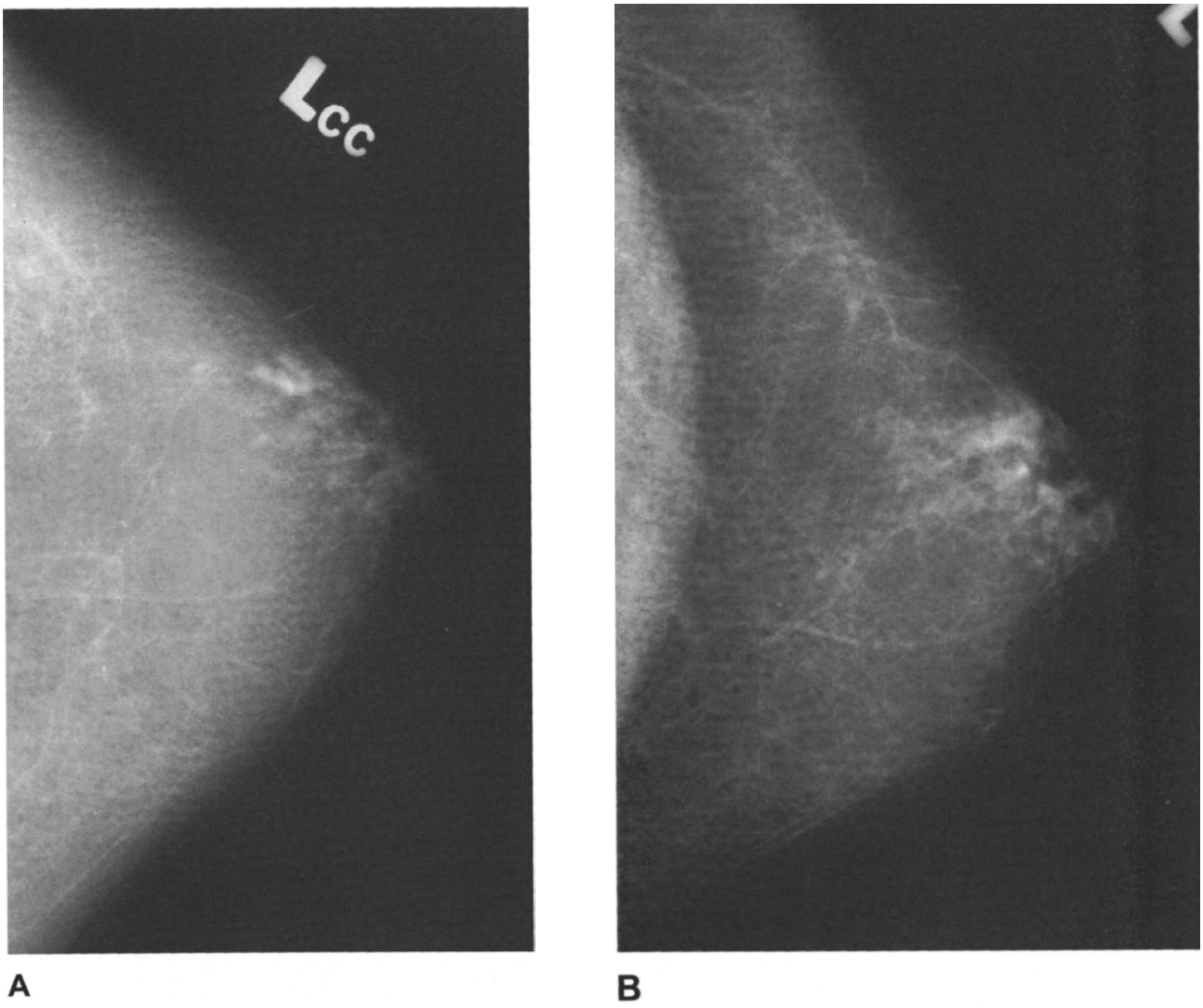


Figures 32A & B. Better exposed image (A) shows a 2-cm, poorly defined carcinoma in the mid breast (arrow) that cannot be identified in (B) due to underexposure of glandular tissues.

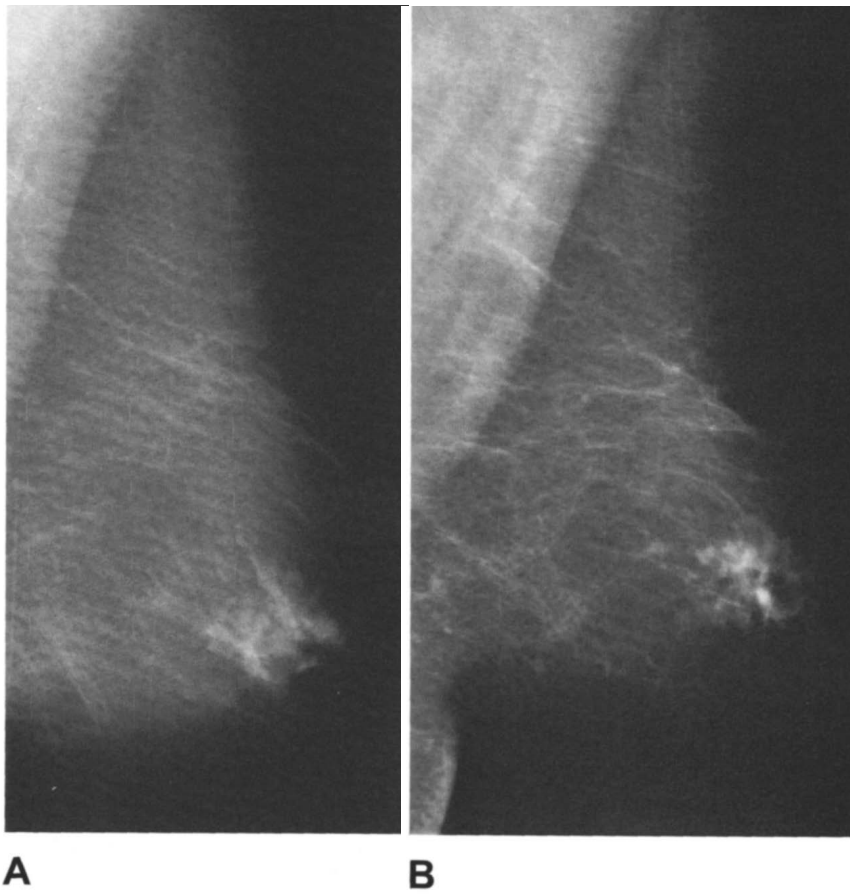
Overexposure is recognized by too much blackening of portions of the breast that are thin or composed of fat. Overexposure is sometimes a "recoverable" error that can be overcome by using high illumination and masking (i.e., "hotlighting"). Underexposure, on the other hand, is an unrecoverable error, in that lost contrast cannot be restored in the light areas of the film, and the film has to be repeated with greater film exposure. Extreme cases of overexposure will result in decreased radiologic contrast.

6. CONTRAST

Radiographic contrast can be defined as the differences in optical density between adjacent areas of the film. Contrast allows us to see subtle attenuation differences in the breast (Figures 33 and 34). Contrast is usually highest in thinner breasts and lowest in thicker breasts due to more scattered radiation and greater tissue absorption of low kVp radiation in thicker breasts.



Figures 33A & B. Two CC views of the same breast taken 1 year apart (A and B). Improved contrast can be attributed to better compression, proper exposure, and higher contrast film (B).



Figures 34A & B. Better compression, proper exposure, and higher contrast film provided some improvement in contrast on comparison of MLO views of the same breast taken 1 year apart (A and B). The latter image (B) also shows a greater inclusion of the pectoralis muscle, presence of the IMF, inclusion of more posterior-inferior breast tissue, and improved sharpness.

If a mammographic examination does not have sufficient contrast, the breast tissues will have a rather uniform appearance, regardless of the complexity of the underlying anatomy. In such cases, parenchymal tissues of different thicknesses may have very similar optical densities. Ready visualization of the skin line can be a sign of poor image contrast.

Causes of poor contrast include inadequate exposure, processing deficiencies, inadequate compression, use of low-contrast film, inappropriate target material and/or filtration, failure to use a grid, and excessive kVp. Although excessive kVp will reduce contrast, many current mammography films have significantly higher inherent contrast allowing the use of higher kVps without sacrificing image contrast.

Images that are either underexposed or overexposed will have suboptimal contrast. To ensure adequate contrast, fatty tissues should have at least an optical density of 1.2; however, optical densities of 1.5 to 2.0 are preferable. Glandular tissues should have an optical density of at least 1.0. Generalized underexposure is a common cause of decreased image contrast. When generalized underexposure is present, it is difficult to assess other potentially coexistent contrast-related defects.

Proper processing is essential for proper image contrast. Selection of an appropriate combination of film, processing chemicals, processing cycle and temperature, and processing quality control are discussed in the Radiologic Technologist's Section of this manual.

Inadequate compression can result in beam hardening and in increased scatter, both of which cause decreased contrast. To ensure that the breast is compressed sufficiently, compression should be applied until the skin is taut. Some breasts, however, are relatively incompressible despite their mammographic appearance.

Use of a mammographic grid improves contrast by decreasing the amount of scattered radiation that reaches the image receptor. Moving grids are preferable to fixed grids since the latter will produce grid lines on the image.

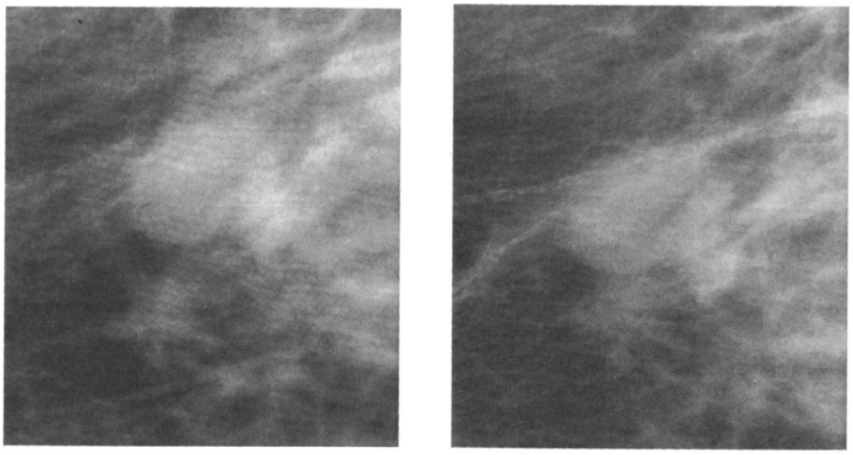
Although an increase in kVp may reduce contrast, this effect is relatively minor when optical density is constant. On the other hand, kVp has a major effect on exposure time and dose. For example, when kVp is increased from 26 to 28, exposure time decreases 50% and dose decreases 15%-20%. Therefore, in some instances, an increase to 28 or 30 kVp may be necessary to achieve adequate exposure with a sufficiently short exposure time. An increase in kVp might obviate long exposures that would either be beyond the capabilities of the mammographic unit or that would lead to motion unsharpness.

Excessive contrast is less frequently encountered than insufficient contrast. If fatty tissues require bright light viewing, and fibroglandular tissues are near the base plus fog density level, the contrast of the image is too high. Prominent radiopacity of the pectoralis muscle, limiting visualization of overlying structures, on a film that is otherwise well exposed, may also indicate that contrast is too great. Although high contrast is desirable, excessive contrast may preclude visualization of both thin and thick tissues in the same image. Thus, a balance has to be found between contrast and latitude when selecting film for mammography.

7. SHARPNESS

Sharpness is the ability of the mammographic system to capture fine detail in an image, such as the edges of spiculations. Unsharpness is often referred to as "blur." In the image, unsharpness is manifested by blurring of the edges of fine linear structures, tissue borders and calcifications (Figure 35). Types of blur that may be encountered in mammograms include motion blur, poor screen-film contact, screen unsharpness, geometric unsharpness, and parallax unsharpness.

Patient motion is the most commonly encountered cause of readily detectable image unsharpness. Blurring from motion unsharpness usually has a unidirectional character that is readily recognized and distinguished from generalized unsharpness that may be due to recording system or geometric effects. Breast compression may prevent motion unsharpness by reducing breast thickness to allow shorter exposure times and by immobilizing the breast. Motion unsharpness is more likely to be seen when the exposure times exceed 2 seconds. Therefore, the mammography generator should have sufficient output to adequately expose large breasts and dense breasts in reasonably short exposure times. Unsharpness on only one portion of an image is often due to motion and suggests non-uniform breast compression.



Figures 35A & B. Magnification. Motion unsharpness of vascular calcifications, mass margins, and linear structures (A) compared with (B) is due to the longer exposure time: 4.0 seconds versus 1.5 seconds. Underexposure (A) was due to inability of the mammographic unit to compensate adequately for lower kVp by sufficiently increasing mAs. Despite a lower kVp, (A) has less contrast than (B) due to underexposure.

As mentioned under the section on breast compression, motion unsharpness is more likely to occur on the MLO than on the CC view.

Localized unsharpness of an image also may be seen with poor screen-film contact, which is due to the further spread of light from the screen before reaching the film. This form of unsharpness can usually be differentiated from motion unsharpness by the more localized, symmetrical nature of the blurring and the more geometric margination of the unsharp area.

Causes of poor screen-film contact (Figure 36) include poorly designed or damaged cassettes, improper placement of the film in the cassette, and dirt lying between the film and the screen. Air trapped between the film and the screen during loading can also cause poor screen-film contact.

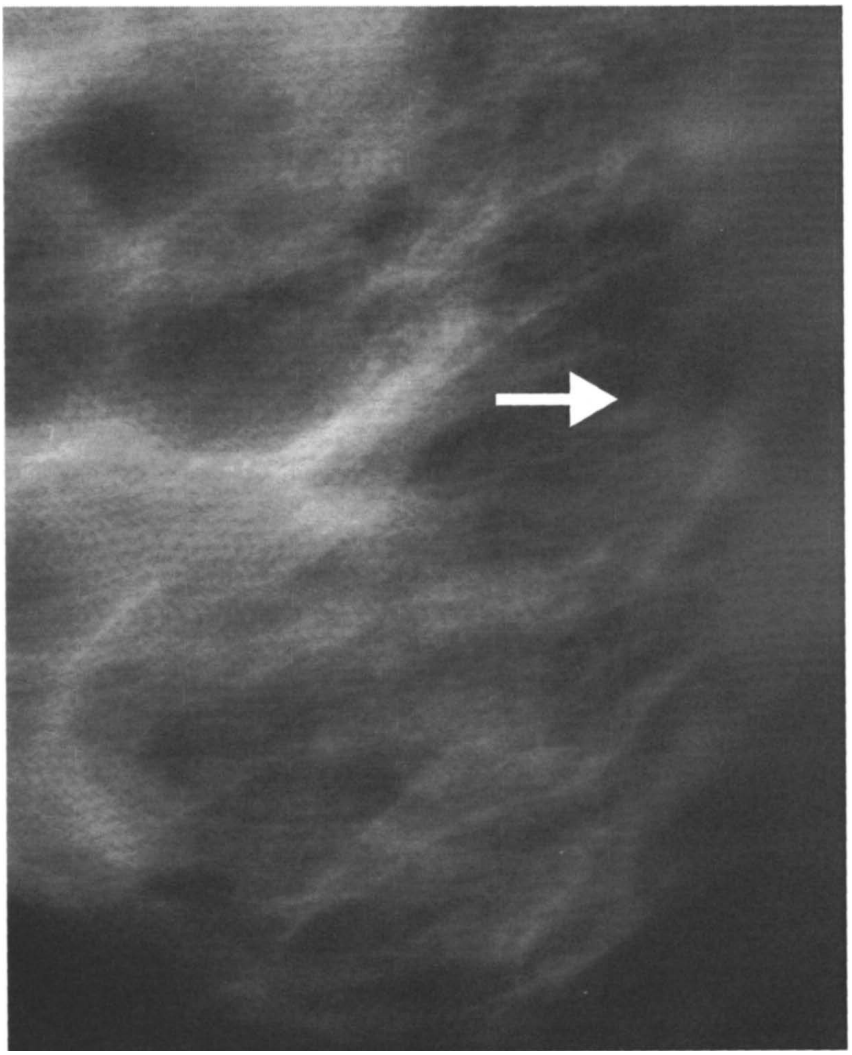


Figure 36. Regional area of blurring due to poor screen-film contact.

Cassettes are designed so that trapped air will be evacuated after cassette closure, but complete removal of the air may take several minutes. Therefore, it is suggested that the radiologic technologist wait at least 15 minutes after loading before exposing many types of cassettes (consult cassette manufacturer for specific wait times).

Mild, generalized, unsharpness in mammographic images may be difficult to detect and assess. Such unsharpness is most likely due to characteristics of the screen-film combination used or to geometric factors. Faster screens usually have thicker phosphor layers and therefore exhibit greater light spread, and so greater unsharpness. Screen unsharpness should affect all structures in the image uniformly. Screen unsharpness results from a single X-ray absorbed in the screen being converted to a large number of visible light photons. These produced photons spread as they travel from the point of X-ray interaction in the screen to the area where they are absorbed by the film. Steps taken to produce faster screens, such as making the screen thicker or placing a reflective coating behind the screen, result in greater photon spread and, as a result, a greater degree of screen unsharpness.

An increase in focal spot size, an increase in object-to-image receptor distance, or a decrease in source-to-image receptor distance increases geometric unsharpness. Over the last decade, the focal spot sizes of dedicated mammography units have been decreased to reduce geometric blurring in both contact and magnification mammography.

Parallax unsharpness refers to the blurring due to the use of double-emulsion films. The image captured on each side of a double-emulsion film is separated by the width of the film base. If the image is viewed from a distance different than the focal spot-to-film distance, the slight offset of the two emulsions results in image blur. Because of this effect, double-emulsion films have not been widely accepted in mammography, despite the benefits of lower radiation dose, shorter exposure times and longer tube life.

8. NOISE

Noise, or radiographic mottle, (Figure 37) decreases the ability of the interpreting physician to discern tiny structures, such as calcifications. The major cause of noise on most mammograms is quantum mottle. Quantum mottle is due to the statistical fluctuation in the number of X-ray photons absorbed at individual locations in the intensifying screen. The fewer X-ray photons that are used to make the image, the greater the amount of quantum mottle that results. Thus underexposure, extended processing and faster image receptors are associated with increased noise. Faster screen-film systems decrease breast dose but yield noisier images, which can reduce the detection of low-contrast structures within the breast. Ironically, quantum mottle is more likely to be seen on high-contrast films, since high-contrast makes the mottle more visible. In mammography, unlike most other radiographic studies, fluctuations related to film grain also represent a sizable component of the total radiographic noise, often being comparable to quantum mottle in magnitude. Processing can also introduce noise, both random and structured (e.g., roller marks, wet pressure marks) into the image.

Figure 37. Noise can be identified by an inhomogeneity in the background density. There is a resultant unsharpness and loss of visualization of low-contrast breast structures.

9. ARTIFACTS

An artifact is any density variation on an image that does not reflect true attenuation differences in the subject. Artifacts can be a sign of problems in darkroom cleanliness, film handling, screen maintenance, processing, or X-ray equipment. The presence of multiple artifacts on images is a sign of deficient quality control. Examples of artifacts are dust or lint (Figure 31), dirt, scratches, fingerprints (Figure 38), and fog. Many of these artifacts are avoided by careful attention to darkroom conditions, including general cleanliness, film handling, regular cleaning of the cassettes and screens, light leaks and safelights.

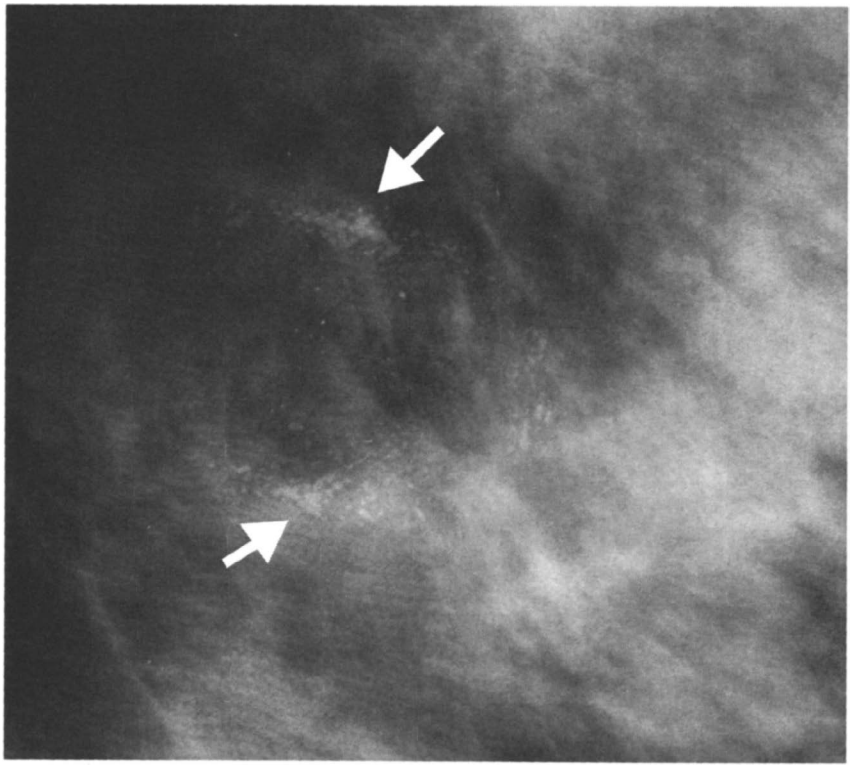


Figure 38. Fingerprints result from manual handling of the film or fluorescent screen surface prior to exposure.

Grid lines and grid non-uniformities are some of the most common equipment artifacts (Figure 39). When using a moving grid, grid lines should not be visible on images. If grid lines are observed regularly, the drive mechanism should be repaired or replaced. Two images of a uniform phantom acquired identically and processed at right angles to each other may be required to determine if artifacts are due to a faulty grid or processor. (See Artifact Evaluation in the Medical Physicist's Section of this manual). Processor artifacts (Figure 40) can usually be distinguished from grid lines. Improper size or alignment of the compression device can also lead to artifacts on the image.

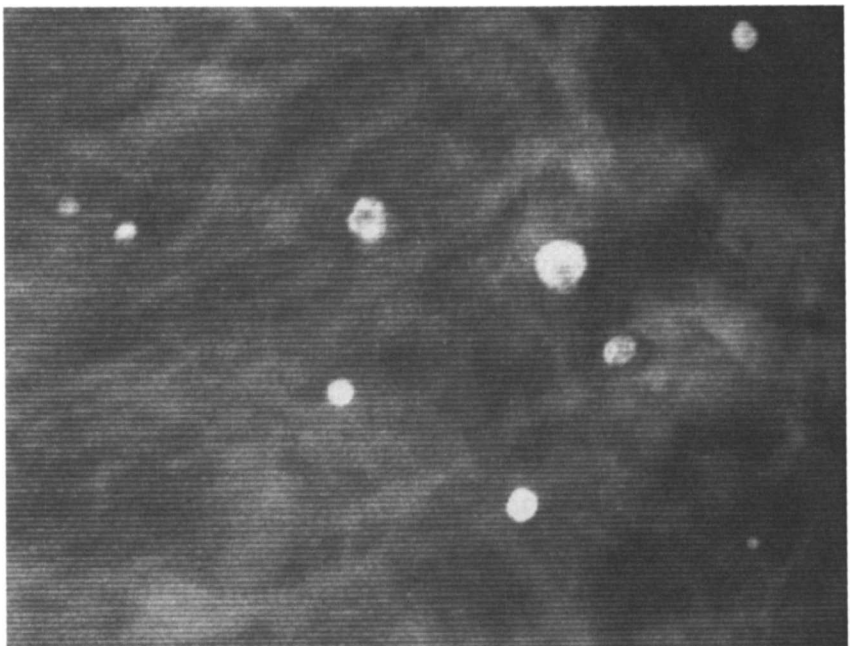


Figure 39. Grid lines are thin, multiple, and run perpendicular to the long axis of the film.

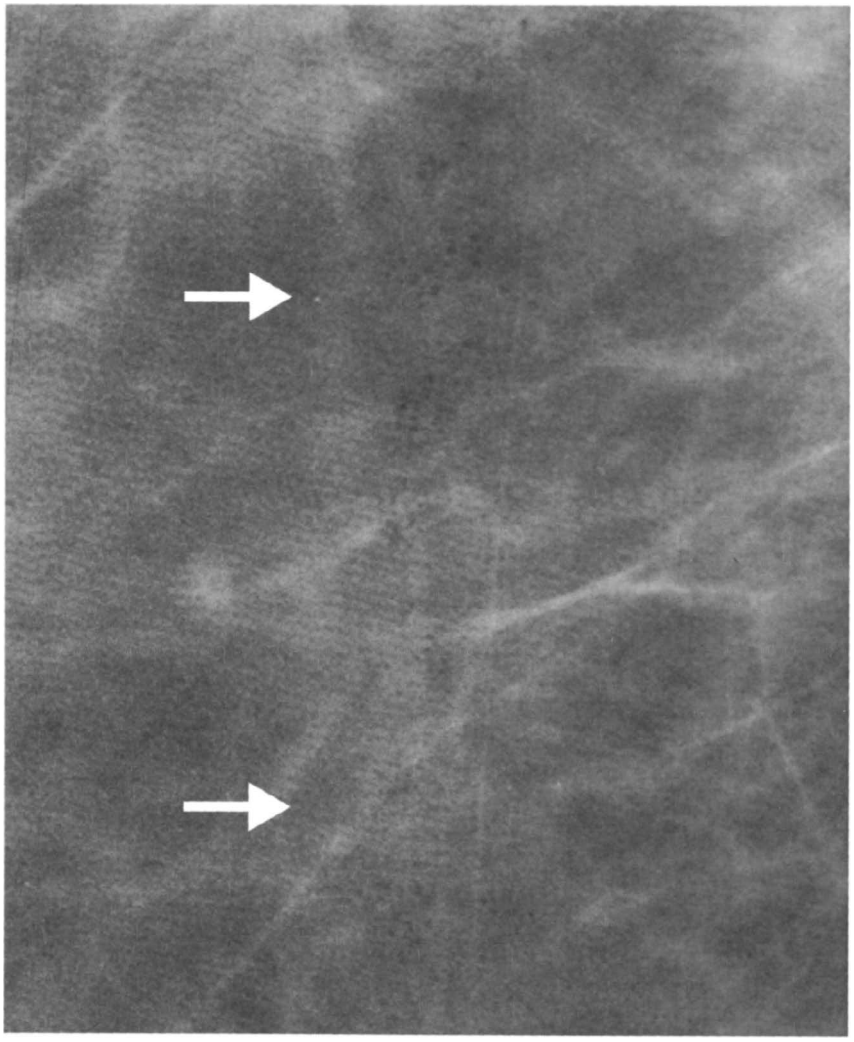


Figure 40. Roller marks from processor. These tend to be broader, fewer in number, and spaced further apart than grid lines.

10. COLLIMATION

The X-ray beam should be collimated as close as possible to the edges of the film, not to the breast. Collimating close to the surface of the breast may result in cut-off of part of the image of the breast. The use of round collimators prevents satisfactory masking of images at the viewbox.

Breast tissue may be excluded from the image if the collimation does not permit the X-ray field to extend slightly beyond the edge of the film on the chest wall side. Breast tissue also may be excluded from the image due to improper placement of the film in the cassette, poor fit of the cassette within the cassette holder or bucky, and misalignment of the compression device so that the posterior lip of the compression paddle is superimposed on posterior breast tissue.

MQSA REQUIREMENTS:

All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge on the image receptor by more than 2% of the SID.

If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2% of the SID.

The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

11. LABELING

Standardized labeling can facilitate the interpretation of images from other facilities and reduce the likelihood of films being lost or misinterpreted. Guidelines for labeling mammography films are divided into three categories: required, highly recommended, and recommended. These are described in Section I of the Clinical Image Quality Section of the manual. The required items include a label identifying patient and facility, a view and laterality marker (e.g., MLO, CC), the cassette number (usually an Arabic numeral), the initials of the radiologic technologist who performed the examination, and an identifier for the mammography unit used when there is more than one dedicated unit (usually a Roman numeral). The identification label should contain the following: facility name and address (at a minimum city, state, and ZIP code), examinees first and last name, and a unique ID number (e.g., medical record number, social security number, or less preferable, date of birth). It is strongly recommended that the identification label be "flashed" on the image to make it as permanent as possible and so that it will be transferred onto copy films. The view and laterality marker should always be placed near the axilla to facilitate orientation of the image.

Additional recommended film labeling includes a date sticker and a record of the technique factors used to make the image. Date stickers, which are used by over 40% of mammography facilities, allow for more efficient sorting of examinations by date because they can be read with overhead light and they are color coded by year. A record of the technical factors used for each image helps the technologist perform quality control checks on image quality and is useful when subsequent mammograms are performed on the same patient.

12. CONCLUSION

Peer review of clinical images performed on each mammography unit is required for a facility applying for mammography accreditation. Clinical image evaluation is also an important daily quality control activity that should be performed by every radiologist who interprets mammograms. It involves the scrutiny of mammograms for technical deficiencies, including an assessment of breast positioning and compression, image quality, and artifacts.

The radiologist's evaluation of clinical images on a daily, ongoing basis is complementary to other quality control activities in the facility. Feedback to the radiologic technologist concerning deficiencies in images is an effective method for maintaining high-quality mammography. Part of the clinical image evaluation process involves recognizing the most likely causes of image deficiencies so that they can be addressed quickly and efficiently.

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1999 Mammography

QUALITY CONTROL MANUAL

Radiologic Technologist's Section

Introduction

For the purposes of this manual, **quality control** is defined as the routine performance and interpretation of equipment function tests and of the corrective actions taken. The point of quality control is to detect, identify and correct equipment-related problems **before** they have a deleterious effect on clinical images. Due to their day-to-day contact and familiarity with their particular mammography equipment, radiologic technologists are the front line of defense against potential imaging problems. The purpose of this section of the manual is to provide an effective and consistent methodology for detecting and identifying image quality problems. Together with the radiologist, the medical physicist, and qualified equipment service personnel, radiologic technologists can eliminate these problems before patient care is affected.

This version of the *ACR Mammography Quality Control Manual* has been modified to be compatible with Mammography Quality Standards Act (MQSA) Final Rules, which go into effect on April 28, 1999. The technologist quality control (QC) test procedures, performance criteria, and minimum test frequencies have been designed to provide a model QC program that satisfies MQSA Final Rule requirements for quality control in mammography. This manual is based on previous ACR mammography QC manuals and has been updated to include new information learned since the last QC manual was published in 1994, to describe test procedures more clearly, and to ensure consistency with MQSA Final Rules.

Some substantive changes since the 1994 version of the *ACR Mammography Quality Control Manual* include conducting phantom evaluation of image quality at least weekly and more detailed instructions for scoring phantom images that includes deductions for artifacts. Other changes include a revision of the control film crossover procedure. Finally, a new subsection has been added to each QC test specifying the minimum MQSA requirements for that test.

For each of the eleven technologist QC tests included in this manual, the purpose and frequency of each test is clearly stated. The equipment and materials required to carry out each test are listed, and a step-by-step procedure is provided, followed by a discussion of precautions and caveats. Suggested performance criteria are provided along with suggestions for the types of corrective actions that may be needed to resolve problems. Control charts and data forms are provided in this document and may be copied for use in performing and documenting the QC program.

The minimum frequencies for both the technologist and medical physicist tests are listed in Table 1. It must be stressed that the listed frequencies are minimum frequencies. If problems are occurring or if equipment is unstable, it may be necessary to carry out some or all tests more frequently to identify problems before they affect clinical image quality or patient safety. If the quality control program is just being initiated, one should carry out QC tests more frequently for the first few months. This will provide the QC technologist with more experience in a shorter period of time and will also provide better baseline data regarding the reliability of imaging equipment.

In addition to performing the mammographic quality control tests at the minimum frequencies indicated, tests also should be carried out for new equipment, when problems are suspected, and after service or preventive maintenance. For example, the compression test should be carried out initially when a new X-ray system is installed and after a service adjustment of the compression force; screen-film contact tests should be carried out whenever new cassettes are placed into service; and the darkroom fog should be checked whenever new safelights or filters are installed in the darkroom or when a new type of film is used. Any time the processor is serviced, the processor QC test should be performed. In addition, the phantom image test should be carried out to test for processing artifacts.

If any QC test fails, the MQSA Final Rules require that the source of the problem be identified and corrective action be taken. In some cases, if the test results fall outside of the action limits, MQSA requires that the source of the problem be identified and corrective action taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test. Other test failures must be corrected within 30 days of the test date (Table 1).

Due to the importance of quality control in mammography, it is recommended that the radiologist and, if possible, the medical physicist, review the control charts, other data, and images with the QC technologist at least quarterly, or more frequently if so desired by the radiologist. The medical physicist is required to review the technologist's QC test results at least annually and provide written recommendations if there are problems or suggestions for improvement. Review of the technologists QC program by the radiologist and medical physicist assures that the QC program is carried out consistently and provides oversight to assure that changes in image quality are not inadvertently overlooked.

Table 1. MAMMOGRAPHIC QUALITY CONTROL TESTS

Test	Minimum Frequency	MQSA Requires Corrective Action to be Taken
Technologist Tests		
Darkroom cleanliness	Daily	—
Processor quality control	Daily*	**Immediately**
Mobile unit quality control	Daily*	**Immediately**
Screen cleanliness	Weekly	—
Viewboxes and viewing conditions	Weekly	—
Phantom images	Weekly*	**Immediately**
Visual checklist	Monthly	—
Repeat analysis	Quarterly*	Within 30 days of the test date
Analysis of fixer retention in film	Quarterly*	Within 30 days of the test date
Darkroom fog	Semi-annually*	**Immediately**
Screen-film contact	Semi-annually*	**Immediately**
Compression	Semi-annually*	**Immediately**
Medical Physicist Tests		
Mammographic unit assembly evaluation	Annually*	Within 30 days of the test date
Collimation assessment	Annually*	Within 30 days of the test date
Evaluation of system resolution	Annually*	Within 30 days of the test date
AEC system performance	Annually*	Within 30 days of the test date
Uniformity of screen speed	Annually*	Within 30 days of the test date
Artifact evaluation	Annually*	Within 30 days of the test date
Image quality evaluation	Annually*	**Immediately**
kVp accuracy and reproducibility	Annually*	Within 30 days of the test date
Beam quality assessment	Annually*	Within 30 days of the test date
Breast exposure and AEC reproducibility	Annually*	Within 30 days of the test date
Average glandular dose	Annually*	**Immediately**
Radiation output rate	Annually*	Within 30 days of the test date
Measurement of viewbox luminance and room illuminance	Annually	—
*Required under the MQSA Final Rules		

Note that under MQSA, corrective action required immediately means "before any further examinations are performed or any films are processed using the component of the mammography system that failed the test."

The medical physicist's QC tests in this manual have also been updated to include some new test procedures and to be compatible with MQSA Final Rule requirements. The medical physicist has the primary responsibility for performing QC testing on the X-ray equipment itself, including tests such as focal spot performance, half-value layer, entrance exposure and dose measurements, kVp accuracy, and reproducibility. In addition, the medical physicist should be available to answer questions for the QC technologist carrying out the QC tests listed in this manual whenever problems are encountered. The medical physicist is a resource that both the radiologist and QC technologist should rely on for questions and problems regarding mammography image quality and quality control.

A new MQSA Final Rule requirement is that new equipment or existing equipment that has undergone major changes, including X-ray units and processors, should be evaluated by a qualified medical physicist before being placed in clinical use. Therefore, the site's medical physicist should be made aware of upcoming equipment additions and changes so that an evaluation can be scheduled after installation or modification and prior to use of the equipment for mammography. Equipment must be evaluated by a qualified medical physicist after the modifications shown in Table 2 are done. It may also be helpful to have a physicist evaluate the equipment after other, more minor, modifications.

Table 2. MAMMOGRAPHY EQUIPMENT EVALUATION BY MEDICAL PHYSICIST REQUIRED AFTER THESE CHANGES

Newly installed X-ray unit (even if used)
Newly installed processor (even if used)
X-ray unit or processor disassembled and reassembled at the same or new location
X-ray tube replacement
Collimator replacement
Filter replacement
AEC replacement

In a facility where more than one technologist does mammography, one technologist should be assigned the responsibilities of quality control. Other qualified individuals may perform specific QC tests but they must be reviewed and evaluated by the designated QC technologist. The designated QC technologist is responsible for ensuring that the tasks are done properly by standardizing test methodology, reviewing all data, overseeing repeat testing before calling the medical physicist or service personnel, and conferring with the radiologist and medical physicist. The radiologist, medical physicist, and QC technologist, working together as a team, are the keys to providing optimum quality mammography images, which will ultimately provide the best medical care possible to the patient.

There are a number of points that are important to an effective mammography quality control program. These "Important Points" are applicable to most of the tests described in this manual and are presented in Section II. A detailed description of each QA test is presented in Section III. Section IV contains some additional, less frequently performed processor QC tests for monitoring developer temperature and replenishment rates. Section V is a new section on the problems and requirements of mobile mammography. Section VI contains new information on the importance of infection control in mammography. Section VII is a list of references for the technologist QC tests.

1. TIME FOR QUALITY CONTROL PROCEDURES

The approximate times to carry out the QC procedures described in this manual are listed in Table 3. Processor quality control must be conducted daily. It is recommended that the site have procedures for ensuring daily darkroom cleaning, although this need not be performed by the mammography QC technologist if it is being performed adequately by other facility personnel. The QC technologist, however, should check darkroom cleanliness on a daily basis.

Some of the technologist's QC tasks can be carried out at the same time. For example, as soon as the processor is turned on, and while waiting for it to warm up, the darkroom can be cleaned, screens can be cleaned, and the viewbox and viewing conditions can be checked. Consequently, once an efficient routine is established, only a modest amount of time is required for a successful mammographic QC program.

Table 3. RESPONSIBILITIES OF THE QC TECHNOLOGIST AND APPROXIMATE AMOUNT OF TIME NEEDED

Nature of Procedure/Task and Minimum Performance Frequency	Time Needed*
Daily	
Darkroom cleanliness	5 min
Processor QC	20 min
Weekly	
Screen cleanliness	10 min
Viewbox cleanliness	5 min
Phantom images	30 min
Monthly	
Visual checklist	10 min
Quarterly	
Repeat analysis	60 min
Analysis of fixer retention	5 min
Meetings with radiologist	45 min
Semiannually	
Darkroom fog	10 min
Screen-film contact	80 min
Compression	10 min
Total Time for QC per Year	160 hours

* Estimated times include setup, testing, and recording of results for a facility with two mammography units, one processor and 16 cassettes.

Adapted from Farria DM et al. 1994

2. DARKROOM CLEANLINESS

The darkroom is a major source of problems in mammography. Any dust or dirt in the darkroom will result in artifacts in the mammographic images. A clean darkroom will result in fewer artifacts and reduce the amount of effort required for cleaning the cassettes and screens. There are a few basic rules regarding darkroom design and cleanliness that will help reduce the amount of dust and dirt and, consequently, the number of dust artifacts in mammographic images.

There should be no smoking, eating, or drinking in the darkroom. In addition, food and drink should not be taken into the darkroom at any time. There should be nothing on the countertop used for loading and unloading the cassettes. Items on the countertop make cleaning more difficult and provide a convenient place for dust and dirt to accumulate.

Although convenient for film storage, there should be no shelves above the countertops in the darkroom. Such shelves provide another place for dust and dirt to accumulate. Whenever a box of film is removed from the shelves above the countertop, the accumulated dust and dirt are deposited on the area used for loading and unloading cassettes.

The ceiling of the darkroom should be constructed of a solid material such as drywall. Ceiling tiles, often set in metal channels, allow dust and dirt to sift through the ceiling and fall on the surfaces used for handling cassettes. In addition, light can often enter the darkroom through such tiles, resulting in fog on mammographic films.

The vent for heating and air conditioning should not enter the room over the counter used for handling cassettes. This provides another source for dust and dirt to be deposited on the counter.

Ultraviolet lights are available (inexpensive ones can be purchased at novelty stores) that help demonstrate the dust and dirt in darkrooms. Some dust and dirt particles fluoresce when exposed to ultraviolet light and can readily be seen if all other lights are turned off. However, not all dust and dirt particles fluoresce.

Electrostatic air cleaners may prove useful in reducing the amount of dirt and dust in the darkroom. In addition, static electricity can be reduced in several ways. The humidity level in the darkroom should be maintained between 40% and 60% throughout the year. If a new darkroom is being designed, countertop materials that reduce static electricity should be considered. Finally, static discharge systems are available that provide a continuous flow of ionized air to reduce static during the loading and unloading of cassettes.

Other sources of dust and dirt must be controlled. For example, if cassettes are placed on the floor beneath the passbox or on the floor in the mammography room, they will accumulate dust that may be carried into the darkroom. In addition to other darkroom cleaning tasks, the passbox should be cleaned every day to prevent dust and dirt from being introduced into the darkroom.

If a daylight film autoloading system is used, similar care should be used in controlling dust and dirt in the area of the film autoloading system. Dust and dirt on the outside of cassettes can work their way into the autoloading system and end up causing dust and dirt artifacts on films. The areas above and around autoloading systems and the surfaces on which cassettes are stored should be kept as free of dust and dirt as the darkroom.

3. MAMMOGRAPHY UNIT IDENTIFICATION

MQSA Final Rules not only require that mammography films contain unique identifiers for the patient and facility (see "Film Labeling" in the Clinical Image Quality Section), but also require that each mammography unit be labeled on the film. At sites with more than one mammography unit, this can be done by including a mammography unit identification on the film flash labeling system or by having radiographically visible markers that uniquely label the mammography unit on each film. A Roman numeral is suggested.

4. CASSETTE IDENTIFICATION

It is important to be able to uniquely identify each cassette. For example, if the QC technologist or radiologist notices dust artifacts on some mammographic images, appropriate identification will allow the QC technologist to locate the dirty cassettes quickly and clean the screens.

Each screen should be marked with a unique identification near the left or right edge of the screen using an opaque, permanent marking method. An Arabic number is suggested to differentiate the screen ID from the unit ID. (Note: some markers may damage the screens. The screen manufacturer can provide information regarding appropriate markers or marking methods.) The same identification number also should be placed on the outside of each cassette.

5. SELECTING THE APPROPRIATE FILM, PROCESSING CHEMICALS, PROCESSOR AND PROCESSING TIME

To obtain the best results, it is necessary to select the appropriate combination of mammographic film, film processor, processing chemistry, developer temperature and processing cycle. Film should be appropriate for mammography. Intensifying screens should also be appropriate for mammography and spectrally matched to the film's sensitivity.

> NOTE: Due to the large number of combinations of film, processor, chemistry, etc., it is extremely important to use the processor, chemistry, developer temperature, immersion time and replenishment rate recommended by the film manufacturer or those combinations that result in equivalent performance. See Section IV of the "Medical Physicist's Section."

The film selected for processor quality control should be the film used clinically. If more than one film is used, then the fastest film should be used for processor QC.

6. FILM AND CHEMICAL STORAGE

As recommended in the National Council on Radiation Protection and Measurements Report #99, photographic materials should be stored at temperatures less than 24°C (75°F), preferably in the range of 15° to 21°C (60° to 70°F). Open packages of film should be stored in an area with humidity ranging between 40% and 60%. Photographic materials should not be stored in areas where they can be exposed to chemical fumes or radiation. Sources of ionizing radiation include radioisotopes, radioactive wastes and direct or scattered X-rays. Photographic materials are also sensitive to pressure damage; consequently, film should be stored standing on edge.

Photographic chemicals should be stored with care. Never allow liquid photochemicals to freeze. If chemicals are frozen and there is any evidence of sedimentation in the container, the chemicals should not be used and should be returned to the vendor.

The emulsion batch that will expire first should be used first. Film should not be allowed to remain in the film bin past the expiration date. New shipments of film should be checked and should not be accepted from the vendor unless they can be used before the expiration date.

7. SELECTING THE APPROPRIATE THERMOMETER

Only digital thermometers should be used for monitoring mammographic film processors. Glass thermometers are easily broken in the processor and should be avoided. Most importantly, a thermometer containing mercury should never be used in a photographic processor because mercury is a photographic contaminant. Even small amounts of mercury, on the order of a few parts per million, will permanently contaminate the processor and cause erratic results.

The thermometer used for monitoring the developer temperature must be accurate to at least ±0.5°E Many inexpensive digital thermometers are available, but they are seldom accurate enough for use in a mammographic QC program. A clinical fever thermometer is inexpensive, however, and usually has an accuracy of better than ±0.5°F over a range from 90° to 100°F. Fever thermometers must be reset after each reading because they are designed to take a peak reading and hold that reading, i. e., they are not continuous reading thermometers. In addition, most fever thermometers do not function properly, or at all, below 90°F.

8. SELECTING THE APPROPRIATE SENSITOMETER

It is essential to select a sensitometer for the QC program that exposes the film in a manner similar to the exposure received by the film in clinical use. A 21-step sensitometer should be used to provide an adequate number of different levels of light exposure to the film. Matching the sensitometer to the clinical exposure conditions is important because some film may respond differently to changes in the processing chemicals, depending on the type of exposure received. If a single-sided film is used, then the sensitometer should provide a single-sided exposure. Ideally, one should use a sensitometer that exposes the film with an emission spectrum similar to that of the intensifying screen used clinically. Unfortunately, no such sensitometers are readily available. One should be aware that the "green light-emitting" sensitometers in common use emit primarily a broad blue spectrum that is somewhat extended into the green. As a result, comparison of the sensitometric response of two different films using a sensitometer may not reliably predict the relative sensitometric response of the two films when exposed with a mammographic intensifying screen. Nevertheless, if green light-emitting screens and green light-sensitive films are used for mammographic imaging, choose a sensitometer that provides some green light emission, as opposed to one with only blue light output or a sensitometer with an unfiltered tungsten light source.

9. PROCESSING AND READING OF SENSITOMETRIC CONTROL STRIPS

The purpose of processing a sensitometric control strip is to determine the developer activity level of the processor before processing clinical films. Consequently, it is essential (and required under MQSA) that the sensitometric strip be exposed, processed, read with a densitometer, and the data plotted to determine whether the processor is operating properly first thing in the morning before processing any mammograms. Sensitometric strips that are pre-exposed (hours or days in advance) suffer from latent image changes and may not have the same results as freshly exposed strips to changes in the processor. In addition, changes in the film optical density may result over time due to latent image decay, so it will be difficult to determine whether the processor is operating properly. Likewise, the densities of the strips must be read and plotted immediately to determine whether any processor changes have occurred. It is inappropriate to process clinical films and then determine hours or days later that the film processor was not operating optimally. Likewise, the processed sensitometric strips must be read with a densitometer; i.e., it is inappropriate to compare sensitometric control strips visually.

The consistency of the densitometer used for mammography QC should also be checked. This can be done using the densitometer calibration strip that came with the densitometer or by setting aside a processed sensitometer strip. In either case, the calibration strip should contain a low, medium, and high optical density test area marked with the optical density read by that particular densitometer when it was new or in good calibration. The test strip should be kept with the densitometer so that current readings can be compared to the original readings in those three areas. If the current readings in any area differ from the original readings by more than 0.05, the densitometer should be repaired. Note that the densitometer should be "zeroed" with nothing between the light source and the photometer according to the manufacturers directions prior to measuring optical densities with the device.

10. CONTROL CHARTS

It is essential to immediately plot data on control charts for reliable monitoring of the measurements in a quality control program. For example, the film density, optical density difference, exposure time or mAs, and the number of visible objects seen on the phantom image should be plotted on a control chart (See sample charts in Section III). The date should be indicated, along with the initials of the individual performing the test. Notes regarding changes in operating conditions, e.g., a change in the developer temperature or replenishment rate, should be recorded on the control chart.

Control charts provide an easy means of reviewing related data. Whenever a data point reaches or exceeds the control limits, the test should be repeated immediately. If the repeated measurement data still reach or exceed the control limits, then immediate corrective action is required. In this case, the out-of-control data point should be circled, the cause of the problem noted, the corrective action documented, and the in-control data point plotted.

Control charts also allow the detection of trends that indicate an unstable process. A trend is an upward or downward change in the measured data when three data points move in the same direction. The cause of a trend should be investigated before the control limits are reached or exceeded.

11. ESTABLISHING OPERATING LEVELS AND CONTROL LIMITS

When a QC program is started, it is necessary to establish operating levels and control limits. The operating level is that level that is normally expected. For example, the background optical density measured on a phantom image would be expected to be at, or close to, some particular value that is the background density operating level. The control limits are values established based on operating levels that, if reached or exceeded by subsequent measurements, require additional action. Normally, if the control limits are reached or exceeded, the test is repeated immediately to confirm the problem. If a repeat of the test gives the same measurement, then corrective action is required. Corrective action may include contacting the medical physicist to investigate the problem and recommend corrective actions or contacting a service engineer to correct a confirmed problem.

If the suggested performance criteria or control limits from this manual are consistently exceeded, then it will be necessary to determine the cause of the problem. The cause may be the measurement technique. For example, if the sensitometric control strip is processed on the left side of the processor one time and on the right the next, with the emulsion up one time and down the next, or immediately after exposure one time and after a delay the next, such variations in technique may be responsible for results that vary beyond control limits. All of these "human variables" should be eliminated and data collected for another period of time before making a decision. If the control limits are still consistently exceeded, then the measurement equipment, e.g., the sensitometer and densitometer, should be evaluated. If the measurement equipment is found to be functioning properly and all "human variables" have been eliminated, then it is probably time for equipment repair, or in extreme situations, replacement. All of the problem data should be reviewed by the medical physicist, and recommendations regarding modifications to the QC program, the repair or renovation of present equipment, or the purchase of new equipment should be discussed with the radiologist.

If it is apparent that the suggested performance criteria are too wide, then one can consider narrowing the control limits. This should be done in consultation with the medical physicist and radiologist.

For example, the suggested performance criteria for the processor sensitometric evaluation indicate a retest if the measured density reaches or exceeds the operating level by ±0.10 and immediate corrective action if it exceeds the operating level by +0.15. However, if the data seldom exceed the operating level by ±0.10, then one may wish to make this thecontrol limit, the limit that requires immediate corrective action. In this case, one is assured of even better, more consistent quality.

NOTE: If the control limits are consistently exceeded, then it is necessary to improve the QC procedures or repair or replace the appropriate equipment. DO NOT widen the control limits since the data are indicating that the process is "out of control" and corrective action is essential.

Finally, there may be situations when operating levels and control limits need to be re-established. Typical examples are when the film type is changed or new X-ray equipment is installed. This is further described in the processor quality control and phantom images test in Section III.

12. MAMMOGRAPHY QC CHECKLISTS

To assist in the oversight of the QC tests, two mammography QC checklists are provided (Figures 1A and B). These checklists provide a quick reminder of when QC tasks are due and also provide a record indicating that the appropriate tasks have been completed in a timely manner. All dates should be filled in prior to use of the checklist. Each time a task is completed, the individual carrying out the task should initial the appropriate area on the checklist.

Mammography Quality Control Checklist

Department of Diagnostic Radiology

Daily and Weekly Tests

Year																															
Month																															
Date																															
Initials																															
Darkroom Cleanliness (daily)																															
Processor QC (daily)																															
Phantom Images (weekly)																															
Screen Cleanliness (weekly)																															
Viewing Conditions (weekly)																															

Year																															
Month																															
Date																															
Initials																															
Darkroom Cleanliness (daily)																															
Processor QC (daily)																															
Phantom Images (weekly)																															
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Darkroom Cleanliness (daily)																															
Processor QC (daily)																															
Phantom Images (weekly)																															
Screen Cleanliness (weekly)																															
Viewing Conditions (weekly)																															

Figure 1A. Mammography QC checklist: daily and weekly checks.

Mammography Quality Control Checklist

Department of Diagnostic Radiology

Monthly, Quarterly, and Semi-Annual Tests

(date, initial and enter number where appropriate)

Year												
Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Visual Checklist (monthly)												
Repeat Analysis (%) (quarterly)												
Fixer (≤/= 0.05 gm/sq m) (quarterly)												
Darkroom Fog (≤/= 0.05) (Semi-annually)												
Screen-film Contact (Semi-annually)												
Compression (25-40 lb) (Semi-annually)												

Date:	**Test:**	**Comments:**

Figure 1B. Mammography QC checklist: monthly, quarterly and semiannual tests.

13. TEST FREQUENCIES

The frequency of tests specified in this manual (Table 1) is the minimum frequency. The frequency of QC tests can vary considerably, depending on many factors, including the age and stability of the imaging equipment and the number of problems being encountered, to name just a few. The baseline operating levels should be determined just after calibration of X-ray equipment and with seasoned fresh chemicals in the processor.

After the operating levels have been determined, the tests should be run more frequently than specified in this document for 10 to 20 test periods. For example, if the recommended frequency is weekly, then the test should be performed daily for a few weeks. This provides a large amount of data quickly to determine whether rapid changes are occurring and allows for an accurate determination of operating levels, when appropriate. It also allows the individual performing the tests to gain more experience in a shorter period of time.

The frequency of the tests may be modified in consultation with the radiologist responsible for the facility and the consulting medical physicist after significant experience has been gained. It may be necessary to increase the frequency of the tests if problems are frequently detected. One may wish to decrease the control limits while maintaining the frequency of the test and operate with tighter controls and more consistent image quality.

> NOTE: If problems are seldom detected, DO NOT discontinue testing or reduce the frequencies below MQSA minimums of any tests in the QC program! The lack of problems indicates that the process is "in control" at the present time but does not predict the stability of the process in the future.

As noted in "Establishing Operating Levels and Control Limits," the control limits should not be increased. If the equipment produces results that are consistently outside of the control limits suggested in this manual, then it will be necessary to have the appropriate repairs made or the equipment replaced.

14. CASSETTE USE

Many screen-film cassettes require a minimum of approximately 15 minutes between film loading and exposure to ensure that air trapped between the screen and film has time to "bleed" out of the cassette. (Check with the cassette manufacturer for its recommended elapsed time.) Only if this time interval is allowed will there be good screen-film contact. Poor screen-film contact will result in image blur in areas of the film with poor contact, decreasing the sharpness of the image. Minimizing image blur is especially important for the detection and resolution of groups of small calcifications and for the visualization of spiculations on malignant lesions.

If the work load at a mammography site is high and the number of cassettes is inadequate, there can be less than 15 minutes between loading and exposure of the screen-film cassette. In such cases, the site should obtain additional cassettes of the appropriate size and screen type to be consistent with existing cassettes, thereby permitting adequate "air-bleed time" of each cassette after loading.

15. ADEQUATE OPTICAL DENSITIES IN SCREEN-FILM MAMMOGRAPHY

Film optical densities have a significant effect on image contrast. All existing films in screen-film mammography lose contrast at optical densities that are too low or too high. As a result, any part of a mammogram that is acquired at too low or too high an optical density will have inadequate contrast, reducing the likelihood of detecting cancer when it is present. All films have reduced contrast at optical densities below 1.00-1.25 (the farther below, the more contrast is lost) and have reduced contrast above 2.50-3.00. In addition, even with extremely bright viewboxes or hotlighting along with film masking and low ambient room light, the human eye has difficulty in detecting lesions in images of optical densities above about 3.00.

The most significant problem in mammography, however, is that glandular tissues, from which cancers arise, produce the lowest optical densities on the film. If glandular tissues are captured on the film at too low an optical density, detection of low-contrast lesions within those glandular tissues is compromised. To ensure that glandular tissues are exposed to adequately high optical densities, the automatic exposure control (AEC) setup should set target optical densities for a uniform acrylic or breast-equivalent material at optical densities between 1.40 and 2.00. This will ensure that the typical optical densities in the mammogram match the region of maximum film contrast and that glandular tissues are not exposed to too low an optical density to detect cancers. To verify that images are not underexposed, use a calibrated densitometer to measure the optical densities in the glandular regions of the breast image. If glandular tissues are consistently imaged at optical densities below 1.00, AEC setup should be revised to increase the target optical densities of the system. This will help ensure that adequate contrast exists in all parts of the mammogram, including glandular tissues.

16. ADEQUATELY SHORT EXPOSURE TIMES IN MAMMOGRAPHY

It is important to have an adequately short exposure time for each film to: (1) minimize breast motion and (2) avoid back-up timer termination of the X-ray exposure. Doubling X-ray exposure time at least doubles the probability of breast motion during exposure. Breast motion during exposure causes blurring of sharp edges and can decrease the visibility of both calcifications and fibrous structures such as spiculations in the breast. Termination of the X-ray exposure by back-up timer occurs when a maximum exposure time or maximum mAs occurs. This will occur on thicker and denser breasts when inadequate beam quality (too low a kVp setting) is used. An unwanted adverse result of back-up timer exposure termination is that overall film optical densities will be lower than prescribed by the AEC system. It is important to know the exposure time or mAs at which exposure termination will occur on each of your mammography units (usually around 4 seconds). Choosing technique factors to keep exposure times under 2 seconds, regardless of breast thickness and composition, is a reasonable way to minimize breast motion and to avoid back-up timer termination of the X-ray exposure. If exposure times for thicker and denser breasts are consistently higher than 2 seconds, the technique chart should be revised to increase beam quality (changing target-filtration materials or raising kVp) for thicker and denser breasts.

Conversely, exposure times that are too short may result in the appearance of grid lines on some X-ray units. Techniques should also be adjusted to prevent this. Exposure times should typically range from 0.5 to 2 seconds.

17. TECHNIQUE CHARTS

Ideally, phototimers (AEC systems) should result in consistent image optical density regardless of breast thickness or size. Some older units may not produce consistent densities for all breast thickness, densities, or kVp settings. This problem may be reduced by using a phototimer technique chart (Figure 2) that should be developed by the mammography technologist in consultation with the medical physicist. By modifying kVp and density control settings, consistent film optical densities can be produced, while keeping exposure times between 0.5 and 2 seconds for most breast thicknesses and compositions. Use of this technique chart improves image contrast and minimizes motion blur on units with suboptimal phototimer performance. One should note, however, that after October 28, 2002, the MQSA Final Rules no longer permit the use of a technique chart to overcome the deficiencies of an AEC system (for 2 to 6 cm breast thicknesses).

Some mammography units offer the selection of an anode target material and X-ray beam filter. In cases where the choices of target and filter are prescribed by the radiologic technologist, those choices should be included on the mammography phototimer technique chart.

In all cases the AEC sensor must be placed correctly and consistently. In most cases this means that the sensor should be placed under an appropriately dense area of the breast.

It may be necessary to use manual techniques to obtain appropriate optical densities on images of breasts containing implants. The appropriate information can be recorded on the mammography phototimer technique chart (Figure 2).

Once the phototimer technique charts have been filled out, they should be posted on the mammographic unit adjacent to the control panel and followed by every technologist using the equipment.

Mammography Phototimer Technique Chart

Room No. _____ Unit _____

Compressed Breast Thickness	Fatty Breast				50% Fatty – 50% Dense				Dense Breast			
	Target	Filter	kVp	Density	Target	Filter	kVp	Density	Target	Filter	kVp	Density
<3 cm												
3 to 5 cm												
5 to 7 cm												
>7 cm												

Technique based upon proper photocell placement under the densest protion of the breast, screen-film combinations, and processing.
Taut compression should be used for all patients except where noted.

Focal spot size for:

Nonmagnification Technique: _____mm

Magnification Technique: _____mm

Special Techniques –

Implant Displaced Views

Phototiming same as above chart

Manual Techniques for Implant Views

Breast Size	Target	Filter	kVp	mAs
Small				
Medium				
Large				

Apply minimal compression – enough to prevent motion.

Specimens: (Manual Technique Only)

Breast Size	Target	Filter	kVp	mAs
Small				
Medium				
Large				

Specimens must be compressed.

Figure 2. Mammography phototimer technique chart.

18. FILM VIEWING CONDITIONS

Viewing conditions are extremely critical in mammography. The information under " Viewboxes and Viewing Conditions" should be read and followed with great care. The higher optical density mammograms needed to maximize lesion detection require high-luminance viewboxes, proper masking of each film, and low ambient room light. All mammograms and mammography test images must be completely masked when being viewed, i.e., no light should come directly from the viewbox surface to the eye of the observer. These viewing conditions apply to the technologist QC area as well as the area where the radiologist interprets images.

Whenever mammograms or phantom images are viewed, they should be viewed under identical conditions. For example, phantom images should be viewed on the same viewbox, with the same lighting conditions, and using the same magnifier as used for viewing clinical mammographic images and at the same time of day, for example, first thing in the morning. In addition, the same viewbox masking should be used for both clinical and phantom images.

Whenever it is necessary to make subjective judgments about phantom images, e.g., determining the number of objects in the phantom image, the evaluation should be carried out by the same person using conditions identical to those used for previous evaluations.

1. PROCEDURE

DARKROOM CLEANLINESS

OBJECTIVE

To minimize artifacts on film images by maintaining the cleanest possible conditions in the darkroom.

Artifacts due to bits of dirt and dust between the screen and film are particularly troublesome with single-emulsion imaging in mammography, not only because they are much more prominent than on double-emulsion films, but because they may mimic microcalcifications and lead to misdiagnosis.

FREQUENCY

This procedure should be carried out daily at the beginning of the workday before processing or handling any films in the darkroom. The QC technologist can designate a person or persons to perform darkroom cleaning but must verify that it is done.

REQUIRED EQUIPMENT

Wet mop and pail

Lint-free towels

Antistatic cleaning solution

1. Turn the processor water and power on so that the developer temperature can stabilize during this procedure.
2. Remove all unnecessary items from countertops and work surfaces.
3. Use a clean, damp, lint-free towel to wipe off the countertops and other surfaces in the darkroom. Clean the processor film feed tray last. A small amount of the antistatic cleaning solution used for intensifying screens may be used on a lint-free wipe.
4. Damp mop the darkroom floor.
5. Wipe or vacuum overhead air vents and safelights weekly **before cleaning the feed tray and countertops.**

PRECAUTIONS AND CAVEATS

Smoking and eating in the darkroom should be prohibited. Keep hands clean to minimize fingerprints and film-handling artifacts.

Adequate storage space is required to minimize dirt-collecting clutter. There should be no open shelving, especially above darkroom countertops. Eliminate non-essential items that contribute to dust. Maintain relative humidity between 40% and 60% to minimize the attraction of dust particles onto films and intensifying screens. Filter air coming into the darkroom.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Darkroomcleanliness may be evaluated best in terms of screen cleanliness, i.e., the number of dust artifacts appearing on the mammographic images.

MQSA REQUIREMENTS:

Facility cleanliness. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness. The facility shall document that all leaning procedures are performed at the frequencies specified in the protocols.

2. PROCEDURE: PROCESSOR QUALITY CONTROL

OBJECTIVE

To confirm and verify that the film processor and processor chemistry system are working in a consistent manner. Three distinct procedures are described. The first procedure describes the steps necessary to establish the correct operating levels for the processor. This procedure will be carried out when the QC program is initiated or when a significant change is made in imaging procedures, i.e., different film, brand or type of chemicals, or processing conditions (such as development time). The second procedure is carried out daily at the beginning of the workday, before processing any patient films but after processor warm-up. This procedure ensures consistent film quality through consistent film processing. The third procedure, control film crossover, is carried out whenever a new box of film is opened for QC use.

FREQUENCY

Regular processor QC must be carried out at the beginning of each day that mammography is conducted before processing any patient films. For mobile mammographic equipment, daily processor QC must also be carried out before processing any mammograms. This is essential whether the processor is located near the mobile equipment site or whether the films are processed later at the home location of the mobile equipment.

REQUIRED TEST EQUIPMENT

Sensitometer. A sensitometer that exposes one side of the film should be used for single-emulsion film, whereas a sensitometer that exposes both sides of the film simultaneously should be used for double-emulsion films. The spectral characteristics of the light source of the sensitometer should be similar to the light source used for exposing the film in clinical use, i.e., it should be green if green-emitting screens are used. The sensitometer must be a 21-step sensitometer.

Densitometer.

Fresh box of control film. If more than one type of film is used clinically for contact mammography, then the fastest film should be used for processor QC.

Control chart.

Clinical digital fever thermometer accurate to at least ±0.5°F.

2A. ESTABLISHING PROCESSOR QC OPERATING LEVELS

PROCEDURE STEPS

1. Select a fresh box of film of the same type used for mammography, and reserve this box for QC purposes only. (Note the emulsion number of the box of film on the remarks section of the control chart, Figures 3A and B.)
2. Drain the chemicals from the processor and thoroughly flush the racks and tanks with water.
3. Drain the replenisher tanks and refill with fresh replenisher.
4. Fill the fixer tank with fixer solution.
5. Once again flush the developer tank with water.
6. Fill the developer tank about one-half full with developer solution and add the specified amount of developer starter solution. Add sufficient developer solution to fill the developer tank.
7. Set the solution (developer, fixer, and water) temperatures at **the temperature specified in the film manufacturer's literature**. The dryer temperature should be set as low as possible while still providing good drying. The dryer temperature should never exceed the film manufacturers recommendations.
8. Set the developer and fixer replenishment rates as specified by the film manufacturer.
9. After the developer temperature has stabilized, check the temperature of the developer solution with a clinical fever thermometer and assure that the processor is operating at the temperature specified by the film manufacturer. Clean the thermometer stem of developer solution after each use.

> NOTE: A thermometer containing mercury should never be used in a photographic processor. If the thermometer were to break, minute amounts of mercury could permanently contaminate the processor and cause inconsistent processing results.

10. The darkroom environment should be evaluated and the darkroom fog test performed satisfactorily before establishing the processor QC program.
11. Using a sensitometer, expose and process a sensitometric strip. Repeat this exposure and processing once each day for 5 consecutive days. It's important that this be done at the time of day when the sensimetric strips will be routinely processed.

NOTE: Before processing sensitometric strips be sure that the

- developer temperature is correct;
- sensitometric strip is processed with the less-exposed end being fed into the processor first;
- sensitometric strip is processed on the same side of the processor, i.e., it is inserted on the same side of the processor feed tray each time;
- sensitometric strip is processed with the emulsion in the same orientation (for single-emulsion films), for example, with the emulsion side up; and
- delay between exposure and processing is similar each day to avoid any latent image changes that may occur with time.

12. Read and record the densities of each step of the sensitometric strip using the densitometer, including an area of processed film that has not been exposed. The densities of the steps should be measured in the center of each step.
13. Determine the average of the densities for each step using the densities for that step from the five strips done on the 5 consecutive days.
14. Determine which step has an average density **closest to but not less than 1.20**. Designate this step the **mid-density (MD)** step. (This step is often referred to as the speed point, speed index, or speed step.) Identify and record the step number and average density on the center line of the processor control chart. (This step number should be used consistently unless the processor QC program is re-established and another step number is chosen).
15. Determine which step has average density **closest to 2.20** and which step has an average density **closest to but not less than 0.45.** Designate these steps the high-density (HD) and low-density (LD) steps. The difference in densities between these two steps should be designated the **density difference (DD)**. Identify and record these step numbers and the DD on the center line of the processor control chart (Figure 3A). (These step numbers should be used consistently unless the processor QC program is re-established and another step number is chosen.)

NOTE: The density difference determined by this method is to be used only to assess consistency of film and processing. It is not appropriate for comparing different film types or for comparing film types processed at different facilities.

16. Determine the average of the densities from step one or any clear or the unexposed area of the five strips, measuring the same area consistently. This density will be designated as the **base-plus-fog level (B+F)** of the film. Record this value on the center line of the processor control chart (Figure 3A).

17. The numerical values for MD, DD, and B+F recorded on the center line of the appropriate areas of the control chart are the operating levels for the processor (Figure 3A).

18. Record the upper and lower control limits for MD, DD and B+F on the control chart. (See Figure 4A and the section entitled "Recommended Performance Criteria" for examples and further information.)

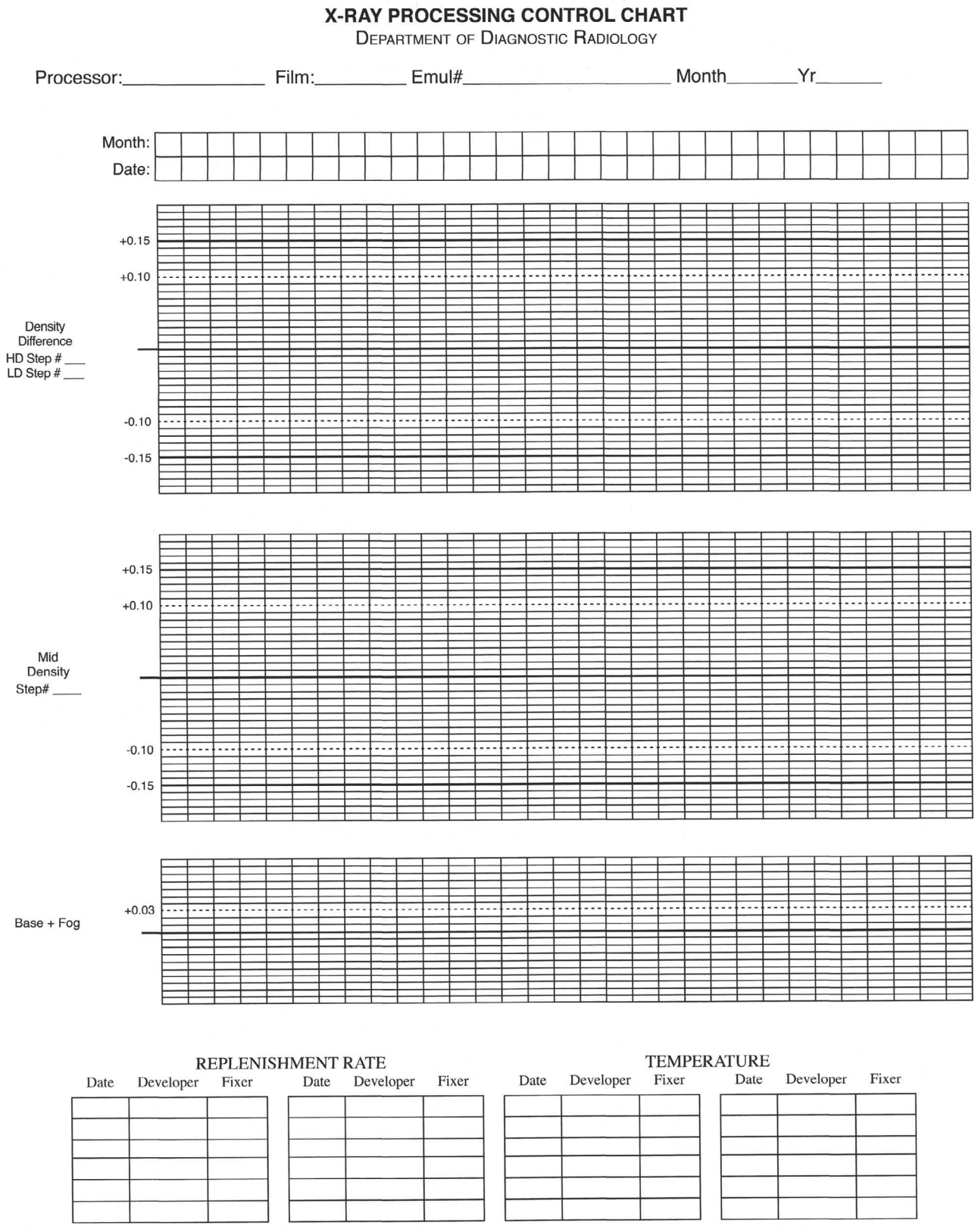


Figure 3A. X-ray processing control chart.

X-RAY PROCESSING CONTROL CHART

(cont'd)

Remarks

Date	Action

Figure 3B. X-ray processing control chart remarks.

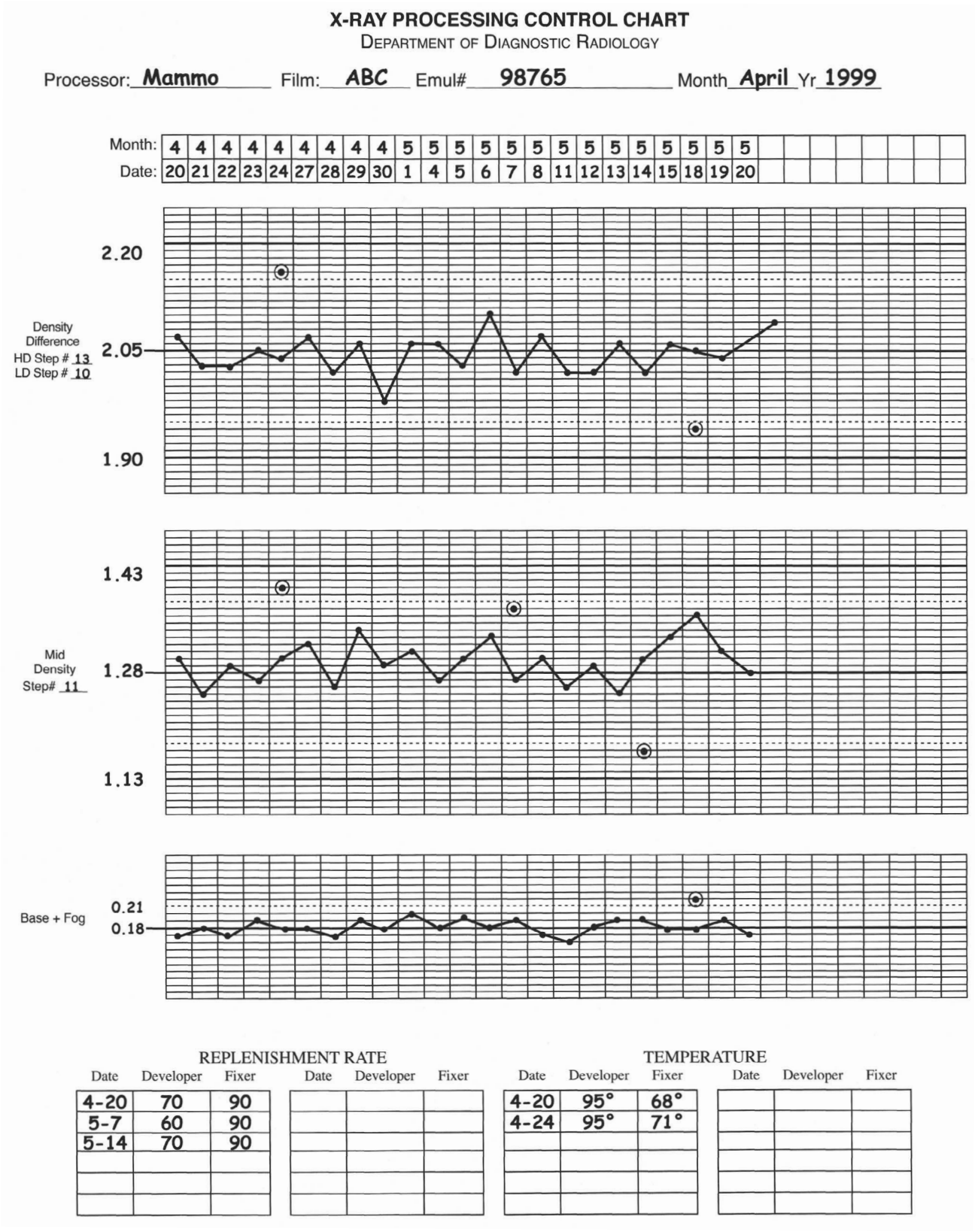


Figure 4A. Sample X-ray processing control chart.

X-RAY PROCESSING CONTROL CHART

(cont'd)

Remarks

Date	Action
4-24	**Temperature high; lovered to 95º**
5-7	**Lowered replenishment rate for developer**
5-14	**Increased replenishment rate for developer**
5-18	**Correct light leak besides processor**

Figure 4B. Sample X-ray processing control chart remarks.

2B. DAILY PROCESSOR QUALITY CONTROL

PROCEDURE STEPS

1. Expose and immediately process a sensitometric strip before processing clinical mammograms.

NOTE: Before processing sensitometric strips be sure that the

- developer temperature is correct;
- sensitometric strip is processed with the less-exposed end fed into the processor first;
- sensitometric strip is processed on the same side of the processor, i. e., it is inserted on the same side of the processor feed tray each time;
- sensitometric strip is processed with the emulsion in the same orientation (for single-emulsion films), for example, with the emulsion side up; and
- delay between exposure and processing is similar each day to avoid any latent image changes that may occur with time.

2. Read the densities of the identified steps for MD, DD and B+E
3. Plot the mid-density (MD), the density difference (DD), and the base-plus-fog level (B+F) on the control chart.
4. Determine whether any of the data points exceed the control limits. If not, go to step 6. **If so, expose and process a second sensitometric strip, double-checking that correct procedure is followed. If the same results are obtained, proceed to step 5.**
5. Circle the out-of-control data points and repeat the test. If any data point is still out of control, correct the cause of the problem and repeat the test to verify that the problem has been corrected. Note the cause of the problem and the corrective action in the "Remarks" section of the control chart, and plot the in-control data point.
6. Determine if there are any trends, i.e., three or more data points moving in one direction (either upward or downward), in the MD, DD, or B+E If trends are present but the data points have not, as yet, exceeded the control limits, clinical mammograms can be processed. However, it will be necessary to determine the cause of the trend and to monitor the processor closely to assure that the control limits are not exceeded.

NOTE: It is essential (and required under MQSA) that sensitometric strips be exposed and processed and the data evaluated and plotted before clinical films are processed each day. If problems are detected, corrective action must be taken before clinical films are processed under less than optimal conditions.

PRECAUTIONS AND CAVEATS

The use of sensitometric strips exposed more than an hour or two before processing is not acceptable because these strips may be less sensitive to changes in the processor than freshly exposed strips. In addition, as noted above, the sensitometric strip must be evaluated before clinical films are processed. Reading the sensitometric strips and evaluating the results hours or days after the strip has been processed do not provide adequate QC; many clinical films may be improperly processed before the results are available. In order to maintain good QC of the photographic processor, it is essential to read the densities of the sensitometric control strips with a calibrated densitometer. Visual comparison of the steps of the control strips is not adequate.

As indicated above, each sensitometric strip must be processed the same way each time. The film must be consistently fed into the processor on the same side of the feed tray (i.e., right versus left), with the emulsion in the same orientation (i.e., up versus down), and with the less-exposed (lower-density) end of the strip leading. This reduces variation in the results and avoids development artifacts.

QC must also be performed on the densitometer, sensitometer, and thermometer themselves, to ensure their proper calibration. Manufacturer recommendations for QC on these instruments, where available, should be followed.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

If the MD and DD are within ±0.10 of their respective operating levels and the B+F is within +0.03 of its operating level, the processor is in control and no further action is required. If the MD or DD fall outside of the ±0.10 control limit but within ±0.15 limit, the test should be repeated immediately. If the same result is obtained, it is acceptable to process clinical films, but the processor should be monitored closely. **If the MD or DD exceeds the control limit of ±0.15, the source of the problem must be determined and corrected before clinical mammograms are processed.** Likewise, if the B+F exceeds the operating level by +0.03, immediate corrective action must be taken before clinical mammograms are processed.

NOTE: Processor QC control charts should be retained in the QC records for 1 year. Sensitometric films for the last full months QC chart should be retained.

If a change in the MD, DD, or B+F exceeds the suggested performance criteria, it will be necessary to determine the source or sources of this change (temperature, chemistry, replenishment, etc.) and correct the problem(s) immediately. For example, developer temperature should be within ±0.5°F of the value specified by the film manufacturer. In addition, the out-of-control data points should be circled, the cause of the problem and the corrective action noted in the remarks section of the control chart, and the in-control data point plotted (Figures 4A and B).

MQSA REQUIREMENTS:

Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using mammography film used clinically at the facility. The base plus fog density shall be within +0.03 of the established operating level. The mid-density shall be within ±0.15 of the established operating level. The density difference shall be within ±0.15 of the established operating levels.

RE-ESTABLISHING PROCESSOR QUALITY CONTROL OPERATING LEVEL

If the test results fall outside the ±0.15 action limits, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

There are a number of circumstances under which it may be appropriate to **re-establish the processor QC operating levels**. These events include:

- when a film manufacturer makes a change to a film currently in use and recommends that the processor QC program be re-established;
- a change in film volume;
- a change of brand or types of chemicals used;
- a change in film brand or type;
- a change in replenishment rates;

- a change in development time (e.g., going from extended to standard cycle);
- a change in the settings on a specific gravity automixer;
- using a different sensitometer or densitometer;
- a change in film processor;
- running out of film thus preventing a crossover from being done correctly.

Re-establishing the QC program may also be necessary if the values for MD and DD on the steps initially selected are no longer consistent with the guidelines for establishing processor QC (i.e., the MD step should be the one closest to but not less than 1.20; the LD step should be the one closest to but not less than 0.45 and the HD step should be the one closest to 2.20.) If the step chosen to monitor MD, for example, is now lower than 1.0, the control chart will be relatively insensitive to processing changes that could affect clinical image quality. Many of these changes may occur over time due to adjustments of operating levels made during crossover procedure.

Finally, merely changing the chemistry as part of routine preventative maintenance is not justification for changing the QC operating levels.

Keep in mind that re-establishing the processor QC program means carefully following the procedure for establishing processor QC operating levels (Test 2A). This includes starting with a clean processor and fresh chemistry and taking a 5-day density average of sensitometric strips. The reason for re-establishing the operating levels must be noted in the remarks section of the QC chart.

2C. CONTROL FILM CROSSOVER

TEST PROCEDURE STEPS

Radiographic film is produced in batches. Consequently, there may be slight variations in the characteristics of film between batches. In addition, film aging and storage conditions can aifect the sensitometric characteristics of the film. Whenever a new box of film is opened for QC purposes it is necessary to perform a "crossover" with the old film. **The crossover should be carried out only with a processor with seasoned chemistry that is operating within the ±0.10 control limits.**

1. While there are at least five sheets of the old QC film remaining, select a new box of film for processor QC.
2. Assure that the processor is in control as described above.
3. At the same time of day that the processor QC is normally performed, expose and immediately process five sensitometric strips each from the old and new boxes of film (the data calculations may be done at a later time if necessary).
4. Determine the average of the steps previously identified for processor QC for MD, DD, and B+F from the five films from the old box and from the five films from the new box. The top half of Figure 5A is a blank worksheet that should be copied and used for each crossover; the bottom half provides an example of the crossover procedure. Step 11 is the MD step, steps 10 and 13 are the DD steps.
5. Determine the difference in the average values between the new and old boxes of film, as shown in the example.
6. Adjust the old operating levels for MD, DD, and B+F by this difference to establish the new operating levels. This is accomplished by adding the difference (new – old), including the sign, to the old operating level. If the difference (new – old) is positive, the new operating level is increased. If the difference (new – old) is negative, the new operating level is decreased.
7. Record the new operating levels and their new control limits on a new control chart. Record the complete emulsion number of the new box of film on the new processor control chart (Figure 5B).
8. Note the date the crossover was performed in the remarks section of the processing quality control chart.

CROSSOVER WORKSHEET

Site		Date	
Film Type		Technologist	

New Emulsion #					Old Emulsion #				
Film #	Low Density (LD) Step #	Mid Density (MD) Step #	High Density (HD) Step #	B+F	Film #	Low Density (LD) Step #	Mid Density (MD) Step #	High Density (HD) Step #	B+F
1					1				
2					2				
3					3				
4					4				
5					5				
Average					Average				
Average Density Difference: DD = HD – LD =					Average Density Difference: DD = HD – LD =				

MD difference between new and old film (New MD – Old MD)	
DD difference between new and old film (New DD – Old DD)	
B+F difference between new and old film (New – Old)	

	MD	DD	B+F
Old Operating Levels			
Difference between new and old film			
New operating levels			

CROSSOVER WORKSHEET
EXAMPLE

New Emulsion #			24578		Old Emulsion #			23456	
Film #	Low Density (LD) Step # 10	Mid Density (MD) Step # 11	High Density (HD) Step # 13	B+F	Film #	Low Density (LD) Step # 10	Mid Density (MD) Step # 11	High Density (HD) Step # 13	B+F
1	0.49	1.25	2.39	0.18	1	0.46	1.27	2.33	0.17
2	0.50	1.23	2.43	0.18	2	0.48	1.30	2.30	0.17
3	0.49	1.26	2.40	0.17	3	0.46	1.27	2.28	0.18
4	0.53	1.28	2.41	0.18	4	0.48	1.28	2.32	0.17
5	0.49	1.28	2.43	0.18	5	0.47	1.31	2.35	0.18
Average	0.50	1.26	2.41	0.18	Average	0.47	1.29	2.31	0.17
Average Density Difference: DD = HD – LD = 1.91					Average Density Difference: DD = HD – LD = 1.84				

MD difference between new and old film (New MD – Old MD)	-0.03
DD difference between new and old film (New DD – Old DD)	+0.07
B+F difference between new and old film (New – Old)	+0.01

	MD	DD	B+F
Old Operating Levels	1.34	1.9	0.17
Difference between new and old film	-0.03	+0.07	+0.01
New operating levels	1.31	1.97	0.18

Figure 5A. Crossover worksheet.

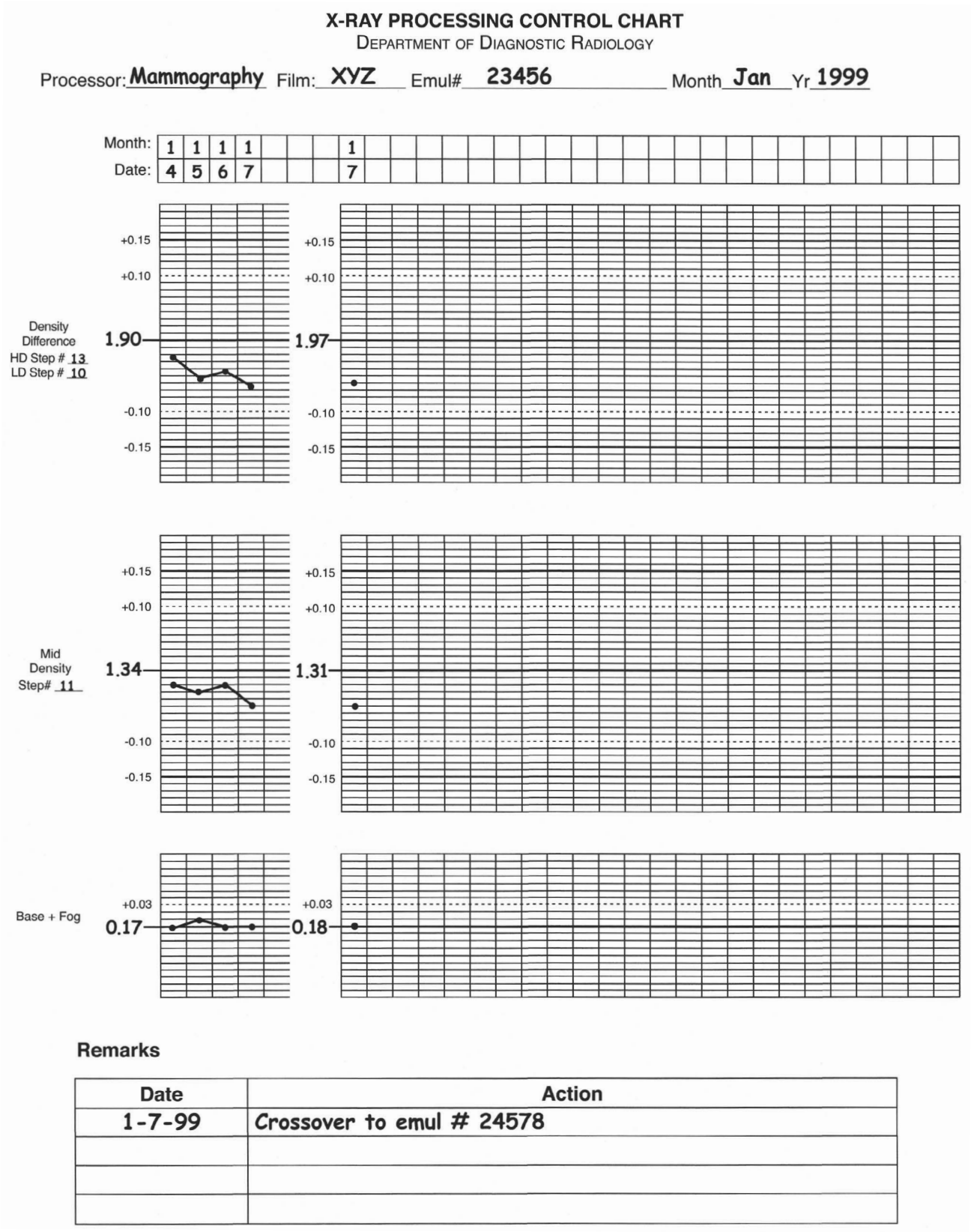


Figure 5B. Crossover example on control chart.

Finally, if the new box of film produces step densities that are so different from the old that the monitored steps are no longer the best choices, then new operating levels need to be established following the procedures establishing processor QC operating levels (Test 2A). (These should be the steps with densities greater than or equal to 0.45 for the low-density step, closest to but not less than 1.20 for the mid-density step and closest to 2.20 for the high-density step.)

3. PROCEDURE: SCREEN CLEANLINESS

OBJECTIVE

To assure that mammographic cassettes and screens are free of dust and dirt particles that may degrade image quality or mimic microcalcifications.

FREQUENCY

The frequency of screen cleaning is determined by environment and usage but should be carried out at least weekly.

> NOTE: Any time dust artifacts are noted in an image by the technologist or radiologist, the screens should be cleaned immediately.

REQUIRED TEST EQUIPMENT

Screen cleaner (as recommended by screen manufacturer)

Lint-free wipes, camel's hair brush, or anti-static brush

Canned air (available from photographic supply stores)

TEST PROCEDURE STEPS

1. Choose a clean location to clean screens and cassettes.
2. Check screens for dirt, dust, lint, pencil marks, fingernail polish and other marks under a bright light.
3. Clean screens using manufacturer's recommended materials and procedures.

> NOTE: Cleaning may be limited to dusting with a camel's hair antistatic brush or canned air at least weekly. Wet cleaning (i.e., using liquid screen cleaner) may be performed less frequently (e.g., monthly) or as needed.

4. After cleaning with liquid cleaners, screens should be allowed to air dry by standing cassettes vertically, on edge, and partially open.
5. Inspect the screen and cassette cover for any stray particles of dust before reloading the cassette with film. Wait at least 15 minutes or manufacturer's recommended time after loading and before using.

PRECAUTIONS AND CAVEATS

If compressed air is used to clean screens, care must be taken to assure that it is "clean" air. Compressed air often contains moisture, oil and other contaminants, all of which could damage the screen or cause artifacts. Also, air compressed with Freon comes out very cold and may damage screens.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Review clinical mammograms on a routine basis for white spots (minus density artifacts).

MQSA REQUIREMENTS:

Facility cleanliness. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness. The facility shall decument that all cleaning procedures are performed at the frequencies specified in the protocols

4. PROCEDURE: PHANTOM IMAGES

OBJECTIVE

To assure that film optical density, contrast (density difference), uniformity, and image quality due to the X-ray imaging system and film processor are maintained at optimum levels.

FREQUENCY

To establish a baseline level, this procedure should be carried out initially after appropriate calibration of the equipment and with seasoned fresh chemistry in the processor, i.e., after processing a sufficient volume of film through fresh chemistry to reach chemical equilibrium. Subsequently, this test should be carried out at least weekly, after service to any equipment (i.e., the X-ray generator or processor), whenever the film or screen type is changed, and whenever changes in image quality are suspected.

REQUIRED TEST EQUIPMENT

Mammographic phantom (approximately equivalent to a 4.2 cm thick compressed breast consisting of 50% glandular, 50% adipose tissue) containing appropriate details ranging from visible to invisible on the mammography image. At the time of publication, either the Radiation Measurement, Inc. RMI-156 or Nuclear Associates 18-220 mammography phantom may be used for the ACR Mammography Accreditation Program (MAP). These phantoms have fibers with diameters of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 mm; specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 mm; and masses with decreasing diameters and thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 mm.

Acrylic disc (4-mm thick, 1-cm diameter) placed on the top of the phantom in a consistent location in the image area so it will not obscure details in the phantom and where it cannot cast a shadow on any portion of the AEC detector (Figure 6). With current equipment, significant variability in film optical density can result from placing the disc along the central anode-cathode axis, where a varying fraction of the AEC detector area might be covered by the disc's shadow, depending on the position of the detector. A suitable location is between and slightly below the first and second largest fibers. A glue such as "SuperGlue" may be used to attach the disc permanently to the phantom.

Cassette and film of the types used clinically for mammography. Use the same cassette each time for phantom QC to eliminate inconsistent results due to cassette or screen variability.

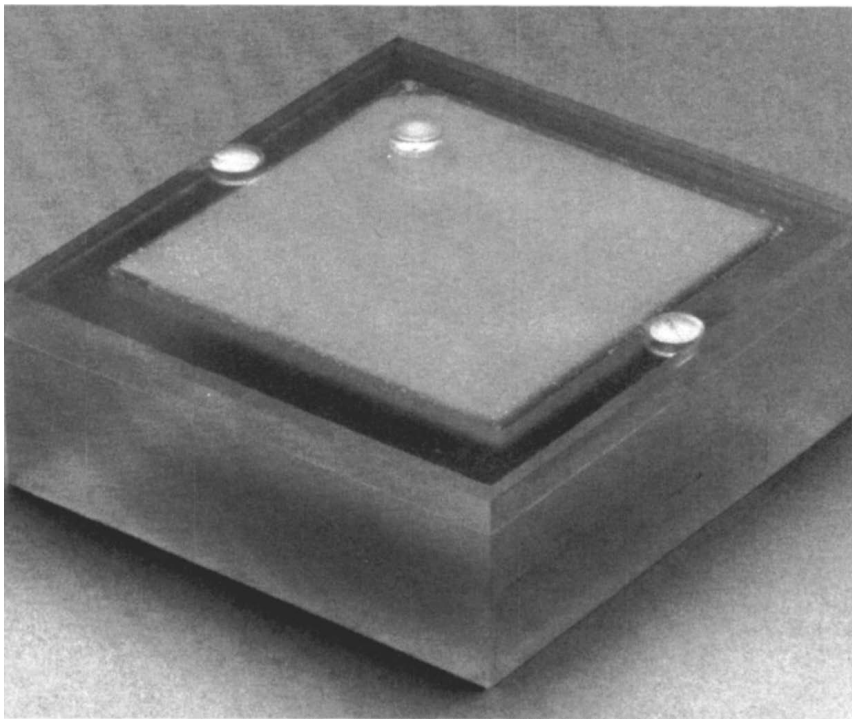


Figure 6A. Photograph of phantom with 1-cm diameter, 4-mm-thick disc for contrast measurement.

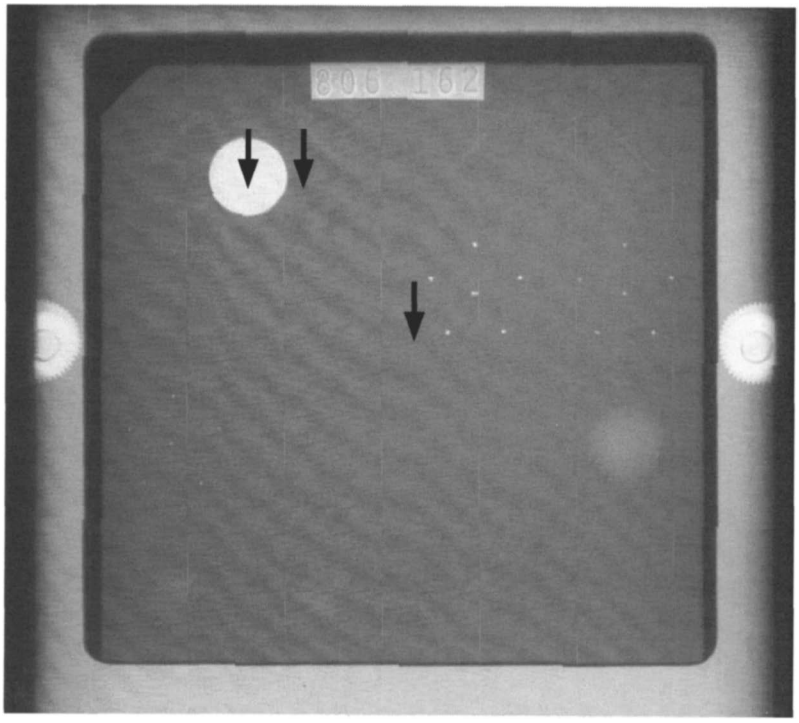


Figure 6B. Radiograph of phantom shown in Figure 6A. Arrows indicate points where density measurements should be made.

Appropriate masking to eliminate light reaching the viewer's eye from beyond the borders of the exposed phantom image. Images should be viewed on the same viewbox(es) used clinically. If a 14 X 17 inch viewbox is used, a film mask can be made by exposing a 14 X 17 inch film to light, processing it, and cutting a hole the size and shape of the phantom being used.

A magnifying lens of 2x or higher

Densitometer

Phantom Control Chart

TEST PROCEDURE STEPS

1. Load a sheet of film from the film that is used for patient images into the cassette. Be sure to wait an adequate length of time for good screen-film contact to occur.
2. If this is the first phantom image taken on this film emulsion, record the new film emulsion number in the log (Figure 7B).
3. Place the cassette in the cassette holder.
4. Place the phantom on the cassette holder and position it so the chest-wall edge of the phantom is aligned with the chest-wall side of the image receptor. Center the phantom, left to right.
5. Lower the compression paddle so that it just touches the top of the phantom. Do not compress the phantom because doing so may damage the compression paddle. (On some units, mild compression is needed to enable exposures.)
6. Verify that the AEC detector is under the center of the wax insert and in the same location as used for previous phantom images.
7. Make an exposure using the technical factors (target, filter, kVp, grid, density control setting, etc.) currently in use clinically for a 4.2-cm compressed breast of average density.
8. Plot the mAs on the control chart (Figure 7A) after making the exposure.
9. Record the density control setting on the control chart.
10. Process the film in the processor used for mammographic films, always in the same orientation.

11. Measure the film optical densities at three locations. Hie background optical density should be measured at the geometric center of the phantom image (Figure 6B). To determine the DD, measure the optical density inside the disc and directly adjacent to the disc, to its left or right, perpendicular to the anode-cathode axis (Figure 6B). The DD is the difference between the optical density measured inside the disc and that measured outside the disc. For consistent results, these measurements must be made in the same locations each time.

12. Plot the background optical density and the DD on the control chart. An example is provided in Figures 8A and B.

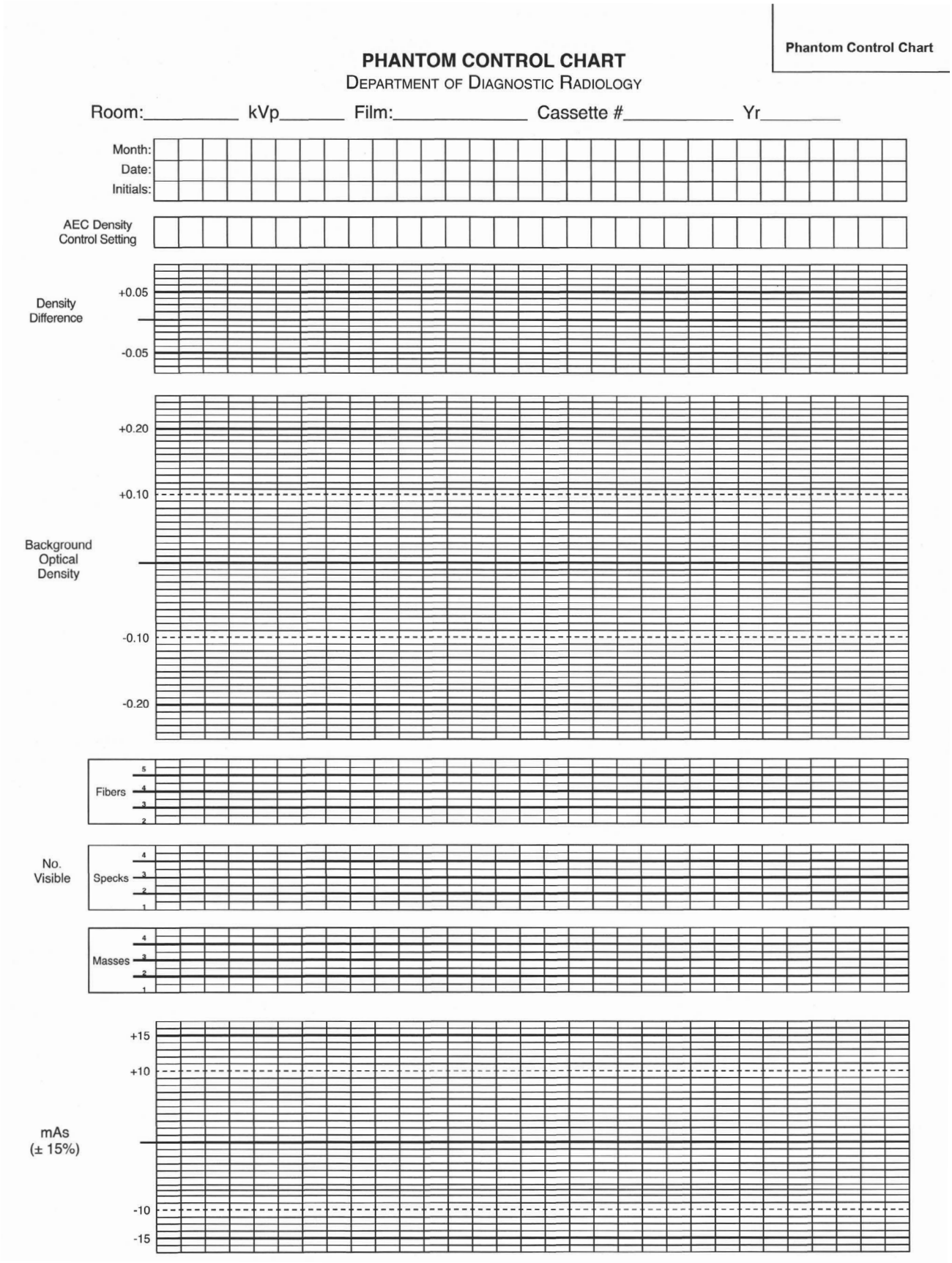


Figure 7A. Phantom control chart.

PHANTOM CONTROL CHART

(CONT'D)

Emulsion Log

Date	Size	Emulsion Number

Emulsion Log

Date	Size	Emulsion Number

Remarks

Date	Action

Figure 7B. Phantom control chart: emulsion log and remarks.

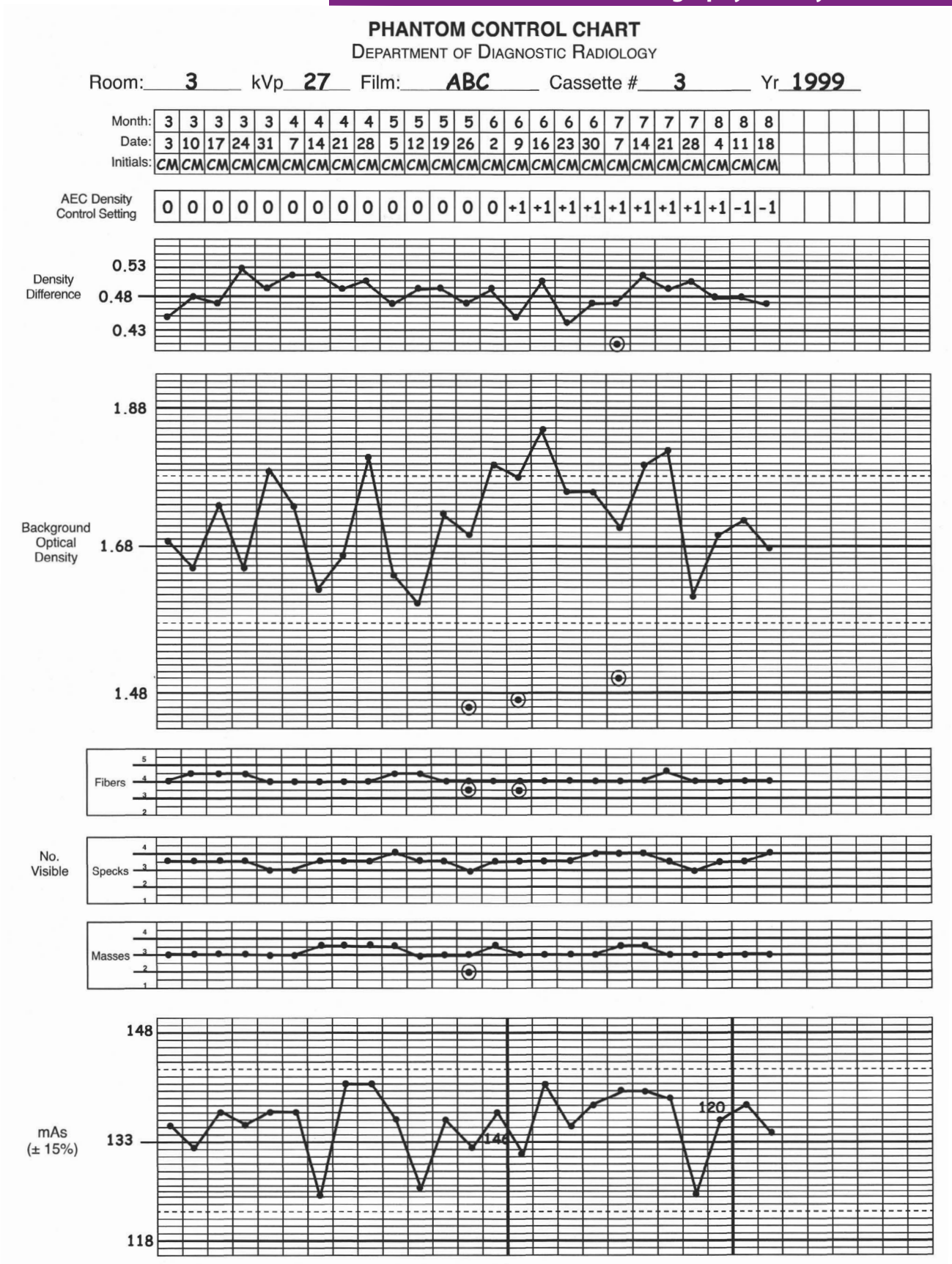


Figure 8A. Sample phantom control chart.

PHANTOM CONTROL CHART

(CONT'D)

Emulsion Log

Date	Size	Emulsion Number
3-3	18x24	12345
3-17		12351
3-31		12351
4-14		12351
4-28		12469
5-19		12469
6-9		12518
6-23		12518
8-4		12691
8-11		13052

Emulsion Log

Date	Size	Emulsion Number
3-3	24x30	98761
3-20		98761
3-31		98782
4-16		98782
5-12		98931
6-9		98931
7-7		98940
8-4		98940

Remarks

Date	Action
4-21	replaced screen – poor contact
5-26	recalibrated generator
6-9	new emulsion batch (slower) – raised
	density control setting to +1
7-7	developer temperature low – ↑ developer temp
8-11	new emulsion batch (faster) – reduced
	density control setting to –1

Figure 8B. Sample phantom control chart emulsion log and remarks.

VIEWING CONDITIONS

Phantom images should be read under optimal viewing conditions. General lighting should be at a low level and diffuse. Viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. Images should be masked to eliminate extraneous light. Use a magnifying glass of 2x or higher for scoring speck groups as well as any other appropriate test objects.

DATA ANALYSIS AND INTERPRETATION

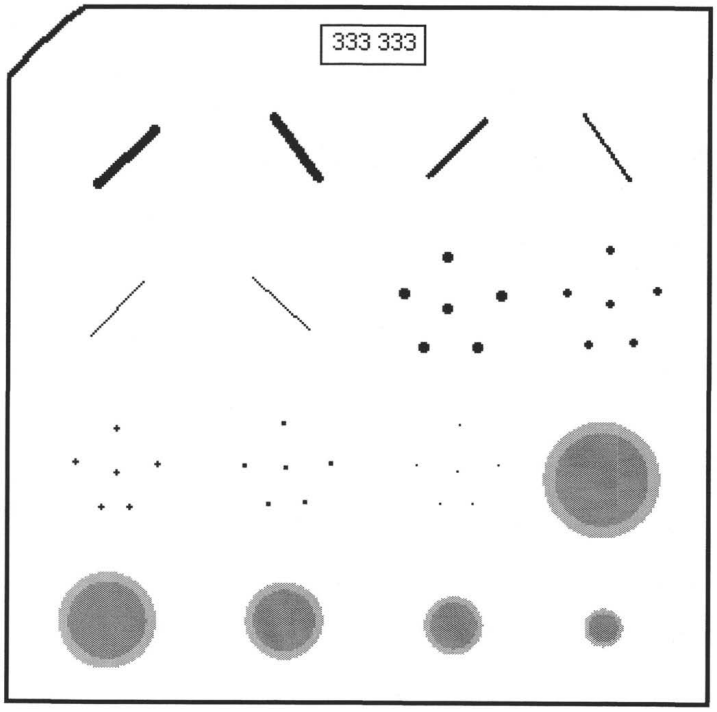
Figures 9A through E illustrate the use of the following criteria to score the phantom.

1. When scoring the image of one of the ACR-approved accreditation phantoms, e.g., Radiation Measurement, Inc. (RMI 156) or Nuclear Associates (18-220), each object type is scored separately. Always count the number of visible objects from the largest object of a given type (i.e., fiber, speck group, or mass) downward until a score of 0 or 0.5 is reached, then stop counting for that object type.

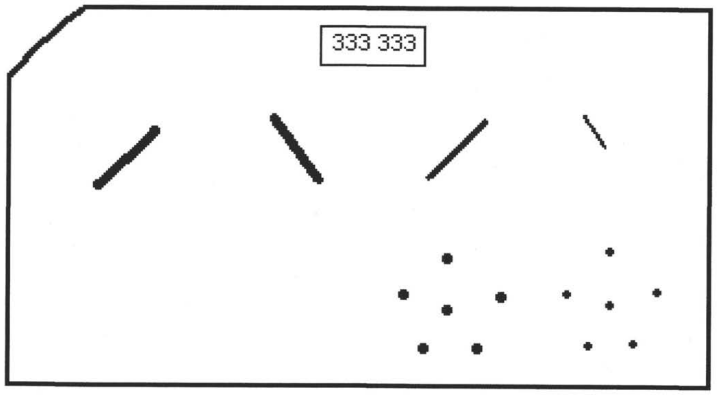
2. Count each fiber as 1 point if the full length of the fiber is visible and the location and orientation of the fiber are correct. Count a fiber as 0.5 point if not all, but more than half, of the fiber is visible, and its location and orientation are correct. Add each full or partial fiber to the total score, from largest down to smallest visible, until a score of 0 or 0.5 is reached (Figure 9A).

3. After determining the last fiber to be counted, look at the overall background for artifacts. If a fiber-like artifact appears anywhere in the wax insert area of the image, but not in an appropriate location or orientation, deduct the "artifactual" fiber from the last "real" half or whole fiber scored if the artifactual fiber is equally or more apparent. Deduct only from the last real fiber, not from additional fibers. (Figures 9A and B). Record the final score after artifact deduction in the appropriate space on the chart (Figure 7A).

4. Use a large field-of-view magnifying lens (approximately 2x or higher) to assist in the visualization of specks. Starting with the largest speck group, count each speck group as 1 point if 4 or more of the 6 specks in the group are visible in the proper locations. Count a speck group as 0.5 if 2 or 3 of the 6 specks in the group are visible in the proper locations. Add each full or partial speck group to the total speck group score, from largest down to smallest visible group, until a score of 0 or 0.5 is reached (Figure 9C).

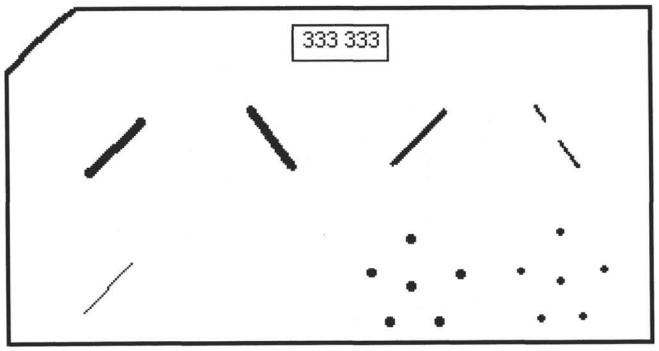


Fibers: 6
Speck groups: 5
Masses: 5

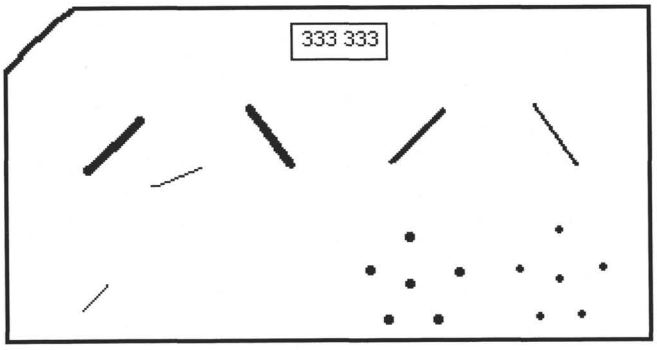


Fibers: 3.5
(not all but at least half of the 4th fiber is visible)

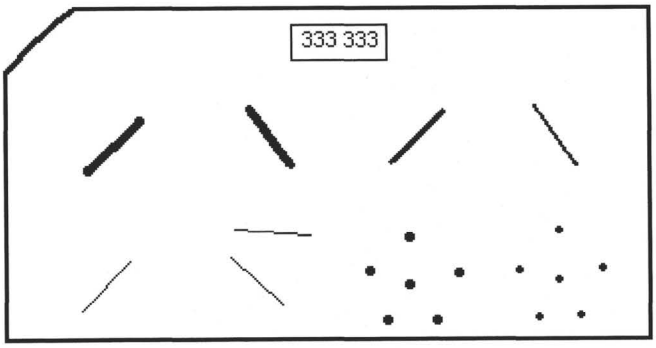
Figure 9A. Phantom diagrams of fiber scoring examples.



Fibers: 3.5
(the entire, unbroken length of the 4th fiber is not visible)

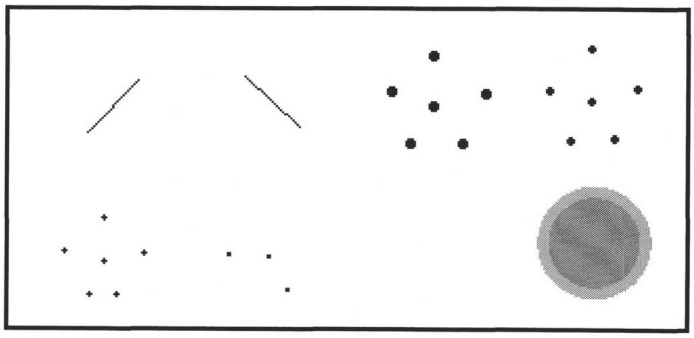


Fibers: 4.0 (4.5 – 0.5)
(the fiber-like artifact between the 1st and 2nd fiber must be subtracted from the last real fiber scored)

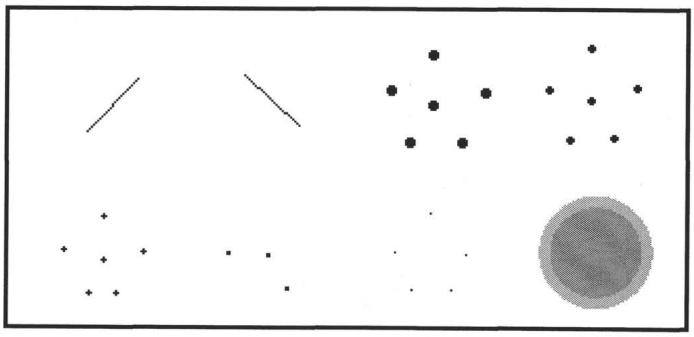


Fibers: 5.0 (6.0 – 1.0)
(the fiber-like artifact above the 6th fiber must be subtracted from the last real fiber scored)

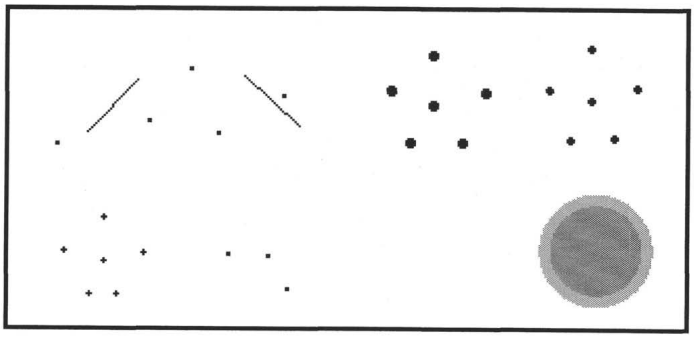
Figure 9B. Phantom diagrams of fiber scoring examples (continued).



Speck groups: 3.5 (only 3 specks in the 4th speck group are visible)

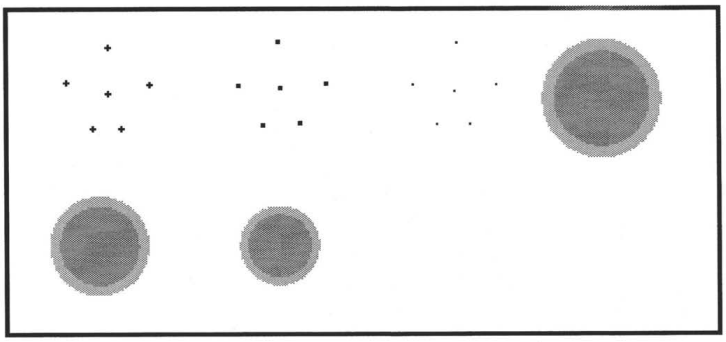


Speck groups: 3.5 (although 5 specks in the 5th speck group are visible, only 3 are visible in the 4th group)

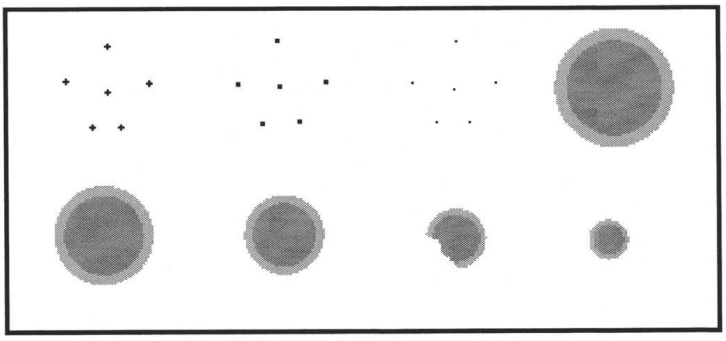


Speck groups: 3.0 (3.5 – 0.5) (speck-like artifacts around the 5th and 6th fibers must be subtracted one for one from the specks in the last real speck group)

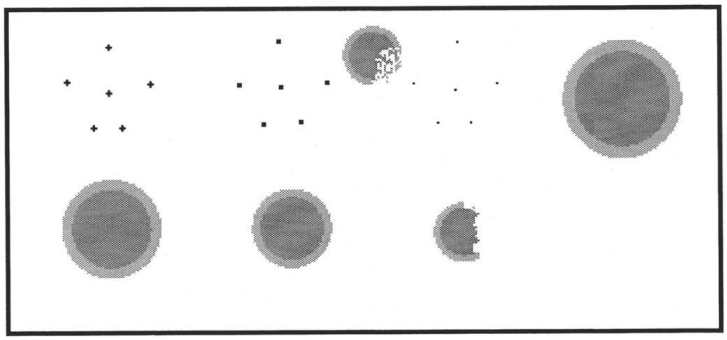
Figure 9C. Phantom diagrams of speck group scoring examples.



Masses: 3.0

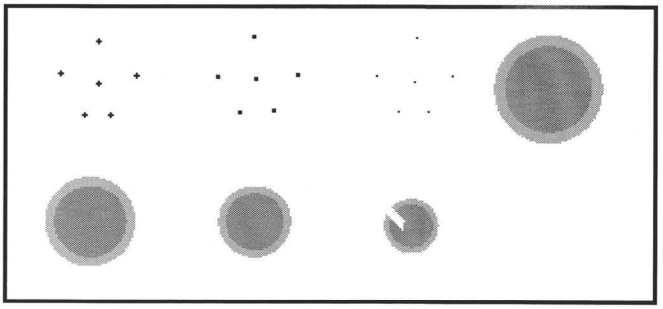


Masses: 3.5 (greater than 3/4 of the round perimeter should be visible for a full point)

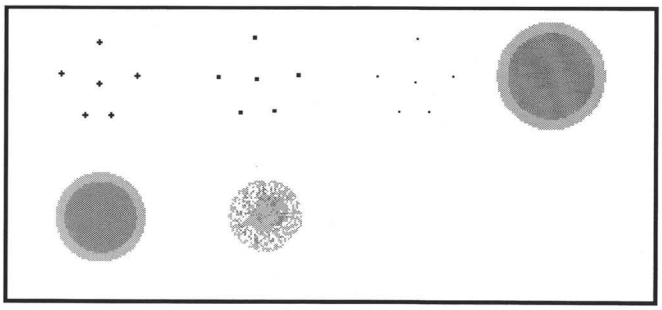


Masses: 3.0 (3.5 – 0.5) (the mass-like artifact between the 4th and 5th speck groups must be subtracted from the last real mass scored)

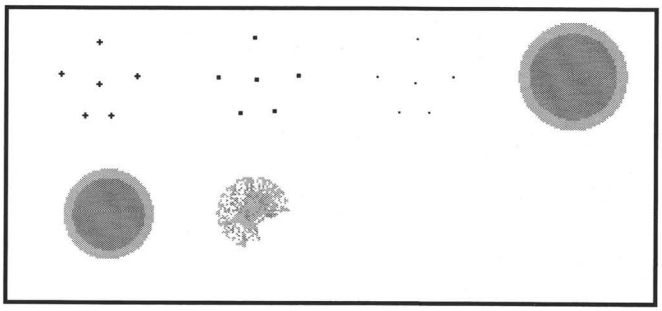
Figure 9D. Phantom diagrams of mass scoring examples.



Masses: 4.0
(the 4th mass is given a full point in spite of the linear artifact since it is still generally circular)



Masses: 3.0
(although the 3rd mass has less contrast, it is still generally circular and is given a full point)



Masses: 2.5
(the 3rd mass is of less contrast and is not generally circular)

Figure 9E. Phantom diagrams of mass scoring examples (continued).

5. After determining the last speck group to be counted, look at the overall background for artifacts. If noise or speck-like artifacts are visible in the wrong locations within the area of the wax insert, and are as apparent as the "real" specks, deduct them one for one from the individual specks counted in the last whole or half speck group scored, and adjust the score of the last group appropriately (Figure 9C). Record the final score after artifact deduction in the appropriate space on the chart (Figure 7A).
6. Count each mass as 1 point if a minus density object is visible in the correct location, and the mass appears to be generally circular against the background (i.e., greater than 3/4 of the perimeter is visible). A mass is counted as 0.5 point if a minus density object is visible in the correct location, but the mass does not have a generally circular appearance. Add each full or partial mass to the total mass score, from the largest mass down and until a score of 0 or 0.5 is reached. Record the "raw" mass score before artifact deduction (Figure 9D).
7. After determining the last mass to be counted, look at the overall background for artifacts. If a mass-like artifact is seen in the wrong location within the area of the wax insert, deduct the "artifactual" mass from only the last "real" whole or half mass scored if the artifactual mass is equally or more apparent (Figures 9D and E). Record the final score after artifact deduction on the appropriate space on the chart (Figure 7A).
8. Using the magnifying lens, carefully examine the image for non-uniform areas, the presence of dirt or dust artifacts, grid lines or artifacts (if a moving grid is used), processing artifacts, or any other artifacts (Figure 10), and compare the film to the original and previous films.
9. Circle any artifacts or grid lines on the film.
10. Investigate the source of any artifacts or grid lines. The medical physicist can provide assistance in identifying the sources of artifacts (See Section II in the "Medical Physicist's Section").

NOTE: Mammographic phantom films should always be viewed:

- by the same person;
- on the same viewbox;
- under the same viewing conditions;
- using the same type of magnifier used for reading mammograms; and
- at the same time of day.

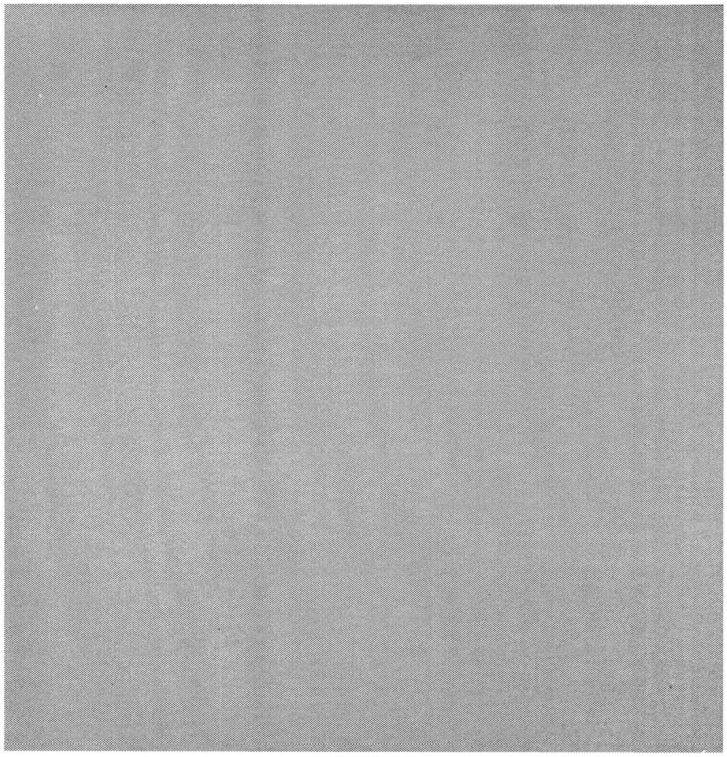


Figure 10A. Image of uniform mammographic phantoms exhibiting processor artifacts.

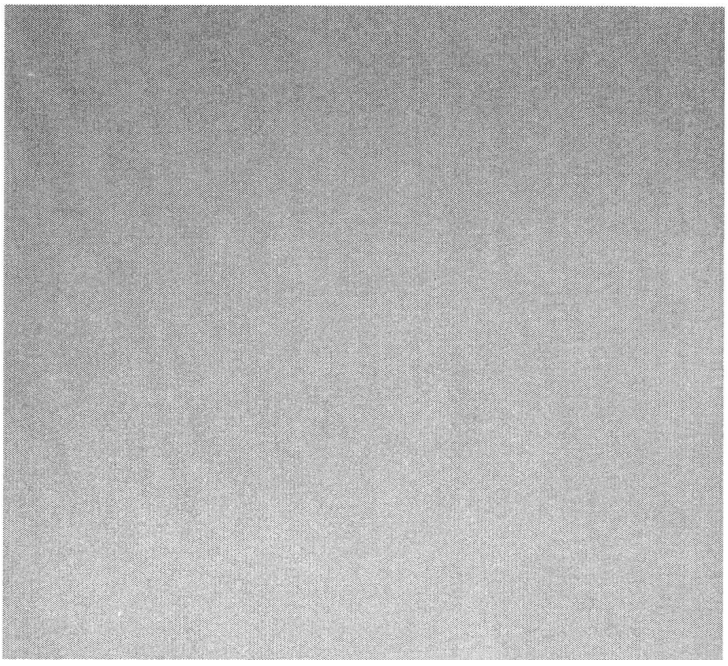


Figure 10B. Image of uniform mammographic phantoms exhibiting grid artifacts.

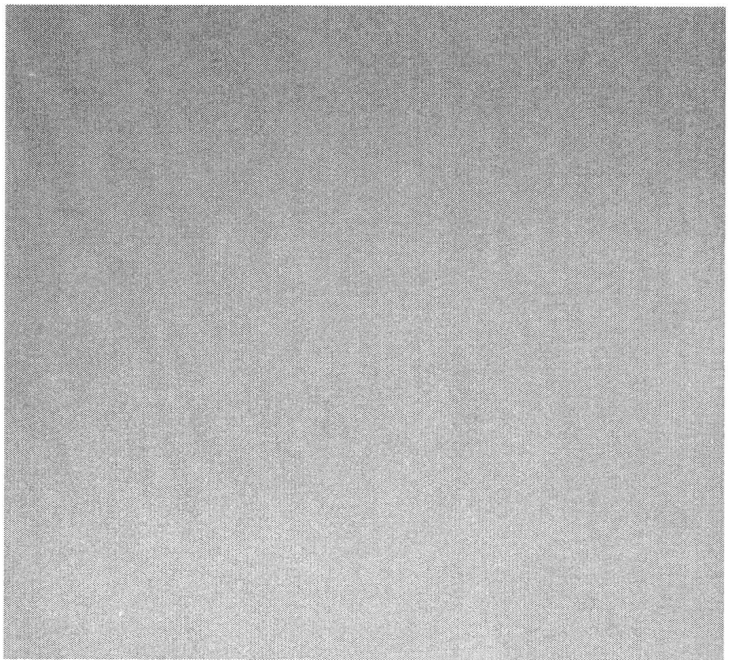


Figure 10C. Image of uniform mammographic phantoms exhibiting grid lines.

PRECAUTIONS AND CAVEATS

This procedure measures contributions from all components in the imaging chain. Changes in image quality may be due to any component, e.g., the film, cassette and screen, X-ray generator, added filtration, processor, or viewbox. Consequently, other tests will be necessary to determine the component, or components, causing the change. For example, if the film optical density is too high or too low, it will be necessary to review the processor sensitometry records to see if a change in processing has occurred, determine if the mAs recorded on the control chart for the phantom image has changed, check the consistency of the screens used, and check to see if a new film emulsion batch is being used, etc.

Although weekly phantom image evaluation is required for only the most commonly used cassette size (18 x 24 cm) it may also be useful to image the phantom periodically with a large (24 x 30 cm) cassette. A phantom image should be produced and evaluated if clinical images suggest problems with either the small or large formats. Typical examples of problems which are specific to the film-cassette size are grid lines, film performance or compression paddle artifacts.

Subjective judgments about images are always difficult. Different individuals will perceive different numbers of test objects in the image. The same individual may count a different number of objects in the same image at different times. Consequently, the same individual should view the images each time using the same criteria for better consistency. In addition, the same viewbox, viewing conditions, and magnification should be used each time, and these should be the same as those used for

reading mammograms. If a different number of objects is noted, then the present image should be compared with previous images and the original image to determine if a change has really occurred. Be sure to save the orginal image so that this comparison can be made.

Any non-uniformity in the images can degrade the quality of clinical mammograms. It may be worthwhile to expose a mammographic cassette on top of the cassette holder, as opposed to under the moving grid, to demonstrate the uniformity possible without the grid. In addition, it may be worthwhile to expose the mammographic cassette on top of the cassette holder and process the film in a different processor in order to demonstrate processor artifact differences.

The 4-mm, thick acrylic discs used to produce an image for the measurement of the density difference may vary slightly in thickness. Consequently, the density difference is a relative, not absolute, measurement and is to be used only for QC purposes. It is essential to use the same phantom and same acrylic disc when comparisons are made between different units.

> NOTE: If more than one type of film is used for mammographic imaging, it is necessary to carry out this test with each type of film used clinically for a breast thickness of 4.2 cm.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The present criteria for the number of objects to pass the ACR Mammography Accreditation is **a minimum of the four largest fibers, the three largest speck groups, and the three largest masses.** Furthermore, the number of test objects of each group type (fibers, specks, and masses) visible in the phantom image should not decrease by more than one half, assuming the same individual is viewing the images under identical conditions. If a greater change in the number of test objects is noted, then the present image should be compared with the original image and the previous image to determine whether the change is real or if the individual viewing the film has changed his or her criteria.

The phantom image background optical density should never be less than 1.20, and the control limits for the phantom image background density should be ±0.20. Thus, in order to have the full +0.20 density control limits available, the **operating level for phantom image background optical density should be at least 1.40.** Substantially higher phantom image background optical density operating levels may provide improved mammography image quality and avoid underpenetration of dense tissue. However, increasing mAs to achieve higher film optical density will increase the mean glandular dose, and higher average film optical densities will require higher-luminance viewing conditions to see important diagnostic detail.

Generally, the operating level for DD due to the 4.0-mm acrylic disc should be at least 0.40. The DD will vary depending on disc thickness, choice of film, kVp processing conditions, and background image optical density. Higher mAs and background optical density may result in significant increases in density difference even when using the same film, kVp and processing conditions. Once an operating level for density difference is established, control limits are ±0.05 for subsequent phantom images. The density difference control limits are only applicable when the 4.0-mm acrylic disc is used. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established as well.

In addition to assuring that each mammography imaging system produces similar film optical density and DD over time, it is also essential that all mammography units and mammography processors at one facility produce similar film optical densities. It is not acceptable to have one unit or processor producing film optical densities of 1.40 and another producing optical densities of 1.80. Likewise, one should expect each mammography unit and mammography processor at a facility to produce images with similar DD and images of similar image quality.

The mAs noted on the generator readout should not change by more than ±15% for a given density control setting. If the density control setting is changed to accommodate batch-to-batch differences in film speed or as a result of a conscious decision to change the background optical density operating level, then the operating level for mAs should be adjusted appropriately and this action documented in the remarks log (Figure 7B).

If the recommended performance criteria and corrective action for this test are not met, a second phantom image should be taken and evaluated. If the criteria are still not met, the reasons for this failure should be investigated, corrective action taken, and the results documented before patients are examined with this system. Other testing methodolgies may exist to help isolate the source of system change (e.g., processing versus X-ray unit) that could be applied in addition to the phantom and the 4.0-mm disc.

NOTE:

- At a minimum, the four largest fibers, the three largest speck groups, and the three largest masses must be visible and should not decrease by more than 1/2 from the operating level.
- The phantom image background optical density should be at least 1.40 and should not vary by more than ±0.20 from the operating level.
- The DD due to the 4.0-mm acrylic disc should be at least 0.40 and should not vary by more than ±0.05 from the operating level.

Any visual differences between the current phantom film and the saved original phantom film should be investigated. Processor artifacts should not be present, nor should grid lines or grid artifacts (for systems using a moving grid) since any of these that are visible on the phantom image will degrade clinical images.

If a change in phantom image background optical density or DD reaches or exceeds the recommended performance criteria, then it will be necessary to determine the source, or sources, of this change, e.g., the processor, film emulsion batch, X-ray generator, etc., and the problem should be corrected immediately. Document corrective action for future reference and compliance with MQSA regulations. If the change in film optical density is confirmed to be due to a change in the film emulsion batch, and if the magnitude of the change is within the expected batch-to-batch variation for that film type, then an adjustment of the density control setting to bring the phantom background optical density back into control is an appropriate corrective action. The film manufacturer should be consulted for guidance on expected batch-to-batch variation, and if the change in film optical density due to the film batch change is greater than should be expected, then the non-compliant batch should be replaced by a new batch. The 1995 ACR publication, *Recommended Specifications for New Mammography Equipment*, suggests that a difference in film optical density of 0.30 at an optical density of about 1.2 is a reasonable maximum to expect between any two films of the same type when given the same mammographic exposure and processed together. The appearance of artifacts, grid lines, or grid artifacts; the number of masses, specks, and fibers visualized; or any other change in the visual appearance of the image should be reported immediately to the medical physicist for further evaluation.

All sources of significant artifacts or grid lines should be eliminated. This may require careful cleaning and readjustment of the processor or cleaning of the screens and cassettes, as an example. Slow grid motion may introduce a structured pattern (Figure 10B), especially with higher speed screen-film mammographic image receptors for which the exposure times are relatively short. The grid moving only a few millimeters during the exposure may result in a partial image of the grid structure.

NOTE: Phantom image films should be retained in the QC records for the last full year. Original (baseline) images should be retained until it is necessary to extablish a new baseline.

A mammography film emulsion log is provided (Figure 7B) to help keep track of film emulsions that are used clinically. Doing so will help the mammography facility determine if optical density changes are due to film emulsion changes or some other component of the mammography system. It will also help film manufacturers make comparisons in speed, contrast and maximum optical density between current clinical images and images taken 1 year earlier or more. Such comparisons may assist in troubleshooting image quality problems. Record the film emulsion number every time a new case with a new emulsion number is opened.

MQSA REQUIREMENTS:

Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition. The optical density of the film shall not change by more than ±0.20 from the established operating level. The phantom image shall achieve at least the minimum score established by the accrediting body and accepted by FDA. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than ±0.05 from the established operating level.

If the test results fall outside of the action limits, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

5. PROCEDURE: DARKROOM FOG

OBJECTIVE

To assure that darkroom safelights and other light sources inside and outside of the darkroom do not fog mammographic films.

Fog on mammographic films reduces contrast and results in variations in film optical density from one sheet of film to another (the latter effect being due to sheets of film receiving varying amounts of fog exposure).

FREQUENCY

This test should be carried out initially and then every 6 months (semi-annually). The initial test should be made with new safelight filters using the filters, filter-to-tabletop distances, and bulb wattages specified by the film manufacturer. In addition to the semiannual test, this test should be performed whenever bulbs or filters are changed or when fog is suspected.

It should be stressed that safelight filters fade over time, especially when light bulbs with higher-than-recommended wattage are used in the safelights.

REQUIRED TEST EQUIPMENT

Mammography X-ray unit

Mammographic phantom

Densitometer

Mammographic film, one sheet of each type of film used for mammography in the darkroom (from a new box; not from the film bin)

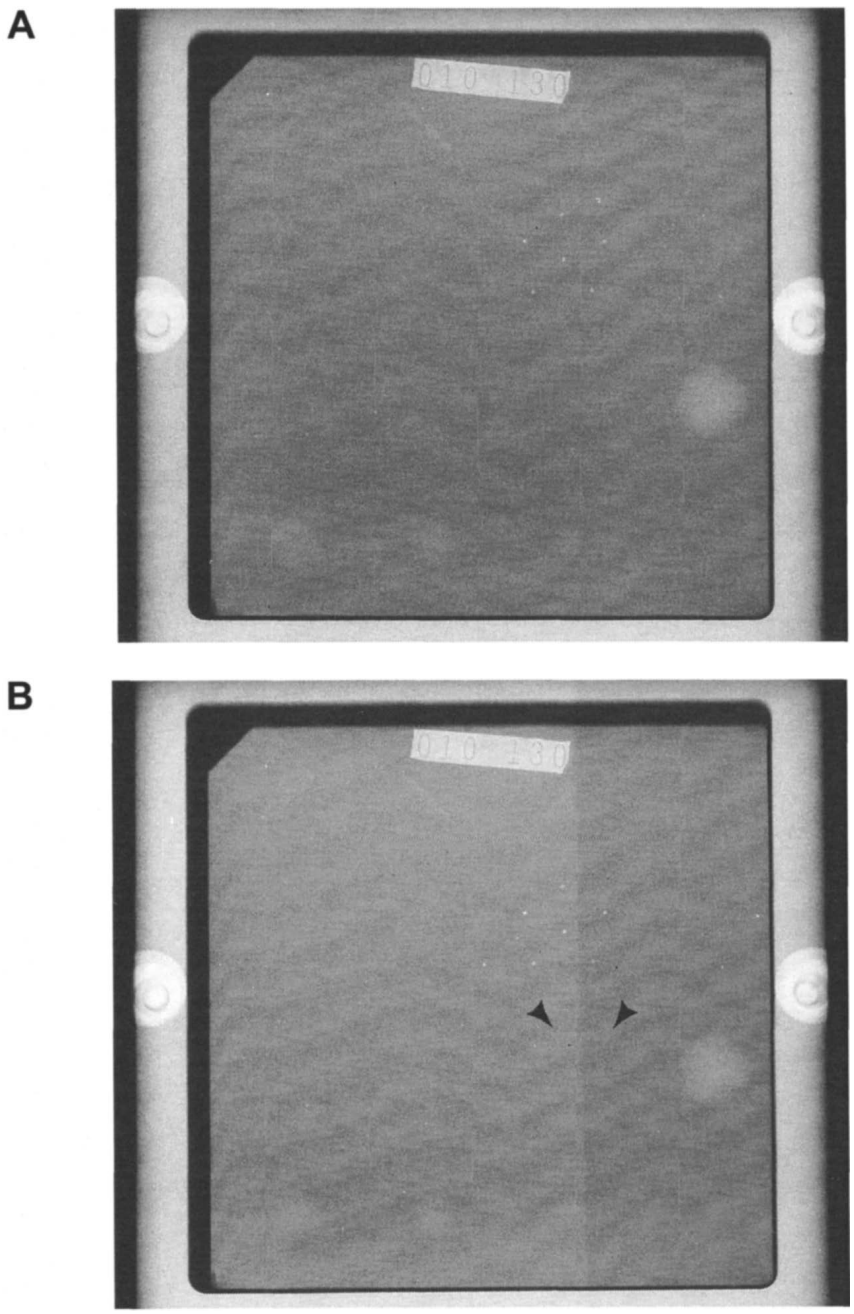
Opaque card

Watch or timer

TEST PROCEDURE STEPS

1. Assure that all safelight filters are those specified by the film manufacturer and do not appear faded or cracked. Also assure that the wattage and type of the light bulbs and the distance from the safelights to the film-handling surface are those specified by the film manufacturer.
2. Turn out all lights in the darkroom and wait 5 minutes for the eyes to adjust.
3. Look for obvious light leaks around doors, around the passbox and processor, and in the ceiling. Light leaks may be quite directional, i.e., they may not be visible from one position but quite evident from another as one moves around. Be careful in moving around a darkroom without safelight illumination. Accidents can happen.
4. Correct all visible light leaks before proceeding.
5. In total darkness, load a film from the box of film into a cassette appropriate for that film.
6. Prepare to make an X-ray exposure by placing the cassette in the cassette holder of the mammography unit.

7. Place the phantom on the breast support surface and position it so the edge of the phantom is aligned with the chest wall side of the image receptor and centered left to right.
8. Bring the compression device into contact with the phantom.
9. Verify the location of the phototimer sensor, i.e., it should be in the same location used for previous phantom images and under the center of the wax insert.
10. Make an exposure using the technical factors (target, filter, kVp, grid, etc.) used clinically for a 4.2-cm compressed breast.
11. In total darkness, remove the exposed film from the cassette and place it on the countertop, emulsion side up. Cover one half of the phantom image with the card perpendicular to the chest wall edge of the film. Be sure that the opaque card is in contact with the film so that light cannot pass under it.
12. Turn on all safelights and let the film and opaque card lie on the countertop for 2 minutes.
13. Process the film.
14. Using the densitometer, measure the density of the unfogged portion of the image (that portion that was covered with the card) (Figure 11). The density should be measured away from any test objects, close to the edge separating the fogged and unfogged portion of the phantom image (if one is seen).
15. Measure, in a similar manner, the density of the fogged portion of the phantom image (the portion that was uncovered). This measurement should be made immediately adjacent to the area where the measurement of the unfogged portion was made, directly across the boundary created by the opaque card and away from test objects.
16. To determine the amount of fog, subtract the density of the unfogged portion of the phantom image from the density of the fogged portion of the phantom image.
17. Record this optical density difference (DD) on the monthly, quarterly, semiannual checklist (Figure 11B).



Figures 11A & B. Phantom images demonstrate acceptable darkroom fog level (A) and excessive darkroom fog (B).

PRECAUTIONS AND CAVEATS

To effectively carry out this test, it is important to use film exposed to a clinical optical density (between 1.40 to 2.00). Unexposed, underexposed, or overexposed film is much less sensitive to the effects of darkroom fog.

The date the safelights are installed should be written on the filter using an opaque, permanent marker for future reference. Some safelight filter manufacturers indicate that the filter should be replaced quarterly. However, this is usually not necessary if the darkroom passes the darkroom fog test.

It is essential that this test be carried out with the different types of film used in the darkroom. The results from one type of film can be entirely different from those for another type of film, i.e., the amount of fog on one type of film cannot predict the amount of fog on another type of film.

Darkroom fog failures can be isolated to safelight problems or room environment light leaks by repeating the test with the safelight off.

Even if daylight film processors are routinely used to process the mammography film, the test should be conducted in the darkroom that is used to load the film magazines.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The fog (the optical DD measured between the fogged and unfogged areas of the film) should be no greater than 0.05. If the fog is greater than 0.05, the source of fog must be determined and immediate corrective action taken and documented. (Although this criterion may appear quite stringent, it is easy to meet if the appropriate safelight filters are used at the distance and with the type and wattage bulbs recommended by the film manufacturer.) If the test fails due to the safelight, mammography films can continue to be processed in the darkroom with the safelight off until appropriate corrective action can be taken.

Sources of fog include:

- Incorrect or faded safelight filters
- Cracked filters or safelight housing
- Safelights too close to the film handling area
- Incorrect light bulb wattage or type
- Indicator lights such as those on processors, timers, etc.
- Light leaks around doors, processors, or passboxes
- Light leaks through perforated ceiling tiles or incorrectly placed tiles in suspended ceilings

OBJECTIVE

MQSA REQUIREMENTS:

Darkroom Fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during the test.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

6. PROCEDURE: SCREEN-FILM CONTACT

To assure that optimum contact is maintained between the screen(s) and film in each cassette.

Screen-film contact has a significant influence on image sharpness. Since mammographic screen-film systems have significantly higher resolution than conventional systems (16 to 20 cycles/mm for mammography as opposed to 4 to 8 cycles/mm for conventional systems), contact becomes even more important in order to produce optimum quality images.

FREQUENCY

This test should be carried out initially and for all new cassettes as they are placed in service, then every 6 months (semiannually) and when reduced image sharpness is suspected.

REQUIRED TEST EQUIPMENT

Copper screen, 40 mesh (40 wires per inch), 24 X 30 cm. The mesh may have been placed between two thin sheets of acrylic (1/8-inch thick) by the manufacturer to protect it (Figure 12).

Acrylic sheets (sufficient to provide 4-cm thickness), if needed

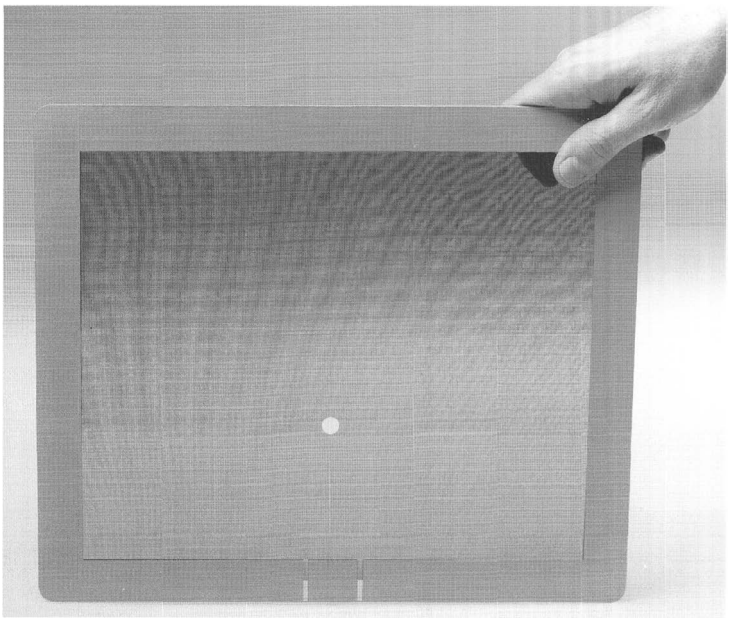


Figure 12. Photograph of mammographic cassette contact test mesh. The circular hole in the mesh is no longer used or needed. Newer versions of the test mesh may not contain this hole.

Mammographic film of the appropriate size

Densitometer with an aperture 2.0 mm in diameter or larger

Screens and cassettes to be tested

TEST PROCEDURE STEPS

1. Carefully and thoroughly clean the screens and the cassettes to be tested using an acceptable screen cleaner. While cleaning the screens, be sure to also clean all inside surfaces of the cassette.
2. Allow the screens to air dry at least 15 minutes after cleaning before closing the cassette or loading it with film. Inspect the screens to make sure they are dry before loading.
3. Load all cassettes with film. (Each cassette should have a unique identification number that is visible on the acquired image.)
4. Wait 15 minutes (or follow the waiting period specified by the cassette manufacturer) so that any entrapped air has sufficient time to escape.
5. Place the cassette to be tested on top of the cassette holder, i.e., without any grid between the X-ray tube and the cassette.
6. Place the copper screen on top of the cassette.
7. Place the acrylic sheets, if needed, on top of the compression device and move the compression device as close as possible to the X-ray tube.

NOTE: The acrylic is used to assure a reasonable exposure time, e.g., at least 0.5 second, and hence good exposure reproducibility, while obtaining a realistic density on the film. The additional acrylic may not be needed if the exposure time to produce a density of about 0.75 is approximately 0.5 second. The size of the acrylic must be sufficient for its projected area to cover the entire cassette when the acrylic is placed as close to the X-ray tube as possible. The acrylic is moved as close to the X-ray tube as possible, i.e., as far as possible from the cassette, to reduce the amount of scattered radiation reaching the cassette.

8. Select a manual technique (at 25 to 28 kVp) that will provide a film density between 0.70 and 0.80 when measured in the image over the mesh near the chest-wall edge.
9. Expose and process the film.
10. Repeat steps 1 through 9 for each mammographic cassette.
11. View the films on a viewbox at a distance of at least 3 feet (1 meter). Look for areas of poor contact, i.e., darker areas in the mesh image (Figures 13A and B).

12. The cassettes that pass this test (see Performance Criteria) should be placed into clinical use.
13. Select those cassettes that did not pass the initial test. Once again clean the screens and interior cassette surfaces using the screen cleaner recommended by the screen manufacturer. Repeat steps 2 through 11 for each cassette.
14. Cassettes that pass after the second cleaning and retesting can be used for clinical purposes.
15. For those cassettes that do not pass the retest, place the two films (original and retest films) on a viewbox side by side and aligned in the same orientation.
16. Observe and compare the locations of the areas of poor contact (dark areas) on the films.

PRECAUTIONS AND CAVEATS

This test must be carried out using the 40 mesh copper screens in order to be sensitive enough to detect poor contact in mammographic cassettes. Large mesh used to test conventional (non-mammography) cassettes will not detect small dust particles that produce poor contact, nor will it detect larger areas of poor contact when exposed at 28 kVp (thicker wires produce an image with contrast that is too high).

Small specks of dust can reduce screen-film contact and degrade the image for significant distances (up to 1 cm or more) away from the dust particle. Poor contact can also result from improperly designed or damaged cassettes or from insufficient pressure as a result of deterioration of the foam in the cassette.

The images must be viewed on a viewbox from a distance of at least 3 feet in order to not visualize the actual wires in the mesh. It is much easier to look for the areas of increased density than for "fuzzy" wires in the fine mesh. The high density of the film is required to assist in visualising the darker areas that indicate poor contact (Figure 13B).

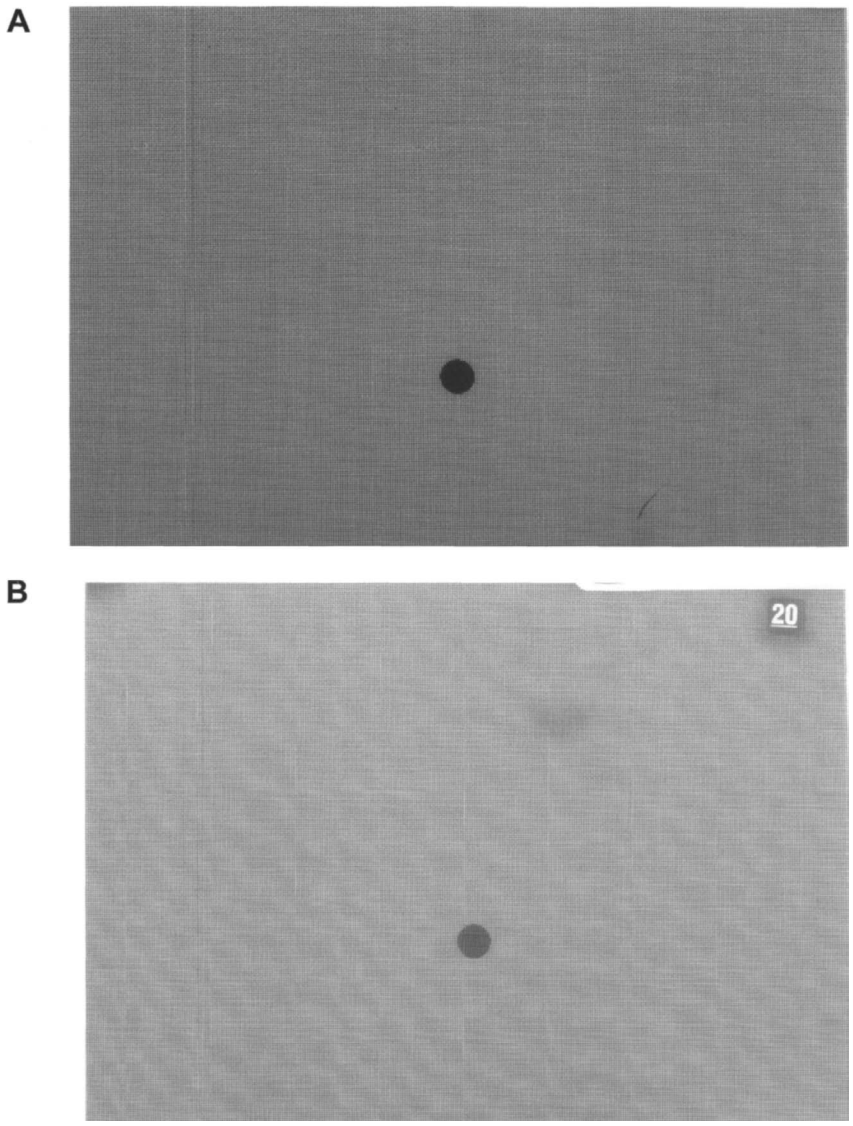


Figure 13. Mammogram of fine (40 mesh) copper screen demonstrate (A) good screen-fiim contact and (B) unacceptable screen-film contact.

Entrapped air, i.e., air trapped between the screen and film, may be a cause of poor screen-film contact. This is particularly evident in single-screen mammographic imaging systems. This problem can be alleviated by waiting about 15 minutes after loading the cassette with film (or following the cassette manufacturer's recommended wait time) before making an exposure (assuming appropriate cassette design and adequate pressure from the foam on the screen and film). This, of course, applies whether the cassette is being tested for screen-film contact or being used for clinical exposures. The facility should have enough cassettes for clinical use so that there is adequate time after loading for entrapped air to escape.

It is important to obtain an image optical density (measured with a 2-mm diameter aperture or larger and measured over the mesh near the chest-wall side of the film) between 0.70 and 0.80. Some mammography units do not have small enough exposure time steps to obtain densities in this narrow range. In this case one can add thin sheets of acrylic near the X-ray tube port to adjust the film optical density to the appropriate level.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Large areas (>1 cm in diameter) of poor contact that are not eliminated by screen cleaning and remain in the same location during subsequent tests should not be tolerated, i.e., the cassettes should be replaced. Multiple small areas (<1 cm in diameter) are acceptable, and the cassette may be returned to clinical use.

MQSA REQUIREMENTS:

Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested. No performance criterion is specified. This test must be carried out every six months.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

7. PROCEDURE: COMPRESSION

OBJECTIVE

To assure that the mammography system can provide adequate compression in the manual and powered mode and that the equipment does not allow too much compression to be applied.

Adequate compression is essential for high-quality mammography. Compression reduces the thickness of tissue that must be penetrated by radiation, thereby reducing scattered radiation and increasing contrast, while reducing radiation exposure to the breast. Compression improves image sharpness by reducing the breast thickness, thereby minimizing focal spot blurring of structures in the image, and by minimizing patient motion. In addition, compression makes the thickness of the breast more uniform, resulting in more uniform image densities and an image that is easier to interpret.

FREQUENCY

This test should be carried out initially, then every 6 months (semiannually), and whenever reduced compression is suspected.

REQUIRED TEST EQUIPMENT

Bathroom scale. The scale should be a flat, conventional, analog type. Digital scales sample the data and may not respond properly as additional pressure is applied slowly to the scale. Digital scales designed specifically to measure compression force may be used.

Several towels

TEST PROCEDURE STEPS

Power Mode

1. Place a towel on the cassette holder (to protect the cassette holder), then place the bathroom scale on the towel with the dial or read-out positioned for easy reading. Locate the center of the scale directly under the compression device (Figure 14).
2. Place one or more towels on top of the scale to prevent damage to the compression device.
3. Using the initial power drive, activate the compression device and allow it to operate until it stops automatically.
4. Read and record the compression force on the Monthly, Quarterly and Semiannual Tests checklist (Figure 1B).
5. Release the compression device.

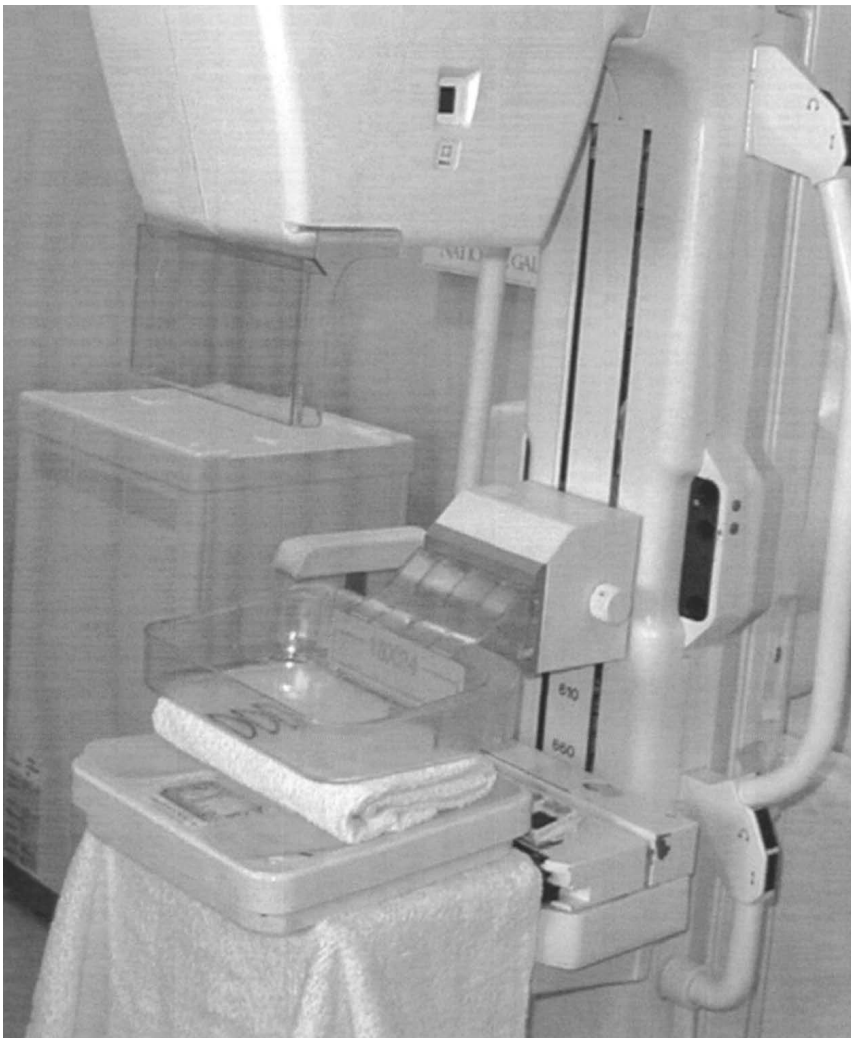


Figure 14. Bathroom scale being used to measure compression force.

Manual Mode

1. Using the initial manual drive, move the compression device downward until it stops.
2. Read and record the compression force on the monthly, quarterly and semiannual checklist (Figure 1B).
3. Release the compression device.

PRECAUTIONS AND CAVEATS

If the safety mechanism is not properly adjusted, it may be possible to damage the compression device and associated components. If the compression exceeds 200 newtons (20 decanewtons or 45 pounds) in the initial power drive mode, immediately release the compression device and ask a service engineer to make the appropriate adjustments.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

If the MQSA requirements are not met, a qualified service engineer should make the appropriate internal adjustments.

MQSA REQUIREMENTS:

Compression device performance. A compression force of at least 111 newtons (25 pounds) shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive must be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

If the test results fall outside of the action limits, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

8. PROCEDURE: REPEAT ANALYSIS

OBJECTIVE

To determine the number and cause of repeated mammograms and rejected films. Analysis of these data will help identify ways to improve efficiency and reduce costs as well as patient exposures.

FREQUENCY

This test must be carried out at least every 3 months (quarterly). In order for the repeat rates to be meaningful, a patient volume of at least 250 patients is needed, if possible.

REQUIRED TEST EQUIPMENT

All rejected mammograms (including data for repeated mammograms that may have been placed in the patient's film jacket)

Means to count the total number of films consumed during the test period

Means for sorting films during analysis

TEST PROCEDURE STEPS

1. Start by disposing of all existing rejected films in the department.
2. Take inventory of film supply as a starting point to determine total number of films consumed during this test.
3. Start to collect all rejected films and continue collection for the length of time needed to radiograph at least 250 consecutive patients.
4. Sort the rejected films into the categories listed in Figure 15A. Films may be repeated for a number of reasons including poor positioning, patient motion, being too light or too dark (these might be due to exposure or processing) or artifacts (streaks, spots, etc.). Good films (which appear to be acceptable mammograms when retrospectively evaluated during the repeat analysis) may have also been repeated. Some films may not have resulted in an additional exposure of the patient but may have also been rejected. These include clear films and QC films. Although it is appropriate to include wire localization films as part of the reject analysis, they should not be included in the repeat analysis because they are taken as part of the wire localization process.

NOTE: Rejected films are all films that are in the reject bin, including repeated films. Repeated films are those patient films that had to be repeated and resulted in additional exposure to the patient.

5. Some facilities place all films (repeated and good films) in the patient jackets so there are no repeated films in the department. In this case, Figure 15A should be completed as patient examinations are carried out, entering data as shown in Figure 15B.

6. Tabulate the counts from steps 4 and 5 and determine the total number of repeated films, rejected films, and the total number of films exposed.

7. Determine the overall percentage of repeated films by dividing the total number of repeated films (categories 1 - 11) by the total number of films exposed during the analysis period, and multiply by 100. Likewise, determine the overall percentage of rejected films by dividing the total number of rejected films (categories 1 — 14) by the total number of films exposed during the analysis period, and multiply by 100.

8. Determine the percentage of repeats in each "reason for repeat" category by dividing the repeats in the category by the total number of repeated films (categories 1-11) and multiply by 100.

Mammography Repeat-Reject Analysis

From _____ **to** _____

Reason for Reject	Projection Repeated (Check one for each Repeated Film)						Number of Films	% of Repeats
	Left CC	Right CC	Left MLO	Right MLO	Left Other	Right Other		
1. Positioning								
2. Patient Motion								
3. Light Films								
4. Dark Films								
5. Black Films								
6. Static, Artifacts								
7. Fog								
8. Incorrect ID or Double Exposure								
9. Mechanical								
10. Misscellaneous								
11. Good Films (no apparent reason)								
12. Clear Film								
13. Wire localization								
14. Q.C.								

	Number	%
Repeats (1-11)		
Rejects (All; 1-14)		

Total Films Used ____

Remarks: _____

Corrective Action: _____

Figure 15A. Form for repeat analysis data collection.

Mammography Repeat-Reject Analysis

From _____ **to** _____

Reason for Reject	Projection Repeated (Check one for each Repeated Film)						Number of Films	% of Repeats
	Left CC	Right CC	Left MLO	Right MLO	Left Other	Right Other		
1. Positioning		||||					4	17
2. Patient Motion	|	|					2	9
3. Light Films			||	||			4	17
4. Dark Films		|			|		2	9
5. Black Films			|				1	4
6. Static, Artifacts							0	0
7. Fog	|				|		2	9
8. Incorrect ID or Double Exposure		||					2	9
9. Mechanical			|				1	4
10. Misscellaneous		||				|	3	13
11. Good Films (no apparent reason)			|			|	2	9
12. Clear Film							3	
13. Wire localization							8	
14. Q.C.							6	

	Number	%
Repeats (1-11)	23	1.9%
Rejects (All; 1-14)	40	3.2%

Total Films Used: 1236

Remarks: Good work!

Corrective Action: None Needed

Figure 15B. Sample form for repeat analysis data collection.

PRECAUTIONS AND CAVEATS

All films that are repeated should be included in the repeat analysis, not just those that the radiologist asked to have repeated. Some facilities may place repeated films in the patient jacket along with good films. These repeated films must be included in the repeat analysis.

At a minimum, the repeat analysis must be done at least quarterly. This process of reviewing the rejected films provides mammography technologists with an educational benefit. Many higher work load facilities choose to conduct a repeat analysis monthly.

Including examinations on at least 250 patients (approximately 1000 films) allows for a minimum number of rejected films so that reasonable statistics can be obtained for the analysis. Collecting rejected films from a larger number of patients is encouraged because it will yield more reliable data when evaluating causes for repeats. Facilities that do not examine 250 patients in a quarter should still assess repeat films at least quarterly to determine the primary causes of repeated films and reap the educational benefit of the process.

There is a real danger that technologists may alter their routine procedures or criteria for accepting films if they know their repeated films will be analyzed. This should be avoided.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The overall repeat rate ideally should be approximately 2% or less, but a rate of 5% is probably adequate if the radiologist and medical physicist agree that this is a reasonable level. These rates should be based on a film volume of at least 250 patients to be meaningful. A "reason for repeat" that is significantly higher than the others indicates an area for potential improvement.

If the repeat rate exceeds the selected acceptance level of either 2% or 5%, or if the repeat or reject rate changes from the previously measured rate by more than ±2%, the change should be investigated and corrective action taken if necessary. For example, if the previous repeat rate was 1.8% and the new repeat rate is 4.2%, then the follow-up described above is required.

Any corrective actions should be recorded on the bottom of the mammography repeat analysis form. In addition, the effectiveness of the corrective actions must be assessed by performing another repeat analysis after the corrective actions have been implemented.

It is important to study films that are too dark or too light to determine whether the underlying cause is the equipment, exposure technique, or processing.

MQSA REQUIREMENTS:

Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed. This test must be carried out quarterly.

If the test results fall outside the action limits, the source of the problem must be identified and corrective actions must be taken within 30 days of the test date.

9. PROCEDURE: VIEWBOXES AND VIEWING CONDITIONS

OBJECTIVE

To assure that the viewboxes and viewing conditions are optimized and maintained at an optimum level.

FREQUENCY

This procedure should be carried out weekly.

REQUIRED TEST EQUIPMENT

Window cleaner, e.g., Windex or Glass Plus

Soft towels

PROCEDURE STEP

1. Clean viewbox surfaces using window cleaner and soft paper towels.
2. Assure that all marks have been removed.
3. Visually inspect the viewboxes for uniformity of luminance.
4. Assure that all viewbox masking equipment is functioning properly and easily.
5. Visually check the room illumination levels and assure that sources of bright light are not present in the room and are not being reflected from the viewbox surface.

PRECAUTIONS AND CAVEATS

The accuracy of the diagnosis and the efficiency of the radiologist are influenced by the conditions under which the mammograms are viewed. Viewing conditions may affect the diagnostic potential of even the best quality mammograms. These conditions are determined by the luminance of the viewboxes, the ambient room illumination or the amount of light falling on the viewbox surface, and good masking of films on the viewbox.

Viewboxes are a vital link in the process of reading a mammogram yet receive little attention even after extensive efforts have been invested in producing high-quality mammograms. If it were not for the superb performance of the human eye and brain in reading the film, a very complicated viewing system would be needed. In practice, film viewboxes are often used under less than ideal conditions.

Contrast is extremely important in the mammography image and is degraded by extraneous light. Consequently, viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting in the room should be at a low level and diffuse.

Viewboxes used in mammography should provide a relatively high luminance level, generally higher than for viewing conventional radiographs. Consequently, it is essential to mask the area around the mammograms to exclude extraneous light, which reduces image contrast and limits the maximum densities that can be seen without "bright-lighting" each film.

10. PROCEDURE:

Since viewboxes are usually a long-term investment, i.e., most last 10 to 20 years, care should be taken in selecting them. Particular attention should be paid to the uniformity of the luminance of the viewbox and the luminance level. Viewboxes used in general radiography have luminance levels on the order of 1,500 candela/m^2 (nit). It is suggested that the luminance level of mammography viewboxes should be at least 3,000 candela/m^2. All viewboxes should be checked periodically to assure that they are in optimal condition. (See Viewbox Luminence and Viewing Illuminence Test in the "Medical Physicist's Section").

Fluorescent tubes decrease in brightness with time, although not rapidly, i.e., about 10% in 2,000 hours. It is advisable to replace fluorescent tubes every 18 to 24 months. All tubes should be replaced at one time. In addition, all of the replacement tubes should be of the same type and color. If it is necessary to replace any fluorescent tubes due to decreased light output or for any other reason, such as flickering, then all tubes should be replaced at the same time to assure uniformity in color and luminance.

If a separate viewbox is used by the QC technologist to check the density and quality of the mammography images, this viewbox should be similar to the reading viewbox in luminance and color of the light and should be used with ambient lighting conditions similar to those in the room where the mammograms are interpreted.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Any marks that are not easily removed with window cleaner should be removed with a safe and appropriate cleaner. If viewboxes appear non-uniform, all of the fluorescent lamps should be replaced as soon as possible. If viewbox masks are difficult to use, appropriate service or modifications should be requested.

MQSA REQUIREMENTS:

Facility cleanliness. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

ANALYSIS OF FIXER RETENTION IN FILM

OBJECTIVE

To determine the quantity of residual fixer (hypo) in processed film as an indicator of keeping quality. Residual hypo indicates insufficient washing and considerably degrades image stability.

FREQUENCY

This test should be carried out every 3 months (quarterly).

REQUIRED TEST EQUIPMENT

Hypo estimator (e.g., Kodak Hypo Estimator, Publication No. N-405, or equivalent)

Hypo test solution (commercially available, or see note at the end of this section)

TEST PROCEDURE STEP

1. Process one sheet of unexposed film in the mammography processor.
2. Place one drop of the hypo test solution on the emulsion (less shiny) side of the film.
3. Allow the solution to stand for 2 minutes.
4. Blot off the excess solution.
5. Place the film on a sheet of white paper.
6. Compare the stain with a hypo estimator strip (Figure 16) by looking at the radiographic film on a sheet of white paper. The comparison should be made with the estimator over the film sample to help compensate for differences in the color of the base of the film and with the hypo estimator strip in its sleeve for protection.
7. Record the results on the Monthly, Quarterly and Semiannual Tests checklist (Figure 1B).

PRECAUTIONS AND CAVEATS

The comparison should be made immediately after the excess test solution has been removed from the film. Direct sunlight causes the spot to darken rapidly and a prolonged delay between the blotting of the solution and comparison also allows the spot to darken.

The test hypo estimator solution has a shelf life of about 2 years, provided that it is stored in a dark, airtight bottle and away from light.

Both acetic acid and silver nitrate are dangerous and must be handled with caution. If either of these chemicals comes in contact with your skin, wash the area with cold water immediately.

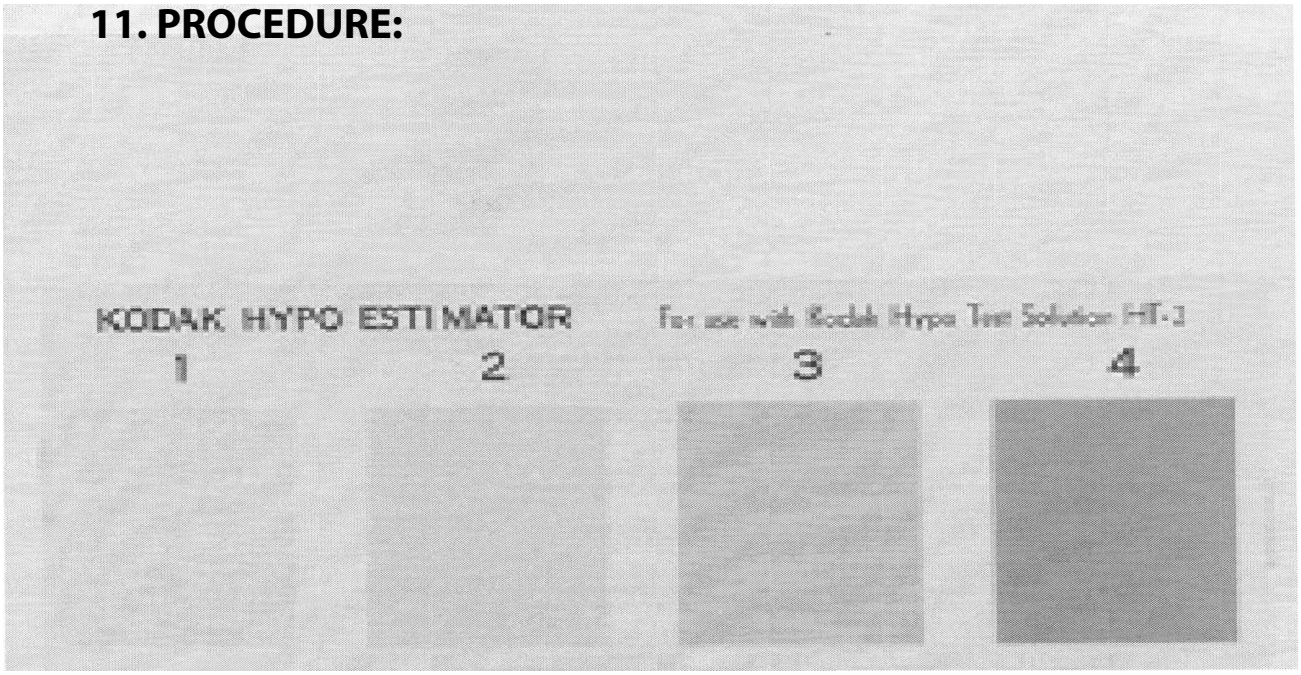


Figure 16. Hypo estimator and test film, showing a match with step 2. This indicated a lower amount of retained fixer than the suggested performance criteria.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The hypo estimator provides estimates of the amount of residual hypo in the film in units of grams per square meter. The estimated amount of residual hypo should be 0.05g/m^2 (5µg/cm^2) or less.

If the stain indicates that there is more than 0.05g/m^2 residual hypo in the film, the test should be repeated. If the same result is obtained, then corrective action is necessary.

The processor wash water tank should be checked to assure that it is full of water, if appropriate. The wash water flow rate should be verified to determine that it meets the specifications of the processor manufacturer. Also, the fixer replenishment rate should be checked to determine that it is close to the recommended rate because the efficiency of the wash water in removing fixer from the film is dependent on the correct fixing of the film. If these items appear to be correct, a technical representative of the film manufacturer should be consulted to assist in resolving the problem of excessive fixer retention.

MQSA REQUIREMENTS:

Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm. If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

VISUAL CHECKLIST

OBJECTIVE

To assure that mammographic X-ray system indicator lights, displays, mechanical locks and detents are working properly and that the mechanical rigidity and stability of the equipment is optimum.

FREQUENCY

This test should be carried out monthly or after any service or maintenance on the mammographic X-ray system.

REQUIRED TEST EQUIPMENT

Visual checklist (Figure 17)

TEST PROCEDURE STEPS

1. Review all of the items listed on the visual checklist and indicate the status. Be sure to rotate the C-arm the way you would for patient imaging.
2. Date and initial the checklist where indicated.

PRECAUTIONS AND CAVEATS.

Some of the items on the visual checklist are operator convenience features. Many of the items, however, are essential for patient safety and high-quality diagnostic images. It may be necessary to add additional items to the list that are specific to particular equipment or procedures. These should be included on the checklist and in each evaluation.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Each of the items listed in the Visual Checklist should pass and receive a check mark. Items not passing the visual check should be replaced or corrected immediately.

Items missing from the room should be replaced immediately. Malfunctioning equipment should be reported to the X-ray service engineer for repair or replacement as soon as possible.

MQSA REQUIREMENTS:

There are no MQSA requirements for conducting a visual checklist.

MAMMOGRAPHY QUALITY CONTROL VISUAL CHECKLIST

Facility: _____ Room # _____ Unit: _____

C-ARM	SID indicator or marks													
	Angulation indicator													
	Locks (all)													
	Field light													
	High tension cable/other cables													
	Smoothness of motion													
	_____													
CASSETTE HOLDER	Cassette lock (small and large)													
	Compression device													
	Compression scale													
	Amount of compression: Automatic .													
	Manual													
	Grid													
	_____													
CONTROL BOOTH	Hand switch placement													
	Window													
	Panel switches/lights/meters													
	Technique charts													
	_____													
OTHER	Cones or collimators													
	Cleaning solution													
	_____													
	_____													
	_____													
	_____													
PASS =	✓ Month:													
FAIL =	F Date:													
DOES NOT APPLY =	NA Initials:													

Figure 17. Visual checklist.

1. DEVELOPER TEMPERATURE

OBJECTIVE

To confirm and ensure that developer and fixer temperatures are within the manufacturer's recommendations for a particular processor and processing cycle. Low developer temperature can result in underdevelopment, which results in reduced image contrast and is often compensated by increased patient exposure. Fluctuating developer temperature can result in fluctuating image quality.

REQUIRED TEST EQUIPMENT

Alcohol, dial, or clinical digital fever thermometer - accurate to at least ±0.5°F

Built-in thermometer

TEST PROCEDURE STEPS

1. Measure and read the temperature of developer and fixer solutions and record on the control chart. Place the thermometer in the same location, usually the non-gear side, each time. Clean the thermometer stem of any chemical traces between measurements of developer and fixer and before storage.
2. Compare the measured developer temperature with the temperature reading from the built-in thermometer. If there is a significant discrepancy, e.g., greater than 0.5°F, the calibration of both thermometers should be verified, with any necessary corrections (i.e., calibrations) being made by a qualified service engineer.

PRECAUTIONS AND CAVEATS

Mercury-filled thermometers should never be used to monitor temperatures in a photographic or X-ray film processor. Mercury is a sensitizing agent for films, and minute amounts in the processor or darkroom can cause serious problems.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The developer temperature should be within ±0.5°F (±0.3°C) of that recommended by the manufacturer for the specific film-developer combination being used. Fixer temperature is not as critical and should be maintained within ±5°F (±3°C) of the developer temperature.

If developer or fixer temperature is not within specifications, it should be adjusted appropriately.

2. REPLENISHMENT RATE

OBJECTIVE

To verify that the replenishment rate is appropriate for the mammography film and processor used. This ensures (1) proper film speed and film contrast, and (2) appropriate solution tank operating levels.

REQUIRED TEST EQUIPMENT

Consult the manufacturers processor service manual for required equipment and procedures.

TEST PROCEDURE STEPS

1. Consult the manufacturer's processor service manual to obtain this information.
2. The person performing the replenishment rate check must have proper training from the manufacturer or a local service representative (dealer, vendor, etc.).
3. Replenishment rates should be compared with the chemistry manufacturer's pre-established rate per sheet of film based on the daily volume of processed film and whether one or two films are processed at the same time.

PRECAUTIONS AND CAVEATS

Replenishment rate checks vary from direct visual readings on some processors to invasive, more labor-intensive procedures.

Replenishment rate recommendations are available from most film and chemical manufacturers. However, there are no readily available tables or charts that provide replenishment rate information in a concise and standardized format.

MOBILE MOMMOGRAPHY

Mobile mammography units are subject to all the QC requirements that apply to stationary units. In addition, each mobile mammography unit must be tested each time it is moved to a different examination location, and before examining any patients, in order to verify the adequacy of the image quality produced by each unit.

1. IF PROCESSING IS IMMEDIATELY ACCESSIBLE

There are a number of ways in which this required testing can be carried out. For example, a phantom image can be taken (following the procedure outlined in this section) after each relocation of the mobile unit and prior to any patients being examined. This image should then be processed and evaluated (scored) at the mobile unit's site of operation. The score should then be compared to the standard score and the background density and density difference determined to verify that the unit is performing adequately before any patient examinations are conducted. If the image quality and densities are inadequate, then immediate corrective action is required and the results of the corrective action need to be verified by a repeated phantom image test before any patient examinations can be conducted. If the score is above the standard but below the previous or typical score, the reasons for the low score should be investigated but patient examinations may be conducted. This approach is the ideal but clearly requires on-board processing or local processing at the site of operation of the mobile unit.

2. IF PROCESSING IS NOT IMMEDIATELY ACCESSIBLE

APPROACH A. **Phantom image obtained and processed prior to obtaining mammograms.** An alternative approach can be used in the absence of on-board or local processing capability. In this case the phantom image is taken as described above and the unprocessed image sent to the central site where the clinical mammograms will ultimately be batch processed. Once the image is processed, it is evaluated as described above and corrective action taken and performance re-tested, as necessary, prior to beginning patient examinations. If the score is above the standard but below the previous or typical score, the reasons for the low score should be investigated but patient examinations may be conducted. This approach obviously requires additional time and might be convenient only when the mobile unit is moved and set up the day or evening before examinations are scheduled.

APPROACH B. **Phantom obtained but not processed prior to obtaining mammograms.** Another approach that can be used in the absence of on-board or local processing involves monitoring the mobile unit's radiation output or the postexposure mAs when a phantom image is made using the AEC mode of operation under typical clinical conditions. The measured radiation output or the data from the post-exposure mAs display is then compared to an acceptable operating level (of output or mAs) previously established and correlated with acceptable phantom image quality. If the reading is within ±10% of the established operating level then the unit can be used for clinical examinations. Otherwise, immediate corrective action is needed to bring the value to within ± 10% of the established operating level. Re-testing to verify the effectiveness of the corrective action is then necessary before proceeding with clinical examinations.

This last approach is indirect and therefore is not as reliable as the other approaches, which involve producing and evaluating a phantom image before conducting clinical examinations. However, a critical step in this indirect approach is to send the unprocessed phantom image, along with any clinical images taken subsequently, to the remote processing site for batch processing. The phantom image should be processed and scored at the earliest available time and before the clinical images are batch processed. The evaluation of the processed phantom image can verify that the image quality is adequate. If the phantom image fails because of processing problems, the problems should be corrected before processing clinical images. If the phantom image fails for other reasons, then image quality may be compromised. In this case the facility should process and evaluate each clinical image carefully to determine whether any patients need to be recalled to have repeat examinations.

If the radiation output or mAs monitoring method is to be used, then an acceptable operating level that is correlated with acceptable phantom image quality must be established. This should be done by collecting radiation output or mAs data while making phantom images with the unit in question. This should be done for at least 5 consecutive days of operation, which include sampling all the environments that will be experienced by the mobile unit (in terms of both travel and site conditions). These data can then be used to determine an acceptable operating level (a value of the output or mAs that is associated with acceptable phantom image quality).

If the mobile unit receives major repairs, it is necessary to re-establish the operating level.

MQSA REQUIREMENTS:

Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

INFECTION CONTROL

To prevent and control the spread of infection to employees, patients, and visitors within the mammography facility.

GENERAL INFORMATION

Questions regarding the techniques or infection control policies shall be referred to the infection control policy manual, or the infection control specialist.

1. Universal-Standard Precautions is the established standard of care. Employees must wear barrier precautions (gloves, gown, etc.) when they are likely to be in contact with any patient's moist body substances, mucous membranes or non-intact skin.
2. Staff should wash hands when soiled with any bodily substance, between patient contacts, and after glove removal.
3. Patients with communicable diseases shall be cared for according to infection control policies.
4. All employees should undergo tuberculosis testing at time of hire and annually thereafter.
5. Personnel with active upper respiratory, skin or gastrointestinal infections should not have direct patient contact.
6. Personnel are required to attend an annual infection control in-service.

RESPONSIBILITIES

Department Manager or Supervisor

1. Oversees and enforces infection control recommendation for nosocomial infection prevention.
2. Approves (or appoints a designee to approve) policies and procedures for infection control in the mammography facility.
3. Assures proper practice of infection control.
4. Consults with the infection control specialist for infection control-related issues.

Infection Control Specialist

1. Consults with the department director, managers, and supervisors as needed.
2. Provides infection control in-services as requested by the department.
3. Assists in review of infection control policies and procedures for the department.

FREQUENCY

This procedure should be carried out between patients.

REQUIRED TEST EQUIPMENT

Facility-approved disinfectant (QC technologist should verify with manufacturer that approved disinfectant will not damage equipment.)

Disposable wipes

PRECEDURE STEPS

1. The mammography rooms are be straightened between patients.
2. All surfaces in contact with patient are to be wiped clean with a facility-approved disinfectant at the end of each examination.
3. All staff should wash their hands between contact with different patients.
4. All linens are for single patient use. Following use, they are to be deposited in appropriate bag for transport to laundry.
5. Any spills or drips on floors or equipment must be washed with a facility-approved disinfectant.

ISOLATION PATIENTS

Patients who are in isolation are seen in the department only if absolutely necessary.

1. Isolation patients are scheduled to cause the least amount of exposure to other patients. Patients who are found to have infectious diseases are to be separated from other patients.
2. The staff will adhere to the established isolation precautions as described in the infection control manual.

MQSA REQUIREMENTS:

Infection control. 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:

(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

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1999 Mammography

QUALITY CONTROL MANUAL

Medical Physicist's Section

Introduction

The success of mammography, whether for screening or diagnosis, depends on the production of high-quality, low-dose images. Production of such images is a complex and difficult task. Poor-quality mammograms lower the detection rate of early breast cancer, reducing the patient's chances of survival and undermining the public's confidence in the value of mammography. Furthermore, substandard mammography generates equivocal examinations leading to increased cost and anxiety to the patient. Achieving high-quality studies at low dose requires vigilant attention to quality control, not only on the part of the radiologist and mammography QC technologist, but also on the part of the medical physicist.

This section of the manual provides detailed procedures for tests to be conducted at least annually by a medical physicist in mammography. These tests, designed to assess the continuing performance of screen-film mammography equipment, comply with the Mammography Quality Standards Act (MQSA) Final Rules that take effect April 28, 1999. Other tests, which are not covered under MQSA, are also included for a more complete assessment of system performance. Similar updated tests are included for the mammography QC technologist, detailing the procedures appropriate for routine QC testing. The tests presented in the "Medical Physicist's Section" are considered the minimum test set that should be conducted on an annual basis to help assure proper mammographic system performance. Tests should be performed with technique factors used clinically for mammography. It is assumed that mammography equipment will have been subjected to more extensive acceptance testing or a thorough performance evaluation prior to the initiation of QC testing.

It is the responsibility of the medical physicist conducting these tests to convey test results accurately to the facility in a written report, to make recommendations to the facility for corrective actions according to the test results, and to review the results with the radiologist and QC technologist. MQSA inspectors check the medical physicist's report to determine if the facility is in compliance with the regulations and if the medical physicist's recommendations are considered by the facility. Although MQSA Final Rules allow the medical physicist 30 days from the date of the survey to send a report to the facility, a 30-day delay in getting the report to the facility allows the facility no time to take corrective actions. It is essential to note that the MQSA requires **immediate** corrective action by the facility for failure of two of the medical physicist's tests: excessive breast dose (Medical Physicist Test #10) and deficient phantom image quality (Medical Physicist Test #7 and Radiologic Technologist Test #4). If either of these tests fails, a facility may not conduct mammography with that equipment until the problem is corrected. For a facility to comply with this new requirement, the medical physicist must not only collect test data during the survey but must also immediately evaluate phantom image quality and dose results and compare them to the pass/fail criteria. Most importantly, the medical physicist must immediately communicate this failure to the facility. It is strongly recommended that phantom image quality and dose failures be communicated immediately to the facility both verbally and in written form. One way to accomplish this is by

leaving the facility a preliminary report upon departure. A Preliminary Results form is included in Section IV as a form that can be copied, completed, and left at each site or can be modified as desired to provide immediate, written communication of preliminary test results.

Communication of test results and recommendation of corrective actions are areas that can be improved in the practices of most medical physicists. Corrective actions should not be limited to repair of X-ray equipment by a qualified service person but should include recommendations that will improve image quality, including recommendations concerning image receptors, technique factors, processing, viewing conditions, and technologist QC. The medical physicist should periodically review the results of technologist QC tests (at least annually) and make recommendations regarding these tests, if needed. Furthermore, the medical physicist should participate in periodic reviews of the mammography QC program as a whole to assure that the program is meeting its objectives (See Section III).

Because film viewing conditions are an extremely important link in the mammography imaging chain, the measurement of viewbox luminance has now been included as one of the medical physicist QC tests. The tools and methods of measuring viewbox luminance are described in Medical Physicist's Test #11.

To assist the medical physicist in communicating test results and recommendations, summary report forms have been included in Section IV. It is important for the medical physicist to clearly communicate whether each test fails the more rigorous ACR performance recommendations in addition to the minimum-level MQSA regulations. Spaces are provided in the summary report form to permit both responses. A preliminary results form is provided for the medical physicist to leave brief, handwritten results for the facility prior to departure. This immediate communication is particularly essential to allow adequate time for the facility to take corrective action should any tests fail. Finally, a form (Trainee or Assistant Log) is provided for the supervising medical physicist to record the QC tests that are performed by an assistant or trainee (as required under the final MQSA regulations). These forms should be used (or appropriately modified) to summarize the results and recommendations of the medical physicist's QC testing and surveys.

Section V provides data forms to record the site's clinical techniques and detailed results of the eleven QC tests described in this section of the manual. All forms are provided for duplication so that they can be used for recording data collected during medical physicist QC testing.

The MQSA Final Rules present specific requirements for mammography equipment. Section VI includes a checklist to help the medical physicist determine whether the facility meets all of these standards.

Finally, the slit camera evaluation of focal spot performance has been moved to a separate section (Section VII) because it is no longer recommended for routine quality control. However, the test may be useful in isolating the focal spot's contribution to poor spatial resolution. Under the MQSA Final Rules, this is an acceptable method for evaluating system resolution (focal spot performance) until October 28, 2002.

A list of resources and additional references relevant to mammography is included at the end of this manual in Section VIII.

1. PROCEDURE

MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION

OBJECTIVE

To ensure that all locks, detents, angulation indicators, and mechanical support devices for the X-ray tube and image receptor holder assembly are operating properly.

TEST PROCEDURE STEPS

1. Verify that the freestanding dedicated mammography unit is mechanically stable under normal operating conditions.
2. Verify that all moving parts move smoothly, without undue friction; that cushions or bumpers limit the range of available motions; and that no obstructions hinder the full range of motions within these limits.
3. Set and test each lock and detent independently to ensure that mechanical motion is prevented when the lock or detent is set.
4. Verify that the image receptor holder assembly is free from wobble or vibration during normal operation.
5. Verify that the image receptor slides smoothly into the proper position in the image receptor holder assembly and that the image receptor is held in place securely by the image receptor compartment for any orientation of the image receptor holder assembly.
6. If provided, verify that the compressed breast thickness scale (analog or digital) is accurate to within ±0.5 cm under conditions of moderate compression (15 to 20 lbs) and reproducible to within ±2 mm between 1 and 8 cm. The phantom used for this test should be large enough to simulate a typical breast and be positioned towards the chest-wall side of the bucky. The compressed breast thickness should be measured at the center of the chest-wall position of the automatic exposure control (AEC) sensor. This should be done for at least the small and large image receptors and compression paddles.
7. Verify that, in normal operation, the patient and operator are not exposed to sharp or rough edges or other hazards including electrical hazards.
8. Verify that current and accurate technique charts are posted and confirmed by consulting with the mammography technologist.
9. Verify that the operator is protected by adequate radiation shielding during exposure.
10. Verify that all indicator lights are working properly.
11. Verify that autodecompression can be overridden to maintain compression (for procedures such as needle localizations) and its status displayed continuously (if autodecompression is available).

12. Verify that compression can be manually released in the event of a power failure or automatic release failure by turning power off to the equipment with a phantom under compression and using manual controls to release the compression.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Items that are hazardous, inoperative, or operate improperly should be repaired by appropriate service personnel.

MQSA REQUIREMENTS:

If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides: (A) An override capability to allow maintenance of compression; (B) A continuous display of the override status; and (C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

2. PROCEDURE

COLLIMATION ASSESSMENT

OBJECTIVES

To assure that the X-ray field aligns with the light field, that the collimator allows for full coverage of the image receptor by the X-ray field but does not allow significant radiation beyond its edges, and that the chest-wall edge of the compression paddle aligns with the chest-wall edge of the film.

REQUIRED TEST EQUIPMENT

Five coins, four of one size (e.g., pennies) and one of a larger size (e.g., a nickel).

Four mammographic cassettes with film: one small and three large.

Approximately a 1-inch-thick sheet of acrylic or BR-12 large enough to cover the surface of the cassette (if necessary).

TEST PROCEDURE STEPS

1. Place an appropriately sized cassette loaded with film in the normal orientation in the image receptor holder.
2. Load film in the large cassette with the emulsion side of the film away from the intensifying screen.
3. Place the large cassette on top of the image receptor holder with the back of the cassette toward the X-ray source and assure that the large cassette extends beyond the image receptor holder on the chest-wall side by about 1 cm.
4. Place the collimator to be evaluated in position.
5. Remove the compression paddle. (The compression paddle should be removed before placement of the coins to assure a sharp demarcation at the edges of the light field.)
6. Turn on the collimator light and place the four identical smaller coins inside the light field with one edge of each coin just touching the edge of the light field. The coin on the chest-wall side should be shifted to the right of center about 2 inches so it does not superimpose the AEC detector.
7. Replace the compression paddle and position it 4.2 cm from the breast support.
8. Tape the larger coin underneath the compression paddle shifted about 2 inches to the left so it does not superimpose the AEC detector. Be sure the coin's outer edge is tangent to the inner lip of the chest-wall side of the compression paddle. This coin marks the chest-wall edge of the paddle.
9. Place a sheet of acrylic or BR-12 attenuating material on top of the paddle, so that all radiation reaching the cassettes must pass through the attenuator. Make an exposure using AEC.

10. Repeat steps 1 through 9 for all routinely used collimator/bucky/compression paddle combinations and target materials. When testing the large image receptor, the top cassette may be positioned diagonally to capture all four edges of the X-ray field, or two large cassettes may be used on top of the image receptor holder. (The collimator test may also be done using a non-screen cassette on top of the breast support, no attenuator, and a manual technique of approximately 26 kVp and 12 mAs.)

DATA ANALYSIS AND INTERPRETATION

From the film exposed in the top cassette, measure the deviation between theX-ray field (dark portion of the film) and the edge of the light field defined by the exterior edges of the four smaller coins) for all four sides of the field (Figure 1A). The magnitudes of the deviations at the left edge and right edge (ignoring + or - signs) should be entered on the data form and added together. Similarly, the deviations at the anterior and posterior (chest-wall) edges should be entered (without regard to sign) and the magnitudes added together. Record the unit source-to-image distance (SID) on the data form and calculate the % SID by dividing each sum by the SID and multiplying by 100.

Measure the deviations between the edges of the X-ray field and all four sides of the image receptor. If possible, use the film that was placed in the image receptor holder for this measurement; if not, use the top film. This can be done by individually aligning the outer edges of the smaller coin on both films and measuring the distance that the X-ray field edge of the top film extends beyond the film in the image receptor holder. (Figures 1A and B). Note that slight magnification differences between the two films should be taken into account. Enter the measured deviations between the X-ray field and image receptor holder film on the data form. If the X-ray field extends beyond the film, it should be given a "+" sign; if it falls within the film, it should be given a sign. Calculate the % SID for each side, retaining the + or — signs.

Next, measure the deviation between the edge of the compression paddle (delineated by the outer edge of the large coin) and the edge of the image receptor. When measuring the distance, note the difference in sizes of the larger coin on the two films. (The coin image will be bigger on the bottom film.) Distances should be measured on or referred to the film in the image receptor holder cassette.

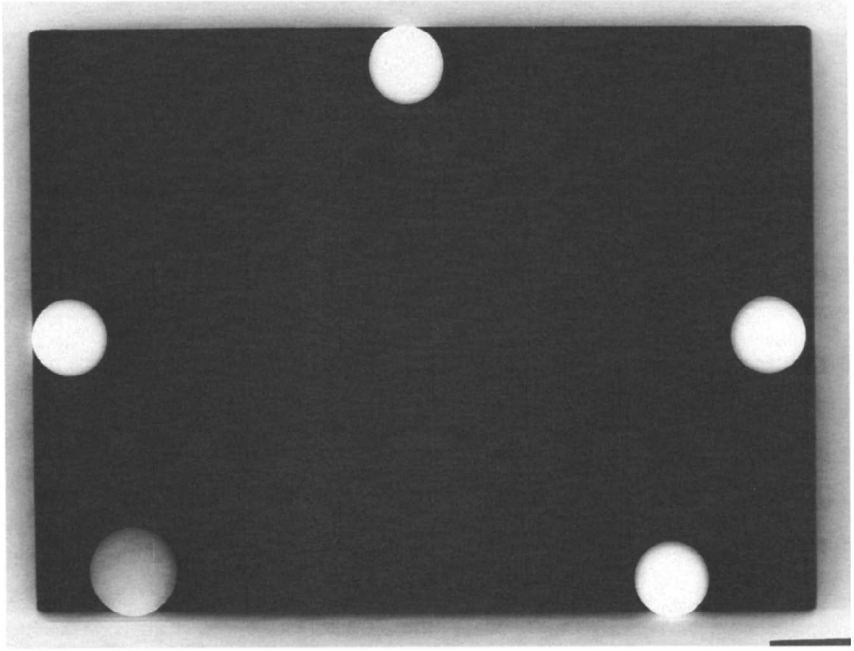


Figure 1A. Sample collimation assessment film. A film exposed in the top cassette; the exposed area indicates the extent of the X-ray field. The outer edges of the four smaller coins indicate the edges of the light field. The outer edge of the larger coin (lower left) indicates the inner chest-wall edge of the compression paddle.

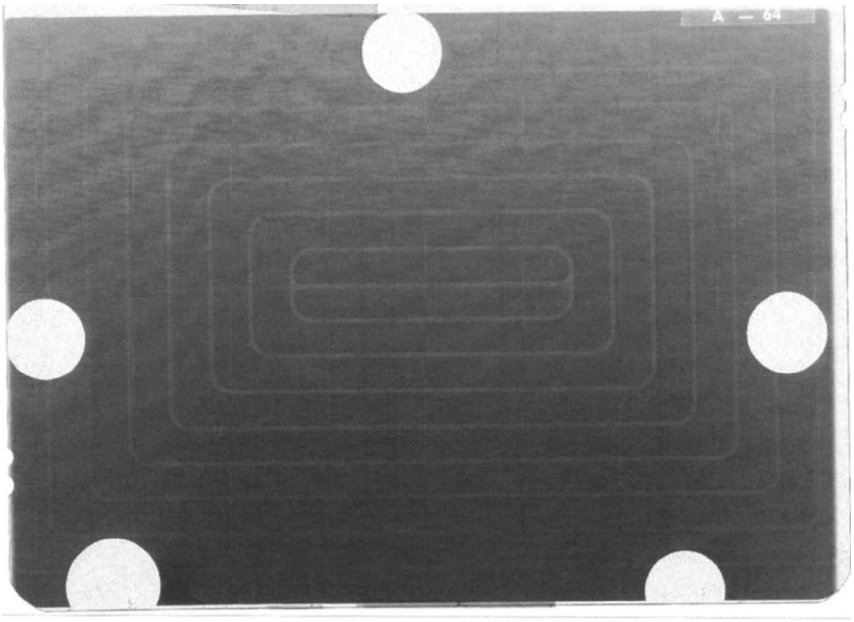


Figure 1B. Sample collimation assessment film. A film exposed in the cassette holder assembly. The film itself defines the location of the image receptor recording area.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

If a light localizer is used, congruence of the light field with the radiation field should be such that the total misalignment (sum of misalignments on opposite sides) is within 2% of SID as required by 21 CFR Chapter I, Subchapter J, 1020.31(d)(2). The X-ray field should not extend beyond any of the four sides of the image receptor by more than +2% of the SID. At the chest-wall side, the radiation field must extend to the edge of the film to ensure that no breast tissue is missed adjacent to the chest wall. Ideally, the entire image receptor (i.e., film) should be blackened (exposing the entire film improves contrast perceptibility as images are viewed on an illuminator). However, since most manufacturers have designed their collimators to meet the FDA manufacturer's requirement for general X-ray equipment that specified that the X-ray field not exceed the size of the image receptor, a tolerance of-2% of the SID on the right and left sides is acceptable. (For example, an image with a 1.1 cm "white gap" on its right and left sides would be acceptable on a unit with an SID of 60 cm). A greater tolerance of -4% of SID is acceptable at the anterior side of the film, to allow for appropriate film marking.

The chest-wall edge of the compression paddle should be aligned just beyond the chest-wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the mammogram. In addition, the chest-wall edge of the compression paddle should not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID. Proper alignment of the edge of the compression paddle with the chest-wall edge of the image receptor holder assembly is necessary for proper positioning and compression of the breast. If the edge of the compression paddle extends too far beyond the image receptor edge, the patient's chest is pushed away from the image receptor and some breast tissue will not be recorded on the image. This situation is unacceptable. If the edge of the compression paddle does not extend far enough, the breast tissue will not be properly compressed for visualization in the image, and a shadow of the vertical edge of the compression paddle may be visible in the image, possibly obscuring clinical information.

If the suggested performance criteria are exceeded, then a qualified service engineer should be called to correct the problem as soon as possible.

MQSA REQUIREMENTS:

All systems shall have beam-limiting devices that allow the entire chest-wall edge of the X-ray field to extend to the chest-wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than 2% of the SID.

If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2% of the SID.

The chest-wall edge of the compression paddle shall not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

3. PROCEDURE

EVALUATION OF SYSTEM RESOLUTION

OBJECTIVE

To evaluate limiting resolution of the entire mammography system, including effects from geometric (focal spot) blurring and screen-film combination.

REQUIRED TEST EQUIPMENT

High-contrast resolution pattern providing a resolution test up to 16 lp/mm and preferably 20 lp/mm (either a bar pattern, a star pattern, or a wedge pattern marked to identify the number of lp/mm in the image at the appropriate points).

A loaded mammographic screen-film cassette from the facility. For best screen-film contact, be sure that the cassette has been loaded an adequate length of time prior to the test to allow trapped air to escape. This time is typically at least 15 minutes, but the cassette manufacturer should be consulted for accurate information.

Lead marker to designate the anode-cathode axis direction.

A 7X to 10X magnifier.

Approximately 2.5 mm of aluminum or 4 cm of acrylic uniform attenuator to place in the beam to allow the test to be performed at a typical mAs.

TEST PROCEDURE STEPS

1. Place the resolution pattern 4.5 cm above the breast support plate. A consistent spacer or support is recommended rather than taping the pattern to the compression paddle since the paddle may not be precisely parallel to the plane of the image receptor and the compression thickness indicator may be in error.
2. Position the pattern within 1 cm of the chest-wall edge of the image receptor, centered laterally. The pattern's bars should lie parallel to the anode-cathode axis for the first image. It is important that the test pattern be positioned in a reproducible manner.
3. Approximately 2.5 mm of aluminum or 4 cm of acrylic should be used to allow the test to be done at a typical mAs so that grid lines, which can appear if the exposure time is too short, do not interfere with the visibility of the pattern.
4. Place the image receptor in the holder for contact mammography at the SID most commonly used clinically.
5. Select the AEC mode and a kVp, mA, focal spot, and density control setting used for imaging a standard breast during normal radiography.
6. Make an exposure and process the film. The resultant film density should be between 1.20 to 1.60.
7. Repeat step 6 with the bars oriented **perpendicular** to the anode-cathode axis and the highest line frequency of the bar pattern (e.g., 20 lp/mm) positioned towards the chest wall, 1 cm from the edge.

8. Repeat steps 1 though 7 for other target materials and other clinically used focal spot sizes. Small focal spots should be tested in the same mode that they are used clinically, i.e., with the bar pattern positioned 4.5 cm above the magnification stand breast support surface and at the kVp and technique factors most commonly used for a magnification view of the standard breast. Use the magnification factor most commonly used clinically and record.

DATA ANALYSIS AND INTERPRETATION

Under masked conditions, view the high-contrast resolution pattern images with 7X to 10X magnification.

Starting from the lowest frequency bar pattern note the highest frequency pattern whose lines are distinctly visible throughout at least half of the bar length. Note that the bars may entirely blur out and then reappear at a higher frequency, with a reversal in the light and dark bars in the image. This "spurious resolution" should not be interpreted as system resolution. Using this criterion, record the highest frequency visible for each test image.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

In the contact mode, measurements made with the bars parallel to the anode-cathode axis must resolve at least 13 lp/mm; measurements with the bars perpendicular to the anode-cathode axis must resolve at least 11 lp/mm. In the magnification mode, the limiting spatial resolution must be no lower than the above specifications.

If the above specifications are not met, try to determine the cause by changing one variable at a time and retesting. For example, use a different cassette, remove the compression paddle, remove the grid, or try a non-screen technique. If the results are still below the above specifications, confirm that the correct test geometry is in use. A more detailed investigation of the focal spot size may be made using a slit camera (See Section VII). The resolution of the screen-film combination can also be evaluated by placing the cassette on top of the breast support and placing the resolution bar pattern directly on top of the cassette. (Only one-third to one-half the mAs is required for this test relative to an in-bucky exposure.)

If the above specifications are not met under magnification conditions with the small focal spot, the magnification factor used may be excessive. The system should be retested with a lower magnification factors and the results discussed with the facility. If the system resolution improves, the facility should consider using the lower magnification factor for their routine clinical magnification procedures.

MQSA REQUIREMENTS:

Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

(A) System resolution. (1) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 line-pairs/mm when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis. (2) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest-wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest-wall edge of the image receptor. (3) When more than one target material is provided, the measurement shall be made using the appropriate focal spot for each target material. (4) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically. (5) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

4. PROCEDURE

AUTOMATIC EXPOSURE CONTROL (AEC) SYSTEM PERFORMANCE ASSESSMENT

OBJECTIVE

To assess the performance of the mammography unit's AEC system, to maintain consistent image optical density as breast thickness and imaging modes change, and to alter optical density using the density control selector function.

REQUIRED TEST EQUIPMENT

A phantom made of either acrylic or BR-12 and consisting of at least four 2-cm-thick slabs to provide thicknesses of 2, 4, 6 and 8 cm of linear dimensions representative of typical breast sizes

Image receptor (i.e., cassette with screen(s) and film) of the type and size routinely used with the mammographic imaging system being evaluated

Lead numbers

A densitometer

TEST PROCEDURE STEPS

Performance Capability

Performance capability refers to the ability of an AEC system to maintain a constant image optical density over a broad range of imaging techniques and patient variables. The following test procedures are designed to assess the ability of a given mammographic system to achieve this goal as well as to determine the range of conditions over which the system will not perform adequately.

1. Prepare the mammographic imaging system for operation in the AEC mode as specified in the unit's technique chart for a breast of 50% fatty and 50% glandular composition. Select the density control setting that is used clinically. For systems equipped with multiple positions for the AEC sensor, select the position used most often clinically.
2. Select the small image receptor size (e.g., 18 X 24 cm) and grid.
3. Select the focal spot, tube current (mA), if available, and AEC mode (e.g., "CONTRAST," "AA") routinely used. If a fixed kVp AEC mode is specified by the technique chart, select the appropriate kVp, target, filtration and density control setting. Record these settings on the data form.
4. Select a single mammographic cassette and a full box of film of the type normally used and of the appropriate size for use in this test and record the cassette identification number on the data form.
5. Load the cassette identified in step 4 with film from the box identified and set aside in step 4.
6. Place the loaded cassette in the cassette holder assembly. Place a lead number in the upper right quadrant on top of the cassette holder assembly to provide identification of the specific image.

7. Position a 2-cm-thick phantom on the cassette holder assembly at the position that would normally be occupied by the patient's breast. Bring the compression device (appropriate to the selected imaging mode) into contact with the phantom. Make sure that the phantom completely covers the active area of the AEC system sensor.
8. Make an exposure and record the target material, filter, kVp, density control setting and mAs used on the data form.
9. Process the exposed film in the film processor normally used for mammographic images.
10. Repeat steps 5 through 9 for a range of breast thicknesses (simulated by varying the phantom thicknesses) from 2-8 cm. Clinically appropriate targets, filters, kVps and density control setting should be selected for each thickness.
11. Repeat steps 5 through 9 for the 4-cm-thick phantom but use the various imaging modes that are used clinically (e.g., small image receptor and grid, large image receptor and grid, magnification mode with small focal spot, and no grid).
12. Measure the image optical density at the center of each phantom image and record the values on the data form.

Density Control Function

1. Follow steps 1 through 9 of the performance capability procedure but use the 4-cm-thick phantom and the most commonly used clinical kVp.
2. Repeat exposures for all clinically used settings of the AEC system's density control selector. Measure the image optical density at the center of each phantom image and record the values on the data form.
3. Using the recorded data for measured mAs and image optical density, calculate the relative mAs (ratio of mAs at each density control setting to that at the "Normal" setting) and relative image optical density (difference between the optical density at each density control setting and the optical density at the "Normal" setting).

DATA ANALYSIS AND INTERPRETATION

Calculate the mean optical density over all performance capability tests and determine the range of densities measured. The performance capability data should be reviewed with respect to mAs and image optical density. In evaluating the performance capability of the system, several general trends should be noted. First, kVp should increase (either manually or automatically) for increasing breast (phantom) thickness. Second, in order to minimize motion unsharpness, exposure times should be approximately 1 second or less for thin or average breast (phantom) thicknesses and no longer than 3 seconds for larger thicknesses. Third, and perhaps most important, the image optical density should ideally remain constant within ±0.15 as phantom thickness and clinical technique factors

are varied; however, variations of up to ±0.30 or greater may be seen in older equipment. Until October 28, 2002, an AEC technique chart can be used to compensate for those breast thickness (2-6 cm) and technique factor combinations that do not fall within ±0.30 of the mean. Variations no greater than ±0.30 should be observed over all imaging modes.

To evaluate the density control performance, calculate the fractional change in mAs and the difference in image optical density with respect to the "NORMAL" or "ZERO" density control value and record. Because the relationship between exposure received by the film and resultant film optical density is not a linear one, do not expect the fractional change in image optical density to necessarily correspond to the fractional change in mAs. The majority of density controls on AEC systems are calibrated on a relative scale and, thus, the purpose of this part of the test is to provide information concerning the capabilities of the density control system in conjunction with the screen-film combination used with the system. In general, however, as the density setting is increased above or decreased below the normal setting, the mAs and image optical density should increase or decrease, respectively. It is recommended that there be a sufficient number of + and - density settings (at least two plus and two minus settings) and that each step should result in a 12% to 15% change in mAs, or approximately a 0.15 change in film optical density.

One last comment needs to be made concerning the overall performance of an AEC system. In a system that has been properly set up and calibrated, the optical density of all performance capability test films should be at least 1.20 if clinically acceptable mammographic images are to be obtained. Most mammography sites, however, choose an AEC setup that yields a much higher optical density target for average breast tissues, so that glandular tissues are adequately exposed and have optimal contrast. This approach also requires adequate viewbox intensity for appropriate film viewing and is the recommended approach to improving clinical image quality in mammography.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

An AEC system with appropriate compensation circuits is functioning properly if it can maintain constant film optical density to within ±0.30 of the average over the phantom thicknesses (2 to 8 cm), and imaging modes tested. Within a narrower range of conditions (2 to 6 cm with the small bucky), the optical density must be maintained to within ±0.15. It is important to note that because some older systems may not have adequate compensation circuits, this level of performance may not be achieved unless the operator makes adjustments to the system's density control selector. If the film optical density cannot be maintained to within **±0.30** of the average over the clinically used techniques tested, a technique chart should be developed that alters density control settings (in addition to kVp, anode, and filter) as a function of breast thicknesses and composition. The medical physicist should assist with the preparation of a revised technique chart if revisions are necessary to meet the AEC performance criteria.

The optical density of the film in the center of the phantom image must not be **less than 1.20**.

As the density control setting tested is increased above or decreased below the normal setting, the mAs and image optical density should increase or decrease, respectively. It is recommended that there be a sufficient number of + and - density settings (at least two plus and two minus settings) and that each step should result in a 12% to 15% change in mAs, or approximately a 0.15 change in film optical density.

Should one or more of the above criteria not be met, the equipment manufacturer's service representative should be contacted to determine the cause of system malfunction and to correct the problem.

MQSA REQUIREMENTS:

The AEC shall be capable of maintaining film optical density within ±0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ±0.30 of the average under phototimed conditions can be produced.

After October 28, 2002, the AEC shall be capable of maintaining film optical density within ±0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

The optical density of the film in the center of the phantom image shall not be less than 1.20.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be within 30 days of the test date.

5. PROCREDURE

UNIFORMITY OF SCREEN SPEED

OBJECTIVE

To assess the uniformity of the radiographic speed of image receptors routinely used for mammographic imaging.

REQUIRED TEST EQUIPMENT

The cassettes normally used for mammographic imaging.

A single box of film of the type used for mammography.

A uniform 4-cm-thick (approximately) cassette-sized phantom made of either acrylic or BR-12

A densitometer

Lead numbers

TEST PROCEDURE STEPS

1. Identify all of the image receptors (cassettes) to be evaluated with some form of numbering system for further reference.
2. Select one of the cassettes and load it with a sheet of film from a box set aside for this test. Record on the data form the specifics of the image receptor being evaluated and the emulsion number of the film used for the test.
3. Select the mammographic imaging mode, including AEC technique, target, filter, kVp, and density control setting most commonly used for clinical examinations.
4. Position the uniform phantom on the cassette holder assembly so that it covers the entire image receptor. Place the appropriately sized compression device in contact with the phantom.
5. Load all of the mammographic imaging cassettes to be evaluated with film from the same box as used in step 2.
6. Sequentially expose each cassette under the conditions determined in step 3. It may be useful to use lead numbers to identify the images. Make sure that the lead numbers are not placed above the AEC detector. Record the actual mAs for each exposure on the data form. It is important to ensure that the position of the phantom is unchanged during all exposures.
7. After half of the cassettes have been exposed, unload the film from the first (control) cassette, process the film, reload the cassette, and expose the control cassette again as noted in step 6. Also repeat this step after all of the cassettes have been exposed. This will result in three control films from the one cassette.
8. Process the exposed films in the film processor routinely used for mammographic image processing.
9. Measure the optical density at the center of the phantom on each of the processed images and record on the data form. It is important that this be done in the same location on each film.
10. If more than one size or type of cassette is used for mammographic imaging, repeat steps 1 through 9 for each. Record data on a separate form if a different type of image receptor is evaluated.

DATA ANALYSIS AND INTERPRETATION

Using the measured optical densities from the three films exposed in the control cassette, calculate the standard deviation of the control film optical densities. If the standard deviation exceeds 0.05, the variability of the X-ray exposures or film processing is excessive and the screen speed uniformity test cannot be carried out adequately under these conditions. Corrective action should be taken to reduce this variability before assessing screen speed uniformity. If the standard deviation of the control film does not exceed 0.05, then determine the maximum and minimum optical densities from all cassettes of a single size or type.

Repeat the evaluation for cassettes of other sizes or types. Note that optical densities may vary between cassette groups of the same type but of different sizes. This may be due to differences in film emulsion rather than cassettes or screens. The cause of any variation between cassette sizes should be investigated and noted.

Each image should also be evaluated for the presence of cassette or screen artifacts. In particular, severe artifacts that could obscure or impair clinical information should be noted.

> NOTE: The uniformity of screen speed test can be done simultaneously with the artifact evaluation by changing the direction of film feed of the control films through the processor. See Test #6.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The difference between the maximum and minimum optical densities should not exceed 0.30. Any individual cassette screen combination within a given speed group of one size that does not meet this criterion should be) checked to try to determine the cause of the problem. One obvious item to check is misidentification of a cassette with the type of screen it contains. Also, if screens of the same speed are contained within cassettes of different manufacturers, it is possible that variations in attenuation of the cassette may cause significant variations in film density. Finally, check for extraneous items, such as date stickers attached to the back of the cassettes that may superimpose the AEC detectors causing excessive attenuation. Should no identifiable cause for image density variation be determined, it is reasonable to replace the cassette that results in optical densities outside the 0.30 range.

Any cassette or screen artifacts should be noted by cassette number and brought to the attention of the mammography facility. Many of these artifacts can be eliminated by gentle cleaning of the cassette or screen.

MQSA REQUIREMENTS:

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.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

6. PROCEDURE

ARTIFACT EVALUATION

OBJECTIVE

To assess the degree and source(s) of artifacts visualized in mammograms or phantom images. This procedure isolates the source of the artifact so that appropriate measures to eliminate the artifact can be taken.

REQUIRED TEST EQUIPMENT

A uniform 4-cm-thick (approximately) cassette-sized phantom made of either acrylic or BR-12

Mammography cassette and film. The same cassette should be used for all tests

A mask appropriate for full-field mammographic films

A densitometer

TEST PROCEDURE STEPS

1. Select the mammographic imaging mode, including AEC technique, target, filter, kVp and density control setting most commonly used for clinical examinations. Be sure that the density control setting results in an optical density greater than 1.20. Use the most commonly used image receptor size (usually 18 X 24 cm). Record these technique factors on the data form.
2. Place a uniform sheet of acrylic or BR-12 that is large enough to cover the mammographic cassette and thick enough to have an exposure time of 0.5 second or greater on the image receptor holder assembly. Use a collimator that permits irradiation of the entire cassette.
3. Use a single mammographic cassette that is known to have good screen-film contact. Load the cassette with the mammography film used clinically.
4. Position a lead marker such as the number 1 or an arrow on the acrylic sheet in a corner of the radiation field, preferably outside the normal location of the breast, and pointing along the long axis of the film and cassette.
5. Make an exposure.
6. Process the film, taking care to insert the film lengthwise into the processor as shown in the upper part of Figure 2 (so that the film travels parallel to the direction of the arrow on the latent image). Also note the orientation of the film emulsion on the processor feed tray (up or down). Measure the optical density in the center of the film, verifying that it is greater than 1.20, and record on the data form for this test.

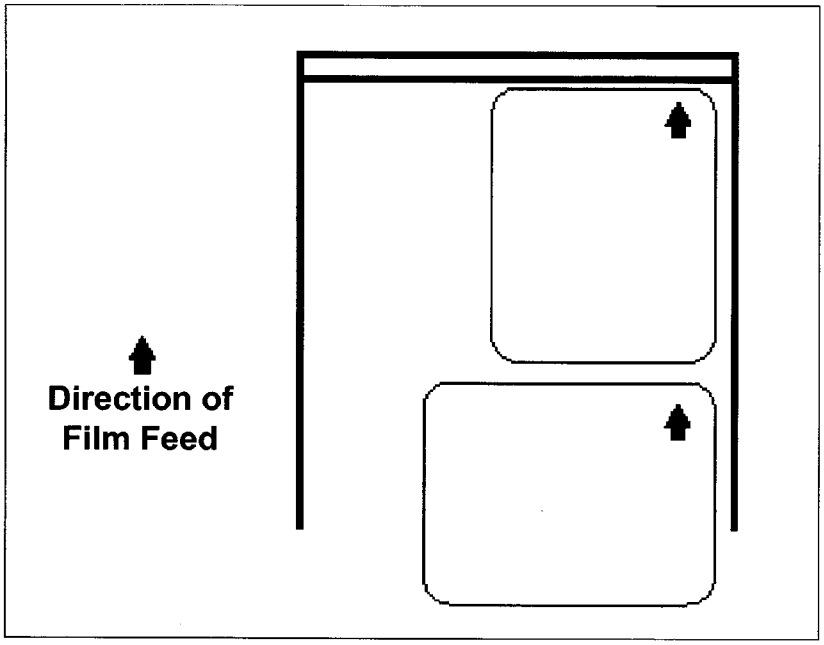


Figure 2. Direction of insertion of film into the film processor. The first exposed film should be inserted lengthwise, parallel to the direction of the arrow on the latent image. The second film should be inserted widthwise, again parallel to the direction of the arrow on the latent image.

7. Reload the same cassette with film; place it in the image receptor holder assembly under the same sheet of acrylic. Orient the lead marker at 90° to its original direction so that the marker runs parallel to the short axis of the film. Repeat the exposure using exposure factors identical to the previous image.

8. Process this film, taking care to insert the film widthwise into the processor as illustrated in the lower part of Figure 2 (at right angles to the previous film) so that the film travels through the processor parallel to the direction of the arrow on the latent image.

9. Repeat this process for other image receptor sizes, using the image receptor holder and compression device appropriate for the other image receptor sizes. Also repeat for the small focal spot used with magnification and each filter used clinically. (Note that some units may have multiple filters of the same material.)

DATA ANALYSIS AND INTERPRETATION

Orient each pair of films acquired under the same imaging conditions for viewing at right angles to one another so that the arrows indicating the direction that they were run through the processor are parallel, as shown in Figures 3 and 4. Using appropriate masking, examine the two processed images acquired for each image receptor size for density variations, especially those that might simulate or mask visualization of breast structures or breast pathology.

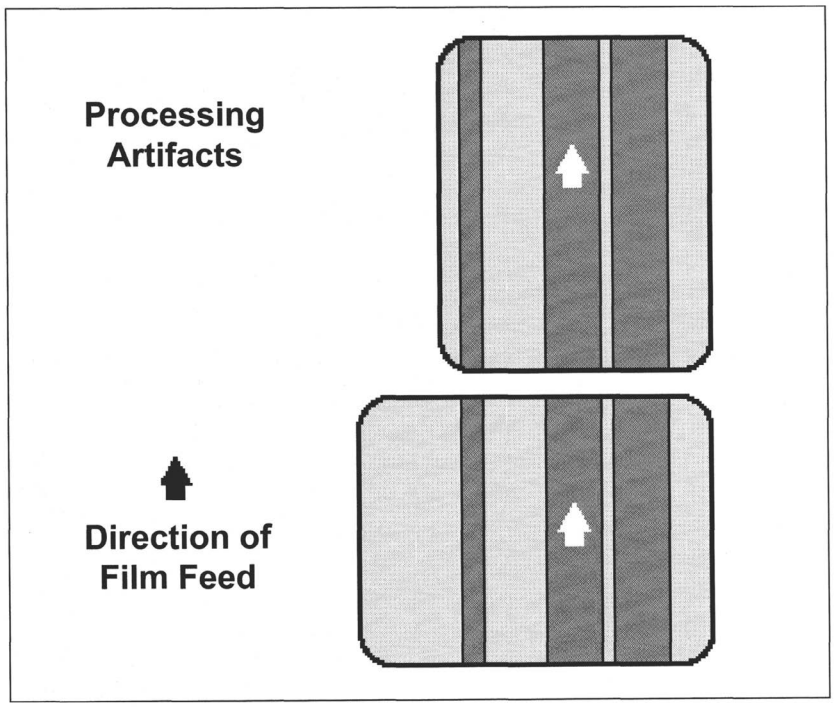


Figure 3. Orient the films for viewing at right angles to one another, so that the arrows or markers indicating the direction of the film travel through the processor are parallel. Any artifacts running parallel in the two films are due to the processor.

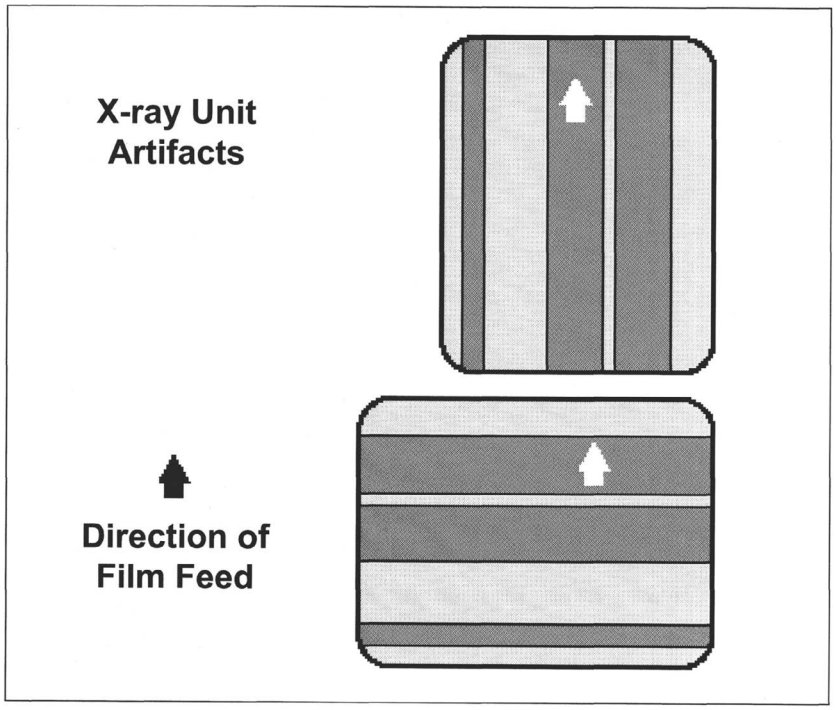
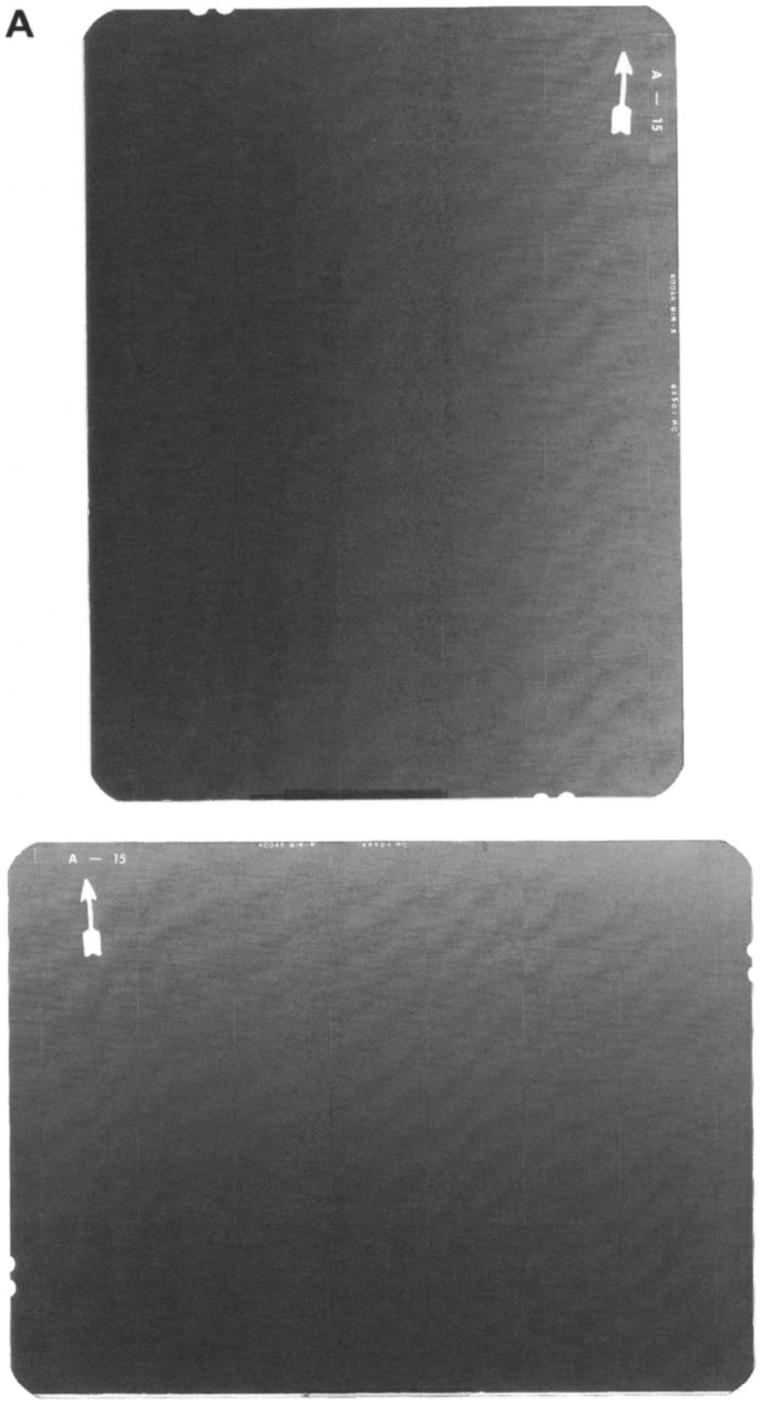


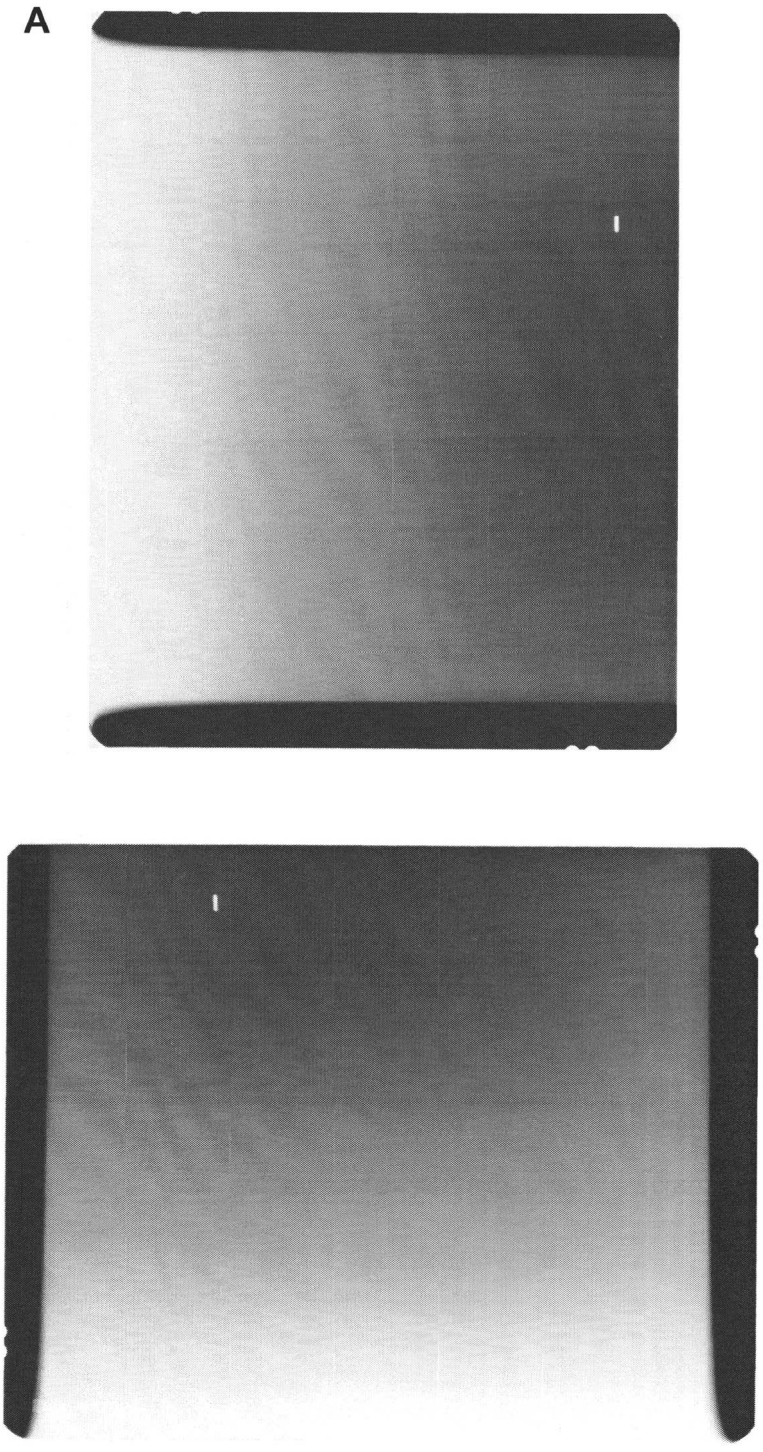
Figure 4. Orient the two films at right angles to one another, as in Figure 3. Any artifacts running perpendicular in the two films are due to X-ray equipment.

Any artifacts that are parallel in the two films, as illustrated in Figure 3, are localized to the processor. This is true whether the artifacts run parallel to or perpendicular to the direction of film travel. For example, film processor artifacts due to dirty or defective rollers can produce plus or minus density streaks running parallel to the direction of film travel (Figure 5) or plus density bands running perpendicular to the direction of film travel (Figure 6). Furthermore, if processing artifacts are more severe when the film is processed emulsion side up, the artifacts may be caused by the inner rollers of the developer rack.

Any artifacts that are oriented perpendicular between the two films, as illustrated in Figure 4, are localized to the X-ray equipment or cassette. Artifacts localized to the X-ray equipment can be due to several sources, including the grid, the image receptor holder, the compression paddle, the collimator, the filter, or the X-ray tube itself. Changing or removing one component at a time can help to determine the specific source within the X-ray equipment that is causing the artifact. Figures 7A and B are test films from a unit with a defective moving grid. The equipment-caused artifacts (plus density bands) run perpendicular in the two films when oriented as in Figure 4. Figure 7C shows an image acquired without grid motion, clearly showing the grid inhomogeneities and defects.



Figures 5A & B. Examples of a processor-induced artifact on a uniform background. (A and B) The subtle, plus density bands running parallel to the direction of film travel are due to uneven roller pressure and the build-up of developer on the processor rollers.



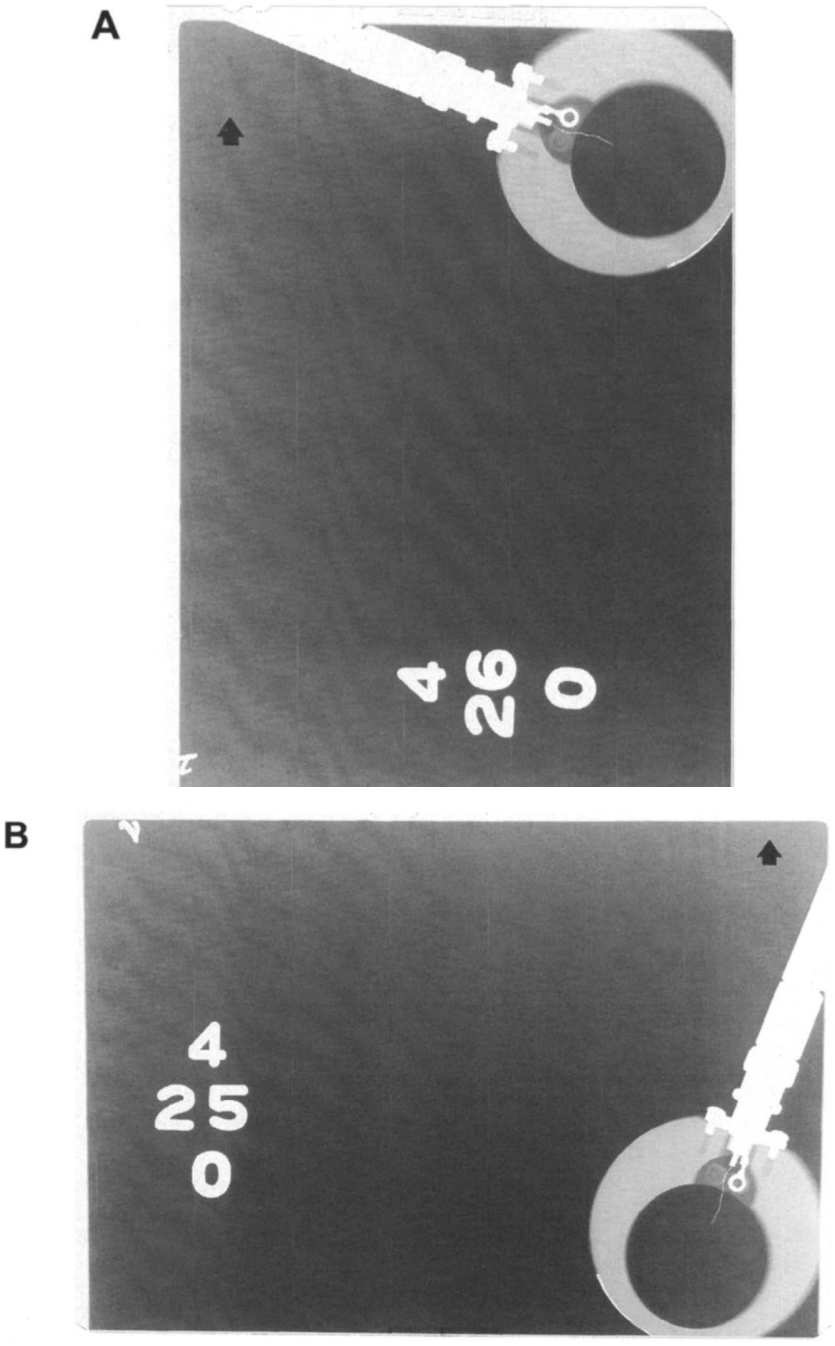
Figures 6A & B. Artifacts due to processor roller marks and "chatter" show up as artifacts running perpendicular to the direction of film travel in both films. (A and B)

Other artifacts may appear sporadically in mammography images, having no consistent appearance in artifact evaluation images. These artifacts may be due to other sources, such as the patient, film handling, a defective cassette screen (that was not used in these tests), or moving grid artifacts that show up only under certain patient or timing conditions. Additional testing under specific conditions may be necessary to isolate the causes of sporadically occurring artifacts.

Most daylight processors allow films to be processed in only one direction. In order to identify processing artifacts, creative approaches can be taken such as running the film through a different processor or exposing a cassette in different orientations on top of the bucky.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

If significant film processor artifacts are detected, contact the person maintaining the processor or the film processor service organization or dealer. Contact the X-ray equipment service person for suggestions on additional testing procedures and for help in correcting X-ray equipment artifacts. Gentle cleaning may be able to eliminate cassette or screen artifacts. Not all artifacts can be totally eliminated. It may be helpful to use the concept of ALARA (as low as reasonably achievable) when attacking artifacts. If they can be easily eliminated, they should. If the artifact is difficult or expensive to eliminate and is subtle (not mimicking or obscuring clinical information), it may be tolerable. The medical physicist should consult with the interpreting physician as to whether the artifact is tolerable. Tolerances for artifacts should be lower with new imaging equipment.



Figures 7A & B. Moving grid artifacts show up as density variations running perpendicular in the two films when oriented parallel to the direction of travel through the processor. (A and B)

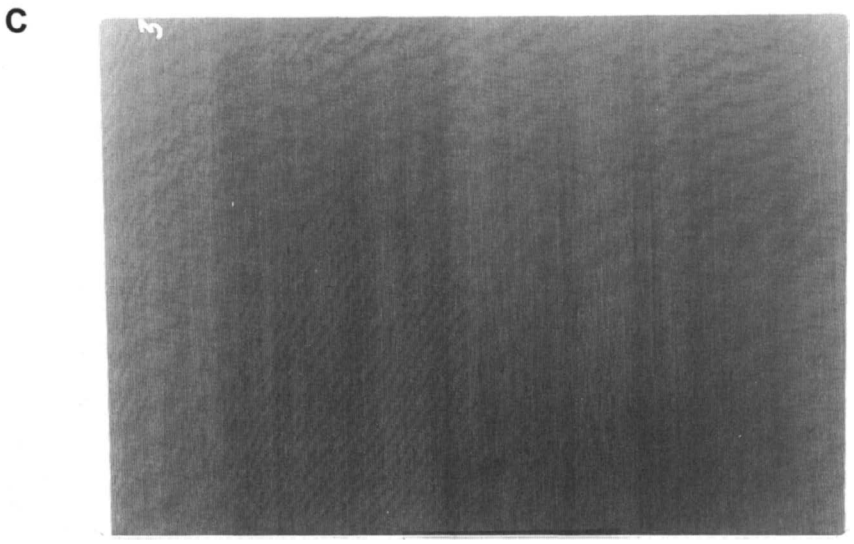


Figure 7C. An image acquired without grid motion reveals the extent of grid inhomogeneities responsible for the artifacts in images A and B. Fixed or moving grids that produce inhomogeneity artifacts in normally acquired images (i.e., with the moving grid in motion) and reasonable imaging times (>0.5 second) should be replaced.

MQSA REQUIREMENTS:

System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target-filter combinations used clinically.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

7. PROCEDURE

IMAGE QUALITY EVALUATION

OBJECTIVE

To assess mammographic image quality and to detect temporal changes in image quality.

REQUIRED TEST EQUIPMENT

Mammographic phantom (approximately equivalent to a 4.2 cm thick compressed breast consisting of 50% glandular, 50% adipose tissue) containing appropriate details ranging from visible to invisible on the mammographic image. At the time of publication, either the Radiation Measurement, Inc. RMI-156 or Nuclear Associates 18-220 mammographic phantom may be used for the ACR Mammography Accreditation Program (MAP). These phantoms have fibers with diameters of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 mm; specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 mm; and masses with decreasing diameters and thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 mm.

Acrylic disc (4 mm thick, 1 cm diameter) placed on the top of the phantom in a consistent location in the image area so it will not obscure details in the phantom and where it cannot cast a shadow on any portion of the AEC detector (Figure 8). With current equipment, significant variability in film optical density can result from placing the disc along the central anode-cathode axis, where a varying fraction of the AEC detector area might be covered by the disc's shadow, depending on the exact position of the phantom and the detector. A suitable location is between and slightly below the first and second largest fibers. A glue such as "SuperGlue" may be used to attach the disc permanently to the phantom.

Cassette and film of the types used clinically for mammography. Use the same cassette used by the facility for their phantom QC to compare results.

Appropriate masking to eliminate light reaching the viewer's eye from beyond the borders of the exposed phantom image. Images should be viewed on the same viewbox(es) used clinically. If a 14 X 17 inch viewbox is used, a film mask can be made by exposing a 14 X 17 inch film to light, processing it, and cutting a hole the size and shape of the phantom being used.

A magnifying lens of 2x or higher

Densitometer

Previous annual phantom image and the original phantom image (acquired when the equipment was new or the QC program began)

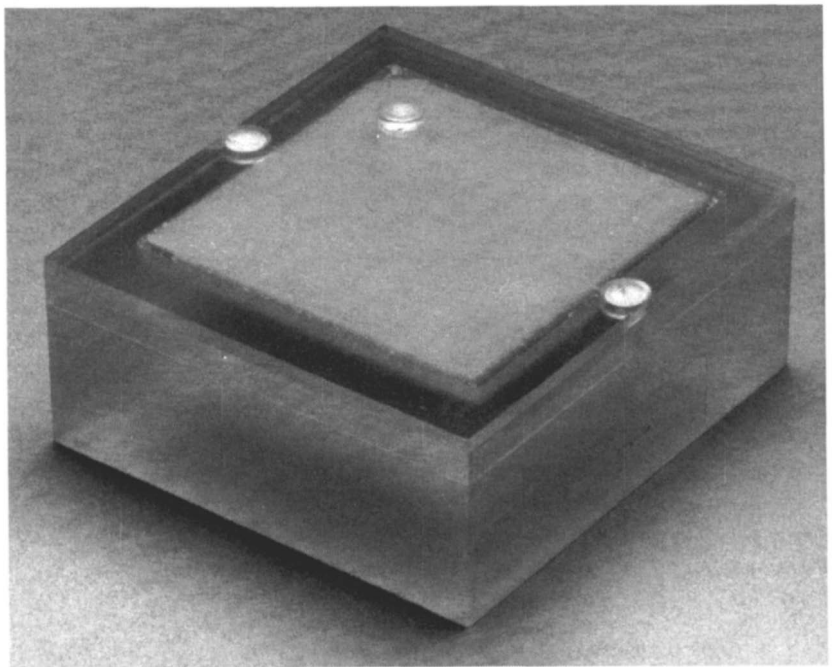


Figure 8A. Photograph of phantom with 1-cm diameter, 4-mm-thick disc for contrast measurement.

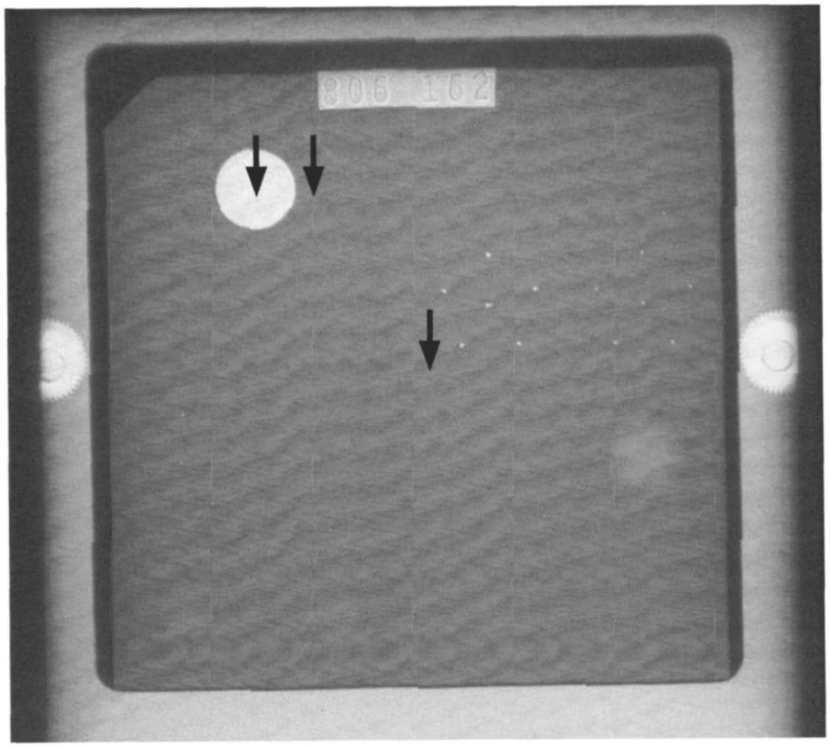


Figure 8B. Radiograph of phantom shown in Figure 8A. Arrows indicate points where density measurements should be made.

TEST PROCEDURE STEPS

1. Load film from the film bin into the cassette. Be sure to wait an adequate length of time for good screen-film contact to occur.
2. Place the cassette in the cassette holder.
3. Place the phantom on the cassette holder, positioning the phantom so that the chest-wall edge of the phantom is aligned with the chest-wall side of the image receptor. Center the phantom, left to right.
4. Lower the compression paddle so that it just touches the top of the phantom. Do not compress the phantom because doing so may damage the compression paddle. (On some units, mild compression is needed to enable exposure.)
5. Verify that the AEC detector is located beneath the center of the phantom and in the same location as used for previously acquired phantom images.
6. Make an exposure using the technical factors (target, filter, kVp, grid, density control setting, etc.) currently in use clinically for a 4.2-cm compressed breast of average tissue density.
7. Record all technique factors on the image quality evaluation form.
8. Process the film in the processor normally used for mammography films.
9. Measure the film optical densities at three locations. The background optical density should be measured at the geometric center of the phantom image. To determine the density difference, measure the optical density inside the disc and directly adjacent to the disc, to its left or right, perpendicular to the anode-cathode axis. The density difference is the difference between the optical density measured inside the disc and that measured outside the disc. For consistent results, these measurements must be made in the same locations each time.
10. Record all measurements on the image quality evaluation form.

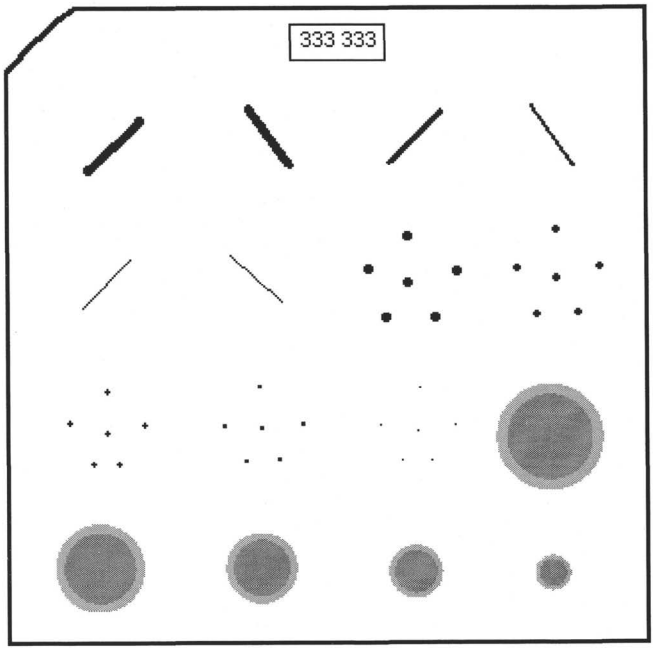
VIEWING CONDITIONS

Phantom images should be read under optimal viewing conditions. General lighting should be at a low level and diffuse. Viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. Images should be masked to eliminate extraneous light. Use a magnifying glass of 2x or higher for scoring speck groups as well as any other appropriate test objects.

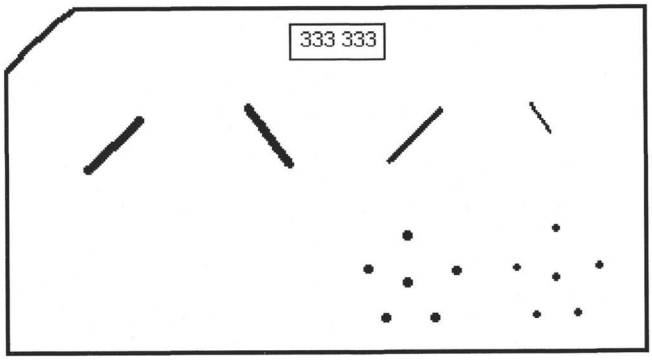
DATA ANALYSIS AND INTERPRETATION

Figures 9A through E illustrate the use of the following criteria to score the phantom:

1. When scoring the image of one of the ACR-approved accreditation phantoms, e.g., Radiation Measurement, Inc. (RMI 156) or Nuclear Associates (18-220), each object type is scored separately. Always count the number of visible objects from the largest object of a given type (i.e., fiber, speck group, or mass) downward until a score of 0 or 0.5 is reached, then stop counting for that object type.

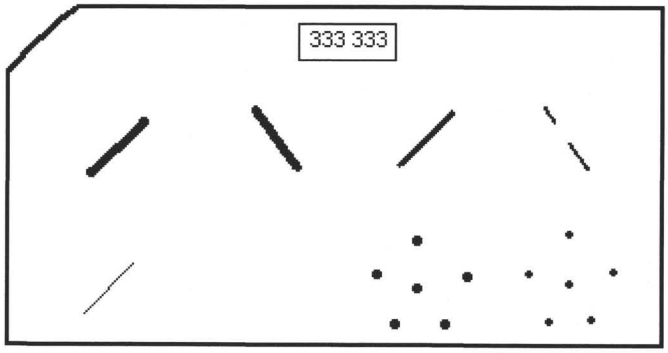


Fibers: 6
Speck groups: 5
Masses: 5

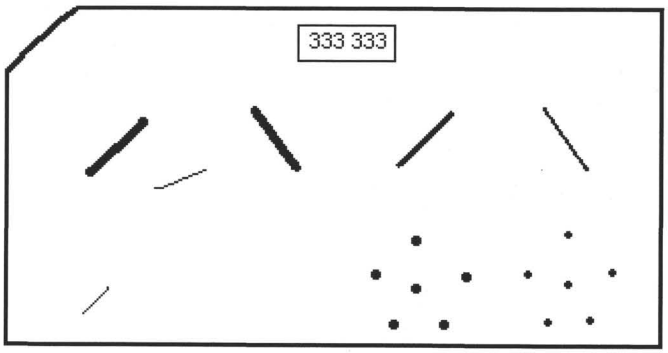


Fibers: 3.5
(not all but at least half of the 4th fiber is visible)

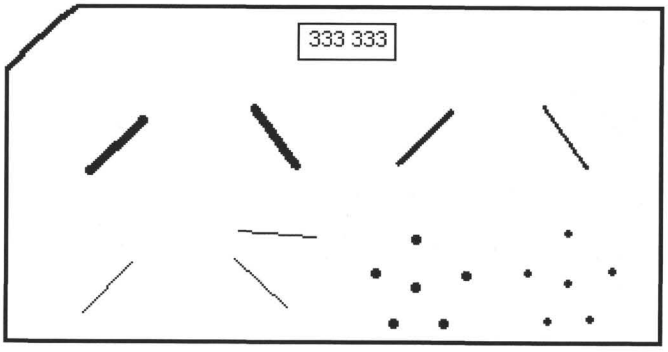
Figure 9A. Phantom diagrams of fiber scoring example.



Fibers: 3.5
(the entire, unbroken length of the 4th fiber is not visible)

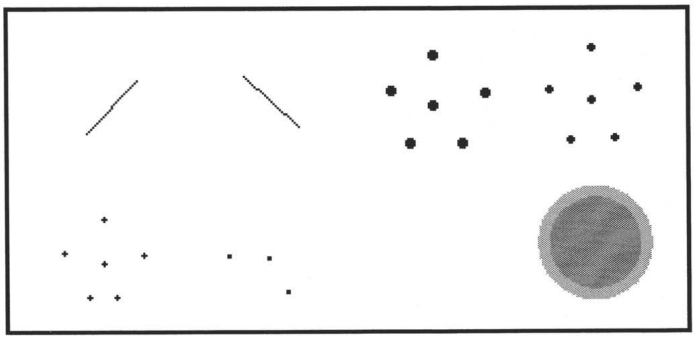


Fibers: 4.0 (4.5 – 0.5)
(the fiber-like artifact between the 1st and 2nd fiber must be subtracted from the last real fiber scored)

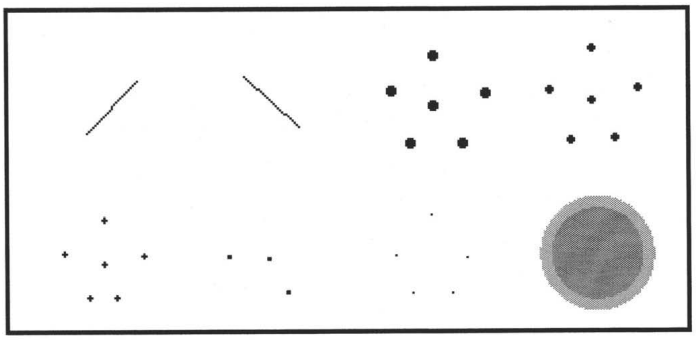


Fibers: 5.0 (6.0 – 1.0)
(the fiber-like artifact above the 6th fiber must be subtracted from the last real fiber scored)

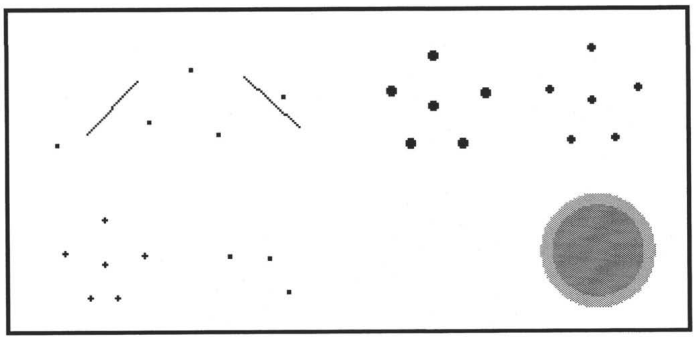
Figure 9B. Phantom diagrams of fiber scoring examples (continued).



Speck groups: 3.5
(only 3 specks in the 4th speck group are visible)

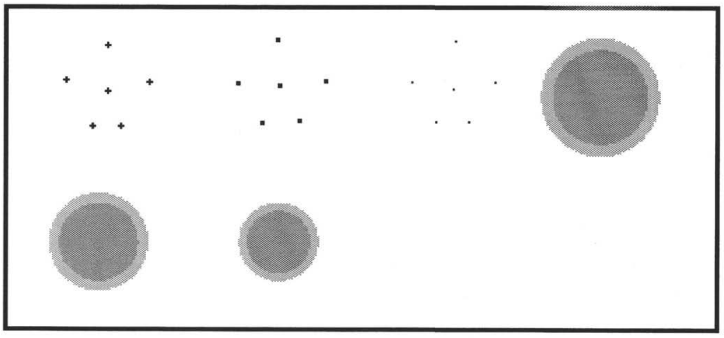


Speck groups: 3.5
(although 5 specks in the 5th speck group are visible, only 3 are visible in the 4th group)

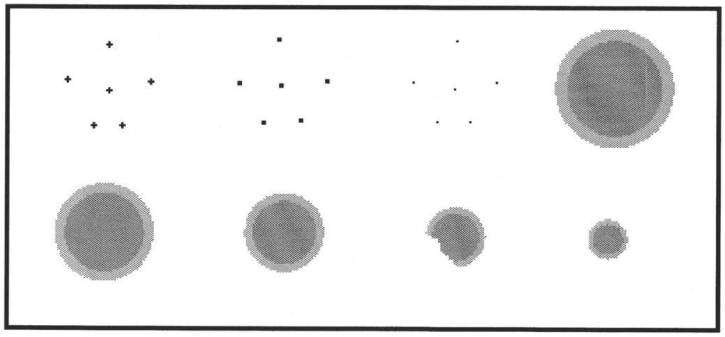


Speck groups: 3.0 (3.5 – 0.5)
(speck-like artifacts around the 5th and 6th fibers must be subtracted one for one from the specks in the last real speck group)

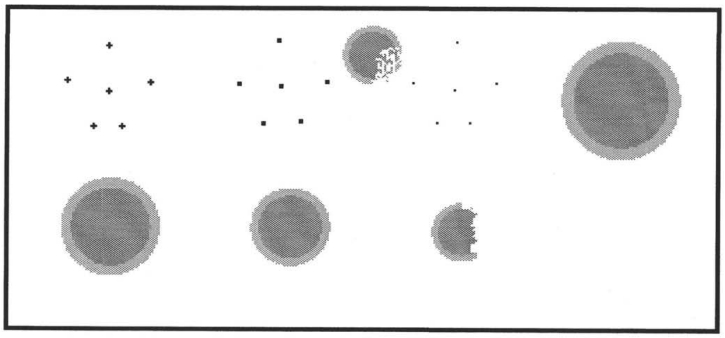
Figure 9C. Phantom diagrams of speck group scoring examples.



Masses: 3.0

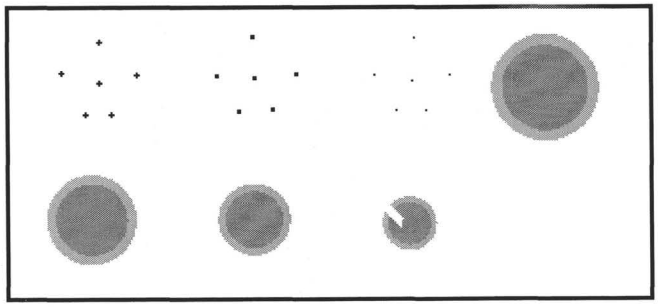


Masses: 3.5 (greater than 3/4 of the round perimeter should be visible for a full point)

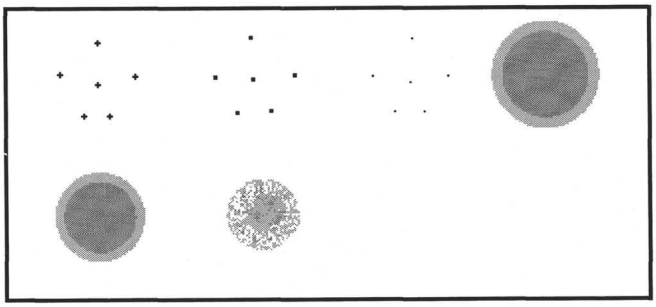


Masses: 3.0 (3.5 – 0.5) (the mass-like artifact between the 4th and 5th speck groups must be subtracted from the last real mass scored)

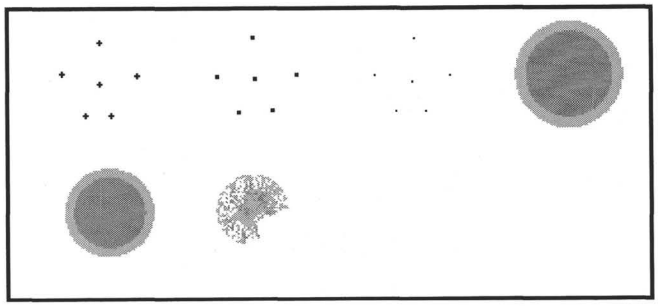
Figure 9D. Phantom diagrams of mass scoring examples.



Masses: 4.0
(the 4th mass is given a full point in spite of the linear artifact since it is still generally circular)



Masses: 3.0
(although the 3rd mass has less contrast, it is still generally circular and is given a full point)



Masses: 2.5
(the 3rd mass is of less contrast and is not generally circular)

Figure 9E. Phantom diagrams of mass scoring examples (continued).

2. Count each fiber as 1 point if the full length of the fiber is visible and the location and orientation of the fiber are correct. Count a fiber as 0.5 point if not all, but more than half, of the fiber is visible, and its location and orientation are correct. Add each full or partial fiber to the total fiber score, from largest down to smallest visible, until a score of 0 or 0.5 is reached. Record the "raw" fiber scores before artifact deduction.

3. After determining the last fiber to be counted, look at the overall background for artifacts. If a fiber-like artifact appears anywhere in the wax insert area of the image, but not in an appropriate location or orientation, deduct the "artifactual" fiber from the last "real" half or whole fiber scored if the artifactual fiber is equally or more apparent. Deduct only from the last real fiber, not from additional fibers. (Figures 9A and B). Record the final score after artifact deduction in the appropriate space on the form.

4. Use a large-field-of-view magnifying lens (approximately 2x or higher) to assist in the visualization of specks. Starting with the largest speck group, count each speck group as 1 point if four or more of the six specks in the group are visible in the proper locations. Count a speck group as 0.5 if two or three of the six specks in the group are visible in the proper locations. Add each full or partial speck group to the total speck group score, from the largest down to smallest visible group, until a score of 0 or 0.5 is reached. Record this "raw" speck score before artifact deduction.

5. After determining the last speck group to be counted, look at the overall background for artifacts. If noise or speck-like artifacts are visible in the wrong locations within the area of the wax insert and are as apparent as the "real" specks, deduct them one for one from the individual specks counted in the last whole or half speck group scored and adjust the score of the last group appropriately (Figure 9C). Record the final score after artifact deduction in the appropriate space on the form.

6. Count each mass as 1 point if a minus density object is visible in the correct location and the mass appears to be generally circular against the background (i.e., greater than 3/4 of the perimeter is visible). A mass is counted as 0.5 point if a minus density object is visible in the correct location, but the mass does not have a generally circular appearance. Add each full or partial mass to the total mass score, from the largest mass down and until a score of 0 or 0.5 is reached. Record the "raw" mass score before artifact deduction.

7. After determining the last mass to be counted, look at the overall background for artifacts. If a mass-like artifact is seen in the wrong location within the area of the wax insert, deduct the "artifactual" mass from only the last "real" whole or half mass scored if the artifactual mass is equally or more apparent (Figures 9D and E). Record the final score after artifact deduction on the appropriate space on the form.

PRECAUTIONS AND CAVEATS

This test measures contributions from all components of the imaging chain, other than breast positioning by the technologist and patient-induced errors such as motion. Changes in image quality may be due to any component, e.g., the film, cassette and screen, X-ray generator, added filtration, processor, or viewbox. As a result, other tests may be needed to determine the component(s) of the imaging chain that is at fault and in need of corrective action. For example, if the film optical density is too high or too low, it will be necessary to test the processor sensitometrically, determine whether the mAs or exposure time has changed, check the consistency of the screens used, and check to see whether a new film emulsion batch is being used, etc.

Subjective judgments about images are always difficult. Different individuals will perceive different numbers of test objects in the image. The same individual may count a different number of objects in the same image at different times. Consequently, the same individual should view the images each time using the same criteria for better consistency. In addition, the same viewbox, viewing conditions, and magnification should be used each time, and these should be the same as those used for reading mammograms. If a different number of objects are noted, then the current image should be compared with previous images and the original image to determine if a change has really occurred.

> NOTE: If more than one type of film is used for mammography imaging, it is necessary to carry out this test with each type of film used clinically for a breast thickness of 4.2 cm.

Because the medical physicist may not have the opportunity to measure phantom image quality as frequently as the QC technologist, it is important to review a sample of the phantom images acquired by the technologist since the previous visit, comparing results with your own assessment of image quality. Any apparent problems in scoring the phantom should be included as a corrective action and lead to a discussion with the QC technologist about phantom scoring.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The present criteria for the number of objects to pass the ACR MAP is a minimum of the four largest fibers, the three largest spec groups, and the three largest masses. Furthermore, the number of test objects of each group type (fibers, specks, and masses) visible in the phantom image should not decrease by more than one half, assuming the same individual is viewing the images under identical conditions. If a greater change in the number of test objects is noted, then the current image

should be compared with the original image and the previous image to determine whether the change is real or if the individual viewing the film has changed his or her criteria.

The phantom image background optical density should never be less than 1.20, and the control limits for the phantom image background density should be ±0.20. Thus, in order to have the full ±0.20 density control limits available, the **operating level for phantom image background optical density should be at least 1.40**. Substantially higher phantom image background optical density operating levels may provide improved mammographic image quality and avoid underpenetration of dense tissue. However, increasing mAs to achieve higher film optical density will increase the mean glandular dose, and higher average film optical densities may require higher-luminance viewing conditions to see important diagnostic detail.

Generally, the operating level for density difference due to the 4.0 mm acrylic disc should be at least 0.40. The density difference will vary depending on disc thickness, the choice of film, kVp, processing conditions, and background image optical density. Higher mAs and background optical density may result in significant increases in density difference even when using the same film, kVp, and processing conditions. Once an operating level for density difference is established, control limits are ±0.05 for subsequent phantom images. The density difference control limits are only applicable when the 4.0 mm acrylic disc is used. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established as well.

In addition to assuring that each mammographic imaging system produces similar film optical density and density difference over time, it is also essential that all mammographic units and mammographic processors at one facility produce similar film optical densities. It is not acceptable to have one unit or processor producing film optical densities of 1.40 and another producing optical densities of 1.80. Likewise, one should expect each mammographic unit and mammographic processor at a facility to produce images with similar density differences and images of similar image quality.

The mAs noted on the generator read out should not change by more than +15% for a given density control setting. It might be helpful to check that the QC technologist has set mAs control limits correctly and is plotting mAs correctly on the control chart.

If the recommended performance criteria and corrective action for this test are not met, a second phantom image should be taken and evaluated. If the criteria are still not met, the reasons for this failure should be investigated; corrective action taken and the results documented before patients are examined with this system. Other testing methodologies may exist to help isolate the source of system change (e.g., processing versus X-ray unit) that could be applied in addition to the phantom and the 4.0 mm disc.

NOTE:

- At a minimum, the four largest fibers, the three largest speck groups, and the three largest masses must be visible.
- The phantom image background optical density should be at least 1.40.
- The density difference due to the 4.0 mm-thick acrylic disc should be at least 0.40.

Possible causes for changes in phantom image background optical density or density differences are the processor, film emulsion batch, X-ray generator, etc. If the change in film optical density is confirmed to be due to a change in the film emulsion batch and if the magnitude of the change is within the expected batch-to-batch variation for that film type, then an adjustment of the density control setting to bring the phantom background optical density back into control is appropriate. The film manufacturer should be consulted for guidance on expected batch-to-batch variation. If the change in film optical density due to the film batch change is greater than should be expected, then the non-compliant batch should be replaced by a new batch. The 1995 ACR publication, *Recommended Specifications for New Mammography Equipment,* suggests that a difference in film optical density of 0.30 is a reasonable maximum to expect between any two films of the same type when given the same mammographic exposure and processed together.

All sources of significant artifacts should be eliminated. This may require careful cleaning and readjustment of the processor or cleaning of the screens and cassettes, as an example. Slow grid motion may introduce a structured pattern (Figure 7), especially with higher-speed screen-film mammography image receptors for which the times are relatively short. The grid may move only a few millimeters during the exposure and this may result in an image that includes grid lines. This can be corrected by service to the grid drive mechanism by a qualified service person.

MQSA REQUIREMENTS:

The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition. The optical density of the film shall not change by more than ±0.20 from the established operating level. The phantom image shall achieve at least the minimum score established by the accrediting body and accepted by FDA. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than ±0.05 from the established operating level.

If the test results fall outside of the action limits, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

8. PROCEDURE

kVp ACCURACY AND REPRODUCIBILITY

OBJECTIVE

To assure that the actual kVp is accurate (within ±5% of the indicated kVp) and that the kVp is reproducible, having a coefficient of variation equal to or less than 0.02.

REQUIRED TEST EQUIPMENT

Test device capable of measuring kVp to an accuracy of ±1.5 kVp and a precision of 0.5 kVp within the mammographic kVp range.

TEST PROCEDURE STEPS

1. In manual timing mode, select the most commonly used clinical kVp and record on a data form. If appropriate, the line voltage should be checked and adjusted so that it is within tolerance. Also record nominal focal spot size, exposure time, and mA (or mAs) setting.
2. Set up the test device following the manufacturer's instructions.
3. Make four exposures in the same manual mode settings and record the measured kVp values.
4. Repeat the procedure at other clinically important kVps but make only one exposure at each setting. (Reproducibility needs to be checked at only the most commonly used clinical kVp unless variability is suspected at other settings.) These measurements should include the lowest clinically used kVp that can be measured by the kVp test device and the highest available clinically used kVp.

DATA ANALYSIS AND INTERPRETATION

To determine kVp accuracy, average the four kVp readings for each kVp setting tested and compare this average value with the value of the preset nominal kVp. If the average measured kVp differs by more than ±5% (±1.5 kVp at 30 kVp) from the nominal kVp setting, the unit should be checked by appropriate service personnel.

To determine kVp reproducibility, compute the standard deviation of the kVp values for each kVp setting and then calculate the coefficient of variation (standard deviation divided by the average value). If the coefficient of variation exceeds 0.02 for any kVp setting, the unit should be checked by appropriate service personnel.

> NOTE: If the accuracy or reproducibility results with four exposures are questionable, make six additional readings and recalculate using all 10 readings.

MQSA REQUIREMENTS:

The kVp shall be accurate within ±5 percent of the indicated or

selected kVp at:

1) The lowest clinical kVp that can be measured by a kVp test device;

2) The most commonly used clinical kVp; and

3) The highest available clinical kVp.

At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

9. PROCEDURE: BEAM QUALITY ASSESSMENT (HALF-VALUE LAYER MEASUREMENT)

OBJECTIVE

To assure that the half-value layer (HVL) of the X-ray beam is adequate to minimize patient breast dose, while not so excessive that contrast is lost in the resultant image.

REQUIRED TEST EQUIPMENT

Ionization chamber and electrometer calibrated at mammographic X-ray beam energies (the calibration factor should be constant to within ±1% over the HVL range from 0.2 to 0.6 mm Al)

Five or six 0.1-mm-thick sheets of 99.9% pure aluminum (type 1145 aluminum alloy) or 99% pure aluminum (type 1100 aluminum alloy) of length and width sufficient to cover the ionization chamber fully. The stated thicknesses should be accurate to within ±1%.

> NOTE: The use of type 1100 aluminum alloy for HVL measurement can give (depending on specific samples) HVL values up to 7.5% lower than those measured using type 1145 aluminum. If type 1100 aluminum is used, results should be corrected to agree with those obtained using type 1145 aluminum alloy.

TEST PROCEDURE STEPS

1. Place the breast compression paddle as close as possible to the X-ray tube.
2. Place the ionization chamber approximately 4.5 cm above the image receptor holder assembly, centered left to right and 4 cm in from the chest-wall edge of the image receptor. The ionization chamber should be fully within the X-ray field.
3. Select the most commonly used clinical kVp and record on the data form. If appropriate, adjust the line voltage to within tolerance and assure that the filtration normally used for that kVp setting is in place.
4. Set the unit to manual timing, with a time setting sufficiently long to provide an exposure of approximately 500 mR, and record mA and time (or mAs).
5. Use a diaphragm to collimate the X-ray beam so that the ionization chamber is just fully exposed (to minimize backscatter production).
6. Make an exposure without any aluminum sheets between the X-ray tube and the ionization chamber.
7. Add 0.2 mm of aluminum between the X-ray tube and the ionization chamber by placing the aluminum on top of the compression paddle. Use the light field (if available) to verify that the X-ray path to the ionization chamber is fully blocked by the aluminum sheet. Make an exposure and record the ionization chamber reading.

8. Repeat step 7 with additional 0.1-mm sheets of aluminum between the X-ray tube and ionization chamber, recording the ionization chamber reading each time until the reading is less than one-half the original exposure reading (taken without any added aluminum sheets between the X-ray tube and chamber).
9. Remove all aluminum sheets from the top of the compression paddle, make a final exposure and record the chamber reading. If the result of this final exposure differs by more than 2% from the exposure in step 6, repeat the measurement sequence.
10. Repeat steps 4 through 9 for other kVp-target-filter settings ranging from the lowest to the highest used clinically.

DATA ANALYSIS AND INTERPRETATION

To calculate the HVL by logarithmic interpolation, use the following notation and procedure. Denote the direct exposure reading, without any added aluminum, as E_0. Divide this value in half and find the two exposure readings and added aluminum thicknesses that bracket the $E_0/2$ exposure. Let E_a be the exposure reading that is just greater than one-half of E_0 and t_a be the corresponding aluminum thickness. Let E_b be the exposure reading that is just less than one-half of E_0 and t_b the corresponding aluminum thickness. E_a will be greater than E_b, while t_a will be less than t_b. With this notation, the HVL may be computed using the formula:

$$HVL = \frac{t_b \ln[2E_a/E_0] - t_a \ln[2E_b/E_0]}{\ln[E_a/E_b]}$$

where the HVL will be given in the same units as t_a and t_b, usually millimeters of aluminum.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

At a given kVp setting in the mammographic kilovoltage range (below 50 kVp), the measured HVL with the compression paddle in place must be equal to or greater than the value:

$$HVL > \frac{kVp}{100} + 0.03 \text{ (in units of mm of aluminum)}$$

For example, if the nominal tube potential is 28 kVp, the HVL must equal or exceed 0.31 mm of aluminum. If the measurement is made without the compression paddle in the beam to simulate mammography performed without a full compression paddle in place (e.g., in needle localization procedures), then the HVL should meet the Federal performance standard: HVL > kVp/100 (in units of mm of aluminum). For example, at 28 kVp without a compression paddle, the HVL must equal or exceed 0.28 mm of aluminum. If the measured HVL is below these limits at any kVp setting, service personnel should be contacted to check whether appropriate filtration is in place.

If the HVL for screen-film units is excessive, both subject contrast and image contrast will be reduced. For screen-film units using Mo/Mo, Mo/Rh, or Rh/Rh target/filtration combinations, it is recommended that the HVL be within a constant value (C) of the minimum acceptable HVL:

$$HVL < \frac{kVp}{100} + C \quad \text{(mm of aluminum)}$$

where C = 0.12 mm A1 for Mo/Mo, C = 0.19 mm A1 for Mo/Rh, C = 0.22 mm A1 for Rh/Rh and C = 0.30 for W/Rh. (Note: these HVL upper bounds are based on molybdenum filter thicknesses of 30 μm or less and rhodium filter thicknesses of 25 μm or less.)

For example, for Mo/Mo, the upper limit is HVL < 0.40 mm of aluminum at 28 kVp. Excessive HVL violates no federal standards but should prompt a check by service personnel to assure that the X-ray tube has an appropriate (beryllium) window and that mirror and filtration are correctly installed.

MQSA REQUIREMENTS:

The HVL shall meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in the table below. Values not shown may be determined by linear interpolation or extrapolation.

X-Ray Tube Voltage (kilovolt peak) and Minimum HVL

Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

10. PROCEDURE: BREAST ENTRANCE EXPOSURE, AEC REPRODUCIBILITY, AVERAGE GLANDULAR DOSE, AND RADIATION OUTPUT RATE

OBJECTIVE

To measure the typical entrance exposure for an average patient (approximately 4.2 cm compressed breast thickness—50% adipose, 50% glandular composition), to calculate the associated average glandular dose, to assess short-term AEC reproducibility, and to measure the air kerma rate.

REQUIRED TEST EQUIPMENT

Ionization chamber and electrometer calibrated at mammographic X-ray beam energies (calibration factor constant to within ±1% over the HVL range from 0.2 to 0.5 mm Al). In order to determine radiation output rate, the electrometer should also be able to measure exposure time. If this feature is not available on the instrument, a separate device may be necessary to measure time.

Mammographic phantom (equivalent to approximately 4.2 cm compressed breast tissue—50-50 composition—at screen-film energies; for example, Radiation Measurement, Inc., RMI 156 or Nuclear Associates, 18-220 mammographic phantom)

A phantom made of either acrylic or BR-12 and consisting of at least four 2 cm-thick slabs to provide thicknesses of 2, 4, 6 and 8 cm of linear dimensions representative of typical breast sizes may be used to determine doses for other breast thicknesses. (optional)

Mammographic cassette loaded with mammography film (film will not be processed or reviewed).

TEST PROCEDURE STEPS

Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose

1. Prepare the mammography system for operation in its most common imaging mode (e.g., grid and 18 X 24 cm image receptor). This step includes appropriate field limitation for the imaging mode and image receptor size to be used. Record the conditions on the data form.
2. For mammography systems with a variable source-to-image receptor distance (SID), adjust the system to the SID most commonly used for mammography and record this value on the data form. Record the source-to-detector and the source-to-bucky top distances. (This will permit inverse-square corrections of exposure if necessary.)
3. Position a loaded cassette (of the type and size consistent with the imaging mode selected in step 1) in the image receptor holder assembly.

4. Select the AEC density control setting that is normally used clinically for an average patient. Place the phantom on the cassette holder, positioning the phantom so that the chest-wall edge of the phantom is aligned with the chest-wall side of the image receptor. Center the phantom, left to right. Position the AEC sensor under the center of the phantom. Make sure that the wax insert of the mammographic phantom completely covers the active area of the sensor.

5. Position the ionization chamber in the X-ray field beside the mammographic phantom, centered 4 cm in from the chest-wall edge of the image receptor and with the center of the chamber level with the top surface of the phantom. Assure that the entire chamber is exposed and that its radiographic shadow does not overlap the active area of the AEC sensor (Figure 10).

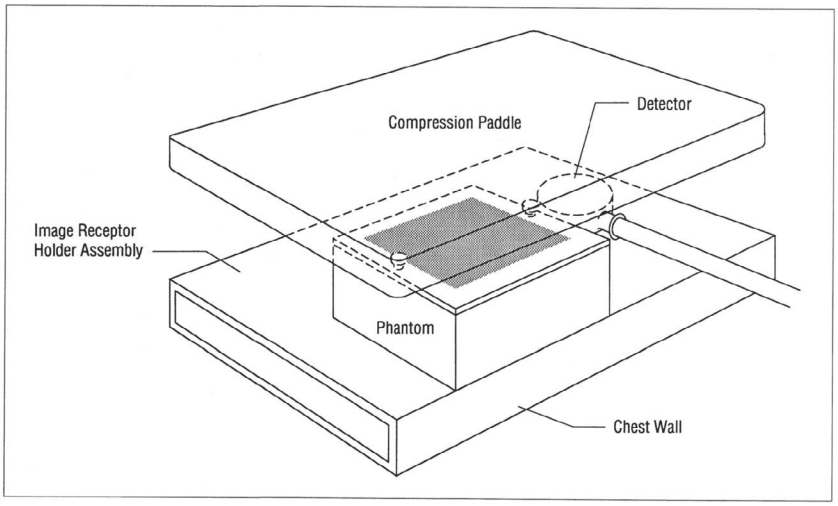


Figure 10. Schematic drawing of placement of the phantom and ionization chamber for measurement of breast entrance exposure. The center of the ionization chamber should be at the same height as the top surface of the phantom.

6. Secure the chamber in position and do not change the position of the chamber during the following measurements.

NOTE: Mammographic imaging systems have a significant X-ray intensity gradient in the X-ray field along the anode-cathode direction. Maintaining a constant chamber position during measurements is critical. When measurements are to be compared with others made previously, it is also critical that the original measurement position be re-established as closely as possible.

7. Position the compression device in the X-ray beam, just in contact with or slightly above the phantom and chamber, as shown in Figure 10.

8. Select the kVp, target material, and filtration at which the system is most commonly used clinically and record the settings on the data form. Also, record the HVL (previously measured in beam quality assessment test) for those same parameters on the data form.

9. Make an exposure and record the measured exposure and the indicated mAs (or exposure time) on the data form.

10. Repeat step 9 until four exposures have been recorded. There is no need to change the cassette or film between exposures (although cassettes may need to be removed and re-inserted to override exposure interlocks on units so equipped).

11. If desired, repeat steps 4 through 9 for other phantom thicknesses; and appropriate kVp-target-filter combinations, and density control settings. Be sure to follow the facility's technique chart. Assure that HVL values have been measured and recorded at any additional kVp and target-filter combinations tested. Additional space is available on the data form if exposure reproducibility (step 10) needs additional evaluation at these other techniques.

Radiation Output Rate

1. To measure the unit's radiation output, prepare the mammographic imaging system for operation in **manual mode** using the 18 X 24 cm image receptor. Set the kVp to 28 and use the Mo/Mo target-filter combination. Adjust the time of exposure to be at least 3 seconds. Record the conditions on the data form.

2. Remove the phantom and position the ionization chamber 4.5 cm above the breast support plate, centered 4 cm in from the chest wall. Assure that the entire chamber is exposed. Position the compression device in the X-ray beam, just in contact with or slightly above the chamber.

3. Secure the chamber in position and do not change the position of the chamber during the following measurements.

4. Make an exposure and record the measured exposure and measured exposure time on the data form. (If the electrometer does not measure exposure time, the X-ray unit's indicated exposure time may be used if it is available or a separate time-measuring device must be used during a separate exposure.)

5. Repeat steps 1 through 4 for all other clinically used SID settings.

6. Make sure the exposed film in the cassette is replaced before the cassette is returned to clinical use.

DATA ANALYSIS AND INTERPRETATION

Compute the mean values and standard deviations for both exposure and mAs(or exposure time) for the four exposures acquired under identical conditions to test AEC reproducibility. Record the values. Determine the coefficient of variation (standard deviation divided by the mean) for the exposure measurements and mAs (or time).

Using each average exposure value, calculate the average glandular dose as follows:

If necessary, correct the average exposure with the chamber's appropriate energy correction factor and with an inverse-square correction factor to obtain the exposure at the skin entrance.

Find the appropriate column in Tables 1, 2, or 3 for the target and filtration combination used clinically.

Find the HVL of the system (see the beam quality assessment test) in the left-hand column of Tables 1 through 3. In the right-hand column of the table appropriate for the target, filter, and kVp setting, find the exposure to average glandular dose conversion factor for a 4.2 cm compressed breast thickness. Multiply this factor by the average entrance exposure value (in roentgens) computed above. The product obtained represents the mean dose received by the glandular tissue for that specific energy, breast composition, and compressed thickness and is an approximation of the actual patient dose.

NOTE: Because the conversion factor and the average glandular dose change substantially for other breast thicknesses, these factors only apply to a 4.2 cm compressed breast thickness. Conversion factors for other breast or phantom thicknesses may be found in the articles by Dance, by Wu et al., and by Sobol et al. that are listed in the reference section of this manual (Section VIII).

Table 1. GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2 CM BREAST THICKNESS—50% ADIPOSE-50% GLANDULAR BREAST TISSUE—USING AN Mo/Mo TARGET-FILTER COMBINATION*

	X-Ray Tube Voltage (kVp)											W/Al Target -Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	116											
0.24	121	124										
0.25	126	129	131									
0.26	130	133	135	138								
0.27	135	138	140	142	143							
0.28	140	142	144	146	147	149						
0.29	144	146	148	150	151	153	154					
0.30	149	151	153	155	156	157	158	159				170
0.31	154	156	157	159	160	161	162	163	164			175
0.32	158	160	162	163	164	166	167	168	168	170	171	180
0.33	163	165	166	168	169	170	171	173	173	174	175	185
0.34	168	170	171	172	173	174	175	176	177	178	179	190
0.35		174	175	176	177	178	179	180	181	182	183	194
0.36			179	181	182	183	184	185	185	186	187	199
0.37				185	186	187	188	189	190	191	191	204
0.38					190	191	192	193	194	195	195	208
0.39						196	197	198	198	199	200	213
0.40							201	202	203	204	204	217
0.41								206	207	208	208	221
0.42									211	212	212	225
0.43										215	216	230
0.44											220	234
0.45												238

To convert from entrance exposure in air in roentgens to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 roentgens from a Mo/Mo target/filter system at 30 kVp with a measured HVL of 0.36 mm aluminum yields an average glandular dose of (0.50 R) x (185 mrad/R) = 93 mrad or 0.93 mGy.

* Adapted from: Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), *Screen Film Mammography: Imaging Considerations and Medical PhysicsResponsibilities.* Madison, Wis: Medical Physics Publishing; 1991;159-175. W/Al conversion factors are derived from fits to data from Stanton L., et al. Dosage evaluation in mammography. Radiology. 1984;150: 577-584.

Table 2. GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2 CM BREAST THICKNESS—50% ADIPOSE-50% GLANDULAR BREAST TISSUE—USING A Mo/Rh TARGET-FILTER COMBINATION*

	X-Ray Tube Voltage (kVp)										
HVL	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**
0.28	149	151	154								
0.29	154	156	158	159							
0.30	158	160	162	162	162	163					
0.31	163	164	166	166	166	167	167				
0.32	167	169	171	171	171	171	172	172			
0.33	171	173	175	176	176	176	176	177			
0.34	176	178	179	179	180	180	180	181	181		
0.35	180	181	183	183	184	185	185	186	187		
0.36	185	186	187	187	188	188	189	190	191	191	
0.37	189	190	191	191	192	193	193	194	195	195	
0.38	193	194	196	196	197	197	197	198	199	199	200
0.39	198	199	200	200	201	201	202	202	203	203	204
0.40	202	203	204	204	205	205	206	207	208	208	208
0.41	206	207	208	208	209	209	210	211	212	212	212
0.42	211	211	212	212	213	213	214	215	216	216	217
0.43	215	216	217	217	218	218	219	219	220	220	221
0.44	220	220	221	221	222	222	223	223	224	224	225
0.45	224	224	225	225	226	226	227	227	228	228	229
0.46		228	229	229	230	231	231	232	233	233	234
0.47			233	233	234	235	235	236	237	237	238
0.48			238	238	239	240	240	241	241	242	242
0.49				242	243	243	244	244	245	245	246
0.50					247	247	248	248	249	250	251
0.51						251	252	253	254	254	255
0.52							257	257	258	258	259
0.53							261	261	262	263	264
0.54								265	266	267	268
0.55								269	270	271	272
0.56									275	276	276
0.57									279	280	281
0.58										284	285
0.59										288	289
0.60											293

* Adapted from: Wu X, Gingold EL, Bames GT, Tucker DM. Normalized average glandular dose in Mo/Rh and Rh/Rh target-filter mammography. *Radiology*. 1994;193:83-89.

Table 3. GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2 CM BREAST THICKNESS—50% ADIPOSE-50% GLANDULAR BREAST TISSUE—USING AN Rh/Rh TARGET-FILTER COMBINATION*

	X-Ray Tube Voltage (kVp)										
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	150	155	159								
0.29	155	160	164	168							
0.30	160	164	168	172	176						
0.31	165	168	172	174	180	182					
0.32	169	173	177	181	184	186	188				
0.33	174	178	181	185	188	190	192				
0.34	179	183	186	190	193	195	196	199			
0.35	184	187	190	194	197	199	201	203			
0.36	189	192	195	198	201	204	205	207	209		
0.37	193	196	199	202	205	207	209	211	213		
0.38	198	201	204	207	209	211	213	215	217	219	221
0.39	203	206	208	211	214	216	217	219	221	223	224
0.40	208	211	213	216	218	220	221	223	224	226	228
0.41	213	215	217	220	222	224	225	227	228	230	232
0.42	218	220	222	224	226	228	229	231	232	234	236
0.43	222	224	226	228	230	232	233	235	236	238	240
0.44	227	229	231	233	235	237	238	239	240	242	243
0.45	232	234	235	237	239	241	242	243	244	246	247
0.46			239	241	243	245	246	247	248	250	251
0.47					247	249	250	251	252	254	255
0.48					251	253	254	255	256	258	259
0.49						257	258	259	260	261	262
0.50						261	262	263	264	265	266
0.51							266	267	268	269	270
0.52							270	271	272	273	274
0.53							275	276	276	277	278
0.54								279	280	280	281
0.55								283	284	284	285
0.56									288	288	289
0.57										292	293
0.58										296	297
0.59											300
0.60											304

* Adapted from: Wu X, Gingold EL, Barnes GT, Tucker DM. Normalized average glandular dose in Mo/Rh and Rh/Rh target-fIlter mammography. Radiology. 1994;193:83-89.

Calculate the exposure rate for each clinically used SID by dividing the measured exposure by the measured (or indicated) exposure time. To compute the air kerma rate, multiply the measured exposure rates by the conversion factor.

Air kerma (mGy/s) = Exposure rate (mR/s) x 0.00873 mGy/mR

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The maximum acceptable coefficient of variation for both exposure and mAs (or time) in the AEC reproducibility test is 0.05. If this value is exceeded, the unit should be checked by appropriate service personnel.

The average glandular dose to an average (4.2 cm compressed) breast must not exceed 3 mGy (0.3 rad) per view for screen-film image receptors. If the values exceed these levels, action must be taken to evaluate and eliminate the cause of excessive dose.

The radiation output of the mammography system should not be less than 7.0 mGy air kerma per second (800 mR/sec) over a 3 second period of time when operating at 28 kVp in the standard mammography (Mo/Mo) mode at any clinically used SID. If values are less than these levels, the unit should be checked by the appropriate service personnel.

MQSA REQUIREMENTS:

Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05. If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA accepted phantom simulating a standard breast shall not exceed 3.0 mGy (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

If the results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test.

Radiation output. (A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 mR per second) when operating at 28 kVp in the standard mammography (Mo/Mo) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard mammography (Mo/Mo) mode at any SID where the system is designed to operate. (B) The system shall be capable of maintaining the required minimum output averaged over a 3.0 second period.

If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date.

11.PROCEDURE VIEWBOX LUMINANCE AND ROOM ILLUMINANCE

OBJECTIVE

To assure that the luminance of the viewboxes for interpretation or quality control of mammography images meet or exceed minimum levels, that the room illuminance levels are below prescribed levels, and that viewing conditions have been optimized.

REQUIRED TEST EQUIPMENT

Photometer designed to measure both luminance and illuminance that meets or exceeds the Photographic Imaging Manufacturers Association (PIMA) draft standards.

PROCEDURE STEPS

NOTE: The measurement procedures described follow, as closely as possible, those recommended by the PIMA draft standard. Additional measurements are described in the PIMA standard that the medical physicist may wish to include, e.g., luminance uniformity.

1. Reproduce the typical ambient lighting conditions for the reading room including overhead and task lighting that is typically used when mammograms are interpreted. Doors and window coverings shall be in their normal (open or closed) position. If light from other viewboxes can fall on the surface of the viewbox being evaluated, these viewboxes shall be on, but the viewing surface shall be covered with radiographs.
2. For each viewbox that is used for mammographic interpretation, turn on the lights in the viewbox at least 30 minutes before taking the following measurements.
3. Place the luminance meter with its detector parallel to and facing the viewbox surface. The detector should be centered in a hole (which is centered in an opaque mask) just slightly larger than the detector itself, and in contact with the viewbox surface (Figure 11).
4. Take the measurement and record the result as the viewbox luminance.

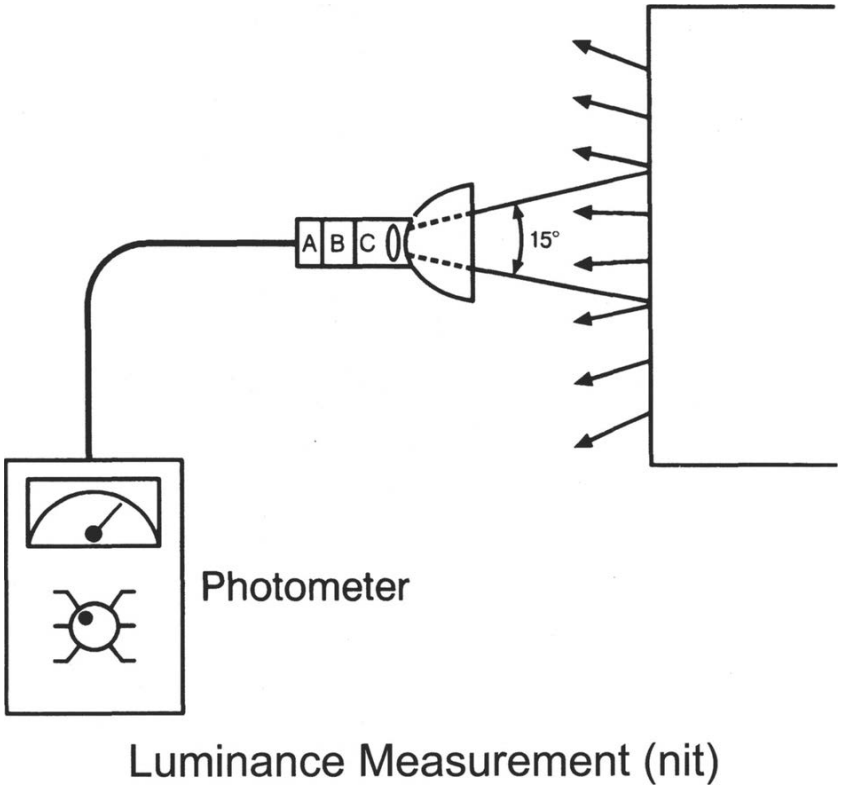
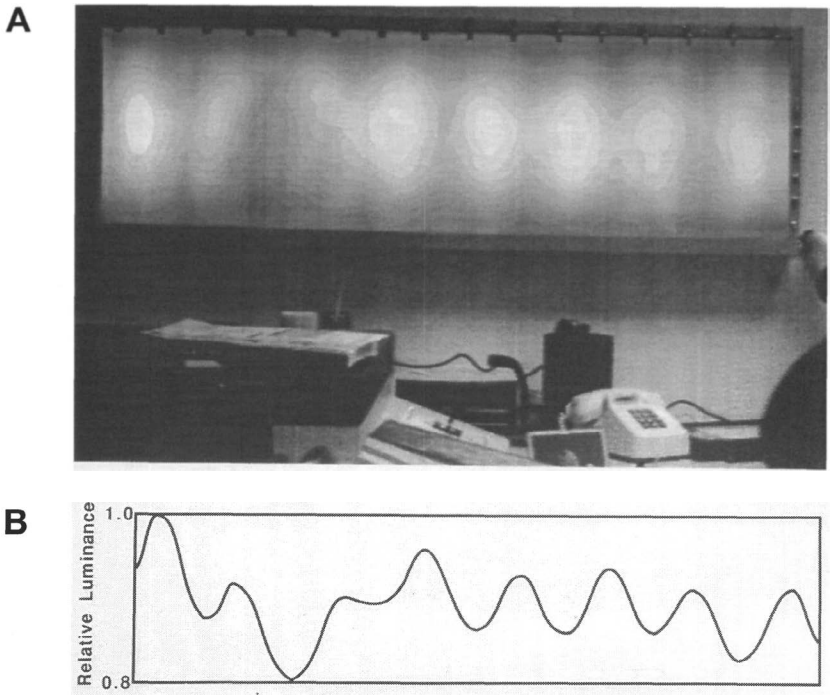


Figure 11. Measurement of luminance of conventional viewbox. The detector head consists of a detector (A), a photometric filter (B), and a lens (C). Exclusion of ambient room lighting is accomplished by placing the soft, black rubber ambient light shade in direct contact with the viewbox surface.

5. Visually inspect each viewbox for uniformity of luminance and for uniformity of color of the lighting. Note nonuniformities (Figure 12). Also evaluate viewboxes for proper function of masking devices, and the presence of dirt or marks as describe in the "Viewboxes and Viewing Conditions" procedure of the "Radiologic Technologist's Section."
6. Take the following illuminance measurements with the viewbox lights of the viewbox being evaluated turned off.
7. Place the illuminance meter so that its detector is parallel to and facing away from the viewbox surface, with the detector in contact with the viewbox surface. The meter must be held so that the medical physicist is not within the angle of acceptance.
8. Make the measurement and record the result of the illuminance falling on the viewbox surface.



Figures 12A & B. Spatial variation in viewbox luminance. (A) Contours showing variation of luminance over a typical viewbox surface. Range of luminance values is approximately 25%. (B) Variation in viewbox luminance measured horizontally across the center of the viewbox.

9. Place the illuminance meter 50 cm from the viewbox with its detector parallel to and facing towards the viewbox surface, centered on the viewbox (Figure 13).
10. Take the measurement and record the result of the illuminance seen by the observer.
11. Repeat the tests for all viewboxes used for interpreting mammograms and for the viewboxes used by the technologist to check the mammograms during the examination.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

Viewboxes used for interpreting mammograms and clinical quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter (cd/m^2). The illumination levels should be 50 lux, or preferably less. All viewboxes used for mammographic interpretation must be masked to the exposed area of the film.

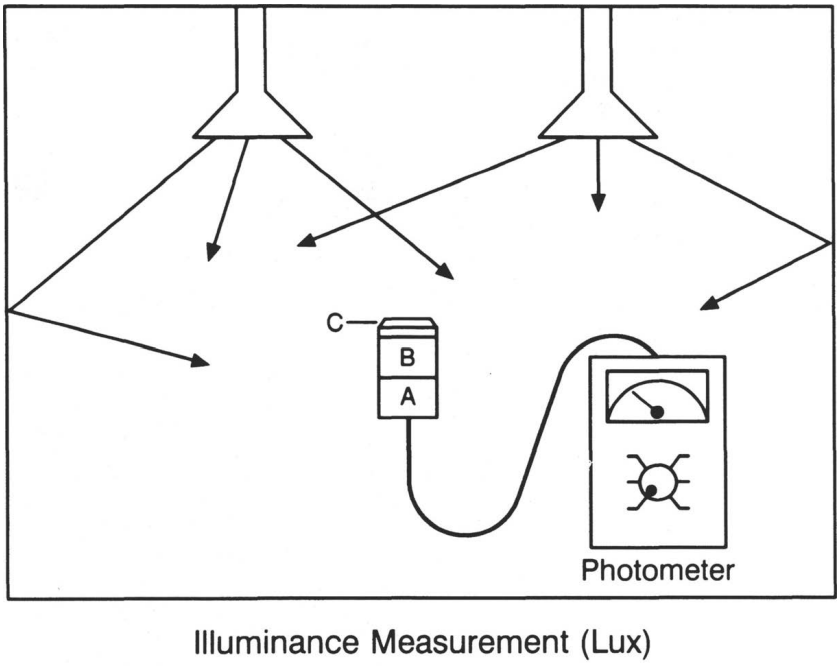


Figure 13. Measurement of illuminance. The detector head consists of the detector (A), the photometric filter (B), and the cosine diffuser (C). Measurements should be made with viewbox lights off. The diffuser must be pointed away from and parallel to the viewbox surface. Care must be taken by the individual taking the measurements to avoid influencing the measurements, e.g., avoid standing between the detector and a light source.

Note: The unit candela per square meter is sometimes referred to as the "nit."

In addition to the measurement procedure described, the "Viewboxes and Viewing Conditions" procedure of the "Radiologic Technologists Section" should be followed. It is essential to mask the area around the mammograms to exclude extraneous light, which reduces image contrast and low-contrast perceptibility and also limits the maximum densities that can be seen without "bright-lighting" each image. Viewboxes should be positioned to avoid light from windows, other viewboxes, CRT monitors and other sources of bright light, either direct or reflected. Visually check the viewboxes to assure that all of the bulbs are producing light of the same color and luminance level.

If the luminance level of the viewbox is less than 3,000 cd/m^2 or if the luminance or the color of light of the individual lamps appears significantly different from others in the same viewbox, then all bulbs in the viewbox should be replaced at the same time.

MQSA REQUIREMENTS:

There are no MQSA requirements for viewbox luminance or viewing conditions.

ADDITIONAL INFORMATION

Photometric Measurements

Photometry is the science of the measurement of light. Photometric measurements of light, like dosimetric measurements of ionizing radiation, are relatively complicated. Photometric measurements take into account the spectral sensitivity of the human eye, i.e., the spectral sensitivity of the cones in the fovea (Figure 14). In contrast, radiometric measurements do not consider the response of the human eye and can be used to characterize electromagnetic radiation far beyond the narrow wavelength band that can be detected by the eye, e.g., the ultraviolet and infrared portions of the spectrum.

Many photometric units of measurement exist but are seldom used. For simplicity we will consider only the SI photometric units of luminance and illuminance, the candela per square meter and lux, respectively.

Luminance is the amount of light either scattered or emitted by a surface, measured in cd/m^2 (nit). Illuminance is the amount of light falling on a surface, measured in lux (1 lux = 1 lumen/m^2). Typical values of luminance and illuminance are provided in Figure 15. One lux falling on a perfectly diffusing (Lambertian) surface with 100% reflectance produces

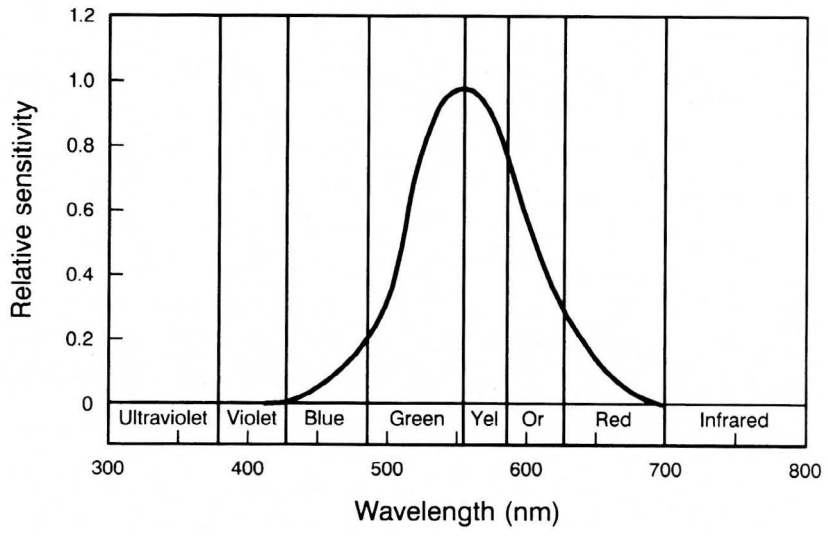
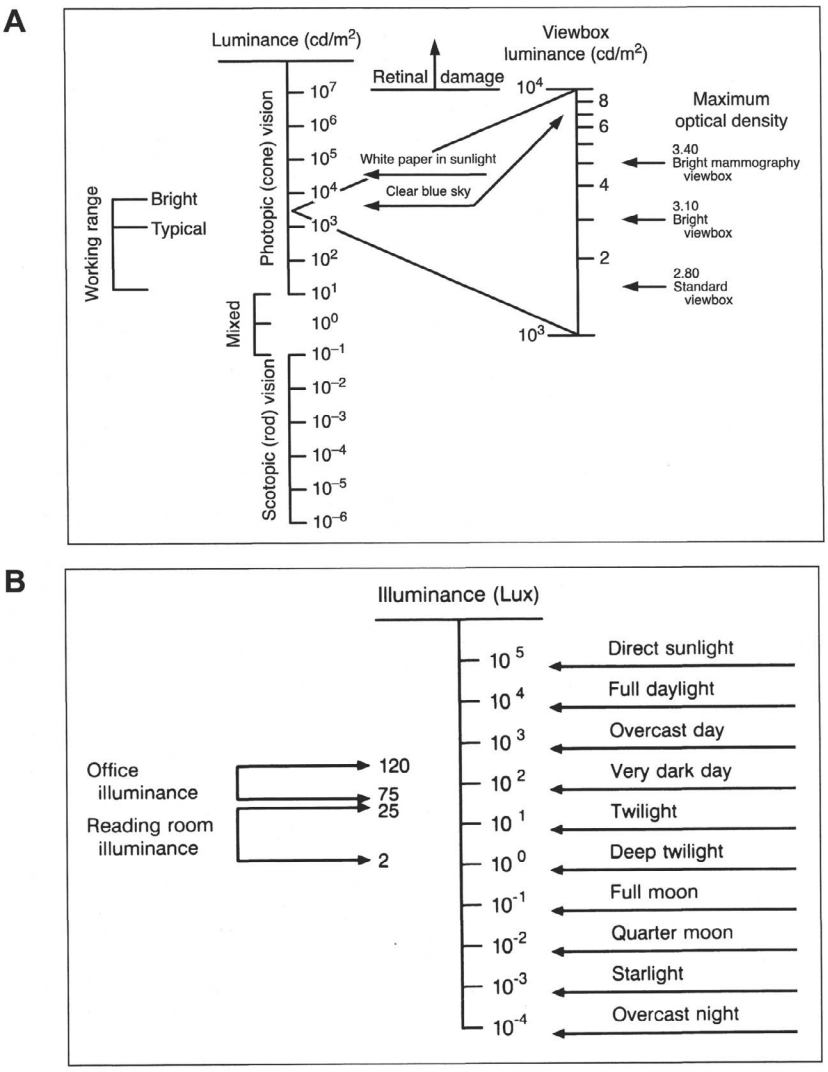


Figure 14. Photopic spectral sensitivity of the human eye.



Figures 15A & B. Luminance and illuminance scales. (A) Luminance scale with typical luminance values and maximum film densities that can be visualized with the photopic vision at specific luminance levels. (B) Illuminance scale with typical illuminance values.

a luminance of $1/\pi$ cd/m^2. Other units often used for luminance and illuminance are footlamberts and footcandles, respectively. To convert footlamberts to cd/m^2, multiply the numerical value by $10.764/\pi$. To convert footcandles to lux, multiply the numerical value by 10.764.

Measurement of Luminance and Illuminance

Measurements of both luminance and illuminance require a detector and a photometric filter. The detector and filter in combination provide a spectral sensitivity similar to that of the human eye. For luminance measurements, a lens or fiberoptic probe must be used in front of the detector-filter combination. Illuminance measurements are made with a cosine diffuser (one in which the amount of light detected at various angles is proportional to the cosine of the angle between the incident ray and the diffuser surface). A microprocessor-based electrometer stores the calibration factors for different detector-filter-optics combinations. Table 4 provides specifics regarding the type of equipment necessary to measure luminance and illuminance.

Table 4: EQUIPMENT FOR BASIC PHOTOMETRIC MEASUREMENTS

Purpose	Description
Luminance and Illuminance	Autoranging hand-held power meter with 13 calibration points*
Luminance	CRT luminance sensor** with photometric filter, lens, and ambient light shade
Illuminance	Illuminance sensor** with photometric filter and cosine diffuser

* Useful for other measurement devices, e.g., fiberoptic probes, telephotometer, etc.

** Must specify SI units for calibration

Viewbox luminance measurements are made with the photometric system shown in Figure 11. The detector-filter-optics combination is placed near the viewbox surface, taking care to exclude any extraneous room light. Typical viewbox luminance values range from 1,500 to 3,500 cd/m^2. The viewbox luminance can vary significantly from one area of the viewbox to another (Figure 12). Typically, measurements should be avoided near the edge of the viewbox (within 1 to 2 inches), where luminance values may be quite low.

Ambient room lighting is as important as viewbox luminance for the radiographic reading environment. Ambient illumination should be minimized to improve low-contrast detectability. Illuminance is measured with the photometric system shown in Figure 13. The detector-filter-diffuser combination is placed at the viewbox surface with the diffuser surface pointed away from and parallel to the viewbox surface. These measurements can be influenced by the individual making the measurement, especially if one stands between a source of light and the detector-filter-diffuser combination.

Table 5 provides results of measurements of mammography viewboxes at five institutions in the United States and Sweden. The average luminance was 2,920 cd/m^2 from this small sample. The average room ambient illumination level was 40 lux.

Table 5: MAMMOGRAPHY VIEWBOX MEASUREMENTS FROM FIVE INSTITUTIONS

	Number of Panels	Average	Minimum	Maximum
Luminance (cd/m2)	23	2,920	1.620	3,630
Illuminance (lux)	23	40	6	97
Color temperature (°K)	23	8,400	4,950	10,900

From Haus AG et al. *Med Phys.* 1993;20:819-821.

Viewbox Reading Conditions

Sufficient viewbox luminance is essential for obtaining diagnostic information from radiographic images. The retina of the eye contains both rods (scotopic vision for seeing at night) and cones (photopic vision for seeing fine detail at high light levels). Because we wish to use the fine-detail capabilities of the eye when viewing radiographs, it is essential that sufficient luminance be provided so that the density range of interest on the mammogram is visualized with photopic vision. Figure 15A relates typical luminance levels to scotopic and photopic vision and to image densities. For example, the maximum optical density at which details can be visualized with a typical viewbox luminance of 1,500 cd/m^2 is 2.80. At 3,000 cd/m^2 (a bright viewbox), one can visualize details at an optical density of 3.10, whereas at 7,000 cd/m^2 (a very bright mammography viewbox), one can visualize details at optical densities of 3.40 and above.

The ambient room lighting and masking of the film to exclude bright areas of the viewbox from being seen by the radiologist are very important. In particular, any unmasked area of the viewbox or bright ambient light results in loss of low-contrast perceptibility, which is of primary importance in mammography image interpretation. This decreased perceived image contrast is a result of light scattered and reflected from the surface of the film being viewed as well as light scattered in the eye.

Fluorescent Lamps

The life expectancy of fluorescent lamps is defined as the amount of time for which only 50% of the original lamps continue to function. According to one manufacturer's data, fluorescent lamps have a typical life expectancy of 20,000 hours (10 years) of operation. However, fluorescent lamps must be replaced much more frequently when used in viewboxes, because of the decrease in fluorescent lamp output with time (Figure 16). Although data available from tube manufacturers indicate typical decrease in light output by 20% after 18,0 hours (9 years), sample viewbox measurement data show a decrease in viewbox luminance of 12% to 18% in only 8 months.

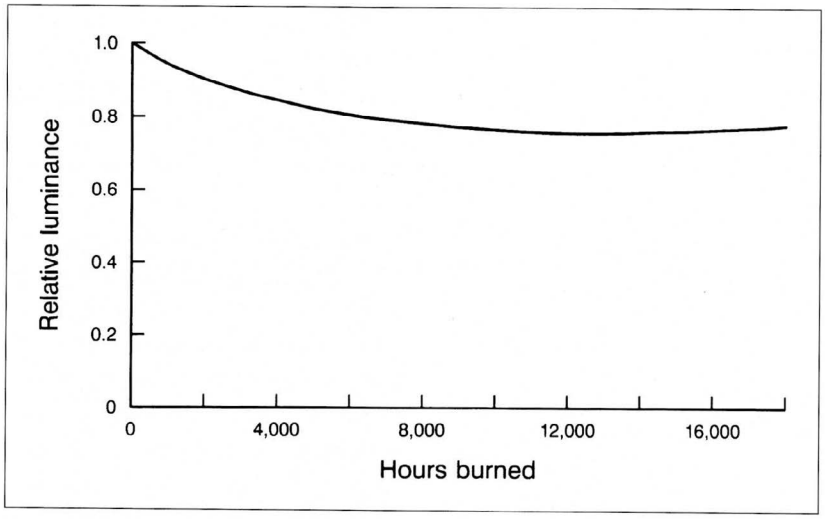


Figure 16. Decrease in light output of typical fluorescent tube in relation to time (manufacturer's data).

ASSESSING THE MAMMOGRAPHY SITE'S QUALITY CONTROL PROGRAM

The medical physicist can provide a valuable service to mammography sites by assessing the sites' quality control programs and identifying areas where quality and QC testing can be improved. At most sites, the visit by the medical physicist can serve as an external assessment of quality and a comparison of quality and QC practices with those of other mammography sites. This review provides an opportunity for valuable feedback to the site on methods of quality improvement.

For this opportunity to be realized, the medical physicist must be familiar with the quality control practices that are performed by the QC technolgist. In addition, the physicist should check that QC tests are properly performed and documented and that appropriate actions are being taken to correct problems when they occur.

Each mammography site should have a QC or quality assurance procedures manual that documents the individuals responsible for QC testing, the testing performed, and the results of that testing. The manual should also document the on-site training of technologists on equipment operation, positioning, compression, mammography technique selection, and patient and operator safety, including radiation safety. (See a more complete listing of the items that should be contained in a procedures manual in the "Radiologist's Section.") The medical physicist should review the procedures manual on each visit to a site, reviewing contents to ensure that the manual is up-to-date and contains at least summary results of the last year's QC tests. A checklist to aid the medical physicist in reviewing the site's QC procedures is provided in Section IV.

Because the film processor is a critical link in the mammography imaging chain, the medical physicist may wish to provide an independent verification that the processor is functioning properly for mammography. This test can be done by carrying a calibrated sensitometer to each site and independently measuring speed, contrast, and base-plus-fog for the site's film and processor. This is possible only if the medical physicist knows the results to expect from a given type of mammography film when it is properly processed. This information can sometimes be obtained from the film manufacturer but also requires experience in film sensitometry.

The medical physicist can also provide a useful independent check of darkroom cleanliness, proper safelight and filter, light leaks, fog levels, and film viewing conditions.

Problems with the mammography site's quality and QC program and recommendations to the site for improvement should be clearly communicated in a cover letter or summary sheet of problems and recommendations. Too often, communications back to mammography sites are ignored by the site because they lack clarity or are too obscure to interpret. The medical physicist's mammography QC test summary forms in Section IV have been included to aid in communicating the results of physics tests to the mammography site. A preliminary results form is also provided in Section IV for the medical physicist to leave brief, handwritten results for the facility prior to departure. This immediate communication is particularly essential to allow adequate time for the facility to take corrective action should any tests fail.

SUMMARY REPORT FORMS

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Screen-Film Systems

Site Name		Report Date	
Address		Survey Date	
Medical Physicist's Name		Signature	
X-Ray Unit Manufacturer		Model	
Date of Installation		Room ID	
Film (mfr & type)		Screen (mfr & type)	

Survey Type: ■ Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist) ■ Annual Survey

Medical Physicist's QC Tests

	Pass/Fail ACR Guides	Pass/Fail MQSA Regs
1. Mammographic Unit Assembly Evaluation		
2. Collimation Assessment		
Deviation between X-ray field and light field ≤ 2% of SID		
X-ray field does not extend beyond any side of the IR by more than 2% of SID		
Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% of SID		
3. Evaluation of Focal Spot Performance		
Measured performance within acceptable limits for large focal spot		
Measured performance within acceptable limits for small focal spot		
4. Automatic Exposure Control (AEC) System Performance		
Exposure reproducibility is within acceptable limits		
AEC compensation for kVp, breast thickness and image mode is adequate		
AEC density control function is adequate		
5. Uniformity of Screen Speed		
Optical density range is ≤ 0.30		
6. Artifact Evaluation		
Artifacts were not apparent or not significant		
7. Phantom image Quality Evaluation		
4 largest fibers, 3 largest speck groups and 3 largest masses are visible		
Phantom image quality scores: Fibers		
Specks		
Masses		
8. kVp Accuracy and Reproducibility		
Measured average kVp within ± 5% of indicated kVp		
kVp coefficient of variation ≤ 0.02		
9. Beam Quality (Half-Value Layer) Assessment		
Half-value layer is within acceptable lower and upper limits at all kVp values tested		
10. Breast Entrance Exposure, Average Glandular Dose and Radiation Output Rate		
Average glandular dose for average breast is below 3 mGy (300 mrad)		
Average glandular dose to a 4.2-cm-thick breast on your unit is ____ mrad		
Radiation output rate is ≥ 800 mR/sec (7.0 mGy/sec) at 28 kVp with Mo/Mo ____ mR/sec		
11. Viewbox Luminance and Room Illuminance		
Mammographic viewbox is capable of a luminance of at least 3000 nit		
Room illuminance (viewbox surface & seen by observer) is 50 lux or less		

Important: If either test #7 (Phantom Image Quality Evaluation) or the Average Glandular Dose component of test #10 fail FDA's MQSA regulations, corrective action must be taken before any further examinations are performed. Corrective action must be taken within 30 days of the test date for all other MQSA failures.

******PLEASE HAVE YOUR MEDICAL PHYSICIST COMPLETE THIS SUMMARY FORM******

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Screen-Film Systems continued

Evaluation of Site's Technologist QC Program

(Required for Annual Surveys. Not required for Equipment Evaluations of new units. However, medical physicists **must** review the site's technologist QC program within 45 days and complete this section so that the facility may submit this form along with the entire Equipment Evaluation report with their phantom and clinical images to the ACR.)

	Pass/Fail	
	ACR Guides	**MQSA Regs**
1. Darkroom cleanliness (daily)		
2. Processor QC - performed, records maintained, action taken when needed (daily)		
3. Screen cleaning (weekly)		
4. Mammo phantom imaging - performed, records maintained, action taken as needed (weekly)		
5. Darkroom fog (semiannually)		
6. Film-screen contact test (semiannually)		
7. Compression pressure monitored (semiannually)		
8. Repeat analysis - performed, records maintained, reviewed by radiologist (quarterly)		
9. Viewboxes and viewing conditions (weekly)		
10. Analysis of fixer retention (quarterly)		
11. Visual checklist (monthly)		

Medical Physicist's Recommendations for Quality Improvement

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Preliminary Results

Site		Survey Date	
		Room ID	
X-Ray Unit Manufacturer		Model	

Medical Physicist's QC Tests

	Pass/Fail	
	ACR Guides	MQSA Regs
1. Mammographic Unit Assembly Evaluation		
2. Collimation Assessment		
3. Evaluation of Focal Spot Performance		
4. Automatic Exposure Control (AEC) System Performance		
5. Uniformity of Screen Speed		
6. Artifact Evaluation		
7. **Phantom Image Quality Evaluation****		
8. kVp Accuracy and Reproducibility		
9. Beam Quality (Half-Value Layer) Assessment		
10. **Breast Entrance Exposure, Average Glandular Dose**** AEC Reproducibility, and Radiation Output Rate		
11. Viewbox Luminance and Room Illuminance		

****If any of the starred MQSA tests fail (Phantom Image Quality and Average Glandular Dose), corrective action must be taken before any further exams are performed. Failure of any other MQSA-mandated tests require corrective action within 30 days of the test date.**

Recommendations for Corrective Actions

Evaluation of Site's Technologist QC Program

	ACR Guides	MQSA Regs
1. Darkroom cleanliness (daily)		
2. Processor QC - performed, records maintained, action taken when needed (daily)		
3. Screen cleaning (weekly)		
4. Mammo phantom imaging - performed, records maintained, action taken as needed (weekly)		
5. Darkroom fog (semiannually)		
6. Fllm-screen contact test (semiannually)		
7. Compression pressure monitored (semiannually)		
8. Repeat analysis - performed, records maintained, reviewed by radiologist (quarterly)		
9. Viewboxes and viewing conditions (weekly)		
10. Analysis of fixer retention (quarterly)		
11. Visual checklist (monthly)		

Specific Comments

This is only a preliminary list of findings. A full and final report will be mailed to you shortly. Please call me if you have any questions about this summary

Signature _____

Physicist's Name _____

Phone Number _____

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Trainee or Assistant Log

Site		Survey Date	
		Room ID	
X-Ray Unit Manufacturer		Model	
Supervising Medical Physicist		Signature	
Trainee or Assistant		Signature	

Medical Physicist's QC Tests Performed by the Trainee or Assistant

1. Mammographic Unit Assembly Evaluation	
2. Collimation Assessment	
3. Evaluation of Focal Spot Performance	
4. Automatic Exposure Control (AEC) System Performance	
5. Uniformity of Screen Speed	
6. Artifact Evaluation	
7. Phantom Image Quality Evaluation	
8. kVp Accuracy and Reproducibility	
9. Beam Quality (Half-Value Layer) Assessment	
10. Breast Entrance Exposure, Average Glandular Dose,	
AEC Reproducibility, and	
Radiation Output Rate	
11. Viewbox Luminance and Room Illuminance	
Evaluation of Site's Technologist QC Program	

Comments:

DATA RECORDING AND ANALYSIS FORMS

MAMMOGRAPHY EQUIPMENT EVALUATION

Site:	
Technologist(s):	

Equipment

Room ID		Date	
X-ray unit manufacturer		Model	
Processor manufacturer		Model	
Film manufacturer		Type	
Screen manufacturer		Type	

Mammography Phototimer Technique Chart

Compressed Breast Thickness	Fatty Breast				50% Fatty - 50% Dense Breast				Dense Breast			
	Target	Filter	kVp	Density	Target	Filter	kVp	Density	Target	Filter	kVp	Density
<3 cm												
3 to 5 cm												
5 to 7 cm												
>7 cm												

1. Mammographic Unit Asssembly Evaluation

	Pass/Fail/N A
Free-standing unit is mechanically stable	
All moving parts move smoothly, without obstructions to motion	
All locks and detents work properly	
Image receptor holder assembly is free from vibrations	
Image receptor slides smoothly into holder assembly	
Image receptor is held securely by assembly in any orientation	
Compressed breast thickness scale accurate to ±0.5 cm, reproducible to ±2 mm	
Patient or operator is not exposed to sharp or rough edges, or other hazards	
Operator technique control charts are posted	
Operator protected during exposure by adequate radiation shielding	
All indicator lights working properly	
Autodecompression can be overridden to maintain compression (and status displayed)	
Manual emergency compression release can be activated in the event of a power failure	

Comments:

2. Collimation Assessment

Source to image receptor distance (SID): _____ cm

Deviation between X-ray field and light field:

Target material	Mo	Mo			
Collimator (cm)	18x24	24x30			
Left edge deviation					
Right edge deviation					
Sum of left and right edge deviations					
Sum as % of SID					
Anterior edge deviation					
Chest edge deviation					
Sum of anterior and chest edge deviations					
Sum as % of SID					

ACTION LIMIT: **ACR/MQSA - If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.**

Deviation between X-ray field and edges of the image receptor:

Left edge deviation					
% of SID (retain sign)					
Right edge deviation					
% of SID (retain sign)					
Anterior edge deviation					
% of SID (retain sign)					
Chest edge deviation					
% of SID (retain sign)					

ACTION LIMIT: **ACR/MQSA - If X-ray field exceeds image receptor at any side by more than 2% of SID or if X-ray field falls within image receptor on the chest wall side, seek service adjustment.**
ACR - If X-ray field falls within image receptor by more than -2% on the left and right sides, or by more than -4% on the anterior side, seek service adjustment.

Alignment of chest wall edges of compression paddle and film:

Difference between paddle edge and film					
Difference as % of SID					

ACTION LIMIT: ACR/MQSA - If chest wall edge of compression paddle is within the image receptor or projects beyond the chest wall edge of the image receptor by more than 1% of SID, seek service correction.

3. Evaluation of System Resolution

X-ray Tube Manufacturer: _____ Model #: _____

Nominal focal spot size (mm)					
Target material					
Nominal kVp setting					
Nominal mA setting					
Density control setting					
mAs					
Magnification factor		**CONTACT**			
Limiting resolution in line-pairs per mm	bars parallel to A-C axis				
	bars perpendicular to A-C axis				

ACTION LIMIT: **ACR/MQSA - If limiting resolution with the bars parallel to the anode-cathode axis is < 13 line-pairs/mm or with the bars perpendicular to the anode-cathode axis is < 11 line-pairs/mm, then a more detailed investigation of the reason should be made and corrective action should be taken. MQSA - Until October 28, 2002, MQSA allows system resolution to also be evaluated by measuring focal spot dimensions. See Section VII for performance criteria.**

4. Automatic Exposure Control (AEC) System Performance

AEC position:		Density control:	
Small cassette ID:		Large cassette ID:	

Performance Capability:

Thickness-kVp Tracking							
Imaging mode:	small image receptor with grid						
Focal spot:	large focal spot						
mA:							
Phantom thickness	Image ID#	AEC Mode	Tarqet-Filter	kVp	Density Control Setting	mAs	Film Optical Density
2 cm							
4 cm							
6 cm							
8 cm							
Mean Optical Density (2-6 cm)		**Optical Density Range**			**MQSA Allowable Optical Density Range**		
		to			to		

Image Mode Tracking							
mA:							
Phantomthickness:							
Target-Filter:		Mo/Mo					
Image Mode	Image ID#	AEC Mode	Focal Spot	kVp	Density Control Setting	mAs	Film Optical Density
small grid							
large grid							
Magnification/no grid							

Overall AEC Performance		
Mean Optical Density	**Optical Density Range**	**Recommended Optical Density Range**
	to	to

ACTION LIMIT: **ACR - The AEC system should be able to maintain constant film optical density to within ±0.30 of the average over the phantom thicknesses and imaging modes tested.**

ACR/MQSA - The AEC system must be capable of maintaining film optical density within ±0.30 of the mean (±0.15 after 10/28/2002) when the thickness of the phantom is varied over 2-6 cm and the kVp is varied over the range of those used clinically for those thicknesses. The optical density in the center of the phantom image must not be less than 1.20. If these standards are not met, seek service adjustment.

4. Automatic Exposure Control (AEC) System Performance (cont.)

Density Control Function:

Imaging mode:	small grid			Focal spot:	large
mA:				kVp:	
Phantom thickness:				Cassette ID:	
					Relative to Normal
Density Control Setting	Image ID#	mAs	Measured Optical Density	**% mAs change**	**Optical Density Change**
-4					
-3					
-2					
-1					
0 (normal)					
+1					
+2					
+3					
+4					

ACTION LIMIT: ACR - Each step should result in a 12% to 15% change in mAs, or approximately a 0.15 change In film optical density. If not, seek service.

5. Uniformity of Screen Speed

Screen type:		Processor used:	
Film type:		kVp setting:	
Focal spot:		AEC dendity control:	

Small Cassettes:

Size:		cm
Film Emulsion #:		

Cassette ID#	Artifacts?	mAs	Density
Control Cassette:			
Mean of control cassette densities			
Standard deviation of control cassette densities			
Other Cassettes:			
Mean Density			
Minimum Density			
Maximum Density			
Density Range			

Large Cassesttes:

Size:		cm
Film Emulsion #:		

Cassette ID#	Artifacts?	mAs	Density
Control Cassette:			
Mean of control cassette densities			
Standard deviation of control cassette densities			
Other Cassettes:			
Mean Density			
Minimum Density			
Maximum Density			
Density Range			

Comments:

ACTION LIMIT: **ACR/MQSA - If standard deviation of control cassette densities is less than 0.05 AND density range exceeds 0.3, then corrective action is needed.**

6. Artifact Evaluation

Type of attenuator:	
Attenuator thickness:	
kVp setting:	
Density control setting:	

Image receptor size	18x24cm	24x30cm			MAG (18x24cm)
Cassette #					
Target	Mo	Mo			Mo
Filter	Mo	Mo			Mo
Focal spot	large	large			small
Emulsion orientation					
Resultant film optical density					
Artifacts visible?					
Processor?					
Acceptable?					
Describe					
Cassette-film-screen?					
Acceptable?					
Describe					
X-ray equipment?					
Acceptable?					
Describe					

ACTION LIMIT: ACR/MQSA - If significant artifacts are visible, contact the appropriate person maintaining or servicing the processor or X-ray equipment.

7. Image Quality Evaluation

Phantom used:	
AEC detector position:	
Cassette size:	
Cassette #:	

	Previous Film	Current Film	Comments
Date			
kVp setting			
Density control			
Phototimed mAs			
mAs change			
% mAs change = mAs change/mAs x 100			
Background density			
Background density change			
Density outside disc			
Density inside disc			
Density diff = outside-inside			
Density difference change			
Number of fibers seen			
Fibers seen after deduction			
Fiber change			
Number of speck groups seen			
Speck groups after deduction			
Speck group change			
Number of masses seen			
Masses seen after deduction			
Mass change			

ACTION LIMIT: **ACR/MQSA - The largest 4 fibers, 3 speck groups, and 3 masses must be visible. Background optical density must be at least 1.20. Corrective action must be taken before any further examinations are performed if the results of this test fail any MQSA regulations. ACR - The density difference should be at least 0.40 for a 4-mm thick acrylic disk. Background optical density should be at least 1.40 and must be at least 1.20. If % mAs change exceeds ±15%, if background density change exceeds ±0.20, if density difference change exceeds ±0.05, or if fiber, speck group or mass score decreases by more than 0.5, the source of change should be identified and corrected.**

8. kVp Accuracy/Reproducibility

kVp meter used: _____ Setting: _____

Nominal kVp setting						
Focal spot						
Exposure time (sec)						
mA						
mAs						
Measured kVp values:						
1						
2						
3						
4						
Mean kVp						
Standard deviation (SD)						
Additional kVp measurements (if needed):						
5						
6						
7						
8						
9						
10						
Recalculated:						
Mean kVp						
Standard deviation (SD)						
Mean kVp - Nominal kVp						
0.05 X Nominal kVp						
% Error						
Coefficient of variation (SD/Mean kVp)						

ACTION LIMIT: ACR/MQSA - If the mean kVp differs from the nominal by more than ±5% of the nominal kVp, or if the coefficient of variation exceeds 0.02, then seek service correction.

9. Beam Quality (HVL) Measurement

Dosimetry system used:

Nominal kVp setting					
Target material	Mo				
Filter	Mo				
mA setting					
Time (sec)					
mAs					
Exposure measurements (mR):					
No aluminum filtration, E(0a)					
0.2 mm of added aluminum, E(2)					
0.3 mm of added aluminum, E(3)					
0.4 mm of added aluminum, E(4)					
0.5 mm of added aluminum, E(5)					
0.6 mm of added aluminum, E(6)					
No aluminum filtration, E(0b)					
Average E(0)					
Average E(0)/2					
Calculated HVL (mm Al)					
Minimum allowed HVL					
Maximum allowed HVL					

$$HVL = \frac{tb\ \ln[2Ea/E0] - ta\ \ln[2Eb/E0]}{\ln[Ea/Eb]}$$

ACTION LIMIT: ACR - If measured HVL < (kVp/100) + 0.03 (in mm Al) or if measured HVL > (kVp/100) + C (in mm Al), where C = 0.12 for Mo/Mo; C = 0.19 for Mo/Rh; C = 0.22 for Rh/Rh; and C = 0.30 for W/Rh, then seek service correction. MQSA - The HVL must meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30):

X-Ray Tube Voltage and Minimum HVL	
Measured Voltage (kV)	**Minimum HVL (mm of Al)**
20	0.20
25	0.25
30	0.30

10. Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate

Imaging mode:		SID (cm):	
Screen type:		Source-detector distance (cm):	
Film type:		Source-bucky distance (cm):	
Cassette size(cm):		Dosimeter used:	
Field Restriction:		Energy correction factor:	

Breast thickness (cm)	4.2			
Phantom				
Nominal kVp setting				
Target material	Mo			
Filter	Mo			
AEC mode				
Density control setting				
Measured HVL (mm Al)				

Breast Entrance Exposure and AEC Reproducibility								
	R	mAs	R	mAs	R	mAs	R	mAs
Exposure #1								
Exposure #2								
Exposure #3								
Exposure #4								
Mean values								
Standard deviations (SD)								
Coefficient of variation (CV)								

ACTION LIMIT: ACR/MQSA - If coefficient of variation for either R or mAs exceeds 0.05, seek service.

Average Glandular Dose:

Inv Sq corrected skin exp				
Dose conversion factor from Tables 1-3 (mrad/R)				
Computed average glandular dose (mrad)				

ACTION LIMIT: ACR/MQSA - If average glandular dose exceeds 300 mrad (3 mGy) for 4.2 cm effective breast thickness, seek service or technique adjustment. <u>Corrective action must be taken before futher examinations are performed if the test results fail MQSA regulations.</u>

Radiation Output Rate:

	kVp	Anode	Filter	SID (cm)	Exp (mR)	mAs	Time (sec)	**Rate (mR/s)**	**Kerma (mGy/s)**
3 sec, 4.5 cm above breast support	28	Mo	Mo						
	28	Mo	Mo						

Air Kerma (mGy/sec) - Exp Rate (mR/s) x 0.00873 mGy/mR

ACTION LIMIT: ACR - If output rate is less than 800 mR/s (7.0 mGy/s), seek service. MQSA - If output rate is less than 513 mR/s (4.5 mGy/s), seek service. After 10/28/2002, this value changes to 800 mR/s (7.0 mGy/s).

11. Viewbox Luminance and Room Illuminance

	Radiologist's Viewboxes			Technologist's Viewboxes
	Reading Area 1	Reading Area 2	Reading Area 3	
Viewbox location				
Viewbox luminance (cd/m²)				
Illuminance on viewbox surface (lux)				
Illuminance seen by observer (lux)				
Dirt and Marks	Y N	Y N	Y N	Y N
Color Difference	Y N	Y N	Y N	Y N
Luminance Difference	Y N	Y N	Y N	Y N
Uniformity	Y N	Y N	Y N	Y N
Functioning Masks	Y N	Y N	Y N	Y N

Comments:

ACTION LIMIT: ACR - The illuminance on the viewbox surface or the illuminance seen by the observer should be 50 lux or less. The mammography viewboxes should be capable of a luminance of 3000 cd/m². If these levels are not met, corrective action should be taken.

MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

Section 900.12(b) of FDA's Final Rules for Mammography set specific requirements for mammography equipment. Mammography facilities must meet most of these requirements by April 28, 1999. (Some, more stringent requirements do not go into effect until October 28, 2002.) Note that Part 900.12(b) requires that all radiographic equipment used for mammography be specifically designed for mammography and that compression be available.

The medical physicist should assist the facility in evaluating each mammography unit for compliance with these rules. The following checklist (Table 6) itemizes each of these new requirements to aid in a complete system evaluation.

Table 6. MQSA Requirements for Mammography Equipment

Feature	Requirement	Rule Section	Effective Date	Meets Rqmts? Yes No NA
Motion of tube-image receptor assembly	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	30(i)	4/28/99	
	This mechanism shall not fail in the event of power interruption.	3(ii)	4/28/99	
Image receptor sizes	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 X 24 cm and 24 X 30 cm.	4(i)	4/28/99	
	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.	4(ii)	4/28/99	
	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	4(iii)	4/28/99	
Beam limitation and light fields	All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest-wall edge of the image receptor.	5(i)	4/28/99	
	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at the maximum SID.	5(ii)	4/28/99	
Magnification	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.	6(i)	4/28/99	
	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	6(ii)	4/28/99	

Table 6. Continued

Feature	Requirement	Rule Section	Effective Date	Meets Rqmts? Yes No NA
Focal spot selection	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	7(i)	4/28/99	
	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	7(ii)	4/28/99	
	When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.	7(iii)	4/28/99	
Application of compression	Each system shall provide initial power-driven compression activated by hands-free controls operable from both sides of the patient.	8(i)(A)	10/28/02	
	Each system shall provide fine adjustment compression controls operable from both sides of the patient.	8(i)(B)	10/28/02	
Compression paddle	Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.	8(ii)(A)	4/28/99	
	The compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.	8(ii)(B)	4/28/99	
	Paddles intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.	8(ii)(C)	4/28/99	

Table 6. Continued

Feature	Requirement	Rule Section	Effective Date	Meets Rqmts? Yes No NA
Compression paddle (continued)	The chest-wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.	8(ii)(D)	4/28/99	
	The chest-wall edge may be bent upward to allow for patient comfort but shall not appear on the image.	8(ii)(E)	4/28/99	
Technique factor selection and display	Manual selection of mAs or at least one of its component parts (mA and/or time) shall be available.	9(i)	4/28/99	
	The technique factors (kVp and either mAs or mA and seconds) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.	9(ii)	4/28/99	
	Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure.	9(iii)	4/28/99	
Automatic exposure control	Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid; magnification, non-magnification; and various target-filter combinations.	10(i)	4/28/99	
	The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue. The size and the available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle. The selected position of the detector shall be clearly indicated.	10(ii)	4/28/99	

Table 6. Continued

Feature	Requirement	Rule Section	Effective Date	Meets Rqmts? Yes No NA
	The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.	10(iii)	4/28/99	
X-ray film	Hie facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.	11	4/28/99	
Intensifying screens	The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screens spectral output as specified by the manufacturer.	12	4/28/99	
Film processing solutions	For processing mammography films, the facility shall use chemical solutions that are capable of developing the film in a manner equivalent to the minimum requirements specified by the film manufacturer.	13	4/28/99	
Lighting	The facility shall make special lights for film illumination, i.e., hotlights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physician.	14	4/28/99	
Film masking devices	Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.	15	4/28/99	

SLIT CAMERA EVALUATION OF FOCAL SPOT PERFORMANCE

OBJECTIVE

If the performance criteria for the high-contrast-resolution test are not met and focal spot size is a possible cause, then focal spot size may be determined by using a slit camera. (Although using this method as the primary means to evaluate system resolution is acceptable under MQSA only until October 28, 2002, it remains a useful method to isolate contributors to poor resolution or during acceptance testing.)

REQUIRED TEST EQUIPMENT

Slit camera (10 pm width) with appropriate test stand or mounting jig

A loaded mammography screen-film cassette from the facility. For best screen-film contact, be sure that the cassette has been loaded at least 15 minutes prior to the test, or

Direct exposure, ready-pack film (such as Kodak XTL-2)

Lead marker to designate the anode-cathode axis direction

Tape measure or long ruler

An optical comparator, having a built-in graticule of 0.1 mm divisions and 10X to 50X magnification

TEST PROCEDURE STEPS

1. Remove the compression paddle and cone from the mammographic unit.
2. Place the focal spot test stand on top of the cassette holder with the aperture at the top of the camera near the chest-wall side of the cassette holder.
3. Extend the legs of the test stand to place the top of the stand as close as possible to the focal spot, resulting in maximum magnification.
4. Place the test stand alignment device in the test stand and use the collimator light to align the five lead beads. This will probably result in part of the focal spot test stand extending beyond the cassette holder (Figure 17).
5. Place a piece of intensifying screen on the base of the focal spot test stand.
6. With the room lights turned off, make a 1 second exposure at 28 kVp while observing the image of the alignment device. Adjust the position of the focal spot test stand so that the image of the single upper bead is centered within the image of the four lower beads.

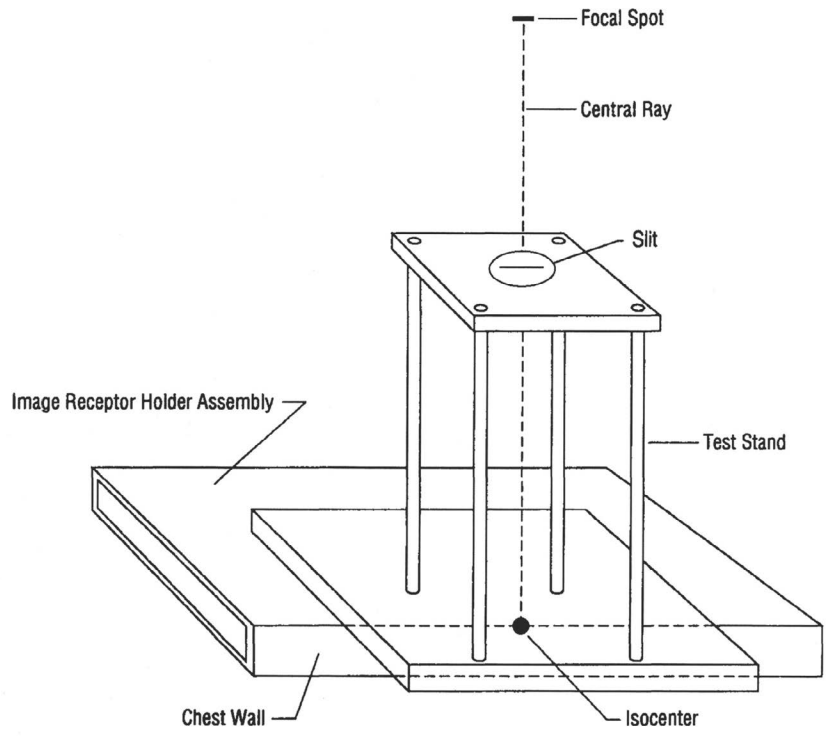


Figure 17. Schematic drawing of the positioning of a slit camera test stand for focal spot size determination. It is crucial to align the slit along the central ray of the X-ray beam, with the plane of the slit device perpendicular to the central ray.

7. Place the slit camera on top of the focal spot test stand in place of the test stand alignment device.
8. Place the mammography screen-film cassette or the ready-pack film in the tunnel of the focal spot test stand.
9. Select a nominal focal spot size, a kVp setting commonly used for mammographic imaging (26 to 30 kVp), and the highest mA station available on the mammographic unit for that focal spot size. (Note that the National Electrical Manufacturers Association [NEMA] testing standard requires that the focal spot size be measured at 30 kVp and the maximum allowable tube current allowed at 30 kVp and 1.0 second.)
10. Select an exposure time to produce a film optical density between 0.80 and 1.20. The slit camera requires a technique of about 28 kVp and 60 mAs when using a mammographic screen-film combination.
11. Acquire two images: one with the slit parallel to the anode-cathode axis and the other with the slit perpendicular to the anode-cathode axis.

12. Process the exposed film.
13. Measure and record the size of a reference object and the size of its image. This will be used to determine the enlargement factor. (Note that it is essential that the reference object be in the same plane as the slit for an accurate determination of enlargement.)
14. Steps 4 through 13 should be repeated for additional focal spot sizes.
15. The entire process may be repeated at other kVp and mA settings if the dependence of focal spot size on kVp and mA is of concern.

Slit Camera Measurements

1. Calculate the slit enlargement factor from the measurements of the reference object:

$$E = \frac{\text{Image Size}}{\text{Object Size}} - 1$$

2. Use an optical comparator with a built-in graticule of 0.1-mm divisions and 10X to 50X magnification to measure the size of the slit image. The first measurement will determine the width of the focal spot (f_{perp}) perpendicular to the longitudinal axis of the X-ray tube. On the image that was acquired with the slit parallel to the anode-cathode axis, measure the width of the slit image ($d_{parallel}$). The second measurement will determine the length of the focal spot ($f_{parallel}$) parallel to the longitudinal axis of the X-ray tube. On the image that was acquired with the slit perpendicular to the anode-cathode axis, measure the width of the slit image (d_{perp}). NEMA specifies that the extent of the discernible images (i.e., the full width of the increased density) should be measured.
3. Compute the measured focal spot sizes in the directions parallel and perpendicular to the anode-cathode axis using the following formulas, respectively:

$$f_{perp} = \frac{d_{parallel} - s(E + 1)}{E}$$

$$f_{parallel} = \frac{d_{perp} - s(E + 1)}{E}$$

where "s" is the slit width, typically 0.01 mm.

NOTE: Slit camera measurements should be made to compare with manufacturer or NEMA specifications. Correction of focal spot size measurement to calculate the size at the manufacturers reference axis and to account for tube angulation, which changes the central ray direction from that perpendicular to the image receptor, may be necessary for comparison with manufacturer or NEMA specifications.

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

As with all radiographic focal spots, mammographic focal spots may have actual sizes greater than the nominal focal spot sizes. When measured with a slit camera, measured sizes at the reference axis can be up to the following dimensions and still meet the NEMA standard (measurements made at the chest wall can be even larger):

NEMA Focal Spot Tolerance Limits

	Maximum Measured Dimensions*	
	Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

* Width is the dimension perpendicular to the anode-cathode axis, length is parallel.

For example, a nominal 0.1 mm focal spot would be satisfactory if measured to be 0.15 mm or less along the parallel and perpendicular axes after having made the NEMA corrections discussed in the above note. Measured focal spot sizes in excess of these values should be reported to the X-ray equipment service person or vendor immediately for corrective action. Focal spot sizes exceeding specifications may require adjusting the bias voltage (which may adversely affect mR/mAs output) or replacing the X-ray tube to correct the problem.

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Glossary

GLOSSARY

A

Artifact. Any structure visible in the image that is not part of the object being imaged.

Automatic exposure control (AEC) systems. Automatic exposure control systems, often referred to as phototimers, are designed to automatically determine and provide the exposure needed to produce an adequate optical density image by sampling the X-ray intensity after passage through the patient and image receptor.

Average glandular dose. Calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness, average glandular dose is the energy deposited per unit mass of glandular tissue (by far the most radiosensitive tissue in the breast) averaged over all the glandular tissue in the breast. The average glandular dose should be less than 3 mGy (0.3 rad) for a single screen-film craniocaudal view of a standard (4.2 cm thick, 50% glandular, 50% adipose) breast. See also: dose. The average, or mean, glandular dose is the value that can be used to estimate the risk of the exposure, as opposed to the entrance exposure. While specified in different units, the mean glandular dose is usually between 10% and 20% of the numerical value of the entrance exposure.

B

Base density. The optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

Base-plus-fog density. The optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base-plus-fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density. A low base-plus-fog density is desirable. Factors such as exposure of the film to heat or high humidity can cause an undesirable increase in the base-plus-fog density.

C

Cassette. A light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. Intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact with the film. Almost all mammography cassettes today are equipped with single screens.

Compression device. A plastic paddle used to reduce blurring due to motion by holding the breast stationary, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film. Ideally, the compression device is made of rigid, thin plastic and has a flat bottom surface that is parallel to the plane of the image receptor and with edges perpendicular to the plane of the image receptor to assist in moving breast tissue away from the chest wall and into the field of view.

Control chart. A graphical means of displaying data in which the variable of interest is plotted on the vertical axis as a function of time on the horizontal axis. The control chart allows for easy and rapid review of the data to determine whether the process is within the desired control limits ("in control").

Control limit. The upper and lower control limits are those values which when reached or exceeded indicate that the process is "out of control" and require that corrective action be taken immediately. It is prudent to immediately repeat the measurement to verify that the system is "out of control" before taking corrective action. If the repeated measurement is "out of control," then corrective action is required immediately (or in some cases within 30 days) as specified in the MQSA Final Regulations.

Craniocaudal (CC) view. One of two routine views for mammography. The image receptor is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

D

Dedicated mammography equipment. X-ray systems designed specifically for breast imaging. Such a unit provides a specialized imaging geometry and a device for breast compression and can consistently produce mammographic images of high quality.

Densitometer. An instrument that measures the optical density or degree of blackening of film.

Detents. Mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system or that allow exposures with specified tube orientations.

Developer. A chemical solution that changes the film latent image to a visible image composed of black metallic silver.

Developer replenishment. The process whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper chemical activity and level of solution in the developer tank that would otherwise decrease through use.

Diagnostic mammography. Mammography performed on patients who, by virtue of symptoms, physical findings, or screening mammograms, are considered to have a substantial likelihood of having breast disease.

Dose. The amount of energy deposited in tissue due to X-ray exposure. The S.I. unit of absorbed dose is the gray (Gy). One gray is equal to 100 rads; 1 milligray (mGy) is equal to 0.1 rad.

E

Exposure. The amount of X-irradiation, quantitated by measuring the amount of ionization in air caused by the radiation, measured in units of coulombs/kilogram or roentgen (1 roentgen (R) = 2.58×10^{-4} C/kg).

F

Fixer. A chemical solution that removes the undeveloped silver halide crystals from film. Fixer also helps to harden the gelatin containing the black metallic silver so the film may be dried more readily.

Fixer retention. The inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes brown discoloration of the radiograph (often within a year or less).

Focal spot. The focal spot is the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limiting spatial resolution of the X-ray system, especially in magnification mammography.

Fog. The unwanted density added to a radiograph by the action of the developer on the unexposed silver halide crystals or by exposure of the film to light, radiation, or heat during storage, handling, and processing.

G

Grid. A set of thin, closely spaced lead strips interspaced by fiber or aluminum. In mammography the grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor. Scattered radiation reduces image contrast in mammography and limits the detection of low-contrast structures such as fibers and masses.

H

Half-value layer (HVL). The thickness of a specified substance that, when introduced into the path of a beam of radiation, reduces the exposure rate by one-half. HVL is a measure of beam quality and is usually specified in millimeters of aluminum for diagnostic X-ray equipment. The higher the HVL, the more penetrating the X-ray beam.

I

Image contrast. The optical density difference between adjacent areas in a radiographic image resulting from an attenuation difference in the imaged object.

Image noise. See radiographic noise.

Image quality. The overall clarity of a radiographic image. Image sharpness, image contrast and image noise are three common measures of image quality.

Image sharpness. The overall impression of detail in a radiographic image.

K

Kilovoltage, peak (kVp). The maximum value of the potential difference (kVp) between anode and cathode in an X-ray tube. The kVp determines the maximum energy of X rays emitted by the X-ray tube in kilo-electron volts (keV).

M

Mean glandular dose. See average glandular dose.

Mediolateral view. Previously, one of the more common routine views for mammography in addition to the craniocaudal view. The image receptor is placed lateral to the breast, and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

Mediolateral oblique (MLO) view. Now one of the standard two views of the breast. The image receptor is angled 30°-60° from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the superomedial to the inferolateral aspect of the breast.

Milliampere (mA) setting. The electron current (mA) passing from the cathode to the anode in an X-ray tube. For a fixed kVp, the output of X-rays per unit time from the tube is linearly proportional to the mA setting.

Milliampere-seconds (mAs). The product of electron current (mA) and the exposure time (in seconds). For a fixed kVp, total X-ray output is linearly proportional to mAs.

MQSA. The Mammography Quality Standards Act (MQSA) was signed by President Bush in 1993. This law went into effect in 1994 and required all mammography facilities in the United States to be accredited by an approved body and undergo annual inspections by state or Federal inspectors. The Food and Drug Administration is responsible for implementing MQSA and developing national mammography regulations.

O

Operating level. The central value about which we expect day-to-day measurements to fluctuate: for example, the empirically determined mid-density on a sensitometric film.

P

Phantom. A test object that simulates the average composition of and various structures within the patient. A "good breast phantom" should simulate the breast, should allow objective rather than subjective analysis, and should be sensitive to small changes in mammographic image quality.

Processor. An automated device that transports film at a constant speed by a system of rollers through developing, fixing, washing, and drying cycles.

Processor artifact. Any unwanted or artificial image feature appearing on a radiograph due to malfunction or misuse of the film processor.

Q

Quality assurance (QA). QA is a management tool that includes policies and procedures (including quality control tests and tasks) designed to optimize the performance of facility personnel and equipment.

Quality control (QC). The routine performance of tests and tasks and the interpretation of data from the tests of equipment function and the corrective actions taken.

Quality control technologist. The technologist assigned the task of QC testing and maintaining QC records for radiographic imaging systems.

R

Radiographic noise. Unwanted fluctuations in optical density on the mammographic image.

Radiographic sharpness. The distinctness or perceptibility of the boundary or edge of the structure in a mammogram.

Repeat analysis. A systematic approach to determine the number of and causes for radiographs being repeated. Analysis of data on repeats helps identify ways to improve mammography quality.

Replenishment rate. The amount of chemicals added per sheet of film processed in order to maintain the proper chemical activity of developer and fixer solutions.

S

Safelight. A lighting fixture used to provide a minimal amount of working light in a darkroom. A safelight has appropriate filters and produces light that will not fog exposed radiographic film within a specified period of time. The filter removes most of the light to which the radiographic film is sensitive. Most safelights will fog film if the amount of light (wattage of the bulb) is excessive, if the filter is damaged or of the wrong type, or if the time a film is exposed to the safelight is too long.

Screen. Phosphor crystals coated on a plastic support that emit visible light when exposed to X-irradiation. The light emitted by the screen exposes the film that is in contact with the screen creating a latent image on X-ray film.

Screen-film combination. A particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of sides of the film on which emulsion is coated and to match the light output spectrum of the screen to the light sensitivity of the film.

Screen-film contact. The close proximity of the intensifying screen to the emulsion of the film. Good screen-film contact is essential in order to achieve a sharp image on the film.

Screen-film mammography. Mammography performed with a high-detail intensifying screen(s) that is in close contact with matched film in the cassette, both of which are designed for breast imaging.

Screening mammography. X-ray breast examination of asymptomatic women in an attempt to detect breast cancer when it is small, nonpalpable and confined to the breast.

Sensitometer. A device used to reproducibly expose film to a number of different known levels of light intensity. The film produced by the use of a sensitometer is used to check the consistency of performance of a film processor.

Sensitometric strip. A sheet of film exposed to a series of different light intensities by a sensitometer. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible exposure.

Sensitometry. A quantitative measurement of the response of film to light exposure and photographic processing.

T

Thermoluminescent dosimeter (TLD). A radiation exposure measurement device using a chip or powder that absorbs radiation and when subsequently heated produces light whose intensity is proportional to the amount of radiation absorbed. "Film" badges worn by X-ray personnel typically contain TLDs.

V

Viewbox. A device providing a relatively uniform surface luminance forviewing mammographic films. Mammographic viewboxes should have a luminance level of at least 3,000 candela per square meter (cd/m2 or nit).

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